



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

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FOREWORD

Rwanda Food and Drugs Authority, hereinafter abbreviated as Rwanda FDA, is a regulatory body established by Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to formulate and enforce 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. Rwanda FDA 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 required to familiarize and comply with the Guidelines 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, aimed at protecting the consumers of the products.

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

Dr. Emile BIENVENU
Director General



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Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
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Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
30/08/2020	0	First Issue
12/07/2021	1	<ol style="list-style-type: none"> Chapter II is renamed LICENSING & INSPECTIONS instead of Licensing Requirements Application forms, Formats of w license, Format of notification letter for withdrawal of premises license / Certificate and requirements for application for renewal of the premises license are included
28/12/2021	2	<ol style="list-style-type: none"> The timeline for standards of service delivery has been added. Description of different sections of the inspection report has been added. Revision of requirements to obtain a premises license. 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. Categorization of inspection findings has been added The application form was revised to be used for all categories of premises to replace the former application forms by category
24/08/2022	3	<ol style="list-style-type: none"> Amendment of space requirements of premises of medical products: Private and public Wholesalers, Retailers, Orthopedic and optical shops, health Centre and health posts Clarification on the validity of the premises license for renewal and other variations The Annex I: Process flow chart was revised The Annex III: Premises registration certificate was added The Annex VI: was revised Editorial changes to align with the new format
16/01/2023	4	<ol style="list-style-type: none"> Review and/or adding of definition: substantial modification Review of the types of inspection (Based on WHO guidelines) Review the licensing requirements of the manufacturer of medical products. Minimum requirements for magistral preparation in the human retail pharmacies have been added. The responsibilities of authorized personnel in manufacturing facilities have been added. The definition of authorized personnel for manufacturer, wholesale and retail of medical products have been added.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

TABLE OF CONTENTS

FOREWORD	2
Document Revision History	4
TABLE OF CONTENTS	5
ACRONYMS AND ABBREVIATIONS	8
GLOSSARY / Definitions	9
1. INTRODUCTION	12
1.1 Scope.....	12
2. LICENSING AND INSPECTIONS	12
2.2 Inspections	13
2.2.1 Types of inspections	13
2.2.2 Approval of the premises	14
3. MEDICAL PRODUCTS MANUFACTURING FACILITY	15
4. PREMISES OF DISTRIBUTORS, WHOLESALERS AND RETAILERS OF MEDICAL PRODUCTS	16
4.1 Location of premises for distributors, wholesalers and retailers of medical products.....	16
4.2 Standards of construction	16
4.3 Premises shall be in good state of repair, maintenance and sanitation	16
4.4 Storage areas.....	17
4.4 Minimum floor space and height	17
4.5 Documentation and related controls	19
5. PERSONNEL	19
5.1 Personnel for the medical products manufacturing facility	19
5.1.1 Training.....	23
5.2.1 Training.....	25
6. REQUIREMENTS FOR PREMISES REGISTRATION AND LICENSING	25
6.2 Requirements to open a human wholesale pharmacy	27
6.3. Requirements for opening a human wholesale of medical device.....	28
6.4. Requirements to open a veterinary wholesale pharmacy.....	28
6.5 Requirements to open a veterinary retail pharmacy	29
6.6 Requirements to open a veterinary drug shop	29
6.7 Requirements to open a human retail pharmacy	30
6.8 Requirements to open an orthopedic shop.....	31
6.9 Requirements to open an optical shop	32
6.10 Requirements for assistant technician.....	33
7. REQUIREMENTS TO RE-GRANT A LICENSE OR APPROVAL OF A SUBSTANTIAL MODIFICATION	34
7.1 Requirements for relocation or additional storage space of the licensed premises	34
7.2 Requirements to change the authorized person of the licensed premises	35
7.3 Requirements to change the name of establishment	36
7.4 Requirements to change the ownership of the licensed premises	36

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

7.5 Requirements to close the licensed establishment.....	36
7.6 Requirements for renewal of the premises license	36
8. LICENSING OF PUBLIC AND PRIVATE HOSPITAL PHARMACIES.....	37
8.1 Personnel.....	37
8.2 Premises	37
8.3 Equipment.....	38
8.4 Requirements for licensing hospital pharmacies (referral, districts hospitals for public institutions and all private hospital pharmacies)	39
8.5 Documentation and related controls	39
9. LICENSING OF MEDICAL STORAGE FACILITIES	40
9.2 Premises	40
9.3 Equipment.....	40
9.4 Requirements for licensing the medical storage facilities	41
10.1 Personnel.....	42
10.2 Premises	42
10.3 Equipment.....	42
10.4 Requirements for licensing the health center and health post pharmacies	43
10.5 Documentation and related controls	43
10.6 Management of controlled substances	44
11. GOOD PRACTICES	44
11.1 Good Distribution Practice	44
11.1.1. Transport and delivery Validation	44
11.2 Good Manufacturing Practice.....	44
11.3 Good Dispensing Practice.....	45
12. ESTABLISHMENT OF LICENSING AND INSPECTION TECHNICAL AND ADVISORY COMMITTEE.....	45
13. VALIDITY OF AN APPLICATION AND AUTHORIZATION.....	45
13.1 Validity of an application	45
13.2 Validity of a premises license	45
13.3 Display license	45
13.4 Display of sign post	45
14. CATEGORIZATION OF INSPECTION FINDINGS	46
14.1 Manufacturing facilities.....	47
14.1.1 Critical non-compliances	47
14.1.2 Major non-compliances	48
14.1.3 Minor (other) non-compliances	50
14.2 Public and private distributors/wholesalers of medical products	51
14.2.1 Critical non-compliances	51
14.2.2 Major non-compliances	52
14.2.3 Minor (other) non-compliances	52
14.3 Public and private retailers of medical products.....	53
14.3.1 Critical non-compliances	53
14.3.2 Major non-compliances	53

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

14.3.3 Minor (other) non-compliances	54
15. WARNING, SUSPENSION AND REVOCATION	55
16. APPEALS AND REVIEW	57
17. COMMENCEMENT	57
ENDORSEMENT OF THE GUIDELINES	58
ANNEX I: PROCESS FLOW CHART	60
ANNEX II: APPLICATION FORM	61
ANNEX III: PREMISES REGISTRATION CERTIFICATE	66
ANNEX IV: FORMAT OF AUTHORIZATION ISSUED	66
ANNEX V: LIST OF NOTIFICATION FOR USE WITH THESE GUIDELINES.....	70

