RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR LICENSING OF MEDICATED COSMETICS, PESTICIDES, LABORATORY AND HOUSEHOLD CHEMICALS PREMISES

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FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law No 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to formulate regulations and guidelines and to regulate matters related to quality, safety and efficacy of medicated cosmetics, pesticides, laboratory and household chemicals on the Rwandan market.

Considering the provision of the Regulations No. FDISM/FDIC/TRG/004 Rev_0 Governing licensing of pesticides, laboratory and household chemicals premises and Regulations No. CBD/TRG/011 Rev_0 Governing Control of Medicated Cosmetics especially in its articles 29,30,31,32,33 and 34; the Authority Issues Guidelines No. FDISM/FDIC/GDL/009 for Licensing of Medicated Cosmetics, Pesticides, Laboratory and Household Chemicals Premises.

These guidelines provide guidance to applicants to ensure that they comply with the prescribed requirements.

Applicants are encouraged to familiarize with the guidelines and follow them when preparing and submitting applications for licensing of their premises dealing with manufacturing, wholesaling, importing and retailing medicated cosmetics, pesticides, laboratory and household chemicals.

Adherence to these guidelines will ensure that all relevant information is provided for licensing of medicated cosmetics, pesticides, laboratory and household chemicals premises. This will facilitate efficient and effective analysis of the applications and speed up the approval processes.

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

Dr. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

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25/08/2022	0	First Issue

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ACRONYMS AND ABBREVIATIONS

CAPA : Corrective Action and Preventive Action
GDP : Good Distribution Practice
GMP : Good Manufacturing Practices
GSP : Good Storage Practices

GLOSSARY / DEFINITIONS

In these guidelines, unless the context otherwise requires:

"**Applicants**" means a person, company or their representative manufacturing or selling pesticides, laboratory and household chemicals applying for inspection for suitability of premises licensing of the product.

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

"**Authorization**" means a legal document granted by Rwanda Food and Drugs Authority to an applicant under the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning; it includes premise registration certificate and licenses.

"**Chemicals**" means laboratory chemicals, industrial chemicals and cleaning chemicals.

"Cosmetic" means any substance or preparation intended to be placed in contact with the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance or correcting body odours, protecting them or keeping them in good conditions.

"Counterfeit product" A product which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeit products may include products with the correct ingredients, or with the wrong ingredients, without active ingredients, with insufficient/incorrect active ingredients or with fake packaging.

"Critical Deficiency" when the deviation affects a quality attribute, a critical process parameter, an equipment or instrument critical for process or control, of which the impact to personnel or environment is highly probable, including life threatening situation, the deviation is categorized as critical requiring immediate action, investigated and documented. A "Critical deficiency" may consist of several related deficiencies, none of which on its own may be "Critical", but which may together represent a" Critical" deficiency, or systems' failure where a risk of harm was identified and should be explained and reported as such.

"Critical equipment": means any piece of the equipment, instrumentation, or systems, whose malfunction or failure may cause variation in the quality and safety of the products.

"**Distribution** "The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of products.

"**Good Distribution Practice (GDP)**" is a 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 counterfeits, unapproved, substandard, falsified or misbranded products.

"**Good Manufacturing Practices (GMP)**" means that part of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorisation, Clinical Trial Authorisation or product specification. Good Manufacturing Practice is concerned with both production and quality control.

"**Good Storage Practices (GSP)**" is that part of quality assurance that ensures that the quality of a product is maintained by means of adequate control throughout the storage thereof.

"**Household Chemical Substance** "means a substance or mixture of substances packaged for use in a domestic or office setting as a germicide, an antiseptic, disinfectant, pesticide, insecticide, vermicide, rodenticide, detergent or any other substance or mixture of substances declared by the competent Authority to be a chemical substance.

"Household Pesticide" means Any material or mixture of substances used for the control of the pests (e.g. flies, mosquitos, cockroaches, ants, rodents) found in places of human habitation, work and recreation. Products that are intended for use in domestic or commercial establishments for the control of flying, crawling and structural insect pests (e.g. termiticides, rodenticides and wood preservative).

"Importer" means a person or body corporate permitted and authorized to import under the laws and regulations in Rwanda pertaining to pesticides, laboratory and household chemicals not for sale purposes. e.g. Raw materials importers used in the factory, other products imported for in-house use (e.g.: in hotels, etc.)

"Labeling" means 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 and/or the supplier.

"Laboratory chemical" refers to any chemical that is used in laboratory testing and experiments (research/teaching/diagnostic laboratories). Most are standard chemical reagents or simple chemicals that serve as basic ingredients to synthetize more complex chemicals. They can be used for investigative or diagnostic propose such as in the preparation of drugs or in laboratory experiments.

"Major Deficiency" means a deficiency that is not a "Critical" deficiency, but could have major effects on the overall safety, efficacy and quality of the products. This consists of several "Minor/Other" related deficiencies, none of which on its own may be "Major", but which may together represent a "Major" deficiency or systems failure and should be explained and reported as such.

"Manufacturer" means a person or corporation, or other entity engaged in the business of manufacturing Pesticides and laboratories or Household Chemicals.

"Medicated cosmetics "or "cosmeceuticals" are products that have both cosmetic and therapeutic (cosmetic or drug-like) effects, and are intended to have a beneficial effect on skin health and beauty. Like medicated cosmetics, they are topically applied as creams or lotions but contain active ingredients that have an effect on skin cell function. In some cases, their action is limited to the skin surface (such as exfoliants), while others can penetrate to deeper levels, either enhancing or limiting normal skin functions.

"Minor/Other Deficiency" means a deficiency that is not classified as either "Critical" or "Major", but indicates failure to meet the standards of premises suitability. A deficiency may be judged as "Minor" because there is insufficient information to classify it as "Critical" or "Major".

"Online shop" means a premise that delivers, distributes, or dispenses pesticides, laboratory and household chemicals by means of the internet.

"**Pesticide**" means any substance, or a mixture of substances of chemical or biological ingredients intended for repelling, destroying or controlling any pest, or regulating plant growth.

