ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N°9 of the Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning, in its meeting resolutions of 8th August 2019 delegating power to the management of the authority, hereby ADOPTS and ISSUES these regulations N° CBD/TRG/001 Rev. N° 0, governing authorization to operate as manufacturer or wholesaler or small scale manufacturing/compounding or retail seller of pharmaceutical products, made this 10th day of January, 2020.

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Dr. Charles KARANGWA
Acting Director General
Rwanda Food and Drugs Authority

ARRANGEMENT OF THE REGULATIONS

CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these Regulations

The purpose of these Regulations is to provide a legal framework for the effective and efficient regulation of pharmaceutical products and provide a transparent and non-discriminatory process for authorization to manufacture pharmaceutical products, or to operate as wholesale or a retail seller of a pharmaceutical Product.

Article 2: Citation and commencement

These Regulations may be cited as the *"Regulations CBD/TRG/001 Rev. N° 0, Governing licensing to manufacture pharmaceutical products or to operate as wholesale or a retail seller of pharmaceutical products"* and shall come into operation on the date of publication

Article 3: Application

These regulations shall apply to premises involved in the manufacture, storage, sale, distribution, and dispensing of pharmaceutical products as stipulated in Article 3 of Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organization and functioning.

Article 4: Interpretation

In these regulations, unless the context otherwise requires:

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

"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 licences, permits, and certificates.

"Fee" means the income prescribed in the Fees Regulations in accordance with Article 9 and Article 32 of the Law N° 003/2018 of 09/02/2018.

"Good Manufacturing Practice" 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.

"Law N°. 003/2018" means Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning;

"Law N°. 47/2012" means Law N° 47/2012 of 14/01/2013 relating to the regulations and inspection of food and pharmaceutical products;

"Manufacturer" means a person or corporation, or other entity engaged in the business of manufacturing pharmaceutical products;

"Pharmaceutical product" means any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises where food and drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses;

"Pharmacist" means any person holding a second cycle university degree in pharmacy who is registered and licensed;

"Pharmacy" means any licensed / authorized location used for the practice of the pharmacy profession;

"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.

In these Regulations, the following verbal forms are used:

"shall" indicates a requirement;

"should" indicates a recommendation;

"may" indicates a permission; and

"can" indicates a possibility or a capability.

CHAPTER II: LICENSING REQUIREMENTS

Article 5: Obligation to obtain an Authorization

A person shall not without an authorization issued by the Authority in accordance with the Law and these Regulations:

1) operate as an authorized seller or import or export of pharmaceutical products; or
2) carry out the business of manufacturing or supplying by wholesale or retail of pharmaceutical products or medical representatives

Article 6: Requirements for authorization

The following Part I, Part II and Part III, contain the minimum requirements for the authorization to manufacture pharmaceutical products or to operate as wholesale or a retail seller of any pharmaceutical product, respectively.

PART I: AUTHORIZATION TO OPERATE AS A MANUFACTURER OF PHARMACEUTICAL PRODUCTS

Article 7: Application for a Pharmaceutical Products Manufacturing Authorization

1) The applicant should register the Manufacturing Company, with the Registrar of Companies in a competent authority (Rwanda Development Board) and provide to Rwanda FDA with certified copies of the Memorandum and Articles of Association.

2) The applicant shall submit the following documents:

   a) Letter of intent to manufacture a pharmaceutical product;
   b) Completed application for manufacture of pharmaceutical products, in the standard form *(Doc. N° DIS/FOM/017-Application for pharmaceutical manufacturing authorization;*
   c) Architectural plan of the site; and

d) Environment impact assessment report.

3) After satisfactory review of the preliminary documentation, the company is given approval to start construction.

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

a) Site inspection before construction;

b) Site inspection at completion of construction of the premises;

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

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

a) Completed application for GMP inspection in the standard form *(Doc. N° DIS/FOM/016-Application for Good Manufacturing Practice Inspection for Finished Pharmaceutical Products Manufacturing Facilities);*

b) Site master file;

c) List of products to be manufactured at the facility;

d) Certified copy of the certificate of registration of the pharmacist to be in charge of the manufacturing process;

e) Certificates of the qualification of the key personnel to be involved in the manufacturing process; and

f) Proof of payment of prescribed fees, including fees for GMP inspection.