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

ACRONYMS AND ABBREVIATIONS

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

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

GLOSSARY / DEFINITIONS

In these Guidelines:

- (a) **“Absence of authorized person”** is absence from work of the authorized person for a break of one (1) hour starting from 12:00 noon up to 1:00 pm or any other daily time range agreed upon by the employer and employee for temporary absence or break from work;
- (b) **“Applicant”** means any person or legal entity established within Rwanda or outside Rwanda, seeking to obtain or having obtained the authorization to manufacture, store, distribute, wholesale and retail medical products;
- (c) **“Authority”** means Rwanda FDA or its acronym “Rwanda FDA”, established under Article 2 of the Law N 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning;
- (d) **“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;
- (e) **“Authorized person”** is an individual recognized by the authority as having the necessary basic scientific and technical background and experience.
- (f) **“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;
- (g) **“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;
- (h) **“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 Authority to perform the intended function as prescribed in these Guidelines, 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;
- (i) **“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;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- (j) **“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;
- (k) **“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;
- (l) **“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;
- (m) **“Inspector”** means a person appointed, authorized and designated by the Rwanda FDA in accordance with laws tasked with performing inspection-related duties;
- (n) **“Labelling”** means the process of identifying a product including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer or the supplier;
- (o) **“Magistral preparation”** means medicines prepared in a pharmacy for an individual patient in accordance to a prescription from a doctor;
- (p) **“Manufacturer”** means a person or corporation, or other entity engaged in the business of manufacturing medical products;
- (q) **“Minister”** means the Minister having health in his or her responsibilities;
- (r) **“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;
- (s) **“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.”
- (t) **“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;
- (u) **“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

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

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;

- (v) **“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;
- (w) **“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;
- (x) **“Retailer”** is an entity that is authorized to carry on the business of dispensing or providing medical products directly to a patient;
- (y) **“Sale”** means sell by wholesaler or retailer and includes:
- i. advertise, label, prepare, expose, offer for sale;
 - ii. smuggle, administer, hawk, supply, barter, or dispose of to any person;
 - iii. distribute, deliver or transmit, by way of gift or sample or in any other way;
- (z) **“Substantial modification”** means a change to the premises, equipment, personnel, procedures, and processes that is likely to have significant impact and affect the quality, safety and the integrity of the products manufactured, stored, distributed, and used;
- (aa) **“Tariff/Fees”** includes any charge made or levied in connections with the services rendered by the Rwanda FDA;
- (bb) **“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.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

1. INTRODUCTION

The “Guidelines for Licensing of Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products “*Revision 4*” is a Rwanda FDA 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 premises license

- a) All applications shall be submitted to Rwanda FDA head office or via email addressed to the Director General of Rwanda FDA via official E-mail: info@rwandafda.gov.rw or via integrated management information system;
- b) An applicant for premises 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;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- d) Applicants for manufacturing facility of medical products will be required to meet the Good Manufacturing Practices GMP and Quality Management System requirements as detailed in the relevant guidelines issued by the Authority;
- e) Applicants for wholesalers and retailers of medical products will be required to meet the GDP and GSP requirements as detailed in the relevant guidelines issued by the Authority;
- f) For outsourced GDP and GSP activities: A written and approved contract or formal agreement between the contract giver and contract acceptor;
- g) Incomplete application for registration and licensing a new premises shall not be processed;
- h) Applicants dealing with both veterinary medicines and agricultural products shall apply for premises registration and premises 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 premises license or approval of a major substantial modification.

Premises that do not comply with the requirements shall not be eligible for consideration of a premises registration certificate and premises license.

2.2.1 Types of inspections

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

- a) Routine 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:

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- a) the routine inspection is a full inspection of all applicable components of licensing provisions for manufacturer, wholesaler, distributor and retailers. The routine inspection shall be conducted at any time where the premises has been licensed but before expiry of the license. It may be indicated when the premises is:
- i. Request renewal of a license to operate;
 - ii. Has introduced new product lines or new products, or has made significant modifications to manufacturing methods or processes, or has made changes in key personnel, premises, equipment, among others;
 - iii. Has a history on non-compliance with GMP, GDP and GSP;
 - iv. Has not been inspected during the last three (3) to five (5) years.
- b) Concise inspections are the evaluation of limited aspects relating to licensing compliance within the premises. The premises 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 may also indicate all is not well. 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. Further reasons for special inspection is to gather information or to investigate specific operations and to advise the applicant of regulatory requirements.
- e) Any other types as the Authority may designate, this may include pre-approval inspection for newly established premises.

2.2.2 Approval of the premises

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

3. MEDICAL PRODUCTS MANUFACTURING FACILITY

The Authority shall inspect the facility to determine the suitability for manufacturing of medical products for domestic manufacturers. Applicants should fulfill the prerequisites as detailed below prior to issuance of a manufacturing license.

- 1) Application letter addressed to Director General of Rwanda FDA;
- 2) A dully filled application form for premises licensing of Medical Products-FDISM/FDIC/FOM/002;
- 3) Proof of GMP/QMS Audit application submission to the Authority;
- 4) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- 5) Environment impact assessment report applicable for manufacturing facility;
- 6) Proof of Payment of the prescribed fees;
- 7) Lease/rent contract of the facility;
- 8) Notarized copy of degree (and equivalence if applicable) of authorized person;
- 9) Notarized valid license of the authorized person to Practice Profession issued by Recognized Professional Councils in Rwanda (if applicable);
- 10) A Detailed curriculum vitae of the authorized person;
- 11) Notarized degrees of the key personnel to be involved in the manufacturing process, quality control and quality assurance;
- 12) Copy of the valid contract between authorized person and Managing Director/ Director General/ Chief Executive Officer;
- 13) The copy of Identity Card/Passport of the managing Director/Director General/ Chief Executive Officer and the authorized person;
- 14) Written commitment of the authorized person, to respect the laws and regulations relating to the profession and ethics;
- 15) Signed resignation letter/proof of service delivered issued by the last employer of authorized person, if applicable;

The manufacturing facility (ies) shall be registered and have premises registration certificate issued by the Authority before starting the manufacturing process.