"Premises" means any plot of land, buildings or boats, aircraft, vehicles, a part of a building, a place of storage, manufacturers, wholesalers, importers, retailers of medicated cosmetics, pesticides, laboratory and household chemicals whether open or closed.

"**Qualified personnel**": means an individual who by possession of a recognized degree, who by extensive knowledge, training and experience, has successfully demonstrated his ability to solve or resolve problems relating to the subject matter.

"**Retailer**" means a person or body corporate permitted and authorized to store and sell under the laws and regulations in Rwanda pertaining to pesticides, laboratory and household chemicals to the public in relatively small quantities for use rather than for resale.

"**Storage**" The storing of products up to their point of use.

"Substandard products" refer to products that fail to meet specifications stated in recognized international standards or the manufacturer's approved product dossier submitted for registration.

"Substantial modification" means a change to the premises, equipment, personnel, procedures, and processes that is likely to a have significant impact and affect the quality, safety and the integrity of the products manufactured, stored, distributed, and used.

"**Wholesale**" means a person or body corporate permitted and authorized to import, store, and supply under the laws and regulations in Rwanda pertaining to pesticides, laboratory and household chemicals to authorized retailers.

In these Regulations, the following verbal forms are used:
"**shall**" indicates a requirement;
"**should**" indicates a recommendation;
"**may**" indicates permission; and
"**can**" indicates a possibility or a capability.

CHAPTER ONE: INTRODUCTION

1.1 Purpose

The purpose of these guidelines is to give guidance on the requirements for the licensing premises that manufacture, import, store, exhibit, sale, dispense and distribute medicated cosmetics, pesticides, laboratory and household chemicals as the licensing of such premises forms an integral part of ensuring that products maintain their integrity throughout their distribution channels. Adherence to the guidelines by applicants will facilitate the timely review and processing of applications.

1.2 Scope

These guidelines shall apply to premises involved in the manufacture, import, storage, exhibit, sale, dispensing and distribution of medicated cosmetics, pesticides, laboratory and household chemicals. The premises include but not limited to manufacturers, wholesalers, importers and retailers of pesticides, laboratory and household chemicals.

1.3 Submission of an application

An application for premises registration and licensing shall be made in writing via a cover letter and application form dated and signed by the applicant. The submitted cover letter and application form should be accompanied by the required documents as described in these guidelines.

When an application is made via email or hard copy, the applicant shall submit an application to the Authority on the following address:

Director General

Rwanda Food and Drugs Authority

Nyarutarama Plaza, Rwanda

KG 9 Avenue, Kigali

P.O. Box 1948, Kigali, Rwanda.

E-mail : info@rwandafda.gov.rw

The application for premises registration and licensing may be made via Integrated Regulatory Information Management System (IRIMS) platform.

1.4 Validity of an application

All applications for premise licensing shall comply with the regulatory requirements. All applications shall be valid for a period of ninety (90) calendar days from the date of application.

If the applicant fails to comply with premise licensing requirement (s) within a period of ninety (90) calendar days unless otherwise authorized by the Authority, the application shall be closed. If the applicant wishes to re-submit the application, it shall be considered as a new application and the prescribed fees shall be paid.

The timeline for service delivery upon receipt of complete application with all documents required is thirty (30) working days.

1.5 Registration of activities and premises and license to practice

Any activity related to the manufacture, storing, import or export, sale, packaging, distribution of medicated cosmetics, pesticides, laboratory and household chemical products shall be registered. The registration of activities and premises shall be proven by a certificate issued by the Authority.

The license to operate premises used for carrying out the aforementioned activities is granted according to the types of licenses and other conditions as detailed in these guidelines.

1.6 Validity of a premise registration certificate and license

The premise registration certificate is issued once upon successful registration of premises and activities. It is permanent and should bear a unique identification number of the premise.

A license to operate shall be valid for one-year renewable from the date it is issued. The validity of the renewed license to operate shall refer to the date of the first issuance of the operational license of the premise. Application for renewal of a license to operate shall be made to the Authority one month before the end of the validity period of the license to operate.

An authorization is issued to an applicant and shall not be transferable to another applicant without approval of the Authority.

CHAPTER 2: INSPECTIONS AND LICENSING REQUIREMENTS

2.1 Inspections

The Authority shall conduct an inspection for confirmation of the compliance requirements in order to grant or re-grant a license or approval of a substantial modification and to ensure that premises are suitable to accommodate intended activities.

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

2.2 Types of inspections

The following types of inspection may be conducted:

a) **The routine inspection:** is a full inspection of all applicable components of licensing requirements. It may be conducted when the establishment:

i. Newly established
ii. Requests for renewal of an operational license
iii. Has a history on non-compliance with legal provisions (Laws and regulations)
iv. Has introduced new product lines or new products, or has made significant modifications to manufacturing methods or processes, or has made changes in key personnel, premises, equipment, etc.
v. Has made any substantial modification to registered and licensed premise information

b) **Follow-up inspections** (re-inspection) are made to monitor the result of corrective measures. They are normally carried out 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.

c) **Special licensing inspections** may be necessary to undertake spot checks following complaints, recalls related to suspected quality defects in products or reports of adverse reactions of the product. Such inspections may be focused on one product, a group of related products, or specific operations such as mixing, labelling or packaging.

2.3 Categorization of inspection compliance

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

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

a) **Critical**
b) **Major**
c) **Minor**

2.3.1 Manufacturing Facilities

2.3.1.1 Critical non-compliances

a) Premises

If the premise does not comply with the followings:

i. Site Location which does not comply with environmental requirement to manufacture products
ii. No air filtration system to eliminate airborne contaminants that are likely to be generated during manufacture or packaging.
iii. Generalized malfunctioning of the ventilation system (s) with evidence of widespread cross-contamination.
iv. 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.
v. Lack of clean water, and waste water treatment system
vi. Finishing materials: production floor area, ceiling and walls that are not seamless and easy to clean

b) Equipment

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

c) Personnel

Staff in charge of quality control or production does not hold a university degree in a science related to the work being conducted, insufficient practical experience in their area of responsibility.

d) Sanitation

i. Evidence of widespread accumulation of residues/extraneous matter indicative of inadequate cleaning
ii. Evidence of gross infestation.

