



**RWANDA FDA**  
Rwanda Food and Drugs Authority

**GUIDELINES FOR LICENSING OF PUBLIC AND PRIVATE  
MANUFACTURERS, DISTRIBUTORS, WHOLESALERS AND  
RETAILERS OF MEDICAL PRODUCTS**

**SEPTEMBER, 2022**

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## **FOREWORD**

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA formulate is to regulations and guidelines for regulating the manufacture, import and export, distribution, sale and use of regulated products under the Law stated above.

Pursuant to the provisions of the Regulations N° FDISM/FDIC/TRG/001, Governing Licensing of public and private manufacturers, distributors, wholesalers and retailers of medical Products. The Authority issues Guidelines N° FDISM/FDIC/GDL/005 for licensing of public and private manufacturers, distributors, wholesalers and retailers of medical Products.

These Guidelines provide guidance to applicants to make sure that they comply with the prescribed requirements.

Applicants are encouraged to familiarize with the Guidelines and follow them when preparing and submitting applications for licensing of their establishments dealing with manufacturing, distributors, wholesalers and retailers of medical Products.

Adherence to these guidelines will ensure that all relevant information is provided for licensing of establishments. This will facilitate efficient and effective analysis of the applications and speed up the approval processes.

The Authority acknowledges all the efforts of stakeholders who participated in development and validation of these guidelines.

*E. Bienvenu*  
**Dr. Emile BIENVENU**  
**Director General**



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## GUIDELINES DEVELOPMENT HISTORY

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### Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
12/07/2021	1	<ol style="list-style-type: none"> <li>Chapter II is renamed LICENSING &amp; INSPECTIONS instead of Licensing Requirements</li> <li>Application forms, Formats of w license, Format of notification letter for withdrawal of premise license / Certificate and requirements for application for renewal of the premise license are included</li> </ol>
28/12/2021	2	<ol style="list-style-type: none"> <li>The timeline for standards of service delivery has been added.</li> <li>Description of different sections of the inspection report has been added.</li> <li>Revision of requirements to obtain a premise license.</li> <li>The title is renamed as Guidelines Governing Licensing of public and private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products instead of Guidelines for Licensing to Manufacture, to Operate as Wholesale and Retail Seller of Medical Products.</li> <li>Categorization of inspection findings has been added</li> <li>The application form was revised to be used for all categories of premises to replace the former application forms by category</li> </ol>
24/08/2022	3	<ol style="list-style-type: none"> <li>Amendment of space requirements of premises of medical products: Private and public Wholesalers, Retailers, Orthopedic and optical shops, health Centre and health posts</li> <li>Clarification on the validity of the premise license for renewal and other variations</li> <li>The Annex I: Process flow chart was revised</li> <li>The Annex III: Premise registration certificate was added</li> <li>The Annex VI: was revised</li> <li>Editorial changes to align with the new format</li> </ol>

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**ACRONYMS AND ABBREVIATIONS**

<b>FDA</b>	Food and Drugs Authority
<b>GDP</b>	Good Distribution Practices
<b>GMP</b>	Good Manufacturing Practices
<b>GSP</b>	Good Storage Practices
<b>HVAC</b>	Heating, Ventilation, and Air Conditioning
<b>RDB</b>	Rwanda Development Board

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## **GLOSSARY / DEFINITIONS**

In these Guidelines, unless the context otherwise states:

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

**"Authority"** means Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under Article 2 of the Law;

**"Authorization"** means a legal document granted by Rwanda Food and Drug 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.

**"Authorized personnel"** means an individual who possesses a recognized academic degree, has extensive knowledge, training and experience, and successfully demonstrated his/her ability to solve or resolve problems relating to the subject matter.

**"Critical Non-compliance"** 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" non-compliance may consist of several related non-compliances, none of which on its own may be "Critical", but which may together represent a "Critical" non-compliance, 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, instrument, or systems, whose malfunction or failure may cause variation in the quality and safety of the medical products.

**"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.

**"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.

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**“Good storage practices** or its acronym **“GSP”** means that part of quality assurance that ensures that the quality of products is maintained by means of adequate control throughout the storage thereof.

**“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.**

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

**“Magistral preparation”** means medicines prepared in a pharmacy for an individual patient in accordance to a prescription from a doctor.

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

**“Minister”** means the Minister responsible for health

**“Medical product”** includes human and veterinary drugs; human and animal vaccines and other biological products, poisonous substances, herbal medicines, medicated cosmetics, human and veterinary medical devices, laboratory and cleaning chemicals and pesticides

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

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

**“Minor/Other”** related non-compliances, none of which on its own may be **“Major”**, but which may together represent a **“Major”** non-compliance 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 in which 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.

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**“Quality Risk Management”** means a systematic process for the assessment, control, communication and review of risks to the quality of products in the supply chain

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

**“Sale”** means sell by wholesaler or retailer and includes

- a) advertise, label, prepare, expose, offer for sale;
- b) smuggle, administer, hawk, supply, barter, or dispose of to any person;
- c) distribute, deliver or transmit, by way of gift or sample or in any other way whatsoever

**“Tariff/Fees”** includes any charge made or levied in connections with the 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.

In these Guidelines, 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.

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## **1. INTRODUCTION**

The “*Guidelines for Licensing of Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products “Revision 3”*” is a Rwanda Food and Drugs Authority publication which sets out procedures and requirements for the registration and licensing of premises selling regulated products. They are issued pursuant to of Article 3 of Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning, and Article 1 and 3 of Law N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products as well as registration of activities and premises in terms of the *Regulations FDISM/FDIC/TRG/001, Governing Licensing of Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products.*

The purpose of these guidelines for licensing of public and private manufacturers, distributors, wholesalers and retailers of medical products is to give guidance on the requirements for the registration and licensing of premises that manufacture, store, and distribute regulated products as the licensing of such premises forms an integral part of ensuring that regulated products maintain their integrity throughout their shelf life and supply chain. Adherence to the guidelines by applicants will facilitate timely review and processing of applications.

### **1.1 Scope**

These guidelines should 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.

## **2. LICENSING AND INSPECTIONS**

### **2.1. General requirements for application of registration certificate and premise license**

- a) All applications shall be submitted to Rwanda FDA head office or via email addressed to the Director General at ([info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw)) or via integrated management information system;
- b) An applicant for premise registration and licensing of medical products shall submit the requirements as described in these guidelines;
- c) Applicants shall pay all the prescribed fees as per the relevant regulations at the time of application through the bank accounts as indicated on Rwanda FDA website. Such payment does not mean to be granted a license prior to fulfilling requirements for registration and licensing;
- d) Applicants for manufacturing facility of medical products will be required to meet the Good Manufacturing Practices (GMP) requirements

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- e) Applicants for wholesalers and retailers of medical products will be required to meet the Good Distribution Practices (GDP) and Good Storage Practices (GSP) requirements as detailed in the guidelines for Good Storage and Good Distribution practices.
- f) For outsourced GDP and GSP activities: A written and approved contract or formal agreement between the contract giver and contract acceptor
- g) All applicants intending to establish new manufacturing facilities of medical products are advised to contact Rwanda FDA for guidance before embarking on any establishment;
- h) Incomplete application for registration and licensing a new premise shall not be processed;
- i) Applicants wishing to deal in both veterinary medicines and agricultural products shall apply for premise registration and premise license separately in their respective competent authorities. The veterinary premises shall apply for registration and licensing in Rwanda FDA. Applicants should meet the minimum requirements for suitability of premises and personnel. The two sections shall be separated.

## **2.2 Inspections**

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

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

### **2.2.1 Types of inspections**

There are four types of licensing inspections divided into the following categories:

- a) Pre-approval inspection;
- b) Concise inspection;
- c) Follow-up inspection;
- d) Special inspection; and
- e) Any other types as the Authority may designate.

The inspection should be conducted as follows:

- a) the pre-approval inspection is a full inspection of all applicable components of licensing provisions for manufacturer, wholesaler, distributor and retailers. It may be indicated when the premise is:

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- i. Newly established
  - ii. Requests for renewal of a premise license
  - iii. Has a history on non-compliance with GMP; GDP and GSP
  - iv. 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, etc.
  - v. Has not been inspected during the last 3 to 5 years;
- b) Concise inspections are the evaluation of limited aspects relating to licensing compliance within a premise. The premise with a consistent record of compliance with licensing requirements through previous routine inspections are eligible for concise inspections. The focus of a concise inspection is on a limited number of licensing requirements, plus the identification of any significant changes that could have been introduced since the last inspection. Evidence of non-compliances observed during a concise inspection should trigger a more comprehensive inspection;
- c) Follow-up inspections (re-inspection) are made to monitor the result of corrective measures. They are normally carried out from 6 weeks to 6 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;
- d) Special 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. Special visits may be also made to establish how a specific product is manufactured as a prerequisite for marketing approval or issuance of an export certificate.

