Republic of Rwanda

RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS Nº CBD/TRG/010 Rev_0 GOVERNING REGISTRATION OF MEDICINAL PRODUCTS

(Rwanda FDA law Nº 003/2018 of 09/02/2018, Article 8)

Rwanda Food and Drugs Authority

P.O Box 84 Kigali

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 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/010 Rev_0 Governing Registration of medicinal products, made this 20th day of February, 2020.

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

ARRANGEMENT OF THE REGULATION

CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these Regulations

a. The purpose of these Regulations is to enforce the legal framework to ensure effective and efficient registration of medicinal products, and to provide an open, transparent and non-discriminatory process for the registration of medicinal products.
b. These regulations cover human and veterinary medicinal products, vaccines and biological products for human and animal use, herbal medicinal products, disinfectant and antiseptics excluding cosmetics as well as laboratory and household chemicals.

Article 2: Citation

These regulations may be cited as "*Rwanda FDA Regulations Governing the Registration of medicinal products".*

Article 3: Application

These regulations shall apply to all medicinal products to be registered in Rwanda.

Article 4: Definitions

In these regulations, unless the context otherwise requires**:**

1. "**Authority**" means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under the article 2 of the Law No. 003/2018 of 09/02/2018.
2. "**active pharmaceutical ingredient**" means a substance or compound that that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals;
3. "**applicant**" means a person who applies for registration of a medicinal product to Rwanda FDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured. After the product is registered, the applicant shall be the "Marketing Authorisation Holder".
4. "**Fee**" means the fee prescribed in Regulation CBD/TRG/004 related to regulatory services and charges.
5. "**approve**" or "**approval**" means official consent by the Authority as an acceptance of a medicinal product or practices related to that medicinal product to be available on the market in Rwanda
6. "**batch**" or "**lot**" in relation to a medicinal product means a defined quantity of a medicine manufactured in a single manufacturing cycle and which has homogeneous properties;

7. "**manufacturing batch record**" or its acronym "BMR" means all documents associated with the manufacture of a batch of bulk product or finished medicinal product;
8. "**batch number**" or "**lot number**" means a unique number or combination of numbers or symbols allocated to a lot or a batch by the manufacturer;
9. "**bioequivalence**" means the absence of a significant difference in the bioavailability between two pharmaceutically equivalent products under similar conditions in an appropriately designed study;
10. "**composition**" means the ingredients of which the product consists, proportions, degree of strength, quality and purity in which those ingredients are contained;
11. "**country of origin**" means a country in which the medicinal product has been manufactured;
12. "**Director General**" means the head of the Authority;
13. "**generic medicinal product**" means a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies;
14. "**Good Manufacturing Practice**" or its acronym "**GMP**" is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Authority;
15. "**label**" means any tag, brand, mark, pictorial or other descriptive matter, written, printed stencilled, marked, embossed or impressed on or attached to a container of any medicinal product;
16. "**Law**" means Law N°. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.
17. "**manufacture**" means all operations that involve preparation, processing, filling transforming, packaging, and repackaging and labelling of medicinal products;
18. "**manufacturer**" means a person or a firm that is engaged in the manufacture of medicinal products;
19. **"Marketing authorization"** Means approval from the authority necessary to market and sell a product in Country
20. "**Pharmaceutical product or Medicinal product**" means any substance, or mixture of substances manufactured, sold, or presented as capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises in which food and drugs are

manufactured, prepared or stored, for cleaning hospitals, equipment and farmhouses. It does not include medical devices or their components, parts or accessories.

CHAPTER II: ASSESSMENT AND REGISTRATION OF MEDICINAL PRODUCTS

Article 5: Application for registration of medicinal products

a. All medicinal products shall be registered with the authority before they are placed on Rwanda market. A person who intends to manufacture, import or export a product shall apply to the Authority for registration of medicinal product.
b. An application for registration of medicinal product shall be made to the Authority in writing by the Marketing authorization holder, the manufacturer or local technical Representative.