2.3.1.2 Major non-compliances

a) Premises

i. Malfunctioning of the ventilation system that could result in possible localized or occasional cross-contamination.
ii. Accessory supplies (steam, air, nitrogen, dust collection etc.) not qualified.
iii. Heating Ventilation Air Conditioning (HVAC) not qualified
iv. Temperature and humidity not controlled or monitored when necessary.
v. Damages to walls/ceilings immediately adjacent or above manufacturing areas or equipment where the product is exposed.
vi. Un-cleanable surfaces created by pipes, fixtures or ducts directly above products or manufacturing equipment.
vii. Surface finish (floors, walls, ceilings) that do not permit effective cleaning.
viii. Insufficient manufacturing space that could lead to mix-ups.
ix. Quarantine areas accessible to unauthorized personnel and not well marked.

b) Equipment

i. Equipment does not operate within its specifications
ii. No covers for tanks, hoppers or similar manufacturing equipment if applicable
iii. Equipment used for manufacturing operation not qualified
iv. Stored equipment not protected from contaminations.
v. Inappropriate equipment for production: surfaces porous and non-cleanable/material to shed particles
vi. Equipment location does not prevent cross-contamination or possible mix-ups for operations performed in the common areas.
vii. No calibration program for measuring equipment /no records maintained.
viii. No fire-fighting equipment/Fire alarm systems, emergency doors

c) Personnel

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

d) Sanitation

i. Sanitation program not in writing but premises in acceptable state of cleanliness.
ii. Absence of medical emergency kits.
iii. Absence of Emergency shower.

2.3.1.3 Minor (other) non-compliances

a) Premises

i. Un-trapped floor drains.
ii. Damages to surfaces not directly adjacent or above exposed products.
iii. Inadequate rest, change, wash-up and toilet facilities.

b) Equipment

i. Insufficient space between equipment and walls to permit cleaning.
ii. Base of immovable equipment not adequately sealed at points of contact.
iii. Defective or unused equipment used for non-critical products not qualified.

c) Sanitation

i. Incomplete written sanitation program
ii. Sanitation or health and hygiene programs not properly implemented or followed by employees.

2.3.2 Wholesaler, importer or retail of medicated cosmetics, household pesticides, household chemicals and laboratory chemicals

2.3.2.1 Critical Non-Compliances

a) Premises

If the premise does not comply with the followings:

i. Minimum floor space and height requirements
ii. Natural/Mechanical ventilation/Air handling unit /Heat, Ventilation and Air Conditioning (HVAC).
iii. Temperature and humidity monitoring systems
iv. Surrounding area that can cause contamination from the external environment or other activities.
v. Floor, ceiling and walls maintenance

b) Equipment/documentation

i. Lack of secure and lockable storage place for hazardous products and related documentation
ii. Lack of equipment to store related temperature sensitive products and related documentation

c) Personnel

Operating without a responsible technician where applicable

2.3.2.2 Major Non-Compliances

a) Premises

i. Damage of walls, ceilings, roof, doors and windows
ii. Surface finish (floors, walls, ceilings) that do not permit effective cleaning.
iii. Inappropriate Natural/Mechanical ventilation /Air handling unit /Heat, Ventilation and Air Conditioning (HVAC).
iv. Inappropriate temperature and humidity monitoring systems

b) Equipment/documentation

i. Lack of fire-fighting equipment
ii. Inappropriate storage furniture (Solid shelves, Pallets)
iii. Inappropriate secure and lockable storage place for hazardous products
iv. Inappropriate equipment to store related temperature sensitive products
v. Lack of operational license documents (import & export documents, distribution records, Records of expired/damaged products)
vi. Lack of appropriate transportation means from the wholesaler store to the retailers
vii. Inappropriate sanitation facilities (toilets, etc.)

2.3.2.3 Minor (Other) Non-Compliances

i. Lack of appropriate lighting systems
ii. Premise registration certificate and operational License issued by Rwanda FDA not displayed
iii. License to practice profession issued by professional bodies of the responsible technician not displayed where applicable
iv. Temperature monitoring records not updated where applicable
v. Absence of Filing systems of documents

2.4 Requirements to operate as a manufacturer of medicated cosmetics, pesticides, laboratory or household chemicals

The Authority shall approve the site for product manufacturers. Applicants should fulfill the prerequisites as detailed below prior to new application or premise licensing. Applicants should apply for:

2.4.1 Site location approval

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

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

a) Letter of intent
b) Site master plan (indicating the location /plan of the premise and the surroundings activities)
c) Environmental impact assessment

2.4.2 Architectural Plan Approval and layout to comply with the Good Manufacturing Practices before the start of site construction

The applicant shall submit the following documents:

a) Approval letter for site location from the Authority
b) Architecture plan showing but not limited to the following:
    i. Production process flow chart.
    ii. Sanitation facilities (Clean water and waste water treatment system)
    iii. Mechanical ventilation /Air handling unit /Heat, Ventilation and Air Conditioning (HVAC).
    iv. Construction and process materials (grade material)
    v. Finishing materials (production floor, ceiling and walls should be seamless, easy to clean).