### **2.2.2 Approval of the premises**

Upon approval of findings of the inspection to manufacture, distribute, to operate as wholesalers or retailers of medical products, Rwanda FDA shall notify the applicant the decision based on the findings of the inspections.

In case of compliance to the premise registration and licensing requirements, the registration certificate and premise license shall be granted to the applicant. In case of non-compliances to the premise licensing requirements, a feedback letter with corrective actions shall be issued to the applicant.

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### **3. MEDICAL PRODUCTS MANUFACTURING FACILITY**

The Authority shall inspect the premises to determine their suitability for manufacturing of medical products. Applicants should fulfill the prerequisites as detailed below prior to premise licensing. Premises that do not comply with the requirements for suitability shall not be eligible for consideration of an authorization.

Applicants should apply for:

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, this covers:
- 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.

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

- a) Site inspection before construction
- b) Site inspection at completion of construction of the premises;
- c) Site inspection at the completion of installation of equipment and utilities, e.g., HVAC, water, compressed gases, etc.;

Upon receipt of complete required documents for registration and license to manufacture, Distribute, to operate as Wholesalers or Retailers and payment of prescribed fee, inspection of the premises shall be conducted.

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Prior to issuance of registration certificate and license for premises dealing with medical products, the intended premises shall comply to the following premise suitability requirements.

### **3.1 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.

### **3.2 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;
- j) Proper lighting, 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;

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- 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.

### **3.3 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;

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- 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.

### **3.4 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.

### **3.5 Storage areas and environmental controls**

- 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;
- e) 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;
- f) Be provided with receiving and dispatch bays to protect materials and products from the weather;
- g) Be provided with reception areas which shall be designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage;

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- h) 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;
- i) Have provisions where the starting materials and finished goods are stored under cover and off the floor;
- j) 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;
- k) Have provisions where highly active materials or products are stored in safe and secure areas;
- l) Have safe and secure storage of printed packaging material.

### **3.6 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.

### **3.7 Descriptive materials to be kept secure**

- 1) All product labels, printed packaging and descriptive materials shall:
  - a) Be stored in a secure manner; and
  - b) Be accessed by only authorized personnel.
- 2) Proper records shall be kept for the labels, printed packaging and descriptive materials issued, to avoid any mix-up.

### **3.8 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;

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- 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.

### **3.9 Fire-fighting equipment**

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

### **3.10 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 its Chapter 5.

### **3.11 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.

### **3.12 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.

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- 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.

### **3.13 Minimum floor space and height**

The manufacturing facility of medical products shall have up to a height of 2.5 meters from the floor, be smooth and capable of being kept clean. The minimum floor shall have adequate space to accommodate all manufacturing activities carried out.

### **3.14 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

## **4. PREMISES OF DISTRIBUTORS, WHOLESALERS AND RETAILERS OF MEDICAL PRODUCTS**

### **4.1 Location of premises for distributors, wholesalers and retailers of medical products**

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

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#### **4.2 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;
- f) Be well lit, ventilated and have appropriate air-control facilities including temperature and humidity.

#### **4.3 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;

#### **4.4 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;

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- d) Medical Products that are temperature sensitive shall be kept in a temperature-controlled storage facility;
- e) With separate area in the storage facility where recalled, expired or rejected drugs shall be stored under lock and key.

#### **4.4 Minimum floor space and height**

- a) For a distributor or wholesaler dealing with the human medicines or medical devices, the total floor space shall have a minimum space of 90 square meters. The sales area shall have minimum floor space of 30 square meters, and records shall be maintained in this area. The storage areas shall 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, total floor space shall have a minimum space of 70 square meters. The sales area shall have minimum floor space of 25 square meters, and records shall be maintained in this area. The storage areas shall 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 layout of one room with a minimum space of 40 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 layout of one room with a minimum space of 30 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 magistral preparation, the minimum additional space of 10 square meters in the same establishment shall be dedicated to accommodate magistral preparation activities.**

- e) For an establishment dealing with veterinary medicines, the retail pharmacy shall have a layout of one room with a minimum space of 30 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 layout of one room with a minimum space of 20 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 layout of one room with a minimum space of 30 square meters. The minimum height shall be 2.5 meters from the floor to the ceiling;

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- h) The sales and storage areas shall be orderly, have adequate space, and protected from direct sunlight, heat and moisture;
- i) 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.

#### **4.5 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 retailer’s premises) 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 authorized personnel;
- c) Availability of copy of license to practice of the authorized 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 authorized personnel in charge;
- f) A copy of the premise license and license to practice profession for the responsible authorized personnel shall be conspicuously displayed in the establishment.

### **5. PERSONNEL**

#### **5.1 Personnel for the medical products manufacturing facility**

- a) There are shall be sufficient authorized personnel to carry out all manufacturing activities and the responsibility for every individual has to be clearly understood and recorded;

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- 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 authorized personnel may be delegated to designated deputies of satisfactory qualification level;
- e) There are 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:

- i) Head of production;
- ii) Head of quality unit;
- iii) Head of quality assurance;
- iv) Head of quality control;
- v) Authorized personnel.

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.

- g) The head of production should have bachelor education in Pharmacy but if not, available options should be of a bachelor holder in the following:
  - i) Pharmaceutical sciences and technology;
  - ii) Biological Sciences;
  - iii) Chemistry (analytical or organic) or biochemistry;
  - iv) Chemical engineering;
  - v) Veterinary medicine;
  - vi) Any other relevant qualification.

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8) The head of quality unit shall have bachelor education in any of the following:

- i) Pharmaceutical sciences and technology;
- ii) Biological Sciences;
- iii) Chemistry (analytical or organic) or biochemistry;
- iv) Chemical engineering;
- v) Veterinary medicine;
- vi) Any other relevant qualification.

9) The head of quality control shall have bachelor education in any of the following:

- i) Pharmaceutical sciences and technology;
- ii) Biological Sciences;
- iii) Chemistry (analytical or organic) or biochemistry;
- iv) Chemical engineering;
- v) Veterinary medicine;
- vi) Any other relevant qualification.

10) 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;

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- 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.

11) 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.

12) 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;

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- 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.

### **5.1.1 Training**

It is a requirement to provide on job training for all staff. The following must be undertaken:

- 1) 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;
- 2) 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.
- 3) All personnel shall receive continuing training, evaluated and records be retrieved as per approved training program;
- 4) 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;
- 5) 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;
- 6) Consultants and contract staff shall be qualified for their service and their training records kept.

### **5.2 Personnel for distributors, wholesalers and retailers of medical products**

The supervising personnel of authorized medical products establishments shall:

- 1) For a distributor of medical products, be a pharmacist or any other relevant qualification;
- 2) For a human wholesale pharmacy, be a registered pharmacist;

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- 3) For a wholesale veterinary pharmacy, be a veterinary doctor/pharmacist;
- 4) For wholesale of optical products be optician or any other relevant qualification;
- 5) For a wholesale of medical devices and diagnostics be a biomedical engineer/pharmacist/laboratory technician or any other relevant qualification;
- 6) For wholesale of orthopedic products be an orthopedist / orthopedic technician or any other relevant qualification;
- 7) For a human retail pharmacy, be a registered pharmacist;
- 8) For a retail veterinary pharmacy, be a registered veterinary doctor/pharmacist;
- 9) For a veterinary drug shop, be a registered veterinary technician (A2 Level) or pharmacy technician;
- 10) For a retail of medical devices and diagnostics be registered biomedical engineer or registered pharmacist or any other relevant qualification;
- 11) For a retail of optical products be an optician or any other relevant qualification;
- 12) For a retail orthopedic product, be an orthopedist or any other relevant qualification;
- 13) Public hospital pharmacies (referral, provincial and district hospitals) be a registered pharmacist;
- 14) Public health center pharmacies be a pharmacist or any other relevant qualification as required by the Supervising Institution;
- 15) Private hospital pharmacies be a pharmacist;
- 16) Supporting staffing requirements (optional): Assistant Pharmacist, Pharmacy Technician, Medical Assistant, Veterinary Technician or Nurse depending on the category of the establishment with minimum 3 years of experience in that domain. Assistant staff must be recognized officially by the Authority.