Prior to issuance of manufacturing license for facilities manufacturing medical products, the intended facility shall comply to the minimum requirements of Good Manufacturing practices and/or Quality Management system requirements as detailed in the relevant guidelines issued by the Authority.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

The applicant shall submit the following documents to apply for premises registration certificate:

- 1) Application letter addressed to Director General of Rwanda FDA
- 2) A dully filled application form for premises licensing of Medical Products- FDISM/FDIC/FOM/002
- 3) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government.
- 4) Proof of Payment of the prescribed fees

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

4.2 Standards of construction

The premises shall:

- a) Be of a permanent nature and suitable for storage of medical products;
- b) Be protected against adverse weather conditions including dust, ground water seepage, vermin and pest infestation;
- c) Have adequate space for the carrying out and supervision of the necessary operations;
- d) 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;
- e) 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;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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;
- f) The premises shall be reserved exclusively for storage and distribution of medical products, no other business is done in the same building and not communicating to other business.

4.4 Storage areas

The storage areas for medical products shall be:

- a) Well covered and products stored off the floor;
- b) secure and have adequate space, laid out to allow clear separation of different materials and products to minimize the risk of mix-up;
- c) restricted to authorized person only;
- d) Maintained within acceptable and specified temperature and humidity limits;
- e) Segregated and secured for recalled, expired, or rejected medical products.

4.4 Minimum floor space and height

- a) For a distributor dealing with the human medicines/ veterinary medicines or medical devices, the total floor space shall have a minimum space of 180 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 150 square meters; and minimum height of 2.5 meters from the floor to the ceiling;
- b) For a 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;
- c) For 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;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- d) 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;
- e) 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.
- f) For human retail pharmacy that will apply for magistral preparation, the following shall be considered as minimum requirements:
 - i. A minimum additional space of 10 square meters in the same establishment dedicated to accommodating these activities;
 - ii. Appropriate glassware (e.g: Beakers, measuring cylinders, round bottom flask, etc...);
 - iii. Grinding equipment (e.g: mortar and pestle)
 - iv. Mixing equipment (e.g: magnetic stirrer, spatula)
 - v. Calibrated weighing balance;
 - vi. Documentation (e.g: worksheet)
 - vii. Appropriate packages and labels
 - viii. Source of purified water
 - ix. Drying rack
 - x. Dedicated washing facilities
- g) 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;
- h) 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;
- i) 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;
- j) The sales and storage areas shall be orderly, have adequate space, and protected from direct sunlight, heat, and moisture;
- k) The dispensing area of the retailers of medical products shall:
 - i. be a separate lockable area with no access for the public;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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 premises 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 at the time of inspection when requested for;
- b) All entry and exit of medical products must be approved by the authorized person;
- c) Availability of copy of license to practice of the authorized person 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 person in charge;
- f) A copy of the premises license and license to practice profession for the authorized person shall be conspicuously displayed in the establishment.

5. PERSONNEL

5.1 Personnel for the medical products manufacturing facility

- a) There shall be sufficient authorized person to carry out all manufacturing activities and the responsibility for every individual has to be clearly understood and recorded;
- b) The manufacturer shall have an organization chart;
- c) All responsible staff shall have their duties recorded in written descriptions and adequate authority to carry out their responsibilities;
- d) Duties for authorized person may be delegated to designated deputies of satisfactory qualification level;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- e) There shall be no gaps or unexplained overlaps in responsibilities of personnel concerned;
- f) Unauthorized person 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 person.

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.

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

- i) Pharmaceutical sciences and technology;
- ii) Biological Sciences;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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 at least an academic qualification equivalent to a bachelor's degree 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;
- ix) The performance and evaluation in process controls;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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 program.

13) The authorized person is a key personnel and shall have the following responsibilities among others:

- i. ensure that each batch of finished medical products that has been manufactured is in accordance with market authorization and GMP/ QMS audit requirements;
- ii. release batches of finished medical products according GMP/QMS audit requirements;
- iii. implementation of the quality system;
- iv. participation in the development of quality manual;
- v. supervision of the regular internal audits or self-inspections;
- vi. oversight of the quality control department;
- vii. participation in external audit (vendor audit);
- viii. participation in validation programs;

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;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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, medical storage facilities, and retailers of medical products

The authorized person shall have the following qualification:

- 1) For a human distributor, wholesale, retail, hospital pharmacy: A bachelor's degree in pharmacy and registered by the national pharmacy council;
- 2) For a wholesale and retail veterinary pharmacy: A bachelor's degree of veterinary medicine and registered by the national veterinary council;
- 3) For a wholesale/ retail of medical devices and diagnostics: A bachelor's degree/ diploma in biomedical science/ pharmacy/ veterinary/ health laboratory practice or any other relevant qualification and registered in the relevant national professional council;
- 4) For optical shop: A bachelor's degree/ diploma as ophthalmologist, optician, optometrist, or any other relevant qualification and registered in the relevant national professional council;
- 5) For orthopedic shop: A bachelor's degree/ diploma as orthopedist /prosthetic & orthotics, orthopedic technician or any other relevant qualification and registered in the relevant national professional council;
- 6) For a veterinary drug shop, be a registered as veterinary technician (A2 Level) or pharmacy technician;
- 7) Public health center pharmacies be a pharmacist, or any other relevant qualification as required by the Supervising Institution;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 8) Supporting staffing requirements (optional): Pharmacist, Pharmacy Technician, pharmacist assistant, Veterinary Technician. Assistant staff must be recognized officially by the Authority. All these staffs are accountable to the authorized person;
- 9) Auxiliary staff (optional), including nurses they can perform other duties under the supervision of the authorized person except dispensing of medicines;

The authorized person shall have the following responsibilities:

- i. Ensure good storage, distribution, and dispensing practices in the Pharmacy establishment;
- ii. Patient counseling as appropriate for the patient in the professional judgment of the authorized person;
- iii. implementation of the quality system;
- iv. participation in the development of quality manual;
- v. storage and dispensing medical products directly to the patients for retailer of medical products;
- vi. procuring, purchasing, selling, supplying, importing, exporting, storage and distribution of medical products for wholesaler/distributor of medical products.
- vii. Self-inspection to evaluate the internal process.