Article 8: Inspection of premises for suitability

1) The Authority shall inspect the premises to determine the suitability of premises for manufacturing of pharmaceutical products.

2) An inspecting officer of the Authority shall inspect the premises and make a report in the standard format *(Doc. N°. DIS/FMT/013-Inspection Report for Suitability of Premises for Manufacture of Pharmaceutical Products)*; to be considered during assessment of the application for authorization.

3) Premises that do not comply with the requirements for suitability shall not be eligible for consideration for a Pharmaceutical Manufacturing Authorization.

Article 9: Location of premises for pharmaceutical manufacturing

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

Article 10: Standards of construction

The premises shall:

1) be of a permanent nature;

2) be protected against, adverse weather conditions including dust, ground water seepage, vermin and pest infestation;

3) have sufficient space for the carrying out and supervision of the necessary operations;

4) have air intakes, exhausts, and associated pipe work and trucking sited so as to avoid contamination;

5) 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;

6) have drains that are of an adequate size and that are provided

7) with sufficient traps and proper ventilation;

8) have well marked fire exits and the access to the fire exits kept clear at all times;

9) 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

10) be well lit, ventilated and have appropriate air-control facilities including temperature, humidity, and filtration for the operations to be undertaken.

Article 11: Basic requirements for Good Manufacturing Practice

The basic requirements of GMP shall be met, including, but not limited to the following:

1) Appropriately qualified and trained personnel;

2) Adequate premises and space;

3) Suitable equipment and services;

4) Correct materials, containers and labels;

5) Approved procedures and instructions, in accordance with the Pharmaceutical Quality System; and

6) Suitable storage and transport.

Article 12: Premises to be sanitary and have appropriate ancillary areas

1) 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.

2) Facilities for changing clothes and street shoes should be easily accessible and appropriate for the number of users.

3) Eating and drinking areas or rooms should be separate from other areas.

4) Maintenance workshops should as far as possible be separated from production areas.

5) Whenever parts and tools are stored in the production area, they should be kept in rooms or lockers reserved for that use.

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

Article 13: Suitability of Production areas

1) 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.

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

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

4) 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.

5) 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.

6) 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.

7) 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.

8) 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.

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

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

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

Article 14: Regular water supply

1) The premises shall have a regular and sufficient supply of water.

2) 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.

3) The chemical and microbiological quality of water used in production should be specified and monitored.

4) Water for injections should be produced, stored and distributed in a manner which prevents microbial growth, for example by constant circulation at a temperature above 70°C.

Article 15: Storage areas and environmental controls

Storage areas shall:

1) be designed or adapted to ensure good storage conditions;

2) be secure and with segregated areas for the storage of rejected, recalled or returned materials or products;

3) have access to the materials and goods restricted to authorised personnel only;

4) 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;

5) 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;

6) be provided with receiving and dispatch bays to protect materials and products from the weather;

7) be provided with receptions areas which shall be designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage;

8) where quarantine status is ensured by storage in separate areas, these areas shall be clearly marked and their access restricted to authorised personnel; any system replacing the physical quarantine should give equivalent security;

9) have provisions where the starting materials and finished goods are stored under cover and off the floor;

10) 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;

11) Have provisions where highly active materials or products are stored in safe and secure areas;

12) have safe and secure storage of printed packaging materials

Article 16: Containers to be cleaned

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

Article 17: Descriptive materials to be kept secure

1) All product labels, printed packaging and descriptive materials shall:

   (a) Be stored in a secure manner; and

   (b) Be accessed by only authorised personnel.

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

Article 18: Design, construction, location and maintenance of equipment

1) Manufacturing equipment shall be designed, located and maintained to suit its intended purpose.
2) Repair and maintenance operations shall not present any hazard to the quality of the products.
3) 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.
4) Washing and cleaning equipment shall be chosen and used in order not to be a source of contamination.
5) Equipment shall be installed in such a way as to prevent any risk of error or of contamination.
6) 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.
7) Balances and measuring equipment of an appropriate range and precision shall be available for production and control operations.
8) 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.
9) Fixed pipework shall be clearly labelled to indicate the contents and, where applicable, the direction of flow.
10) Distilled, deionized and, where appropriate, other water pipes shall be sanitised according to written procedures that detail the action limits for microbiological contamination and the measures to be taken.
11) Defective equipment shall, if possible, be removed from production and quality control areas, or at least be clearly labelled as defective.