## **6. REQUIREMENTS FOR PREMISE REGISTRATION AND LICENSING**

### **6.1 Requirements to operate as a manufacturer of medical product**

- 1) Duly filled application form: Application form for premise licensing of medical products;

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- 2) RDB registration certificate of the domestic company;
- 3) Architectural plan of the site;
- 4) Environment impact assessment report;
- 5) Proof of payment of the prescribed fees;
- 6) List of products to be manufactured;
- 7) Lease/rent contract of the premise/house or any other relevant document;
- 8) Notarized copy of Degree and equivalence if applicable of authorized personnel, 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;
- 9) Notarized Valid License of the authorized personnel to Practice Profession issued by Recognized Professional Councils in Rwanda;
- 10) Notarized degrees of the key personnel to be involved in the manufacturing process, quality control and quality assurance;
- 11) Professional agreement between the Managing Director of the manufacturing plant and the authorized personnel in case the Managing Director is not the authorized personnel;
- 12) Copy of the identity card or passport of both the Managing Director and the authorized personnel;
- 13) Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices and oversight the quality of products being manufactured;
- 14) Signed resignation letter/proof of service delivered issued by the last employer of authorized personnel, if applicable;
- 15) Copy of Valid contract between authorized personnel and Managing Director of the manufacturing facility;
- 16) Curriculum vitae of the authorized personnel.

## **6.2 Requirements to open a human wholesale pharmacy**

- 1) Duly filled application form: Application form for premise licensing of medical products;

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- 2) RDB registration certificate of the domestic company;
- 3) Lease/rent contract of the premise/house or any other relevant document;
- 4) Evidence of payment of prescribed fees to Rwanda FDA Accounts Notarized copy of Degree (and Equivalence if applicable) of Authorized personnel, with minimum of 2 months' experience in supply chain management;
- 5) Notarized Valid License to Practice Pharmacy Profession issued National Pharmacy Council;
- 6) Curriculum vitae of the authorized personnel;
- 7) Professional agreement between the Managing Director of the pharmacy and the authorized personnel in case the Managing Director is not the authorized personnel;
- 8) Copy of the identity card or passport of both the Managing Director and the authorized personnel;
- 9) Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices;
- 10) Signed resignation letter/proof of service delivered issued by the last employer of authorized personnel, if applicable;
- 11) Copy of valid contract between authorized personnel and Managing Director of the pharmacy.

### **6.3. Requirements to open a human wholesale of medical device**

- 1) Duly filled application form: Application form for premise licensing of medical products;
- 2) RDB registration certificate of the domestic company;
- 3) Lease/rent contract of the premise/house or any other relevant document;
- 4) Evidence of payment of prescribed fees to Rwanda FDA Accounts;
- 5) Notarized copy of Degree (and equivalence if applicable) of Authorized personnel;
- 6) Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda;
- 7) Curriculum vitae of the authorized personnel;
- 8) Copy of the identity card or passport of both the Managing Director and the authorized personnel;

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- 9) Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices;
- 10) Signed resignation letter/proof of service delivered issued by the last employer of authorized personnel, if applicable;
- 11) Copy of valid contract between authorized personnel and Managing Director of the wholesale.

#### **6.4. Requirements to open a veterinary wholesale pharmacy**

- 1) Duly filled application form: Application form for premise licensing of medical products;
- 2) RDB registration certificate of the domestic company;
- 3) Lease/rent contract of the premise/house or other relevant document;
- 4) Evidence of payment of prescribed fees to Rwanda FDA Accounts;
- 5) Notarized copy of Degree (and equivalence if applicable) of Authorized personnel;
- 6) Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda;
- 7) Curriculum vitae of the authorized personnel;
- 8) Professional agreement between the Managing Director of the wholesale and the authorized personnel in case the Managing Director is not the authorized personnel;
- 9) Copy of the identity card or passport of both the Managing Director and the authorized personnel;
- 10) Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices;
- 11) Signed resignation letter/proof of service delivered issued by the last employer of authorized personnel, if applicable;
- 12) Copy of valid contract between authorized personnel and Managing Director of the veterinary wholesale pharmacy.

#### **6.5 Requirements to open a veterinary retail pharmacy**

- 1) Duly filled application form: Application form for premise licensing of medical products;

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- 2) RDB registration certificate of the domestic company;
- 3) Lease/rent contract of the premise/house or any other relevant document;
- 4) Evidence of payment of prescribed fees to Rwanda FDA Accounts;
- 5) Notarized copy of Degree (and Equivalence if applicable) of authorized personnel;
- 6) Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda;
- 7) Curriculum vitae of the new authorized personnel;
- 8) Professional agreement between the Managing Director of the wholesale and the authorized personnel in case the Managing Director is not the authorized personnel;
- 9) Copy of the identity card or passport of both the Managing Director and the authorized personnel;
- 10) Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices;
- 11) Signed resignation letter/proof of service delivered issued by the last employer of authorized personnel, if applicable;
- 12) Copy of valid contract between authorized personnel and Managing Director of the veterinary retail pharmacy.

#### **6.6 Requirements to open a veterinary drug shop**

- 1) Duly filled application form: Application form for premise licensing of medical products;
- 2) RDB registration certificate of the domestic company;
- 3) Lease/rent contract of the premise/house or any other relevant document;
- 4) Evidence of payment of prescribed fees to Rwanda FDA Accounts;
- 5) Notarized copy of Degree (and equivalence if applicable) of Authorized personnel (A2 Level);
- 6) Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda;
- 7) Curriculum vitae of the authorized personnel;

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- 8) Professional agreement between the Managing Director of the wholesale and the authorized personnel in case the Managing Director is not the authorized personnel;
- 9) Copy of the identity card or passport of both the Managing Director and the authorized personnel;
- 10) Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices;
- 11) Signed resignation letter/proof of service delivered issued by the last employer of authorized personnel, if applicable;
- 12) Copy of valid contract between authorized personnel and Managing Director of the veterinary drug shop.

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

#### **6.7 Requirements to open a human retail pharmacy**

- 1) Duly filled application form: Application form for premise licensing of medical products;
- 2) RDB registration certificate of the domestic company;
- 3) Lease/rent contract of the premise/house or any other relevant document;
- 4) Evidence of payment of prescribed fees to Rwanda FDA Accounts;
- 5) Notarized copy of Degree (and equivalence if applicable) of Authorized personnel, with minimum of 2 months experience in community pharmacy;
- 6) Notarized Valid License to Practice Pharmacy Profession issued National Pharmacy Council
- 7) Curriculum vitae of the authorized personnel;
- 8) Professional agreement between the Managing Director of the pharmacy and the authorized personnel in case the Managing Director is not the authorized personnel;
- 9) Copy of the identity card or passport of both the managing director and the authorized personnel;
- 10) Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices;

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- 11) Signed resignation letter/proof of service delivered issued by the last employer of authorized personnel, if applicable;
- 12) Copy of valid contract between authorized personnel and Managing Director of the pharmacy.

### **6.8 Requirements to open an orthopedic shop**

- 1) Duly filled application form: Application form for premise licensing of medical products;
- 2) RDB registration certificate of the domestic company;
- 3) Lease/rent contract of the premise/house or any other relevant document;
- 4) Evidence of payment of prescribed fees to Rwanda FDA Accounts;
- 5) Notarized copy of Degree (and equivalence if applicable) of Authorized personnel;
- 6) Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda;
- 7) Curriculum vitae of the authorized personnel;
- 8) Professional agreement between the Managing Director of the wholesale and the authorized personnel in case the Managing Director is not the authorized personnel;
- 9) Copy of the identity card or passport of both the Managing Director and the authorized personnel;
- 10) Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices;
- 11) Signed resignation letter/proof of service delivered issued by the last employer of authorized personnel, if applicable;
- 12) Copy of valid contract between authorized personnel and Managing Director of the Orthopedic shop.