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

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

Upon receipt of complete required documents for license to manufacture, import, store, exhibit sale, dispensing and distribution of medicated cosmetics, pesticides, laboratory and household chemicals and payment of prescribed fee, inspection of the premises shall be conducted, personnel shall be

2.4.3 Premise inspection

The Authority shall inspect the premises to determine their suitability for manufacturing of regulated products. The following components during premise inspection shall be covered:

a) Standards of construction

The premises shall:

i. Be of a permanent nature;
ii. Be protected against, adverse weather conditions including dust, ground water seepage, vermin and pest infestation;
iii. Have sufficient space for the carrying out and supervision of the necessary operations;
iv. Have air intakes, exhausts, and associated pipe work and trucking sited so as to avoid contamination;
v. Have the plumbing, electrical and other services in the manufacturing and processing areas sited in a way that creates ease of cleaning and shall for this purpose run outside the processing and manufacturing areas and be well sealed in place;
vi. Have drains that are of an adequate size
vii. With sufficient traps and proper ventilation;
viii. Have well marked fire exits and the access to the fire exits kept clear at all times;
ix. 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;
x. Be well lit, ventilated and have appropriate air-control facilities including temperature and humidity.
xi. The premises shall have appropriate toilet facilities, soap, and hand washing facilities with single-use towels or hand air drier. Toilets should not directly communicate with production or storage areas.
xii. Facilities for changing clothes and street shoes should be easily accessible and appropriate for the number of users.
xiii. Eating and drinking areas or rooms should be separate from other areas.
xiv. Maintenance workshops should as far as possible is separated from production areas.
xv. Whenever parts and tools are stored in the production area, they should be kept in rooms or lockers reserved for that use.
xvi. The premises including the external surroundings shall be maintained in a clean and tidy condition with regular and adequate clearance of waste materials.

b) Suitability of production areas

i. Premises shall be laid out in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels.

ii. The adequacy of the working and in-process storage space should permit the orderly and logical positioning of equipment and materials so as to minimize the risk of confusion between different products or their components, to avoid cross-contamination and to minimize the risk of omission or wrong application of any of the manufacturing or control steps.

iii. Weighing of starting materials shall be carried out in a separate weighing room designed for that use.

iv. Where starting and primary packaging materials, intermediate or bulk products are exposed to the environment, interior surfaces (walls, floors and ceilings) should be smooth, free from cracks and open joints, and should not shed particulate matter and should permit easy and effective cleaning and, if necessary, disinfection.

v. Pipe work, light fittings, ventilation points and other services should be designed and sited to avoid the creation of recesses which are difficult to clean. As far as possible, for maintenance purposes, they should be accessible from outside the manufacturing areas.

vi. Drains should be of adequate size, and have trapped gullies. Open channels should be avoided where possible, but, if necessary, they should be shallow to facilitate cleaning and disinfection.

vii. Production areas should be effectively ventilated, with air control facilities (including temperature and where necessary, humidity and filtration) appropriate both to the products handled, to the operations undertaken within them and to the external environment.

viii. In cases where dust is generated (e.g., during sampling, weighing, mixing and processing operations, packaging of dry products), specific provisions shall be taken to avoid cross-contamination and facilitate cleaning.

ix. Premises for the packaging of products should be specifically designed and laid out so as to avoid mix-ups or cross-contamination.

x. Production areas should be well lit, particularly where visual on-line controls are carried out.

xi. Hand washing facilities with single-use towels or hand air drier; hand sanitizing facilities; and appropriate protective garments prior to entering controlled areas should be available.

c) Regular water supply

i. The premises shall have a regular and sufficient supply of water.
ii. Water treatment plants and distribution systems should be designed, constructed and maintained so as to ensure a reliable source of water of an appropriate quality.
iii. The chemical and microbiological quality of water used in production should be specified and monitored.

d) Storage areas and environmental controls

Storage areas shall:

i. Be designed or adapted to ensure good storage conditions;

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

e) Containers to be cleaned

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

f) Descriptive materials to be kept secure

All product labels, printed packaging and descriptive materials shall:

i. Be stored in a secure manner; and
ii. Be accessed by only authorized personnel.

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

g) Design, construction, location and maintenance of equipment

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

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

h) Fire-fighting equipment

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

i) Weighing, measuring, testing and recording equipment to be checked

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

j) Quality control areas

Quality Control laboratories shall be designed to suit the operations to be carried out in them. Sufficient space shall be given to avoid mix-ups and cross- contamination. There shall be adequate suitable storage space for samples and records.

Separate rooms may be necessary to protect sensitive instruments from vibration, electrical interference, humidity, etc.

k) Documentation

The manufacturing premises shall keep the following records:

i. Manufacturing records
ii. Medical examination records
iii. Distribution records
iv. Suppliers' records
v. Recall records
vi. Complaint records
vii. Maintenance and calibration records
viii. Cleaning and disinfection records
ix. Quality Control Records

2.4.4 Personnel for the products manufacturing facility

a) There are shall be sufficient qualified personnel to carry out all manufacturing activities and the responsibility for every individual has to be clearly understood and recorded.
b) The manufacturer shall have an organization chart.
c) All responsible staff shall have their duties recorded in written descriptions and adequate authority to carry out their responsibilities.
d) Duties for responsible personnel may be delegated to designated deputies of satisfactory qualification level.
e) There are shall be no gaps or unexplained overlaps in responsibilities of personnel concerned.
f) Unauthorized personnel shall not enter production, storage and quality control areas or use them as passage.
g) A manufacturing facility shall have the following key personnel:
   i. Head of production;
   ii. Head of quality assurance;
   iii. Head of quality control; and
   iv. Authorized personnel.

Note: All manufacturing facilities shall inform the Authority about the appointed key personnel for the purpose of their approval.

Key personnel responsible for supervising the manufacture and quality unit including quality assurance and quality control for manufacture of products shall possess the qualification with scientific education and practical experience.