Article 19: Fire-fighting equipment

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

Article 20: Compliance with the Law on Occupational Health and Safety

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

Article 21: 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.

Article 22: Quality Control Areas

1) Quality Control laboratories shall be separated from production areas. This is particularly important for laboratories for the control of biologicals, microbiologicals and radioisotopes, which shall also be separated from each other.

2) 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.

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

Article 23: Good Manufacturing Practices Certificate

1) The Authority shall, for the purposes of assessing the manufacturing practices of the manufacturer, adopt with the necessary modifications, internationally accepted Good Manufacturing Practices Guidelines.

2) A manufacturer who manufactures pharmaceutical products in Rwanda or outside Rwanda for importation into Rwanda shall comply with the Good Manufacturing Practices (GMP) Guidelines adopted by the Authority.

3) The manufacturer shall, prior to manufacturing or importation of pharmaceutical products, as the case may be, make an application to the Authority for assessment of the facility to be used for

manufacturing pharmaceutical products, for compliance with Good Manufacturing Practices Guidelines.

4) An application for assessment for compliance with Good Manufacturing Practices Guidelines shall be made using the standard form *(Doc. N° DIS/FOM/016-Application for Good Manufacturing Practice Inspection for Finished Pharmaceutical Products Manufacturing Facilities)*, and shall be accompanied with evidence of payment of the prescribed fees.

5) An inspecting officer of the Authority shall carry out GMP inspection of the manufacturing site and make a report in the standard format *(Doc. N°. DIS/FMT/014-Inspection Report for Good Manufacturing Practice)*; to be considered during assessment of the application for certificate of compliance with Good Manufacturing Practice.

6) Where a manufacturer complies with the Good Manufacturing Practices Guidelines, the Authority shall issue to the manufacturer a certificate of compliance with Good Manufacturing Practices Guidelines, in the standard format *(Doc. N° DIS/FMT/018-Certificate of Compliance with Good Manufacturing Practice).*

PART II: AUTHORIZATION TO OPERATE A WHOLESALE PHARMACY

Article 24: Application for a Pharmaceutical Wholesale Authorization

A pharmaceutical wholesale authorization can be granted to an establishment dealing with human medicines, Veterinary medicines or Medical equipment where the responsible technician will be required depending on the scope of the activity of the establishment. The establishment for human medicines, veterinary medicines or medical equipment will have pharmacist, veterinary doctor/pharmacist, biomedical engineer/pharmacist respectively as their responsible technicians. Any other category of establishment not mentioned above will have a pharmacist as responsible technician.

An application to operate a wholesale pharmacy shall be made using the standard form *(Doc. N° DIS/FOM/018-Application for pharmaceutical wholesale License)*, and shall be accompanied by the following:

1) Company profile;

2) Business registration certificate and a full registration information of domestic company;

3) Lease contract of the premises;

4) Evidence of payment of prescribed fees;

5) Valid license to practice pharmacy profession for the responsible technician where applicable;

6) Commitment letter from the responsible technician to respect the provisions of the laws and regulations;

7) Valid contract between the owner and the responsible technician;

8) Degree and curriculum vitae of the responsible technician;

9) Copy of the identity card or passport of both the owner and the responsible technician;

10) One recent passport-size photograph of the owner and the responsible technician.

11) Sketch plan of the premises taking into consideration the minimum floor area for sales and storage rooms.

Article 25: Inspection of premises for suitability

1) The Authority shall inspect the premises with respect to Articles 26 to 35 of these Regulations, to determine their suitability for wholesale of pharmaceutical products.

2) A team of inspecting officers of the Authority shall inspect the premises and make a report in the standard format *(Doc. N°. DIS/FMT/015-Inspection Report for Suitability of Premises for Wholesale of Pharmaceutical Products)*; to be considered during assessment of the application for authorization.

3) Premises that do not comply with the requirements for suitability as laid down in Articles 26 to 35 in these Regulations shall not be eligible for consideration for a Pharmaceutical Wholesale Authorization.