### **6.9 Requirements to open an optical shop**

- 1) Duly filled application form: Application form for premise licensing of medical products;
- 2) RDB registration certificate of the domestic company;
- 3) Lease/rent contract of the premise/house or any other relevant document;
- 4) Evidence of payment of prescribed fees to Rwanda FDA Accounts;

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- 5) Notarized copy of Degree (and equivalence if applicable) of Authorized personnel;
- 6) Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda;
- 7) Curriculum vitae of the authorized personnel;
- 8) Professional agreement between the Managing Director of the wholesale and the authorized personnel in case the Managing Director is not the authorized personnel;
- 9) Copy of the identity card or passport of both the Managing Director and the authorized personnel;
- 10) Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices;
- 11) Signed resignation letter/proof of service delivered issued by the last employer of authorized personnel, if applicable;
- 12) Copy of valid contract between authorized personnel and Managing Director of the optical shop.

#### **6.10 Requirements for assistant technician**

- 1) Application letter addressed to Director General of Rwanda FDA
- 2) Original premise license issued by Rwanda FDA
- 3) Notarized degree (and equivalence if applicable) of the assistant technician
- 4) Notarized valid license to practice profession of the assistant technician where applicable
- 5) Copy of valid contract between assistant technician and managing director
- 6) Copy of the identity card or passport of assistant technician

#### **7.REQUIREMENTS TO RE-GRANT A LICENSE OR APPROVAL OF A SUBSTANTIAL MODIFICATION**

The following classes of substantial modifications are allowed. Clients are advised to contact the Rwanda FDA for any guidance in this respect. These include:

- 1) Major substantial modification includes, but not limited to:
  - a) Relocation or additional storage space of the licensed premise;

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- b) Change of the authorized personnel;
  - 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 substantial modification includes, but not limited to:
- a) Change of the name of the establishment;
  - b) Closure of the licensed premise;
  - c) Notification of assistant technician;
  - d) Change of ownership of the licensed premise: The person to whom an ownership has been transferred to shall apply to the Authority within thirty days.

For major substantial modification, the applicant shall wait for the written approval of the Authority before the implementation of the requested variation.

### **7.1 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) Recent copy premise license 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.

### **7.2 Requirements to change the authorized personnel of the licensed premise**

- a) Duly filled application form: Application form for premise licensing of medical products;

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- b) Recent copy premise license issued by Rwanda FDA;
- c) RDB registration certificate of the domestic company;
- d) Evidence of payment of prescribed fees;
- e) Notarized degree of the authorized personnel;
- f) Notarized valid license to practice profession of the responsible authorized personnel where applicable;
- g) Professional agreement between the establishment and the authorized personnel in charge where the managing director is not the responsible authorized personnel;
- h) Curriculum vitae of the new authorized personnel;
- i) Copy of valid contract between authorized personnel and Managing Director;
- j) Resignation letter of the former authorized personnel 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 authorized personnel (if he/she has been working);
- m) Copy of the identity card or passport of both the managing Director and the responsible authorized personnel.

### **7.3 Requirements to change the name of establishment**

- a) Duly filled application form: Application form for premise licensing of medical products;
- b) Recent premise license issued by Rwanda FDA;
- c) RDB registration certificate of the domestic company.

### **7.4 Requirements to change the ownership of the licensed premise**

- a) Dully completed application form for premise licensing of medical products to close the business;
- b) Recent premise license issued by Rwanda FDA;
- c) Notarized sales agreement between former and new owner;

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- d) RDB registration certificate of the domestic company;
- e) Notarized degree of the authorized personnel;
- f) Notarized valid license to practice profession of the responsible authorized personnel where applicable;
- g) Copy of the identity card or passport of both the managing director and the responsible authorized personnel.

#### **7.5 Requirements to close the licensed establishment**

- a) Dully completed application form for premise licensing of medical products to close the business;
- b) Recent premise license issued by Rwanda FDA;
- c) Provide a list of closing stock of medical products and its intended use.

#### **7.6 Requirements for renewal of the premise license**

- a) Duly filled application form: Application form for premise licensing of medical products
- b) Recent premise license 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 authorized personnel where applicable
- g) Copy Contract between authorized personnel and managing director
- h) Copy of the identity card or passport of both the managing director and the responsible authorized personnel

### **8. LICENSING OF PUBLIC AND PRIVATE HOSPITAL PHARMACIES**

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

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## **8.1 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 authorized 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.

## **8.2 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 and a storage area 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 and a storage area 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;

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 provision of clinical and administrative pharmacy services;
- e) The hospital pharmacy medical products rooms shall be well lit, ventilated, and maintained in a clean and orderly manner;
  - f) No person shall prepare, compound, dispense, package or store any medication under unsanitary conditions;

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

### **8.3 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.

### **8.4 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 or any other relevant document;
- 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 Authorized personnel, with minimum of 4 months ‘experience in clinical pharmacy;
- f) Notarized Valid License to Practice Pharmacy Profession issued by National Pharmacy Council;

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- g) Curriculum vitae of the authorized personnel;
- h) Professional agreement between Managing Director/Director General of the hospital and the authorized personnel;
- i) Copy of the identity card or passport of both the Managing Director/ Director General of the hospital and the authorized personnel;
- 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 authorized personnel, if applicable;
- l) Copy of valid contract/appointment letter between authorized personnel and Managing Director/Director General of the hospital.

### **8.5 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 authorized personnel.
- c) Availability of copy of license to practice of the authorized 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 authorized personnel in charge.
- f) A copy of premise license and license to practice profession for the responsible authorized personnel shall be conspicuously displayed in the establishment.

### **9.LICENSING OF CENTRAL MEDICAL STORE AND THE BRANCHES**

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

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### **9.1 Personnel**

The pharmacy shall ensure the professional and technical staffing levels are commensurate with the workload volume.

There shall be written job descriptions for all pharmacy personnel clearly delineating professional and technical functions.

### **9.2 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) For central medical store and the branches dealing with the human medicines or medical devices, the total floor space shall have a minimum space of 90 square meters. The sales area shall have minimum floor space of 30 square meters, and records shall be maintained in this area. The storage areas shall 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:

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

### **9.3 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;

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- 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.

#### **9.4 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 or any other relevant document;
- 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 Authorized personnel, 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 authorized personnel;
- h) Professional agreement between Managing Director and the authorized personnel;
- i) Copy of the identity card or passport of both the Managing Director and the authorized personnel;
- 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 authorized personnel, if applicable;
- l) Copy of valid contract/appointment letter between authorized personnel and Managing Director.

#### **9.5 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;

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*Guidelines for licensing of public and private manufacturers, distributors, wholesalers and retailers of medical Products*

- b) All entry and exit of medical products must be approved by the responsible authorized personnel;
- c) Availability of copy of license to practice of the authorized 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 authorized personnel in charge;
- f) A copy of premise license and license to practice profession for the responsible authorized personnel shall be conspicuously displayed in the establishment.

**10. LICENSING OF HEALTH POSTS AND HEALTH CENTERS PHARMACIES**

- a) The health posts and health centers pharmacies shall be licensed in accordance with these guidelines. The pharmacy shall be managed by licensed authorized personnel having the educational background in pharmacy, nursing and other relevant qualification;
- b) 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.

**10.1 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.

**10.2 Premises**

- a) The health posts and health centers shall have the premise of sufficient size to store and dispense medical products;
- b) The health center pharmacy shall have a minimum floor space of 15 square meters whereas the health post pharmacy shall have a minimum floor space of 10 square meters that can be divided into storage area and the dispensing area 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.

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- c) The pharmacy medical products rooms shall be well lit, ventilated, and maintained in a clean and orderly manner.

### **10.3 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.

### **10.4 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 or any other relevant document;
- d) For licensing of health centers and health posts, the Authority may exempt regulatory service fees;
- e) Notarized copy of Degree (and Equivalence if applicable) of authorized personnel;
- f) Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda;
- g) Curriculum vitae of the authorized personnel;
- h) Professional agreement between Managing Director/Head of health center/health post and the authorized personnel;
- i) Copy of the identity card or passport of both the Managing Director/ Head of health center/health post and the authorized personnel;
- j) Written commitment of the authorized personnel 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 authorized personnel, if applicable;
- l) Copy of valid contract/ appointed letter between authorized personnel and Head of health center/health post.

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## **10.5 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 authorized personnel in charge;
- d) A copy of premise license and license to practice profession for the responsible authorized personnel shall be conspicuously displayed in the establishment.