The head of production shall have bachelor education in Pharmacy and/or Chemist but if not, available options shall be for person with at least a bachelor education in the following:

i. Pharmaceutical sciences and technology;
ii. Chemistry (analytical or organic) or biochemistry;
iii. Chemical engineering;
iv. Any other relevant qualification

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

i. Pharmacy;
ii. Pharmaceutical sciences and technology;
iii. Chemistry (analytical or organic) or biochemistry.
iv. Any other relevant qualification

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

i. Pharmacy;
ii. Pharmaceutical sciences and technology;
iii. Chemistry (analytical or organic) or biochemistry;
iv. Microbiology;
v. Any other relevant qualification

The head of the production and quality control departments generally shall have some shared, or jointly exercised, responsibilities relating to quality in:

i. The authorization of written procedures and other documents, including amendments;
ii. The monitoring and control of the manufacturing environment;
iii. Plant hygiene;
iv. Process validation and calibration of analytical apparatus;
v. Training including the application and principles of quality assurance;
vi. The approval and monitoring of suppliers of materials;
vii. The approval and monitoring of contract manufacturers;
viii. The designation and monitoring of storage conditions for materials and products;
ix. The performance and evaluation in process controls;
x. The retention of records;
xi. The monitoring of compliance with good manufacturing practice requirements;
xii. The inspection, investigation, and taking of samples, in order to monitor factors that may affect product quality.

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.

The head of the quality assurance and quality control department generally shall have the following responsibilities:

i. To approve or reject starting materials, packaging materials, and intermediate, bulk, and finished products;
ii. To evaluate batch records;
iii. To ensure that all necessary testing is carried out;
iv. To approve sampling instructions, specifications, test methods, and other quality control procedures;
v. To approve and monitor analysis carried out under contract;
vi. To check the maintenance of the department, premises and equipment;
vii. To ensure that, appropriate validations, including those of analytical procedures, and calibrations of control equipment are done;
viii. To ensure that the required initial and continuing training of quality control personnel is carried out and adapted according to need;
ix. Establish, implement and maintain the quality system;
x. Supervision of regular internal audits or self-inspections;
xi. Participate in external audits; and
xii. Participate in validation programme.

2.4.4.1 Training

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.

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.

All personnel shall receive continuing training, evaluated and records be retrieved as per approved training program.

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.

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.

Consultants and contract staff shall be qualified for their service and their training records kept.

2.4.5 Documents required for a manufacturer's application

a) Application letter addressed to the Director General of Rwanda FDA
b) Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals
c) Certificate of domestic company registration issued by Rwanda Development Board or equivalent
d) Architectural plan of the site
e) Product process flowchart (s)
f) Environment impact assessment report
g) Proof of payment of the prescribed fees
h) List of products to be manufactured
i) Lease/rent contract of the premise/house
j) Notarized copy of Degree (and equivalence if applicable) of Responsible Technician
k) Notarized Valid License of the responsible technician to Practice Profession issued by Recognized Professional Councils in Rwanda if applicable
l) Notarized degrees of the key personnel to be involved in the manufacturing process, quality control and quality assurance
m) Valid Contract between the Managing Director of the manufacturing plant and the responsible technician in case the Managing Director is not the responsible technician
n) Copy of the identity card or passport of both the Managing Director and the responsible technician
o) Written commitment of the technician, to respect the laws and regulations relating to the manufacturing practices performed and oversight the quality of products being manufactured.
p) Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable
q) Curriculum vitae of the responsible technician

2.5 Requirements to operate a wholesaler, importer and/or retailer of medicated cosmetics, pesticides, laboratory or household chemicals

2.5.1 Premise

a) Location

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

The external surroundings shall be maintained in a clean and tidy condition with regular and adequate clearance of waste materials.

b) Standards of construction

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

i. Be of a permanent nature
ii. Being meant for commercial purposes or warehousing;
iii. Be protected against adverse weather conditions including dust, ground water seepage, vermin and pest infestation;
iv. Have adequate space for the carrying out and supervision of the necessary operations;
v. Have floors and walls made of a washable and impervious material with a flat surface free of cracks and a ceiling covered with a non-flaking finish that allows easy cleaning; and
vi. Be well lit, ventilated and have appropriate air-control facilities including temperature and humidity.
vii. The process of maintenance and repair shall not, while being carried out, cause any contamination of ingredients or products.
viii. The premises shall have a regular and sufficient supply of water of suitable quality.
ix. The premises shall have appropriate toilet facilities and appropriate hand washing facilities.
x. The premises shall have sufficient fire-fighting equipment which shall, at all times, be in good condition and accessible.

c) Storage areas

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

i. That is secure and has adequate space;
ii. That is laid out to allow clear separation of different materials and products to minimize the risk of mix-up;
iii. Access to the materials and goods is restricted to authorized personnel only;

iv. Products that are light (photo) and temperature sensitive shall be stored adequately such a skin lighteners agents that are used among the cosmetic body lotion,
v. With separate area in the storage facility where recalled, expired or rejected products shall be stored under lock and key.

d) Minimum floor space and height

i. For a wholesaler dealing with laboratory chemicals, the total floor space shall have a minimum space of 90 square meters. The sales area shall have a 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.

ii. For a wholesaler dealing with medicated cosmetics, household pesticides and household chemicals, the total floor space shall have a minimum space of 10 square meters and minimum height of 2.5 meters from the floor to the ceiling.

iii. For a retailer dealing with laboratory chemicals, the sales and administrative area shall have minimum floor space of 30 square meters as whole. The minimum height shall be 2.5 meters from the floor to the ceiling.

iv. For a retailer dealing with cosmetics, household pesticides and household chemicals, shall have a minimum space of five (5) square meters as whole. The minimum height shall be 2.5 meters from the floor to the ceiling.

v. For an importer dealing with laboratory chemicals, the storage areas shall have minimum floor area of 40 square meters; and minimum height of 2.5 meters from the floor to the ceiling.

vi. For an importer dealing with cosmetics, household pesticides and household chemicals, the storage areas shall have minimum floor area of 10 square meters; and minimum height of 2.5 meters from the floor to the ceiling.

2.5.2 Documentation and related controls

All records (including but not limited to invoices, purchase orders, import authorizations, sales and distribution records in the wholesale, importer and retailer's premises).

A copy of premise registration certificate and operational license issued by the Authority and license to practice profession (where applicable) for the responsible qualified personnel shall be conspicuously displayed in the premis.

2.5.3 Personnel

For a wholesaler or a retailer of laboratory chemicals, be a pharmacist, chemist or any other relevant qualification.

