RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING LICENSING TO MANUFACTURE, TO OPERATE AS WHOLESALE AND RETAIL SELLER OF MEDICAL PRODUCTS

(Rwanda FDA law N^{o} 003/2018 of 09/02/2018, Article 8)

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N°9 of the Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these regulations N° CBD/TRG/001 Rev. N° 1, governing licensing to manufacture, to operate as wholesale and retail seller of medical products , made this 02nd day of October, 2020.

Dr. Charles KARANGWA
Ag. Director General

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO	**17th August 2020**
ADOPTION BY RWANDA FDA	**24th August 2020**
STAKEHOLDERS CONSULTATION	**26th August 2020**
ADOPTION OF STAKEHOLDERS' COMMENTS	**28th August 2020**
DATE FOR COMING INTO EFFECT	**2nd October 2020**

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CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these Regulations

The purpose of these Regulations is to provide for a detailed framework in the implementation of the law 003/2018 of 09/02/2018 for the effective and efficient regulation of the manufacture, wholesale and retail of medical products.

Article 2: Citation

These Regulations may be cited as the *"Regulations CBD/TRG/001 Rev. N° 1, Governing licensing to manufacture, to operate as wholesale and retail seller of medical products"*

Article 3: Application

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

Article 4: 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 Practices" means that part of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing 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;

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

"Medical product" means medicines, vaccines, diagnostics and medical devices.

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.

"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

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

Article 6: Requirements for authorization to manufacture, to operate as wholesale and retail seller of medical products

All applications for premise licensing shall comply with the technical requirements as determined by the Authority in relevant guidelines

Article 7: Inspection of premises for suitability

1) The Authority shall inspect the premises to determine the suitability of premises for manufacturing, wholesale and retail selling of medical products.
2) Premises that do not comply with the requirements for suitability shall not be eligible for consideration for an authorization.

Article 8: 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 9: Good Distribution Practices

Medical product distributors shall have systems, facilities and operations that comply with relevant Guidelines, as adopted by the Authority.

Article 10: Good Manufacturing Practices

Medical product manufacturers shall have systems, facilities and operations that comply with relevant Guidelines, as adopted by the Authority.

Article 11: Good Dispensing Practices

Medical product retail sellers shall have systems, facilities and operations that comply with relevant Guidelines, as adopted by the Authority.

CHAPTER III: REFUSAL AND VALIDITY OF AN AUTHORIZATION

Article 12: Refusal to grant an Authorization

An authorization to manufacture medical products, or to operate a wholesale establishment; or to operate a retail establishment or to perform small scale manufacturing of any medical product, operate veterinary drug shop; shall not be granted where the Authority finds the applicant not complying with the minimum requirements prescribed in these regulations.

Article 13: 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) Application for renewal of an authorization shall be made to the Authority within the validity period of the authorization.

3) A grace period of 6 months after expiry of the license shall be given to an establishment that has failed to comply with renewal requirements. The establishment shall remain closed after the expiry of the license. After the grace period, the pharmacy shall be removed from the database, and the application made after this period shall be considered as new application.

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

5) Any change to the authorization information shall be notified to the Authority through an application.

Article 14: Display of the Authorization

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

Article 15: Display of Sign post

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

CHAPTER IV: MISCELLANEOUS PROVISIONS

Article 16: Administrative sanctions

Any person contravening any provision of these regulations commits an offense and shall be liable to penalties as stipulated in the regulations related to regulatory service tariff/fee and fines in force.

Article 17: Appeals and Review

1) Any person aggrieved by a decision of the Authority may appeal to the Authority for review of a decision within 15 days from the date of notice.
2) The Authority shall within 15 days from the date of appeal application review, vary or reject its own decision.
3) If a person is dissatisfied with a decision after review, he/she may appeal to the supervising Authority of Rwanda FDA whose decision shall be final.

Article 18: Commencement And Repealing

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

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