## **10.6 Management of controlled substances**

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

## **11. GOOD PRACTICES**

### **11.1 Good Distribution Practice**

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

#### **11.1.1. Transport and delivery Validation**

- a) The applicant should keep the transport validation data available and should submit them to the Authority upon request;
- b) The distributor shall be responsible for reviewing the transport route for suitability by means of assessment of environmental conditions (temperature and relative humidity) on the product including product integrity during transport;
- c) The distributor shall ensure that the products can be safely transported within the temperature profile defined for each product and that compliance can be demonstrated to the Authority;
- d) Storage, distribution and transport validation shall be conducted in line with the World Health Organization (WHO) guidance for the storage and transport of time- and temperature-sensitive medical products. The latest version of these guidelines as revised by the WHO shall be applicable in each case.

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## **11.2 Good Manufacturing Practice**

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

## **11.3 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.

## **12. 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.

## **13. VALIDITY OF AN APPLICATION AND AUTHORIZATION**

### **13.1 Validity of an application**

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. The complete application is processed within a period of thirty (30) working days from the date of submission.

An incomplete application shall be rejected until all requirements are fulfilled as described in section (4) of these guidelines.

### **13.2 Validity of an authorization**

An authorization shall be valid for twelve (12) months of the fiscal year renewable. All authorization issued shall expiry by 30<sup>th</sup> June of the fiscal year.

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

### **13.3 Display of the authorization**

The license to practice, the premise registration certificate and premise license shall be conspicuously displayed in the establishment.

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### 13.4 Display of sign post

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

## 14. CATEGORIZATION OF INSPECTION FINDINGS

The following section provides the classification of compliance based on risk factors that shall guide the Authority on decision-making after conducting premise inspection.

The regulatory actions shall be classified as in the following non-compliance categories:

- a) **Minor/Other Non-compliance:** A non-compliance that is not classified as either “Critical” or “Major”, but indicates a departure from premises suitability. A non-compliance may be judged as “**Minor**” because there is insufficient information to classify it as “Critical” or “Major”.
  
- b) **Major Non-compliance:** A non-compliance that is not a “Critical” non-compliance, but which:
  - i) has produced or may produce a product which does not comply with its Marketing Authorization, Clinical Trial Authorization, product specification; pharmacopoeia requirements, facility and equipment safety, quality control laboratory, authorized personnel.
  
  - ii) does not ensure effective implementation of the required premises control measures;
  
  - iii) indicates a major deviation from the terms of the manufacturing authorization;
  
  - iv) indicates a failure to carry out satisfactory procedures for release of batches or failure of the authorized person to fulfill his/her duties;
  
  - v) consists of several “Minor/Other” related non-compliances, none of which on its own may be “Major”, but which may together represent a “Major” non-compliance or systems failure and should be explained and reported as such.
  
- c) **Critical Non-compliance:** 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 (or personnel or environment) is highly probable, including life threatening situation, the deviation is categorized as Critical requiring immediate action, investigated and documented.

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- i) A non-compliance which has produced, or leads to a significant risk of producing either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food producing animal.
- ii) A “Critical” non-compliance also occurs when it is observed that the manufacturer has engaged in fraud, misrepresentation or falsification of products or data.
- iii) A “Critical” non-compliance may consist of several related non-compliances, none of which on its own may be “Critical”, but which may together represent a” Critical” non-compliance, or systems’ failure where a risk of harm was identified and should be explained and reported as such.

## **14.1 Manufacturing facilities**

### **14.1.1 Critical non-compliances**

#### **1) Premises:**

- a) Site Location which does not comply with environmental requirement to manufacture medical products.
- b) No air filtration system to eliminate airborne contaminants that are likely to be generated during manufacture or packaging (i.e: HVAC/ air handling unit)
- c) Generalized malfunctioning of the ventilation system(s) with evidence of widespread cross-contamination.
- d) Inadequate segregation of manufacturing process and testing areas from other manufacturing areas that may pose serious health hazards and cross contamination depending on the product to be manufactured.
- e) Lack of pharmaceutical water system, clean water, and waste water treatment system
- f) Finishing materials: production floor area, ceiling and walls that are not seamless and easy to clean

#### **2) Equipment**

- a) Equipment used for manufacturing operations of critical products not qualified with evidence of malfunctioning.
- b) Evidence of contamination of products by foreign materials such as grease, oil, rust particles from the equipment.

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### **3) Personnel**

Staff in charge of Quality Control or production does not hold a university degree in a science related to the work being conducted, and does not have sufficient practical experience in their area of responsibility.

### **4) Sanitation**

- a) Evidence of widespread accumulation of residues/extraneous matter indicative of inadequate cleaning,
- b) Evidence of gross infestation

#### **14.1.2 Major non-compliances**

##### **1) Premises**

- a) Malfunctioning of the ventilation system that could result in possible localized or occasional cross-contamination.
- b) Accessory supplies (steam, air, nitrogen, dust collection etc) not qualified.
- c) Heating Ventilation Air Conditioning (HVAC) and purified water (PW) system not qualified.
- d) Absence of temperature and humidity gadgets or monitoring records at the time of the premise license renewal.
- e) Damages to walls/ceilings immediately adjacent or above manufacturing areas or equipment where the product is exposed.
- f) Un-cleanable surfaces created by pipes, fixtures or ducts directly above products or manufacturing equipment.
- g) Surface finish (floors, walls, ceilings) that do not permit effective cleaning.
- h) Unsealed porous finish in manufacturing areas with evidence of contamination (mould, powder from previous productions etc)
- i) Insufficient manufacturing space that could lead to mix ups.

##### **2) Equipment**

- a) Equipment does not operate within its specifications.

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- b) Tanks for manufacturing of liquids and ointments not equipped with sanitary clamps.
- c) Stored equipment not protected from contaminations.
- d) Inappropriate equipment for production: surfaces porous and non-cleanable/material to shed particles
- e) No covers for tanks, hoppers or similar manufacturing equipment.
- f) Equipment location does not prevent cross-contamination or possible mix ups for operations performed in common area.
- g) Purified water not maintained or operated to provide water of adequate quality.
- h) Leaking gaskets.
- i) No calibration program for measuring equipment /no records maintained.
- j) No equipment usage logs.
- k) No fire-fighting equipment/Fire alarm systems, emergency doors.

### **3) Personnel**

- a) Delegation of responsibilities of key personnel for Quality Control and production to insufficiently qualified persons.
- b) Insufficient personnel in Quality Control and production resulting in a high possibility of error.

### **4) Health and Sanitation**

- a) Sanitation program not in writing but premises in acceptable state of cleanliness.
- b) Absence of Medical emergency kits.
- c) Absence of Emergency shower.

#### **14.1.3 Minor (other) non-compliances**

##### **1) Premises**

- a) Doors giving direct access to exterior from manufacturing and packaging areas used by personnel.

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- b) Un-screened/un-trapped floor drains.
- c) Outlets for liquids and gases not identified.
- d) Damages to surfaces not directly adjacent or above exposed products.
- e) Inadequate rest, change, wash-up and toilet facilities.

## **2) Equipment**

- a) Insufficient space between equipment and walls to permit cleaning.
- b) Base of immovable equipment not adequately sealed at points of contact.
- c) Use of temporary means or devices for repair.
- d) Defective or unused equipment used for non-critical products not qualified.

## **3) Sanitation**

- a) Incomplete written sanitation program
- b) Sanitation or Health and hygiene programs not properly implemented or followed by employees.

### **14.2 Public and private distributors/wholesalers of medical products**

#### **14.2.1 Critical non-compliances**

##### **1) Premises:**

- a) Insufficient floor space and height requirements
- b) Surrounding area that can cause contamination from the external environment or other activities.
- c) Floor, ceiling and walls that are not well maintained.
- d) Lack of Proper ventilation/ Air handling unit /Heat, Ventilation and Air Conditioning (HVAC).
- e) Lack of Temperature and humidity monitoring systems
- f) Storage of products requiring refrigeration at ambient temperatures.

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g) Rejected or recalled products found in sellable stock.

**2) Equipment/Furniture**

- a) Lack of storage furniture.
- b) Lack of secure and lockable storage place for controlled medical products
- c) Lack of equipment to store related temperature sensitive medical products
- d) Lack of appropriate vehicle for transportation of medical products

**3) Personnel**

Operating without an authorized personnel

**4) Documentation**

- a) Absence of controlled medical products distribution report.
- b) Falsification of documentation and related controls.
- c) Purchase from or supply of medicinal products to a non-authorized person.