For the wholesaler or retailer of medicated cosmetics, household pesticides and household chemicals, be a managing director of the establishment or her/his delegate.

2.5.4 Documents required for a wholesaler, an importer or retail of laboratory chemicals

a) Application letter addressed to the Director General of Rwanda FDA

b) Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals
c) RDB registration certificate of the domestic company or equivalent
d) Lease/rent contract of the premise/house.
e) Evidence of payment of prescribed fees to Rwanda FDA Accounts.
f) Notarized copy of Degree (and Equivalence if applicable) of responsible technician
g) Notarized valid license to Practice Profession issued by Recognized Professional Councils in Rwanda if applicable.
h) Contract between the managing director and the responsible technician in case the Managing Director is not the responsible technician.
i) Copy of the identity card or passport of both the managing director and the responsible technician.
j) Written commitment of the technician to respect the laws and regulations relating to the management of chemicals.
k) Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable.
l) A detailed curriculum vitae of the responsible technician.

2.5.5 Documents required for wholesaler, importer or retail of cosmetics, household pesticides and household chemicals

a) Application letter addressed to the Director General of Rwanda FDA
b) Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
c) Certificate of domestic company registration issued by Rwanda Development Board or equivalent
d) Lease/rent contract of the premise/house.
e) Evidence of payment of prescribed fees to Rwanda FDA Accounts.
f) Copy of the identity card or passport of the Managing Director.
g) A recent passport-size photo.

2.6 Approval of the premises

Upon approval of findings of the inspection to manufacture, import, wholesale, store, exhibit, sale, dispense and distribute of medicated cosmetics, pesticides, laboratory and household chemicals; the Authority shall notify the applicant the decision based on the findings of the inspections. In case of compliance with the premise licensing requirements, the premise registration certificate and license shall be granted to the applicant.

In case of non-compliances to the premise licensing requirements, a feedback letter with corrective actions may be issued to the applicant.

CHAPTER 3: LICENSE RENEWAL AND SUBSTANTIAL MODIFICATION

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

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

3.1 Documents required for operational license renewal

a) Application letter addressed to the Director General of Rwanda FDA
b) Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
c) Notarized degree (or equivalence if applicable) of the responsible technician.
d) Recent operational license of the establishment issued by Rwanda FDA.
e) Written commitment of the responsible technician, to respect relevant laws and regulations and oversight the quality of products being handled where applicable.
f) Certificate of the domestic company registration
g) Evidence of payment of prescribed fees.
h) Notarized valid license to practice profession of the responsible technician personnel where applicable.
i) Contract between the establishment and the responsible technician in charge where the managing director is not the responsible technician.
j) Copy of the identity card or passport of both the managing director and the responsible technician.

3.2 Documents required for relocation or additional storage space of the licensed premise

a) Application letter addressed to the Director General of Rwanda FDA
b) Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
c) Original operational license of the establishment issued by Rwanda FDA
d) New certificate of domestic company registration
e) Evidence of payment of prescribed fees
f) Lease contract for the establishment

3.3 Documents required for the change of the responsible technician of the licensed premise

a) Application letter addressed to the Director General of Rwanda FDA
b) Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
c) Original operational license of the establishment issued by Rwanda FDA.
d) Certificate of the domestic company registration

e) Evidence of payment of prescribed fees.
f) Notarized degree (or equivalence if applicable) of the responsible technician.
g) Notarized valid license to practice profession of the responsible technician where applicable.
h) Contract between the establishment and the responsible technician in charge where the managing director is not the responsible technician.
i) Written commitment of the responsible technician, to respect relevant laws and regulations and oversight the quality of products being handled.
j) Copy of the identity card or passport of both the managing Director and the responsible technician.
k) Signed resignation letter/proof of service delivered of the outgoing responsible technician
l) Signed resignation letter/proof of service delivered issued by the last employer of the incoming responsible technician, if applicable.
m) A Detailed curriculum vitae of the responsible technician.

3.4 Documents required to change the ownership of the licensed premise

a) Application letter addressed to the Director General of Rwanda FDA
b) Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
c) Original operational license of the establishment issued by Rwanda FDA.
d) Notarized sales agreement between former and new owner.
e) New and/or updated certificate of the domestic company registration
f) Notarized degree (or equivalence degree) of the responsible technician where applicable.
g) Notarized valid license to practice profession of the responsible technician where applicable.
h) Contract between the establishment and the responsible technician in charge where the managing director is not the responsible technician
i) Copy of the identity card or passport of both the new managing director and the responsible technician.

3.5 Documents required to change the name of the license premise

a) Application letter addressed to the Director General of Rwanda FDA
b) Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
c) Original operational license of the licensed premise issued by Rwanda FDA.
d) New certificate of domestic company registration.

3.6 Documents required to close the licensed premise

a) Application letter addressed to the Director General of Rwanda FDA
b) Dully completed application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.

c) Original of the premise registration certificate issued by Rwanda FDA.
d) Recent operational license issued by Rwanda FDA.
e) A list of closing stock of products and its intended use.

CHAPTER 4: GOOD PRACTICES

4.1 Good Distribution Practices

Medicated cosmetics, pesticides, laboratory and household chemical products distributors shall have systems, facilities and operations that comply with the International Code of Conduct on Pesticide and Household Chemicals distribution and Guidelines on good distribution practices as adopted by the Authority.

Areas, where medicated cosmetics, pesticides, laboratory and household chemicals are distributed shall be regularly inspected to ensure that the premises and medicated cosmetics, pesticides, laboratory and household chemicals are in an acceptable condition.

Vehicles used to transport products should be properly designed and equipped to ensure protection from different environmental and weather conditions in which it operates.

The use of vehicles with defects that could affect the quality of the products should be avoided.

4.2 Good Storage Practices

Medicated cosmetics, pesticides, laboratory and household chemicals shall be stored/displayed separately and away from all other materials to avoid any possibility of a source of fire, contamination and confusion with other materials.

Areas, where medicated cosmetics, pesticides, laboratory and household chemicals are stored, shall be regularly inspected to ensure that the premises and medicated cosmetics, pesticides, laboratory and household chemicals are in an acceptable condition.