5.2.1 Training

On job training for all staff must be undertaken:

- 1) Recruited personnel shall receive training appropriate to the duties assigned to them in addition to basic training on theory and practice of good storage and good distribution practices;
- 2) All personnel shall receive continuing training, evaluated and records be retrieved as per approved training program;
- 3) All personnel shall receive continuing training on their standard operating procedures;
- 4) Training on supply chain management;
- 5) Training on pharmacovigilance system.

6. REQUIREMENTS FOR PREMISES REGISTRATION AND LICENSING

6.1 Requirements to operate as a manufacturer of medical product

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 1) Application letter addressed to Director General
- 2) Duly filled application form: Application form for premises licensing of medical products;
- 3) Proof of GMP/QMS audit application
- 4) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- 5) Architectural plan of the site;
- 6) Environment impact assessment report;
- 7) Proof of payment of the prescribed fees;
- 8) List of products to be manufactured;
- 9) Lease/rent contract of the premises/house or any other relevant document;
- 10) Notarized copy of Degree and equivalence if applicable of authorized person, with 2 years' minimum experience for a bachelor's 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;
- 11) Notarized Valid License of the authorized person to Practice Profession issued by Recognized Professional Councils in Rwanda;
- 12) Notarized degrees of the key personnel to be involved in the manufacturing process, quality control and quality assurance;
- 13) Professional agreement between the Managing Director of the manufacturing plant and the authorized person in case the Managing Director is not the authorized person;
- 14) Copy of the identity card or passport of both the Managing Director and the authorized person;
- 15) Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices and oversight the quality of products being manufactured;
- 16) Signed resignation letter/proof of service delivered issued by the last employer of authorized person, if applicable;
- 17) Copy of Valid contract between authorized person and Managing Director of the manufacturing facility;
- 18) Curriculum vitae of the authorized person.

6.1 Requirements for distributor of medical products

- 1) Application letter addressed to Director General
- 2) Duly filled application form: Application form for premises licensing of medical products;
- 3) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- 4) Lease/rent contract of the premises/house or any other relevant document;
- 5) Agreement between the Distributor and the Manufacturing Facility to whom they represent if applicable;
- 6) Evidence of payment of prescribed fees to Rwanda FDA Accounts;
- 7) Valid GSP/GDP compliant premises license issued by Rwanda FDA;
- 8) Notarized copy of Degree (and Equivalence if applicable) of Authorized person, with minimum of 2 months' experience in supply chain management;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 9) Notarized Valid License to Practice Profession issued by recognized professional bodies;
- 10) Curriculum vitae of the authorized person;
- 11) Professional agreement between the Managing Director of the pharmacy and the authorized person in case the Managing Director is not the authorized person;
- 12) Copy of the identity card or passport of both the Managing Director and the authorized person;
- 13) Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices;
- 14) Signed resignation letter/proof of service delivered issued by the last employer of authorized person, if applicable;
- 15) A copy of valid contract between authorized person and Managing Director of the pharmacy.

The Distributor of medical products is allowed to have various distribution points countrywide. Each distribution point shall meet the minimum requirements of related wholesaler. The Distributor shall distribute medical products to Wholesale Pharmacies only.

6.2 Requirements to open a human wholesale pharmacy

Prior to operating a human wholesale pharmacy or a pharmaceutical facility, an applicant must submit the following to Rwanda FDA:

- 1) Application letter addressed to Director General of Rwanda FDA;
- 2) A duly filled application form: Application form for premises licensing of the medical products;
- 3) A certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government, or an equivalent issued by the country of the applicant;
- 4) Lease/rent contract of the premises/house or any other relevant document;
- 5) Evidence of payment of prescribed fees to Rwanda FDA Accounts
- 6) The Notarized copy of Degree (and Equivalence if applicable) of Authorized person, with minimum of 2 months' experience in supply chain management;
- 7) Notarized Valid License to Practice Pharmacy Profession issued National Pharmacy Council;
- 8) Curriculum vitae of the authorized person;
- 9) Professional agreement between the Managing Director of the pharmacy and the authorized person in case the Managing Director is not the authorized person;
- 10) Copy of the identity card or passport of both the Managing Director and the authorized person;
- 11) Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices;
- 12) Signed resignation letter/proof of service delivered issued by the last employer of authorized person, if applicable;
- 13) Copy of valid contract between authorized person and Managing Director of the pharmacy.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

6.3. Requirements for opening a human wholesale of medical device

- 1) Application letter addressed to Director General
- 2) Duly filled application form: Application form for premises licensing of medical products;
- 3) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- 4) Lease/rent contract of the premises/house or any other relevant document;
- 5) Evidence of payment of prescribed fees to Rwanda FDA Accounts;
- 6) Notarized copy of Degree (and equivalence if applicable) of Authorized person;
- 7) Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda or equivalent outside Rwanda;
- 8) Curriculum vitae of the authorized person;
- 9) Copy of the identity card or passport of both the Managing Director and the authorized person;
- 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 person, if applicable;
- 12) Copy of valid contract between authorized person and Managing Director of the wholesale.

6.4. Requirements to open a veterinary wholesale pharmacy

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

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

6.5 Requirements to open a veterinary retail pharmacy

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

6.6 Requirements to open a veterinary drug shop

- 1) Application letter addressed to Director General
- 2) Duly filled application form: Application form for premises licensing of medical products;
- 3) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- 4) Lease/rent contract of the premises/house or any other relevant document;
- 5) Evidence of payment of prescribed fees to Rwanda FDA Accounts;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 6) Notarized copy of Degree (and equivalence if applicable) of Authorized person (A2 Level);
- 7) Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda;
- 8) Curriculum vitae of the authorized person;
- 9) Professional agreement between the Managing Director of the wholesale and the authorized person in case the Managing Director is not the authorized person;
- 10) Copy of the identity card or passport of both the Managing Director and the authorized person;
- 11) Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices;
- 12) Signed resignation letter/proof of service delivered issued by the last employer of authorized person, if applicable;
- 13) Copy of valid contract between authorized person and Managing Director of the veterinary drug shop.