Article 26: Location of premises for wholesale pharmacy

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

Article 27: Standards of construction

The premises shall:

1) be of a permanent nature
2) being meant for commercial purposes or warehousing;
3) be protected against adverse weather conditions including dust, ground water seepage, vermin and pest infestation;
4) have adequate space for the carrying out and supervision of the necessary operations;
5) 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
6) be well lit, ventilated and have appropriate air-control facilities including temperature, humidity, and filtration for the operations to be undertaken.

Article 28: Premises shall be in good state of repair, maintenance and sanitation

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

Article 29: Storage areas

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

1) that is secure and has adequate space;
2) that is laid out to allow clear separation of different materials and products to minimise the risk of mix-up;
3) Access to the materials and goods is restricted to authorised personnel only;
4) Products that are temperature sensitive shall be kept in a temperature-controlled storage facility; and
5) with separate area in the storage facility where recalled, expired or rejected drugs shall be stored under lock and key.

Article 30: Sales area

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

Article 31: Minimum floor space and height

1) For an establishment dealing with human medicines or medical equipment, 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.
2) For an establishment dealing with human medicines or medical equipment, the sales and administrative area shall have minimum continuous floor space of 30 square meters. Within the 30 square meters, there shall be a separate office or administrative area, with a full view of the sales area, for the responsible technician; and records shall be maintained in this office or area.
3) For an establishment dealing with veterinary medicines, 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.
4) For an establishment dealing with veterinary medicines, the sales and administrative area shall have minimum continuous floor space of 25 square meters. Within the 25 square meters, there

shall be a separate office or administrative area, with a full view of the sales area, for the responsible technician; and records shall be maintained in this office or area.

Article 32: Documentation and related controls

1) All records (including but not limited to invoices, purchase orders, import authorizations, sales and distribution records, in the Wholesale Pharmacy, etc.) for all pharmaceutical products and administrative records of the staff shall be properly kept for at least ten (10) years in the pharmaceutical establishment and be readily available to the inspection service when requested for or needed.

2) Current pharmacopoeias recognized by the Authority.

3) All entry and exit of pharmaceutical products must be approved by the responsible pharmacist.

4) Availability of certified copy of license to practice of the pharmacist in charge.

5) Quarterly Reports on the distribution of controlled substances to be submitted to the Authority.

6) A copy of the guideline on Good Distribution Practice (GDP), approved by the Authority.

7) Identify the establishment by a readable sign board with the number of authorization, names and contacts of the pharmacist in charge.

8) A copy of authorization, license to practice for the responsible pharmacist shall be conspicuously displayed in the retail pharmacy premises.

Article 33: Staffing requirements

1) Responsible Pharmacist (must); and

2) Support Staff: Assistant Pharmacist, Pharmacy Technician, Medical Assistant or Nurse. (optional)

Article 34: Management of controlled substances

Controlled substances shall be kept in a secure, fixed separate and lockable storage place.

Article 35: Good Distribution Practice

The pharmaceutical wholesaler shall have systems, facilities and operations that comply with the Good Distribution Practice Guidelines, as adopted by the Authority.

PART III: AUTHORIZATION FOR SMALL SCALE MANUFACTURING/COMPOUNDING

Article 36: Application for authorization for Small Scale Manufacturing/Compounding

An application for authorization for small scale manufacturing/compounding shall be made using the standard form (*Doc. N° DIS/FOM/017-Application for pharmaceutical manufacturing authorization),* and shall be accompanied by the following:

1) Company profile;
2) Business registration certificate and a full registration information of domestic company;
3) Lease contract of the location;
4) Evidence of payment of prescribed fees, including fees for GMP inspection;
5) Valid license to practice pharmacy profession of the responsible pharmacist;
6) Commitment letter from the pharmacist to respect the laws and regulations relating to the pharmacy practices;
7) Valid contract between the owner and the pharmacist in charge where the Owner is not the responsible pharmacist;
8) Degree and curriculum vitae of the pharmacist;
9) Copy of the identity card or passport of both the owner and the pharmacist;
10) One recent passport-size photograph of the owner and the pharmacist; and
11) Sketch plan of the premise taking into consideration the minimum floor area for sales and storage rooms. The minimum floor area acceptable is 120 square meters.