**14.2.2 Major non-compliances**

**1) Premises:**

- a) Damage of walls, ceilings, roof, doors and windows.
- b) Surface finish (floors, walls, ceilings) that do not permit effective cleaning.
- c) Inappropriate ventilation /Air handling unit /Heat, Ventilation and Air Conditioning (HVAC).
- d) Inappropriate temperature and humidity monitoring systems and lack of monitoring records at the time of the routine inspection.
- e) Inappropriate sanitation facilities (toilets, washing station, etc)

**2) Equipment/Furniture**

- a) Lack of Fire-fighting equipment.
- b) Inappropriate storage furniture.
- c) Inappropriate secure and lockable storage place for controlled medical products.

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- d) Inappropriate equipment to store related temperature sensitive medical products.

### **3) Personnel**

Absence of the authorized personnel during working hours

### **4) Documentation**

Lack of premise license, import & export documents, distribution records, records of expired/damaged products

#### **14.2.3 Minor (other) non-compliances**

- a) Lack of appropriate lighting systems
- b) Premise license issued by Rwanda FDA not displayed
- c) License to practice profession issued by professional bodies of the authorized personnel not displayed
- d) Absence of Filing systems of documents

### **14.3 Public and private retailers of medical products**

#### **14.3.1 Critical non-compliances**

##### **1) Premises:**

- a) Insufficient floor space and height requirements
- b) Surrounding area that can cause contamination from the external environment or other activities.
- c) Lack of proper ventilation
- d) Lack of temperature and humidity monitoring systems
- e) Storage of products requiring refrigeration at ambient temperatures;
- f) Rejected or recalled products found in sellable stock.

##### **2) Equipment/ Furniture**

- a) Lack of secure and lockable storage place for controlled medical products
- b) Lack of equipment to store related temperature sensitive medical products

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**3) Personnel**

Operating without an authorized personnel

**4) Documentation**

- a) Lack of Prescription of controlled medical products
- b) Falsification of documentation and related controls

**14.3.2 Major non-compliances**

**1) Premises:**

- a) Damage of walls, ceilings, roof, doors and windows
- b) Surface finish (floors, walls, ceilings) that do not permit effective cleaning.
- c) Inappropriate natural ventilation/Mechanical ventilation
- d) Inappropriate temperature and humidity monitoring systems and lack of monitoring records at the time of the routine inspection.
- e) Inappropriate sanitation facilities (toilets, washing station, etc)

**2) Equipment/Furniture**

- a) Lack of Fire-fighting equipment.
- b) Lack of appropriate storage furniture.
- c) Inappropriate secure and lockable storage place for controlled medical products.
- d) Inappropriate equipment to store related temperature sensitive medical products.

**3) Personnel**

Absence of the authorized personnel during working hours.

**4) Documentation**

Lack of premise license, import & export documents, distribution records, records of expired/damaged products.

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### **14.3.3 Minor (other) non-compliances**

- a) Lack of appropriate lighting systems
- b) Premise license issued by Rwanda FDA not displayed
- c) License to practice profession issued by professional bodies of the authorized personnel not displayed
- d) Absence of Filing systems of documents
- e) Lack of Water filter/water dispenser with drinking water and cups
- f) Lack of appropriate technician overall coat
- g) Failure to put on technician overall coat
- h) Lack of waiting and counselling area with suitable furniture

**N.B:** Note that the listed non-compliances may not be exhausted enough to cover all possible non-compliances. Non-compliances shall be classified upon discretion of the Authority.

### **15. WARNING, SUSPENSION AND REVOCATION**

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

Where the license is suspended, 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.

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Measures towards enforcing this article may include the publication of the Rwanda FDA's action on its website and other relevant media. An authorization holder or applicant may notify Authority his or her grounds when he or she:

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

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) 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) 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) 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.

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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) 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) 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) In relation to a suspension or revocation, or a notice served, which takes immediate effect in accordance with these guidelines; or

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.

## **16. 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 supervising 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.

## **17. COMMENCEMENT**

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

## **LIST OF FORM FOR USE WITH THESE GUIDELINES**

- 1) Doc. FDISMFDIC/FOM/002- Application form for premise licensing of medical products
- 2) Doc. FDISM/FDIC/FOM/010\_premise licensing inspection for medical gas production plant report form
- 3) Doc. FDISM/FDIC/FOM/009\_ Premise licensing inspection for medical manufacturing facility report form

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- 4) Doc. FDISM/FDIC/FOM/008 Premise licensing, GSP&GDP inspection for wholesaler, distributor and retailer of medical products report Form

**LIST OF FORMAT OF PREMISE REGISTRATION CERTIFICATE**

- 1) Doc FDISM/FDIC/FMT/180\_Premise registration certificate

**LIST OF FORMAT OF AUTHORIZATION FOR USE WITH THESE GUIDELINES**

- 1) Doc. N°. FDISM/FDIC/FMT/003\_Premise license for manufacturer of medical products
- 2) Doc N°. FDISM/FDIC/FMT/005 \_Premise license

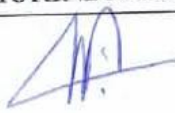



**LIST OF NOTIFICATIONS FOR USE WITH THESE GUIDELINES**

- 1) Withdrawal/suspension of premise license

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**ENDORSEMENT OF THE GUIDELINES**

	Author	Checked by		Approved by
<b>Title</b>	Division manager	Head of Department	Quality Assurance Analyst	Director General
<b>Names</b>	Dr. Marilyn M. MURINDAHABI	Dr. Eric NYIRIMIGABO	Théogène NDAYAMBAJE	Dr. Emile BIENVENU
<b>Signature</b>				
<b>Date</b>	22/09/2022	22/09/2022	22/09/2022	22/10/2022




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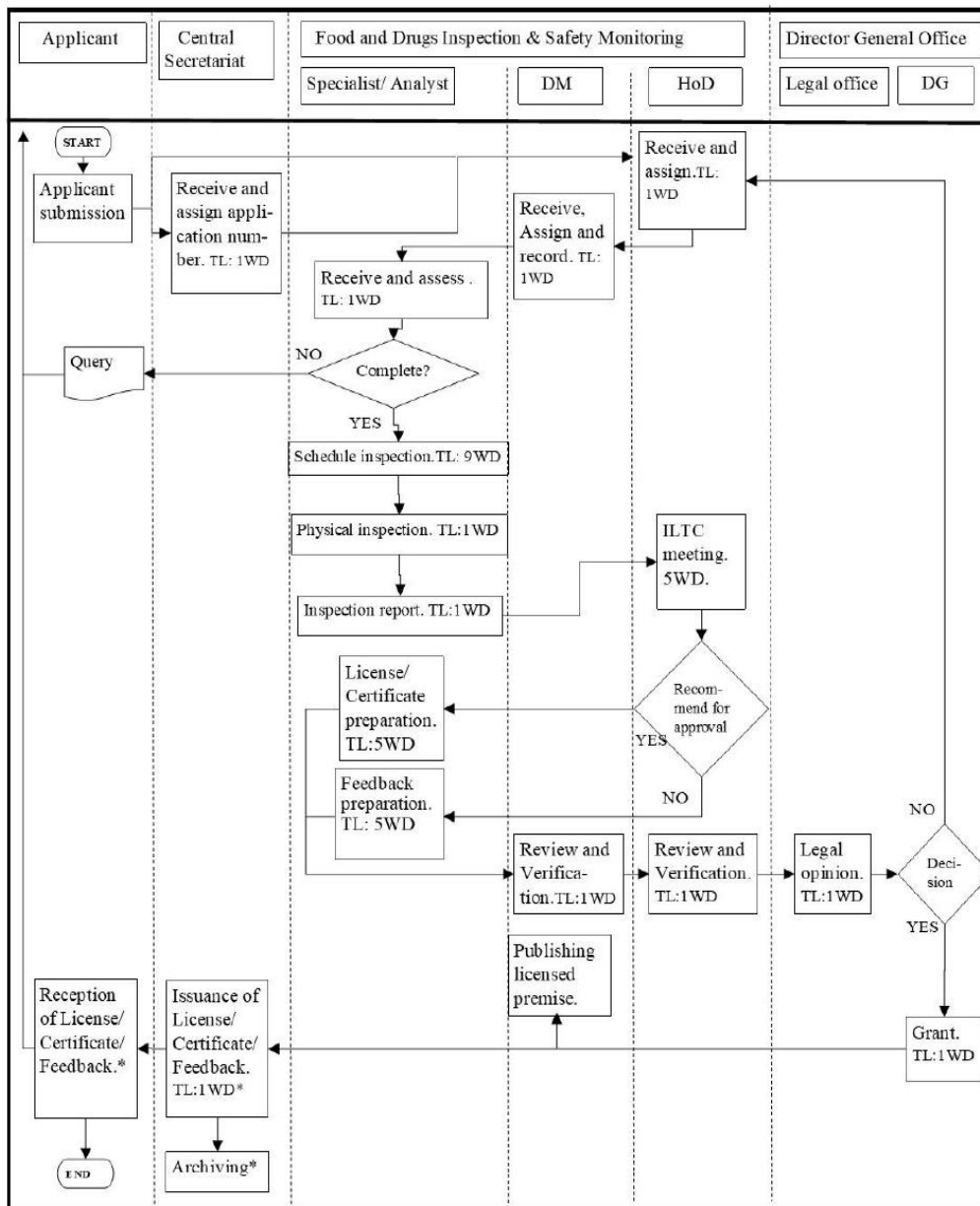
**ANNEXES**