NB: The veterinary drug shops shall not be 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) Application addressed to Director General
- 2) Duly filled application form: Application form for premises licensing of medical products;
- 3) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- 4) Lease/rent contract of the premises/house or any other relevant document;
- 5) Evidence of payment of prescribed fees to Rwanda FDA Accounts;
- 6) Notarized copy of Degree (and equivalence if applicable) of Authorized person, with minimum of 2 months experience in community pharmacy;
- 7) Notarized Valid License to Practice Pharmacy Profession issued National Pharmacy Council
- 8) Curriculum vitae of the authorized person ;
- 9) Professional agreement between the Managing Director of the pharmacy and the authorized person in case the Managing Director is not the authorized person;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 10) Copy of the identity card or passport of both the managing director and the authorized person;
- 11) Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices;
- 12) Signed resignation letter/proof of service delivered issued by the last employer of authorized person, if applicable;
- 13) Copy of valid contract between authorized person and Managing Director of the pharmacy.

6.8 Requirements to open an orthopedic shop

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

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 13) Copy of valid contract between authorized person and Managing Director of the Orthopedic shop.

6.9 Requirements to open an optical shop

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

6.11 Requirements for dental laboratory

- 1) Application letter addressed to Director General
- 2) Duly filled application form: Application form for premises licensing of medical products;
- 3) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

6.10 Requirements for assistant technician

The following are the requirements for the assistant technician:

- 1) Application letter addressed to Director General of Rwanda FDA
- 2) Original premises 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

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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 premises;
 - b) Change of the authorized person;
 - 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) Permanent or temporary closure of the business;
 - c) Notification of assistant technician;
 - d) Change of ownership of the licensed premises: 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 premises

- a) Application letter addressed to Director General
- b) Duly filled application form: Application form for premises licensing of medical products;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- c) Recent copy premises license issued by Rwanda FDA;
- d) New Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- e) Evidence of payment of prescribed fees;
- f) Lease contract of the premises.

7.2 Requirements to change the authorized person of the licensed premises

- a) Application Letter addressed to Director General
- b) Duly filled application form: Application form for premises licensing of medical products;
- c) Recent copy premises license issued by Rwanda FDA;
- d) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- e) Evidence of payment of prescribed fees;
- f) Notarized degree of the authorized person;
- g) Notarized valid license to practice profession of the responsible authorized person where applicable;
- h) Professional agreement between the establishment and the authorized person in charge where the managing director is not the responsible authorized person;
- i) Curriculum vitae of the new authorized person;
- j) Copy of valid contract between authorized person and Managing Director;
- k) Resignation letter of the former authorized person addressed to Director General of Rwanda FDA and acknowledged by the employer;
- l) Written commitment of the technician not practice the cumulative function in the establishment;
- m) Resignation letter with acknowledgement of the employer and addressed to the Director General of Rwanda FDA of the incoming authorized person (if he/she has been working);

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- n) Copy of the identity card or passport of both the managing Director and the responsible authorized person.

7.3 Requirements to change the name of establishment

- a) Application Letter addressed to Director General
- b) Duly filled application form: Application form for premises licensing of medical products;
- c) Recent premises license issued by Rwanda FDA;
- d) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government.

7.4 Requirements to change the ownership of the licensed premises

- a) Application Letter addressed to Director General
- b) Dully completed application form for premises licensing of medical products to close the business;
- c) Recent premises license issued by Rwanda FDA;
- d) Notarized sales agreement between former and new owner;
- e) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- f) Copy of the identity card or passport of both the managing director and the responsible authorized person.

7.5 Requirements to close the licensed establishment

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

7.6 Requirements for renewal of the premises license

Prior to renewal of the premises license, an applicant shall submit the following documents:

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- a) Application Letter addressed to Director General
- b) Duly filled application form: Application form for premises licensing of medical products;
- c) Recent premises license issued by the Authority;
- d) Evidence of prescribed fees;
- e) Valid license to practice profession of the authorized person.

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.

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 person 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 premises 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 premises shall allow safe and proper storage of medical products;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

The premises 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;

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.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

- a) Application Letter addressed to Director General
- b) Duly filled application form: Application Form for premises licensing of medical products;
- c) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- d) Lease/rent contract of the premises/house or any other relevant document;
- e) Evidence of payment of prescribed fees as detailed in the “Regulation Related Regulatory Service Tariff/fees and Fines”;
- f) Notarized copy of Degree (and Equivalence if applicable) of Authorized person, with minimum of 4 months ‘experience in clinical pharmacy;
- g) Notarized Valid License to Practice Pharmacy Profession issued by National Pharmacy Council;
- h) Curriculum vitae of the authorized person ;
- i) Professional agreement between Managing Director/Director General of the hospital and the authorized person;
- j) Copy of the identity card or passport of both the Managing Director/ Director General of the hospital and the authorized person;
- k) Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices;
- l) Signed resignation letter/proof of service delivered issued by the last employer of authorized person, if applicable;
- m) Copy of valid contract/appointment letter between authorized person 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.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

9.LICENSING OF MEDICAL STORAGE FACILITIES

The medical storage facilities shall be licensed in accordance with these guidelines. The medical storage facilities shall be managed by a licensed technician in accordance to the type of medical products to be stored.

9.2 Premises

- a) Shall have the premises of sufficient size to store medical products;
- b) Shall have a separate sales area and storage area;
- c) For medical storage facilities 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;

9.3 Equipment

- a) The medical storage facility shall be equipped with appropriate equipment to store medical products;
- b) The medical storage facility 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 medical storage facility shall also meet the following requirements and contain:

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- i) computerized database and printing system with internet access to manage medical products;
- ii) Equipment to store cold chain products with temperature monitoring devices;
- iii) container for waste disposal;
- iv) Secure cupboards to keep narcotics and other controlled substances;
- v) Appropriate equipment (shelves, cupboards, pallets, etc.) to store medical products and ensure the good storage practices.

9.4 Requirements for licensing the medical storage facilities

- a) Application Letter addressed to Director General
- b) Duly filled application form: Application Form for premises licensing of medical products;
- c) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- d) Lease/rent contract of the premises/house or any other relevant document;
- e) Evidence of payment of prescribed fees as detailed in the “Regulation Related Regulatory Service Tariff/fees and Fines”;
- f) Notarized copy of Degree (and Equivalence if applicable) of Authorized person, with minimum of 2 months’ experience in supply chain management;
- g) Notarized Valid License to Practice the Profession issued by National professional Council;
- h) Curriculum vitae of the authorized person;
- i) Professional agreement between Managing Director and the authorized person;
- j) Copy of the identity card or passport of both the Managing Director and the authorized person;
- k) Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices;
- l) Signed resignation letter/proof of service delivered issued by the last employer of authorized person, if applicable;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- m) Copy of valid contract/appointment letter between authorized person and Managing Director.