12) Degree and curriculum vitae of other qualified support staff

Article 37: Inspection of premises for suitability

1) The Authority shall inspect the premises to determine the suitability of premises for small scale manufacturing/compounding.

2) The inspecting officers of the Authority shall inspect the premises and make a report in the standard format *(Doc. N°. DIS/FMT/016-Inspection Report for Suitability of Premises for Small Scale Manufacture of Pharmaceutical Products)*; to be considered during assessment of the application for authorization.

3) Premises that do not comply with the requirements for suitability shall not be eligible for consideration for a small scale manufacturing/compounding.

Article 38: Location of premises for small scale manufacturing/compounding

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

Article 39: Standards of construction

The premises shall:

1) Be of a permanent nature;

2) be protected against, adverse weather conditions including dust, ground water seepage, vermin and pest infestation;

3) have sufficient space for the carrying out and supervision of the necessary operations;

4) 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;

5) have drains that are of an adequate size and that are provided with sufficient traps and proper ventilation;

6) have well marked fire exits and the access to the fire exists kept clear at all times;

7) 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

8) be well lit, ventilated and have appropriate air-control facilities including temperature, humidity, and filtration for the operations to be undertaken.

Article 40: Good Manufacturing Practice Requirements

The basic requirements of GMP shall be met, including, but not limited to the following:

1) Appropriately qualified and trained personnel;

2) Adequate premises and space;

3) Suitable equipment and services;

4) Correct materials, containers and labels;

5) Approved appropriate procedures and instructions;

6) Suitable storage and transport facilities.

Article 41: Regular water supply

1) The premises shall have a regular and sufficient supply of water.

2) 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.

3) The chemical and microbiological quality of water used in production should be specified and monitored.

Article 42: Premises to be sanitary and have appropriate ancillary areas

1) 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.
2) Facilities for changing clothes and street shoes should be easily accessible and appropriate for the number of users.
3) Eating and drinking areas or rooms should be separate from other areas.
4) Maintenance workshops should be as far as possible separated from production areas.
5) Whenever parts and tools are stored in the production area, they should be kept in rooms or lockers reserved for that use.
6) The premises including the external surroundings shall be maintained in a clean and tidy condition with regular and adequate clearance of waste materials.

Article 43: Production areas to be suitable

1) 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;
2) The adequacy of the working and in-process storage space should permit the orderly and logical positioning of equipment and materials so as to minimize the risk of confusion between different medicinal products or their components, to avoid cross-contamination and to minimize the risk of omission or wrong application of any of the manufacturing or control steps.
3) Weighing of raw materials shall be carried out in a separate weighing room designed for that use as prescribed in the related guideline.
4) In case where dust is generated (e.g. during sampling, weighing, mixing and processing operations, packaging of dry products), specific precautions should be taken to avoid cross-contamination and facilitate cleaning.

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

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

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

Article 44: Storage areas and environmental controls

Storage areas shall:

1) be designed or adapted to ensure good storage conditions;
2) be secure and with segregated areas for the storage of rejected, recalled or returned materials or products;
3) have access to the materials and goods restricted to authorized personnel only;
4) have sufficient capacity to allow orderly storage of the various categories of materials and products; raw and packaging materials, bulk and finished products, products in quarantine, released, rejected, returned or recalled;
5) be clean and dry and maintained within acceptable temperature limits; where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and recorded;
6) be provided with receiving and dispatch bays to protect materials and products from the weather
7) have quarantine area clearly marked and their access restricted to authorized personnel; any system replacing the physical quarantine should give equivalent security; and
8) have safe and secure storage of printed packaging materials.

Article 45: Containers to be cleaned

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

Article 46: Design, construction, location and maintenance of equipment

1) Manufacturing equipment shall be designed, located and maintained to suit its intended purpose.
2) Repair and maintenance operations shall not present any hazard to the quality of the products.
3) 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.
4) Washing and cleaning equipment/ detergents shall be chosen and used in order not to be a source of contamination.
5) Equipment shall be installed in such a way as to prevent any risk of error or of contamination.
6) 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.
7) Balances and measuring equipment of an appropriate range and precision shall be available for production and control operations.
8) Measuring, weighing, recording and control equipment shall be calibrated and checked at defined intervals by appropriate methods. Adequate records of such shall be maintained.
9) Defective equipment shall be removed from production areas, or at least be clearly labelled as defective.