4.3 Good Manufacturing Practices

Medicated cosmetics, pesticides, laboratory and household chemical product manufacturers shall have systems, facilities and operations that comply with guidelines on good manufacturing practices as adopted by the Authority.

Areas, where medicated cosmetics, pesticides, laboratory and household chemicals are manufactured shall be regularly inspected to ensure that the premises and medicated cosmetics, pesticides, laboratory and household chemicals are in an acceptable condition.

ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved by
Title	**Division manager**	**Head of Department**	**Quality Assurance Analyst**	**Director General**
Names	Dr. Marilyn M. MURINDAHABI	Dr. Eric NYIRIMIGABO	Théogène NDAYAMBAJE	Dr. Emile BIENVENU
Signature				
Date	13/09/2022	15/09/2022	16/09/2022	20/09/2022

RWANDA FOOD AND DRUGS AUTHORITY RWANDA FDA

APPENDICES

APPENDIX I: 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/003
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Application Form for Premise Licensing of Cosmetics, Household Pesticides, Household Chemicals and Laboratory Chemicals**		Revision Number : 0 Revision Date: : 02/09/2022 Effective Date : 15/09/2022 Review Due Date : 14/09/2025 Ref Doc. : FDISM/FDIC/GDL/009

Name of Premise: …… ……	**Application date:** / / *DD / MM/ YYYY*
Domestic Company Registration code (TIN): ……	**Premise Registration Certificate Number** (Issued by Rwanda FDA): ……
Physical location: *(Province, District, Sector, Cell, Village)* …… …… …… Global Positioning System (GPS) Coordinates …… ……	Company e-mail: …… Company Telephone: ……
Name of responsible technician: (If applicable) …… …… Email of responsible technician: (if applicable) …… ……	Name of Managing Director: …… …… Email of Managing Director ……

……. Telephone of responsible technician: …… ……	Telephone of the managing Director: …… ……

TYPE OF PREMISE: (Please tick below)	**MAIN ACTIVITY** (Please tick below)	**TYPE OF APPLICATIONS** (Please tick below)
☐ Retailer ☐ Wholesaler ☐ Importer ☐ Manufacturer ☐Other (Please Specify) ……..……	☐ Retailer of Cosmetics ☐ Retailer of Household Pesticides ☐ Retailer of Household Chemicals ☐ Retailer of Laboratory Chemicals ☐Wholesaler of Cosmetics ☐Wholesaler of Household Pesticides ☐Wholesaler of Household Chemicals ☐Wholesaler of Laboratory Chemicals ☐Importer of Cosmetics ☐Importer of Household Pesticides ☐ Importer of Household Chemicals ☐ Importer Laboratory Chemicals ☐ Manufacturer of Cosmetics ☐ Manufacturer of Household Pesticides ☐ Manufacturer of Household Chemicals ☐ Manufacturer of Laboratory Chemicals ☐ Other (specify) …….. ……	☐ Site location approval ☐ New Application (Premise Registration & Licensing ☐ License Renewal ☐ Relocation or additional storage space of the licensed premise ☐ Change of the responsible technician ☐ Change of the ownership ☐ Change the name of the license premise ☐ *Closure of the business activities* ☐ Re-inspection ☐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)**

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*
2. *Incomplete application form **WILL NOT** be accepted.*
3. *Application processes will take 30 working days upon receipt of fully complete documents required.*
4. *All applications shall be valid for a period of ninety (90) calendar days from the date of application. When applicants failed to comply with the requirement (s) within ninety (90) calendar days' period, they shall re-apply and the prescribed premise licensing fees shall be paid.*

LIST OF FORMATS USED WITH THESE GUIDELINES

1) Format of the license to manufacture Cosmetics, Household Pesticides, Household Chemicals or Laboratory Chemicals (Doc. No. **FDISM/FDIC/FMT/004**)
2) Format of the license to operate a Wholesale/Retail of Laboratory Chemicals (Doc. No **FDISM/FDIC/FMT/009**)
3) Format of the license to operate a Wholesale of Cosmetics/Household Pesticides/Household Chemicals **(**Doc. No. **FDISM/FDIC/FMT/010**)
4) Format of the license to operate as a Retail of Cosmetics, Household Pesticides or Household Chemicals **(**Doc. No. **FDISM/FDIC/FMT/011**)
5) License to operate as an Importer of Cosmetics, Household Pesticides, Household Chemicals or Laboratory Chemicals **(**Doc. No. **FDISM/FDIC/FMT/012**)
6) Format for the premise registration certificate (Doc. No. **FDISM/FDIC/FMT/024**)

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 Nº: FDISM/FDIC/FMT/004
Revision No: 0
Effective Date: 15/09/2022

License to manufacture Cosmetics/Household Pesticides/Household Chemicals/Laboratory Chemicals

[Made under article 7(1) of the Regulations Nº FDISM/FDIC/TRG/004 Rev_0*]*

License Number: …… Issue Date: dd/mm/yyyy Valid up to: dd/mm/yyyy

This is to certify that the…….*(Insert the Premise Name) with registration* Nº ……..of dd/mm/yyyy located in …Province Name/Kigali City, District Name, Sector Name, Cell Name, Village Name under the management of ……(insert the names of the managing director) as a **managing director**, Tel:..... and (insert the name of the responsible technician) as **a head of production department/unit;**

Is licensed to carry out the following manufacturing activities:

Product category	**Product type**	**Dosage form (*if applicable*)**	**Manufacturing activities**
e.g. Cosmetics/Household Pesticides/Household Chemicals/Laboratory Chemicals			e.g. Production, packaging, storage, labeling and distribution

Conditions:

1. *The product is put on market after its assessment and registration by Rwanda FDA.*
2. *This authorization may be suspended or withdrawn if the conditions under which it was granted are violated.*
3. *The application for renewal of license shall be done one month before its expiration.*

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

Signature of the Director General and Seal of the Authority

Name of the Director General
Director General

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QMS Nº: FDISM/FDIC/FMT/009
Revision No: 0
Effective Date: 15/09/2022

License to operate a Wholesale/Retail of Laboratory Chemicals

[Made under article 7(1) of the Regulations Nº FDISM/FDIC/TRG/004 Rev_0*]*

License Number: …… Issue Date: dd/mm/yyyy Valid up to: dd/mm/yyyy

This is to certify that the…….*(Insert the Premise Name) with registration* Nº ……..of dd/mm/yyyy located in …Province Name/Kigali City, District Name, Sector Name, Cell Name, Village Name is licensed to operate as a **Wholesale/Retail of Laboratory Chemicals**.