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**ANNEX I: PROCESS FLOW CHART**

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit Food and Drugs Inspection and Safety Monitoring/Food and Drugs Inspection & Compliance	Doc. No :FDISM/FDIC/CHT/001  Revision Number : 0 Revision Date: :10/10/2022 Effective Date :17/10/2022 Review Due Date : 16/10/2025 Ref Doc. : FDISM/FDIC/GDL/005
 <b>RWANDA FDA</b> Rwanda Food and Drugs Authority	Title: <b>Registration and Licensing of Regulated Premises</b>	




Legend:  
 DG: Director General  
 DM: Division Manager  
 HOD: Head of Department  
 TL: Timeline  
 ILTC: Internal Licensing Technical Committee  
 WD: Working Day(s)  
 \* - Four(4) business days

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**ANNEX II: APPLICATION FORM**

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division	Food and Drugs Inspection and Safety Monitoring/Food and Drugs Inspection & Compliance
Document Type: <b>Form</b>		Doc. No : <span style="float: right;">FDISM/FDIC/FOM/002</span>
	Title: <b>Application Form for Premise Licensing of medical products</b>	
	Revision Number : 1	
	Revision Date: : 24/08/2022	
	Effective Date : 22/09/2022	
	Review Due Date : 21/09/2025	
Ref Doc. : <span style="float: right;">FDISM/FDIC/GDL/005</span>		

Name of Premise:	Application date:     /     / <span style="text-align: center;"><i>DD / MM/ YYYY</i></span>	
Domestic Company Registration code:	Registration date in Rwanda FDA:     /     / <span style="text-align: center;"><i>DD/ MM/ YYYY</i></span>	
Physical location: <small>(Province, District, Sector, Cell)</small>	Registered Address:	
Global Positioning System (GPS) Coordinates	Name of responsible technician: (If applicable)	
Company e-mail:  Company Telephone:	Qualification:	
Name of Managing Director:	Email of responsible technician: (if applicable)	
Email of Managing Director  Telephone No:	Tel of responsible technician:	
<b>TYPE OF PREMISE:</b> (Please tick below)	<b>MAIN ACTIVITY</b> (Please tick below)	<b>TYPE OF APPLICATIONS</b> (Please tick below)
<input type="checkbox"/> Retailer <input type="checkbox"/> Wholesaler <input type="checkbox"/> Distributor <input type="checkbox"/> Manufacturer <input type="checkbox"/> Hospital Pharmacy <input type="checkbox"/> Central Medical Stores <input type="checkbox"/> Health Centres <input type="checkbox"/> Health Posts <input type="checkbox"/> Other	<input type="checkbox"/> Human retail pharmacy <input type="checkbox"/> Human wholesale pharmacy <input type="checkbox"/> Human wholesale of medical device <input type="checkbox"/> Small scale manufacturer <input type="checkbox"/> Manufacturer of medical products <input type="checkbox"/> Veterinary Drug shop <input type="checkbox"/> Veterinary retail pharmacy <input type="checkbox"/> Veterinary wholesale pharmacy <input type="checkbox"/> Veterinary manufacturing facility	<input type="checkbox"/> Site location approval <input type="checkbox"/> New Application <input type="checkbox"/> Renewal <input type="checkbox"/> Variation <input type="checkbox"/> <i>Change of ownership</i> <input type="checkbox"/> <i>Change of location &amp; Additional line</i> <input type="checkbox"/> <i>Change authorized personnel</i>

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..... ..... .....	<input type="checkbox"/> Vaccine manufacturing facility <input type="checkbox"/> Herbal drugs wholesaler <input type="checkbox"/> Herbal drugs retailer <input type="checkbox"/> Herbal drugs manufacturer <input type="checkbox"/> Hospital pharmacies <input type="checkbox"/> Central Medical stores <input type="checkbox"/> Health posts & Health Centers <input type="checkbox"/> Orthopedic shop <input type="checkbox"/> Optical shop <input type="checkbox"/> Other specify ..... .....	<input type="checkbox"/> Change of name of the Establishment <input type="checkbox"/> Closure of the business activities <input type="checkbox"/> Re-inspection <input type="checkbox"/> Other specify ..... .....
<b>AFFIDAVIT</b>		
I hereby affirm that the statement in this application is true and correct.		
_____ <b>Applicant's Name and Signature</b>		_____ <b>Date (dd/mm/yyyy)</b>

**FOR OFFICIAL USE ONLY:**

Date Received : ...../...../.....  
 Inspection date: ...../...../.....  
 Approved/ Denial: A / D .  
 Approval date : ...../...../.....

<b>I. REQUIREMENTS FOR PREMISE LICENSING OF MEDICAL PRODUCTS</b>				New application	Renewal	Change ownership	Change technician	Change location	Additional line	Additional branch	Change of name	Closure of business
	Premise name:	Date:										
	Documents	YES	NO									
1	A dully filled application form for premises licensing of Medical Products-FDISM/FDIC/FOM/002			x	x	x	x	x	x	x	x	x
2	RDB registration certificate of the domestic company or equivalent certificate /recommendation from local government			x	x	x		x		x	x	
3	Architectural plan of the site applicable for manufacturing facility			x				x	x	x		
4	Environment impact assessment report applicable for manufacturing facility			x				x	x	x		
5	Proof of Payment of the prescribed fees (referred to regulation related to Regulatory service Tariff/fees and Fines)			x	x		x	x	x	x		

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6	List of products to be manufactured applicable for manufacturing facility			X							
7	Lease/rent contract of the premise/house			X			X			X	
8	Notarized copy of Degree (and equivalence if applicable) of Responsible Technician <b>NB:</b> <i>i.Human Retail Pharmacy: minimum of 2 months experience in community pharmacy</i> <i>ii.Human Wholesale Pharmacy: minimum of 2 months' experience in supply chain management</i> <i>iii.Central medical store and the branches: minimum of 2 months' experience in supply chain management</i> <b>Hospital pharmacy: minimum of 4 months' experience in clinical pharmacy</b>			X		X	X			X	
9	Notarized Valid License of the responsible technician to Practice Profession issued by Recognized Professional Councils in Rwanda (if applicable)			X	X	X	X			X	
10	Notarized degrees of the key personnel to be involved in the manufacturing process, quality control and quality assurance <b>NB:</b> 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			X			X			X	
11	Professional agreement between the Managing Director/ Director General/ Chief Executive Officer and the responsible technician in case the Managing Director is not the responsible technician			X	X	X	X			X	

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12	The copy of Identity Card/Passport of the managing Director/ Director General/ Chief Executive Officer and the Responsible technician			X	X	X	X			X		
13	<b>Written commitment of the responsible technician, to respect the laws and regulations relating to the profession and ethics</b>			X	X		X		X	X		
14	<b>Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable</b>			X			X			X		
15	Copy of Valid contract between responsible technician and Managing Director/ Director General/ Chief Executive Officer			X	X	X	X			X		
16	A Detailed curriculum vitae of the responsible technician			X			X			X		
17	Original authorization of the establishment issued by Rwanda FDA				X	X	X	X	X	X	X	X
18	Notarized sales agreement between former and new owner					X						
19	Provide a list of closing stock of medical products and its intended use											X