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 person 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 premises 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.
- 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.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

10.4 Requirements for licensing the health center and health post pharmacies

- a) Application Letter addressed to Director General
- b) Duly filled application form: Application Form for premises licensing of medical products;
- c) Certificate of domestic company registration issued by Rwanda Development Board or equivalent certificate /recommendation from local government;
- d) Lease/rent contract of the premises/house or any other relevant document;
- e) For licensing of health centers and health posts, the Authority may exempt regulatory service fees;
- f) Notarized copy of Degree (and Equivalence if applicable) of authorized person;
- g) Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda;
- h) Curriculum vitae of the authorized person;
- i) Professional agreement between Managing Director/Head of health center/health post and the authorized person;
- j) Copy of the identity card or passport of both the Managing Director/ Head of health center/health post and the authorized person;
- k) Written commitment of the authorized person to respect the laws and regulations relating to the pharmacy practices;
- l) Signed resignation letter/proof of service delivered issued by the last employer of authorized person, if applicable;
- m) Copy of valid contract/ appointed letter between authorized person and Head of health center/health post.

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;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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 person in charge;
- d) A copy of premises license and license to practice profession for the responsible authorized person 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.

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.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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 application should be sent as one file.

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

13.2 Validity of a premises license

A premises license shall be valid for twelve (12) months of the fiscal year renewable. All premises license issued shall expiry by 30th 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 license

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

13.4 Display of signpost

Authorized establishment shall be identified by a clearly displayed signpost containing the name of establishment, premises registration number, names, and telephone number of the authorized person.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

13.5 Absence of authorized person

No medical prescription may be dispensed without the supervision of an authorized person.

In case of absence of authorized person; he/she shall:

- a) Remain accessible to the Authority and support pharmacy staff;
- b) During this period no narcotics and other controlled drugs or prescriptions drugs shall be dispensed unless there is a recognized assistant pharmacist.
- c) The authorized person is accountable of all pharmacy activities during his/her absence.
- d) During the absence of the authorized person, he or she must put in place measures to prevent unauthorized access to narcotics and controlled drugs.
- e) In case the inspectors concluded that the premises were found operating without of authorized personnel in an authorized premises dealing with regulated products, premises shall pay administrative sanctions as prescribed in the Regulations governing licensing of public and private manufacturers, distributors, wholesalers and retailers of medical Products.
- f) In the meantime, the authorized premises remains close until they found an authorized personnel
- g) The authorized premises shall inform the Authority once the authorized personnel is found and shall wait for the written approval of the Authority before the implementation of the requested variation.

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 premises 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 person.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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.
- 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) Facility:

- 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)

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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 wastewater 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.

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.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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 premises 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.
- 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.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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.
- 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.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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) Storage of products requiring refrigeration at ambient temperatures.
- c) Rejected or recalled products found in sellable stock.

2) Equipment/Furniture

- a) Lack of storage furniture.

3) Personnel

Operating without an authorized person.

4) Documentation

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

5) Other

- a) Evidences of repeated violation or multiple failure to meet the Authority regulatory requirements.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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, among others).

2) Equipment/Furniture

- a) Lack of Fire-fighting equipment.
- b) Inappropriate 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 person during working hours.

4) Documentation

Lack of premises 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) Premises license issued by Rwanda FDA not displayed.
- c) License to practice profession issued by professional bodies of the authorized person not displayed.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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.

3) Personnel

Operating without an authorized person

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:

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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 person during working hours.

4) Documentation

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

14.3.3 Minor (other) non-compliances

- a) Lack of appropriate lighting systems
- b) Premises License issued by the Authority not displayed;
- c) License to practice profession issued by professional bodies of the authorized person not displayed;
- d) Absence of Filing systems of documents;

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- 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 exhaustive to cover all possible non-compliances however non-compliances shall be classified upon discretion of the Authority.

15. WARNING, SUSPENSION AND REVOCATION

- (1) 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 the Regulations governing licensing of public and private manufacturer, distributor, wholesaler, and retailer of medical products; or has ceased to be fit to carry on the business.
- (2) The Authority shall cancel, suspend, or withdraw a license of a facility if the facility contravenes following licensing requirements:
 - (a) Any of the conditions under which the license was issued no longer exist;
 - (b) The information on which the approval was given is later found to be false;
The circumstances under which the approval was given no longer exist; and
 - (c) Repeated violation of the regulatory administrative sanction or decision.
- (3) 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.
- (4) Measures towards enforcing this article may include the publication of the Authority'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:
 - (a) Objects to any suspension or revocation of authorization, or to any notice served;
 - (b) 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.
- (5) 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.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

- (6) 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.
- (7) 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.
- (8) 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.
- (9) The Authority shall take into account any recommendation made pursuant to provisions of paragraph 7 of this Article.
- (10) 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.
- (11) 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:
 - (a) The person appointed pursuant to provisions of paragraph 5 of this Article, has considered the matter in accordance with the provisions of these Guideline and made a recommendation; and,
 - (b) The Director General has informed the complainant concerned of his decision regarding the recommendation pursuant to provisions of paragraph 11 of this Article.
 - (c) 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:
 - (i) 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;
 - (ii) In relation to a suspension or revocation, or a notice served, which takes immediate effect in accordance with these guidelines; or
 - (iii) 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.