Article 47: Fire-fighting equipment

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

Article 48: Compliance with the Law on Occupational Health and Safety

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

Article 49: Weighing, measuring, testing and recording equipment to be checked

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

Article 50: Good Manufacturing Practices Certificate

1) A small scale manufacturer (compounding) who manufactures pharmaceutical products in Rwanda or outside Rwanda for importation into Rwanda shall comply with the Good Manufacturing Practices Guidelines adopted by the Authority.
2) Where a manufacturer complies with the Good Manufacturing Practices requirements, the Authority shall issue to the manufacturer a Certificate of Compliance with Good Manufacturing Practice in the standard format *(Doc. N° DIS/FMT/018-Certificate of Compliance with Good Manufacturing Practice).*

PART IV: AUTHORIZATION TO OPERATE A RETAIL PHARMACY

Article 51: Application for a Pharmaceutical Retail Authorization

A retail pharmacy authorization can be granted to an establishment dealing with human medicines, or Veterinary medicines where the responsible technician will be required depending on the scope of the activity of the establishment. The establishment for human medicines or veterinary medicines will have pharmacist, veterinary doctor/pharmacist respectively as their responsible technicians. Any other category of establishment not mentioned above will have a pharmacist as responsible technician.

An application for an authorization to operate a retail pharmacy shall be made using the standard form *(Doc. N° DIS/FOM/019-Application for pharmaceutical retail License),* and shall be accompanied by the following:

1) Company profile;
2) Business registration certificate and full registration information of domestic company;
3) Lease contract of the premise;
4) Evidence of payment of prescribed fees;
5) Valid license to practice pharmacy profession of responsible technician;
6) Commitment letter from the responsible technician to respect the laws and regulations;
7) Valid contract between the owner and the responsible technician;
8) Degree and curriculum vitae of the responsible technician;
9) Copy of the identity card or passport of both the owner and the responsible technician;

10) One recent passport-size photograph of the owner and the responsible technician.
11) Sketch plan of the premise taking into consideration the minimum floor area for sales and storage rooms.

Article 52: Inspection of premises for suitability

1) The Authority shall inspect the premises with respect to Regulations, to determine that they are suitable for retail of pharmaceutical products.

2) The inspecting officers of the Authority shall inspect the premises and make a report in the standard format *(Doc. N°. DIS/FMT/017-Inspection Report for Suitability of Premises for Retail of Pharmaceutical Products)* to be considered during assessment of the application for authorization.

3) Premises that do not comply with the requirements for suitability as laid down in the Regulations shall not be eligible for consideration for a Pharmaceutical Retail Authorization.

Article 53: Location of premises for retail pharmacy

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

Article 54: Standards of construction

The premises shall:

1) be of a permanent nature;

2) be protected against adverse weather conditions including dust, ground water seepage, vermin and pest infestation;

3) have adequate space for the carrying out and supervision of the necessary operations;

4) have floors and walls made with impervious material with a flat surface free of cracks and a ceiling covered with a non-flaking finish that allows easy cleaning; and

5) be well lit, ventilated and have appropriate air-control facilities including temperature, humidity, and filtration for the operations to be undertaken.

Article 55: Premises shall be in good state of repair, maintenance, and sanitation

1) The external surroundings shall be maintained in a clean and tidy condition with regular and adequate clearance of waste materials.
2) The premises shall have a regular supply of water of suitable quality.
3) The premises shall have appropriate toilet facilities and hand washing facilities with single-use towels.
4) The premises shall have fire-fighting equipment which shall, at all times be in good condition and accessible.

Article 56: Storage areas

The storage areas for pharmaceutical products shall:

1) be secure and have adequate space;
2) have restricted access to unauthorised personnel;
3) keep products that are temperature sensitive in a temperature-controlled storage facility;
4) keep products that are light sensitive in area protected from light; and
5) have a separate area for recalled, expired or rejected drugs.