Names of the Managing Director: **Names…….**
Telephone Number: …….

Names of Responsible Technician: **Names…….**
Name of the Professional Council …*and then write…* Nº: **Registration Number**

CONDITIONS

1. *This license does not authorize the holder to operate business in unregistered premises or during the period of suspension or revocation of the premise registration certificate in respect of which it was issued.*
2. *This license must be prominently displayed in the premises to which it refers to.*
3. *Any change made on details of the company name, physical location, management or responsible pharmacist shall be notified and approved by Rwanda FDA.*
4. *This license is not transferrable and its misuse will result into suspension or revocation.*
5. *The application for license shall be done one month before its expiration.*

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

Signature of the Director General and Seal of the Authority

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Director General

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website: www.rwandafda.gov.rw

QMS Nº: FDISM/FDIC/FMT/010
Revision No: 0
Effective Date: 15/09/2022

License to operate a Wholesale of Cosmetics/Household Pesticides/Household Chemicals

[Made under article 7(1) of the Regulations Nº FDISM/FDIC/TRG/004 Rev_0*]*

License Number: …… Issue Date: dd/mm/yyyy Valid up to: dd/mm/yyyy

This is to certify that the…….*(Insert the Premise Name) with registration* Nº ……..of dd/mm/yyyy located in …Province Name/Kigali City, District Name, Sector Name, Cell Name, Village Name is licensed to operate as a **Wholesale of Cosmetics/Household Pesticides/Household Chemicals**.

Names of the Managing Director: **Names…….**
Telephone Number: …….

CONDITIONS

1. *This license does not authorize the holder to operate business in unregistered premises or during the period of suspension or revocation of the premise registration certificate in respect of which it was issued.*
2. *This license must be prominently displayed in the premises to which it refers to.*
3. *Any change made on details of the company name, physical location, management or responsible pharmacist shall be notified and approved by Rwanda FDA.*
4. *This license is not transferrable and its misuse will result into suspension or revocation.*
5. *The application for license shall be done one month before its expiration.*

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

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QMS Nº: FDISM/FDIC/FMT/011
Revision No: 0
Effective Date: 15/09/2022

License to operate a Retail of Cosmetics/Household Pesticides/Household Chemicals

[Made under article 7(1) of the Regulations Nº FDISM/FDIC/TRG/004 Rev_0*]*

License Number: …… Issue Date: dd/mm/yyyy Valid up to: dd/mm/yyyy

This is to certify that the…….*(Insert the Premise Name) with registration* Nº ……..of dd/mm/yyyy located in …Province Name/Kigali City, District Name, Sector Name, Cell Name, Village Name is licensed to operate as a **Retail of Cosmetics/Household Pesticides/Household Chemicals**.

Names of the Managing Director: **Names…….**
Telephone Number: …….

CONDITIONS

1. *This license does not authorize the holder to operate business in unregistered premises or during the period of suspension or revocation of the premise registration certificate in respect of which it was issued.*
2. *This license must be prominently displayed in the premises to which it refers to.*
3. *Any change made on details of the company name, physical location, management or responsible pharmacist shall be notified and approved by Rwanda FDA.*
4. *This license is not transferrable and its misuse will result into suspension or revocation.*
5. *The application for license shall be done one month before its expiration.*

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

Signature of the Director General and Seal of the Authority

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QMS Nº: FDISM/FDIC/FMT/012
Revision No: 0
Effective Date: 15/09/2022

License to operate an Importer of Cosmetics/Household Pesticides/Household Chemicals/ Laboratory Chemicals

[Made under article 7(1) of the Regulations Nº FDISM/FDIC/TRG/004 Rev_0*]*

License Number: …… Issue Date: dd/mm/yyyy Valid up to: dd/mm/yyyy

This is to certify that the…….*(Insert the Premise Name) with registration* Nº ……..of dd/mm/yyyy located in …Province Name/Kigali City, District Name, Sector Name, Cell Name, Village Name is licensed to operate as an **Importer of Cosmetics/Household Pesticides/Household Chemicals/ Laboratory Chemicals**.
.

Names of the Managing Director: **Names…….**
Telephone Number: …….

CONDITIONS

1. *This license does not authorize the holder to operate business in unregistered premises or during the period of suspension or revocation of the premise registration certificate in respect of which it was issued.*
2. *This license must be prominently displayed in the premises to which it refers to.*
3. *Any change made on details of the company name, physical location, management or responsible pharmacist shall be notified and approved by Rwanda FDA.*
4. *This license is not transferrable and its misuse will result into suspension or revocation.*
5. *The application for license shall be done one month before its expiration.*

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

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website: www.rwandafda.gov.rw

QMS Nº: FDISM/FDIC/FMT/024
Revision No: 0
Effective Date: 05/07/2022

PREMISE REGISTRATION CERTIFICATE

[Made under article 3 of the Law Nº 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.]

This is to certify that the …… *(Premise Name as written on RDB or equivalent certificate)* under the management of Mr/Mrs/Ms. ……located in Kigali City/Province Name, District Name, Sector Name, Cell Name, Village Name, has been registered as…… (*Type of Premise* e.*g: Retail Pharmacy, Wholesale Pharmacy, Pharmaceutical Manufacturing Plan etc.*) ……with Registration Number**……**of dd/mm/yyyy…….

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