<b>II. RE – INSPECTION</b>			
<b>Premise name:</b>			<b>Date:</b> ...../...../.....
<b>Documents</b>			<b>YES</b> <b>NO</b>
1	Re-inspection application letter addressed to the Director General of Rwanda FDA, mentioning the proposed dates.		
2	The proof of payment of prescribed re-inspection fees		
3	A Corrective Actions and Preventive Actions (CAPA) report, detailing what has been implemented with respective visual proof and timelines for non-implemented recommendations.		
<b>III. SITE LOCATION APPROVAL</b>			
<b>Premise name:</b>			<b>Date:</b> ...../...../.....
<b>Documents</b>			<b>YES</b> <b>NO</b>
1	Letter of intent		

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2	Site master plan (indicating the location /plan of the premise and the surroundings activities)		
3	Environmental impact assessment		
<b>VI. ARCHITECTAL PLAN APPROVAL</b>			
<b>Premise name:</b>		<b>Date:</b> ...../...../.....	
<b>Documents</b>		<b>YES</b>	<b>NO</b>
1	Approval letter for site location from the Authority		
2	Architecture plan showing but not limited to the following:		
	i) Production process flow chart.		
	ii) Sanitation facilities (Clean water and waste water treatment system)		
	iii) Mechanical ventilation /Air handling unit /Heat, Ventilation and Air Conditioning (HVAC).		
	iv) Finishing materials (Production floor and walls shall be seamless, ceiling, doors and windows shall be easy to clean).		

**INSTRUCTION FOR APPLICANT:**

1. Ensure that **ALL** sections of the application form are fully completed before submission. Send completed application form with stated requirements (see above) to the official email [:info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw)
2. Incomplete application **WILL NOT** be accepted.
3. Application processes will take 30 working days upon receipt of fully complete documents required.

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**ANNEX III: PREMISE REGISTRATION CERTIFICATE**



Nyarutarama Plaza, KG 9 Avenue  
P.O. Box: 1948 Kigali - Rwanda  
Email: [info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw)  
website: [www.rwandafda.gov.rw](http://www.rwandafda.gov.rw)

QMS N°: FDISM/FDIC/FMT/024  
Revision No: 0  
Effective Date: 22/09/2022

**Ref N°: FDSIM/FDIC/ /FDA/YYYY**

**PREMISE REGISTRATION CERTIFICATE**

*[Made under article 3 of the Law N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.]*

This is to certify that the premise ..... (**company Name**) under the management of Mr/Mrs/Ms. ....located in Kigali City/Province Name, District Name, Sector Name, Cell Name, Village Name, has been registered as..... (**Type of Premise e.g: Retail Pharmacy, Wholesale Pharmacy, Pharmaceutical Manufacturing Plan etc.**) .....with Registration Number...(Bold).....

1. Subject to the following conditions: -The premises and the manner in which the business is to be conducted shall conform to requirements of Rwanda Food and Drugs Authority at all times.
2. Any change in the ownership, name and location of the registered premises shall be approved by the Authority.
3. This certificate is not transferable to other premises or to any other person.
4. This certificate shall be displayed conspicuously in the registered premises.
5. The certificate shall only be used to operate business related to products approved by Rwanda FDA.
6. The certificate does not replace the premise license.

Done at Kigali on ...dd/mm/yyyy

Signature of the Director General and Seal of the Authority

**Name of the Director General**

**Director General**

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**Rwanda Food and Drugs Authority**

Nyarutarama Plaza, KG 9 Avenue

P.O. Box: 1948 Kigali - Rwanda

Email: [info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw)

website: [www.rwandafda.gov.rw](http://www.rwandafda.gov.rw)

QMS N°: FDISM/FDIC/FMT/003

Revision No: 1

Effective Date: 22 Sep 2022

Premise registration certificate N°: RWA-FDA-PPP-IIII-DDDD

**PREMISE LICENSE FOR MANUFACTURER OF  
MEDICAL PRODUCTS**

*Referring to the Law N° 003/2018 of 09/02/2018 and law N° 47/2012 of 14/01/2013*

**This is to certify that**

**Premise license N°:** FDISM/FDIC/ /FDA/YYYY

**Issued on:** / /YYYY **Valid up to:** / /YYYY  
**was granted to:**

**Name of the Company:**

**Company code:**

**Location of the premises:** Province, District, Sector, Cell, Village

**Name of the Managing Director:** Mr (Mrs/Ms)

**Telephone number:** +2507

**Head of Production Department:** Mr (Mrs/Ms)

**to carry out the following manufacturing activities:**

Product category	Product type	Dosage form (if applicable)	Manufacturing activities
i.e Pharmaceutical products		e.g.: Tablet, syrup, capsules	Production, packaging, storage, labeling and distribution

*This premise license may be suspended or withdrawn if the conditions under which it was granted are violated. The product is put on market after its assessment and registration by Rwanda FDA.*

**Name and signature of Director General**

**+ Stamp of the institution**

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Revision No.:3	Approval date: 22/09/2022	Effective Date: 26/09/2022

*Cony*



**Rwanda Food and Drugs Authority**

Nyarutarama Plaza, KG 9 Avenue  
P.O. Box: 1948 Kigali - Rwanda  
Email: [info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw)  
website: [www.rwandafda.gov.rw](http://www.rwandafda.gov.rw)

QMS N°: FDISM/FDIC/FMT/005  
Revision No:1  
Effective Date:22 Sep 2022

Ref N°:FDISM/FDIC/...../FDA/YYYY

Premise registration certificate N°: RWA-FDA-PPP-III-DDDD

**PREMISE LICENSE**

*Referring to the Law N° 003/2018 of 09/02/2018 and law N° 47/2012 of 14/01/2013*

This is to certify that.... *Insert the name of the company*.... with premise license number RWA-FDA-MM-YYYY-SN..... under company code.....is licensed to store and operate as .... **INSERT THE CATEGORY OF THE PREMISE** on the following location: Sales room: Province/District/Sector/Village and store room: Province/District/Sector/Village.

**This premise is GSP&GDP compliant (where applicable)**

Storage conditions of medical products:

.....

Names of the Managing Director: .....

Telephone Number: .....

Names of authorized personnel: .....

National Council Registration N°: .....

**This license is valid until .....**

***N.B***

- 1. This premise license must be prominently displayed in the premises to which it refers to.*
- 2. Any change made on details of the company name, physical location, management or responsible pharmacist shall be notified and approved by Rwanda FDA.*
- 3. This premise license is not transferrable and its misuse will result into suspension or revocation.*

Done at Kigali on .....

**Name and signature of Director General**

**+ Stamp of the institution**

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**ANNEX V: LIST OF NOTIFICATION FOR USE WITH THESE GUIDELINES**



**RWANDA FDA**  
Rwanda Food and Drugs Authority

**P.O. Box 1948 Kigali**

[info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw)

[www.rwandafda.gov.rw](http://www.rwandafda.gov.rw)

**Kigali on** ..... /..... / 2022

**Ref. N°: FDISM/FDIC/ /FDA/YYYY**

(Insert contact name, if available)

Company name

Telephone

Address of License Holder

Dear Sir/Madam

**Re: Withdrawal of premise license**

Reference is made to the **Law N° 003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority and determining its mission, organization and functioning especially in its article (9)2 to grant or withdraw authorization relating to matters regulated under that Law;

Reference is also made to the **Law N° 047/2018 of 14/01/2013** relating to the regulation and inspection of food and pharmaceutical products especially in its article 37(5) to close down premises considered in violation of that Law;

Reference is also made to article 4 of the Law referred to in the preceding paragraph which states that the licensee may have his or her license revoked if he or she contravenes the provisions of this Law;

Further reference is made to the inspection that was conducted at your premise dated....., where it was found that **NAME OF THE PREMISE** ...mention the violations.....

It is against this background that we notify you that operational license License Ref N°: .....of **NAME OF THE PREMISE** is hereby revoked for reason stated above. You are stopped from ....state the relevant (i.e: pharmaceutical) activities in **NAME OF THE PREMISE** with immediate effects

Sincerely,

**Name and signature of Director General**

**+Stamp of the institution**

**End of Document**

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*Cony*