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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 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. FDISM/FDIC/FOM/002- Application form for premises licensing of medical products
- 2) Doc. FDISM/FDIC/FOM/010_premises licensing inspection for medical gas production plant report form
- 3) Doc. FDISM/FDIC/FOM/009_ Premises licensing inspection for medical manufacturing facility report form
- 4) Doc. FDISM/FDIC/FOM/008 Premises licensing, GSP&GDP inspection for wholesaler, distributor, and retailer of medical products report Form

LIST OF FORMATS OF PREMISES REGISTRATION CERTIFICATE

- 1) Doc FDISM/FDIC/FMT/180_Premse registration certificate

LIST OF FORMATS OF AUTHORIZATION FOR USE WITH THESE GUIDELINES

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




LIST OF NOTIFICATIONS FOR USE WITH THESE GUIDELINES

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

1) Withdrawal/suspension of premises license

ENDORSEMENT OF THE GUIDELINES

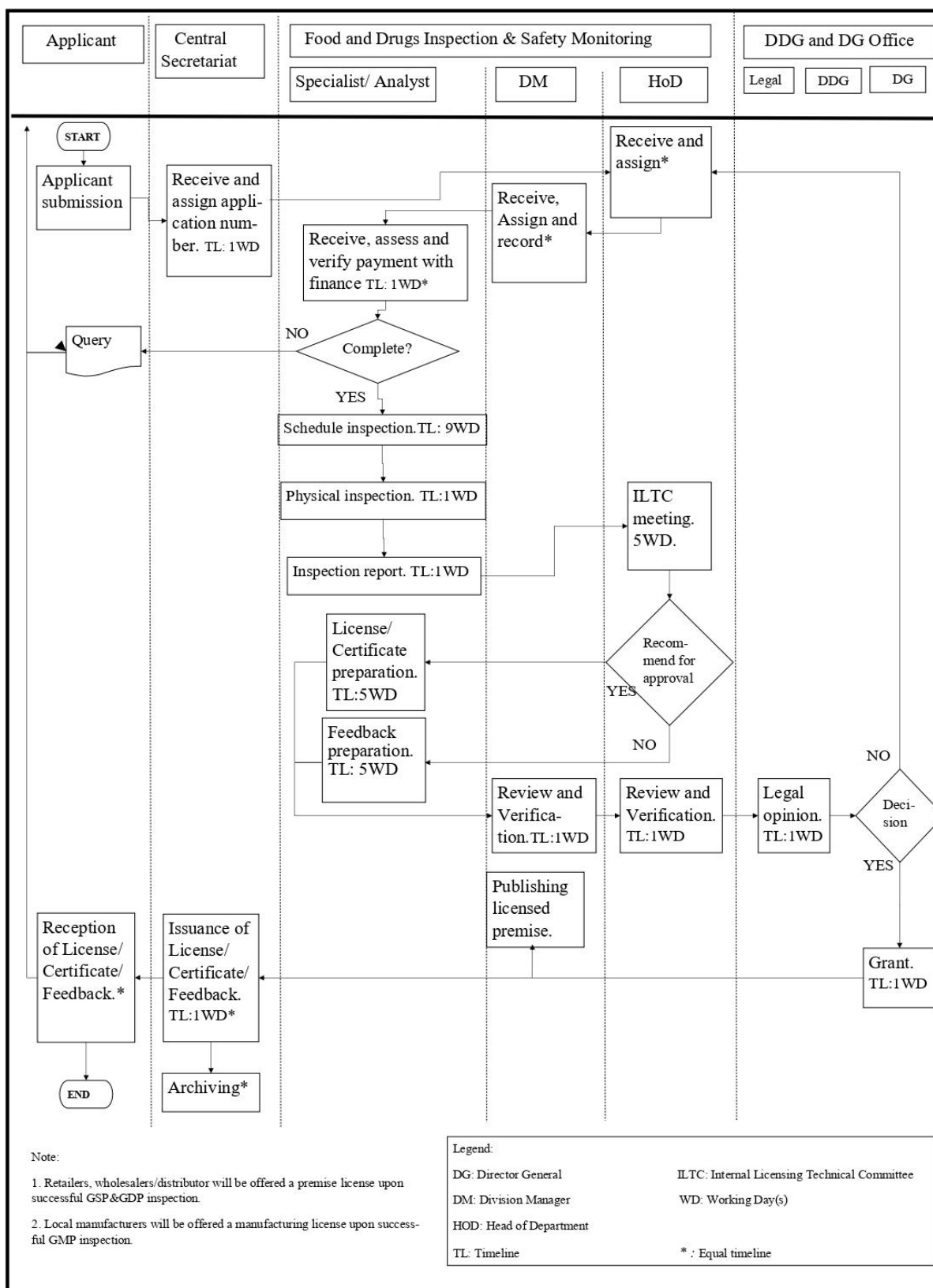
	Author	Checked by		Approved by
Title	Division manager	Head of Department	Quality Assurance Analyst	Director General
Names	Dr.MURINDAHABI .M. MARILYN	Dr.Eric NYIRIMIGABO	Théogène NDAYAMBAJE	Dr.Emile BIENVENU
Signature				Digitally signed by Rwanda FDA (Director General) Date: 2023.04.02 07:46:13 +02'00'
Date	29/03/2023	31/03/2023	01/04/2023	02 /04 / 2023

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

ANNEXES


Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

ANNEX I: PROCESS FLOW CHART



Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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: Form		Doc. No : FDISM/FDIC/FOM/002
 RWANDA FDA Rwanda Food and Drugs Authority	Title: Application Form for Premises Licensing of medical products	Revision Number : 1
		Revision Date: : 24/08/2022
		Effective Date : 22/09/2022
		Review Due Date : 21/09/2025
		Ref Doc. : FDISM/FDIC/GDL/005

Name of Premises:	Application date: / / DD / MM / YYYY	
Domestic Company Registration code:	Registration date in Rwanda FDA: / / DD / MM / YYYY	
Physical location: (Province, District, Sector, Cell)	Registered Address:	
Global Positioning System (GPS) Coordinates	Name of authorized person:(If applicable)	
Company e-mail: Company Telephone:	Qualification:	
Name of Managing Director:	Email of authorized person:(if applicable)	
Email of Managing Director Telephone No:	Tel of authorized person:	
TYPE OF PREMISES: (Please tick below) <input type="checkbox"/> Retailer <input type="checkbox"/> Wholesaler <input type="checkbox"/> Distributor <input type="checkbox"/> Manufacturer <input type="checkbox"/> Hospital Pharmacy	MAIN ACTIVITY (Please tick below) <input type="checkbox"/> Human retail pharmacy <input type="checkbox"/> Human wholesale pharmacy <input type="checkbox"/> Human wholesale of medical device <input type="checkbox"/> Manufacturer of medical products	TYPE OF APPLICATIONS (Please tick below) <input type="checkbox"/> New Application <input type="checkbox"/> Renewal <input type="checkbox"/> Variation <input type="checkbox"/> Change of ownership