Article 57: Sales area

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

Article 58: Minimum floor space and height

6) For an establishment dealing with human medicines, the retail pharmacy shall have a minimum space of 40 square meters continuous that can be separated into sales and administrative area of 30 square metres and storage room of 10 square metres for Kigali City and secondary cities. The minimum height shall be 2.5 metres from the floor to the ceiling.

7) For an establishment dealing with human medicines, the retail pharmacy shall have a minimum space of 30 square meters continuous that can be separated into sales and administrative area of 25 square metres and storage room of 5 square metres for the rest of the country. The minimum height shall be 2.5 metres from the floor to the ceiling.

8) For an establishment dealing with veterinary medicines, the retail pharmacy shall have a minimum space of 30 square meters continuous that can be separated into sales and administrative area of 25 square metres and storage room of 5 square metres for Kigali City and secondary cities. The minimum height shall be 2.5 metres from the floor to the ceiling.

9) For an establishment dealing with veterinary medicines, the retail pharmacy shall have a minimum space of 20 square meters continuous that can be separated into sales and administrative area of 15 square metres and storage room of 5 square metres for the rest of the country. The minimum height shall be 2.5 metres from the floor to the ceiling.

10) The dispensing area shall:

a) be a separate lockable area with no access for the public;
b) have benches and working surfaces with impervious washable tops;
c) be fitted with a sink with running water, soap, single-use towels; and hand sanitising facility.
d) have provision for staff to put on appropriate protective garments.

11) The premises shall not be shared with any medical clinic, veterinary surgery or any other business.

Article 59: Documentation and related controls

1) All records (including but not limited to invoices, purchase orders, sales and dispensing records, in the retail pharmacy), for all pharmaceutical products and administrative records of the staff shall be properly kept for at least ten (10) years in the pharmaceutical establishment and be readily available to the inspection service when requested for or needed.
2) Current pharmacopoeias recognized by the Authority, Standard Treatment Guidelines, National Formulary, and National List of Essential Medicines.
3) All entries and dispensing of pharmaceutical products must be approved by the responsible pharmacist.
4) Quarterly Report on the dispensed controlled substances (Narcotics and psychotropic substances) to be submitted to the Authority.
5) A copy of the Good Dispensing Practice (GDP), approved by the Authority.

6) Identification of the establishment by a readable sign board with the number of authorization, names and contacts of the pharmacist in charge
7) A copy of authorization, license to practice for the responsible pharmacist shall be conspicuously displayed in the retail pharmacy premises.

Article 60: Minimum staffing requirements

1) Responsible Pharmacist (compulsory)
2) Support Staff: Assistant Pharmacist, Pharmacy Technician, Medical Assistant or Nurse. (optional)

Article 61: Management of controlled substances

Controlled substances shall be kept in a secure, fixed separate and lockable storage place.

Article 62: Good Dispensing Practice

The pharmaceutical retailer shall have systems, facilities and operations that comply with the Good Dispensing Practice Guidelines, as adopted by the Authority.

CHAPTER III: REFUSAL AND VALIDITY OF AN AUTHORIZATION

Article 63: Refusal to grant an Authorization

1) An authorization to manufacture pharmaceutical products, or to operate a wholesale pharmacy; or to operate a retail pharmacy; or to perform small scale manufacturing/compounding of any pharmaceutical product; shall not be granted where the Authority finds the applicant not complying with the minimum requirements prescribed in these Regulations.
2) The refusal letter shall be issued to the applicant in the standard format *(Doc. N°. DIS/FMT/019-Refusal to Grant Authorization)*.

Article 64: Format of an Authorization

An authorization shall be granted and issued to an applicant complying with the requirements in these Regulations; in the following standard formats:

1) *Doc. N° DIS/FMT/018-Authorization to Manufacture Pharmaceutical Products;*
2) *Doc. N° DIS/FMT/021-Authorization for Wholesale of Pharmaceutical Products*;
3) *Doc. N° DIS/FMT/022-Authorization for Retail of pharmaceutical products*; and
4) *Doc. N° DIS/FMT/023-Authorization for Small Scale Manufacturing/Compounding.*

Article 65: Display of the Authorization

An authorization shall be prominently displayed on the premises, at all times.