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

<input type="checkbox"/> Medical Stores <input type="checkbox"/> Health Centres <input type="checkbox"/> Health Posts <input type="checkbox"/> Other 	<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"/> 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 location and Additional line <input type="checkbox"/> Change authorized person <input type="checkbox"/> Change of name of the Establishment <input type="checkbox"/> Additional warehouse <input type="checkbox"/> Closure of the business activities <input type="checkbox"/> Re-inspection <input type="checkbox"/> Other specify
AFFIDAVIT		
I hereby affirm that the statement in this application is true and correct.		
_____ Applicant's Name and Signature		_____ Date (dd/mm/yyyy)

FOR OFFICIAL USE ONLY:

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

I. REQUIREMENTS FOR PREMISES LICENSING OF MEDICAL PRODUCTS				New application	Renewal	Change ownership	Change authorized person	Change location	Additional line	Additional branch	Change of name	Closure of business
	Premises 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	

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

3	Proof of GMP/ GMS audit application submission to the Authority			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		
6	List of products to be manufactured applicable for manufacturing facility			X								
7	Lease/rent contract of the premises/house			X				X		X		
8	Notarized copy of Degree (and equivalence if applicable) of Authorized person NB: i. Human Retail Pharmacy: minimum of 2 months experience in community pharmacy ii. Human Wholesale Pharmacy: minimum of 2 months' experience in supply chain management iii. Central medical store and the branches: minimum of 2 months' experience in supply chain management Hospital pharmacy: minimum of 4 months' experience in clinical pharmacy			X		X	X			X		
9	Notarized Valid License of the authorized person 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 NB: 2 years minimum experience for a Bachelor degree holder; or 6 months minimum experience for a Master			X			X			X		

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

	degree holder in the relevant field with working experience in a company that has been approved as manufacturer of medical products												
11	Professional agreement between the Managing Director/ Director General/ Chief Executive Officer and the authorized person in case the Managing Director is not the responsible technician			x	x	x	x				x		
12	The copy of Identity Card/Passport of the managing Director/ Director General/ Chief Executive Officer and the Authorized person			x	x	x	x				x		
13	Written commitment of the authorized person, to respect the laws and regulations relating to the profession and ethics			x	x		x			x	x		
14	Signed resignation letter/proof of service delivered issued by the last employer of authorized person, if applicable			x			x				x		
15	Copy of Valid contract between authorized person and Managing Director/ Director General/ Chief Executive Officer			x	x	x	x				x		
16	A Detailed curriculum vitae of the authorized person			x			x				x		
17	Original authorization of the establishment issued by Rwanda FDA				x	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

II. RE – INSPECTION			
Premises name:			Date:/...../.....
Documents			YES NO
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		

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023


3	Corrective Actions and Preventive Actions (CAPA) report, detailing what has been implemented with respective visual proof and timelines for non-implemented recommendations.		
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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.*

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

ANNEX III: PREMISES REGISTRATION CERTIFICATE

 RWANDA FDA Rwanda Food and Drugs Authority	Nyarutarama Plaza, KG 9 Avenue P.O. Box: 1948 Kigali - Rwanda Email: info@rwandafda.gov.rw website: www.rwandafda.gov.rw	QMS N°: FDISM/FDIC/FMT/024 Revision No: 0 Effective Date: 05/07/2022
Ref No: FDISM/FDIC/ /FDA/YYYY		
<u>PREMISES REGISTRATION CERTIFICATE</u>		
<p>This is to certify that the premises (<i>Premise Name as written on RDB or equivalent certificate</i>) 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..... (<i>Type of Premise e.g: Retail Pharmacy, Wholesale Pharmacy, Pharmaceutical Manufacturing Plant etc.</i>) with Registration Number..... of dd/mm/yyyy.....</p>		
Subject to the following conditions:		
<ol style="list-style-type: none">1. 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 premises 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		

ANNEX IV: FORMAT OF AUTHORIZATION ISSUED

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023



Rwanda Food and Drugs Authority

Nyarutarama Plaza, KG 9 Avenue
P.O. Box: 1948 Kigali - Rwanda
Email: info@rwandafda.gov.rw
website: www.rwandafda.gov.rw

QMS N°: FDISM/FDIC/FMT/003
Revision No: 1
Effective Date: 22 Sep 2022

Premises registration certificate N°: RWA-FDA-PPP-III-

MANUFACTURING LICENSE

This is to certify that
Manufacturing license N°:

FDISM/FDIC/ /FDA/YYYY

Issued on: / /YYYY
was granted to:

Valid up to: / /YYYY

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 premises 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

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023



Rwanda Food and Drugs Authority

Nyarutarama Plaza, KG 9 Avenue

P.O. Box: 1948 Kigali - Rwanda

Email: info@rwandafda.gov.rw

website: www.rwandafda.gov.rw

QMS N°: FDISM/FDIC/FMT/005

Revision No:1

Effective Date:22 Sep 2022

Ref N°:FDISM/FDIC/...../FDA/YYYY

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

PREMISES LICENSE

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

These premises are GSP&GDP compliant (where applicable)

Storage conditions of medical products:

.....

Names of the Managing Director:

Telephone Number:

Names of authorized person:

National Council Registration N°:

This license is valid until

N.B

- 1. This premises 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 authorized person shall be notified and approved by Rwanda FDA.*
- 3. This premises license is not transferrable and its misuse will result into suspension or revocation.*

Done at Kigali on

Name and signature of Director General

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

+ Stamp of the institution

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

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

www.rwandafda.gov.rw

Kigali on / /

Ref. N°: FDISM/FDIC/ **/FDA/YYYY**

(Insert contact name, if available)

Company name

Telephone

Address of License Holder

Dear Sir/Madam

Re: Withdrawal of premises 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 premises dated... .., where it was found that **NAME OF THE PREMISES** ...*mention the violations*.....

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

Sincerely,

Name and signature of Director General

+Stamp of the institution

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023

End of Document

Doc. No.: FDISM/FDIC/GDL/005	Revision Date: 20/01/2023	Review Due Date: 14/04/2026
Revision No.:4	Approval date: 01/04/2023	Effective Date: 15/04/2023