Article 66: Validity of an Authorization

1) An authorization shall be valid for one year renewable from the date it is issued, but may be suspended or withdrawn, if any of the conditions under which it was granted, is violated.
2) An authorization is issued to an applicant and shall not be transferable to another applicant without approval of the authority.

CHAPTER IV: ADMINISTRATIVE SANCTIONS

Article 67: Warning, Suspension, revocation of an authorization and/or monetary fines

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 these Regulations; or has ceased to be fit to carry on the business.
2) The notice of suspension or revocation shall be issued by the Authority in the standard format:
    a) Doc. N°. *DIS/FMT/024-Notification for Suspension of Authorization*; and
    b) *Doc. N°. DIS/FMT/025-Notification for Withdrawal/Revocation of Authorization.*
3) Monetary fines are provided in the Regulations No CBD/TRG/004 Related to regulatory service tariff/fees and charges.

CHAPTER IV: RENEWAL AND VARIATION OF AN AUTHORIZATION

Article 68: Renewal of an authorization

An authorization shall be renewed after one year from the date it was issued, upon submission of an application for renewal and after meeting all the requirements.

Article 69: Variation of an authorization

1) Whenever the Authority varies, amends, or imposes any new conditions on the authorization requirements, the Authority shall communicate the return of such authorization to be duly endorsed within reasonable time.

2) An application shall be made to the Authority for review and approval of any variation made on the details of the issued authorization.

3) Where the Authority finds the premise not complying with premise suitability requirements, the certificate may be suspended or revoked.

CHAPTER V: MISCELLANEOUS PROVISIONS

Article 70: Notification of change in ownership

1) Where there is a change in the ownership of the business, the person to whom an authorization was issued under these Regulations shall, within thirty days of the change, notify the Authority.

2) The person to whom an authorization is issued under these Regulations shall submit to the Authority, a certified copy of the articles of association or partnership deed reflecting the change.

3) When the owner ceases to be responsible for the business for which the authorization is issued before the expiry of the authorization, the owner shall return the authorization to the Authority.

Article 71: Compliance with other requirements

A company that has been granted with an authorization shall comply with any other requirements as may be specified by the Authority.

Article 72: Publication of authorized pharmaceutical premises

Pharmaceutical premises that are granted authorizations shall be published bi-annually on the Rwanda FDA Website, and on any other media, as the Authority may decide from time to time.

List of Formats for use with these Regulations

1) Doc. N°. DIS/FMT/013-Inspection Report for Suitability of Premises for Manufacture of Pharmaceutical Products;
2) Doc. N°. DIS/FMT/014-Inspection Report for Good Manufacturing Practice;
3) Doc. N°. DIS/FMT/015-Inspection Report for Suitability of Premises for Wholesale of Pharmaceutical Product;
4) Doc. N°. DIS/FMT/016-Inspection Report for Suitability of Premises for Small Scale Manufacture of Pharmaceutical Products;
5) Doc. N°. DIS/FMT/017-Inspection Report for Suitability of Premises for Retail of Pharmaceutical Products;
6) Doc. N° DIS/FMT/018-Certificate of Compliance with Good Manufacturing Practice;

7) Doc. N°. DIS/FMT/019- Refusal to Grant Authorization;
8) Doc. N° DIS/FMT/020-Authorization to Manufacture Pharmaceutical Products;
9) Doc. N° DIS/FMT/021-Authorization for Wholesale of Pharmaceutical Products;
10) Doc. N° DIS/FMT/022-Authorization for Retail of pharmaceutical products;
11) Doc. N° DIS/FMT/023-Authorization for Small Scale Manufacturing/Compounding;
12) Doc. N°. DIS/FMT/024-Notification for Suspension of Authorization; and
13) Doc. N°. DIS/FMT/025-Notification for Withdrawal/Revocation of Authorization.

List of Forms for use with these Regulations

1) Doc. N°. DIS/FOM/016- Application for Good Manufacturing Practice Inspection for Finished Pharmaceutical Products Manufacturing Facilities;
2) Doc. N°. DIS/FOM/017-Application for pharmaceutical manufacturing authorization;
3) Doc. N°. DIS/FOM/018-Application for pharmaceutical wholesale authorization;
4) Doc. N°. DIS/FOM/019-Application for pharmaceutical retail authorization.

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