Article 6: Application requirements for registration of medicinal product

a. Application for registration of medicinal product shall be made in hard or electronic copies as detailed in relevant Guidelines.
b. A separate and complete application for registration of products shall be submitted for each medicinal product with different active ingredients, strengths, and dosage forms, site of manufacture or proprietary names.
c. Notwithstanding the requirement of Article 6 b, all parenteral preparations in different pack sizes shall require separate applications.

Article 7: Data requirements for registration of a medicinal product

All applications for registration of medicinal products shall comply with the technical requirements as determined by the Authority in relevant Guidelines and shall be accompanied by data to demonstrate quality, safety and efficacy.

Article 8: Language

All applications and supporting documents shall be in **English.**

Article 9: Authenticity of documents

a. Any document submitted shall be authentic when approved by the applicant or by the authorized person.
b. The Authority shall reject an application for registration of medicinal product if it is satisfied that the submitted documents are not authentic or integrity of data is questionable.

Article 10: Accountability of the applicant and marketing authorisation holder

The applicant shall be accountable for all information supplied in support of his application for registration of the product and variations thereof.

The marketing authorization holder shall be accountable for:

a. manufacturing the product in compliance with the specifications approved according to provisions of these Regulations;
b. updating, when necessary, summary of product characteristics and package inserts for the purpose of enabling a correct and safe use of the product;
c. communicating the variations to the Authority within the framework of the relevant provisions of the guidelines;
d. providing responses to the issues raised/requested by the Authority, in relation to a registered product;
e. to carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the Authority;
f. ensuring that the product continues to comply with the safety, efficacy and quality requirements prescribed in the Law and Regulations.

Article 11: Safe custody and confidentiality of information

a. The Authority shall ensure safe custody of information related to the registration of medicinal products submitted by applicants.
b. All information submitted shall be treated confidential and shall not be disclosed to any third party without a written consent of the applicant.

Article 12: Assessment process of medicinal products

a. The Authority shall, upon being satisfied by the application, conduct assessment to verify the compliance with safety, quality and efficacy requirements through full or abridged assessment procedures. The authority shall set out guidelines, SoPs, forms, and tools for full and abridged assessment procedures.
b. The Authority may, during the assessment of the product, require the applicant to submit additional samples, documents, information, data or clarification to support the application for registration.
c. Where the Authority requires additional samples, documents, information, and data and or clarification pursuant to Article 12 b, the processing of the application shall not proceed until when the applicant makes submission.
d. Where the applicant fails to submit requested information according to Article 12 b, within the period of ninety (90) days from the date of request letter, the application shall be considered **withdrawn**.

e. Pursuant to the requirements of Article 12 d, the applicant may by giving reasons in writing request for extension of time for submission of additional samples, documents, information, data and or clarification requested by the Authority.

f. If the applicant fails to provide satisfactory responses to the requested information according to Article 12 b for a fourth time, the application shall be **rejected.**

g. An application withdrawn pursuant to article 12 d shall only be considered for registration upon submission of a new application as per the requirements of these Regulations.

Article 13: Good Manufacturing Practices and Good Clinical Practices

During the assessment of medicinal product, the Authority shall as it may deem necessary conduct on-site inspection and causal inspection of the non-clinical studies, clinical trials, bio-studies and production site inspection to confirm the authenticity, precision and integrity of information and data submitted.

Article 14: Registration of medicinal products

The authority shall issue a certificate of registration of medicinal products only if:

1. The medicinal product dossier is assessed and fulfil requirements of Safety, quality and efficacy
2. The manufacturing site of the medicinal product is compliant to the Good Manufacturing Practices
3. medicinal product fulfils the requirements of laboratory quality tests

Article 15: Conditional registration of medicinal product

Approval issued for conditional registration shall specify the conditions which need to be fulfilled by marketing authorization holder to acquire full registration.

Article 16: Approval of medicinal product

Upon approval of registration of medicinal product, the Authority shall:

a) enter in the register the prescribed particulars of the medicinal product;

b) allocate a registration number to the medicinal product;

c) issue to the marketing authorization holder a certificate of full or conditional registration as per prescribed format.

Article 17: Publication of a registered medicinal product

The Authority shall publish a list of registered medicinal products on the authority's website specifying the registration number, name under which the product is registered(brand and International Non

Proprietary Name), Dosage form, Product strength, name and country of the marketing authorization holder, name and country of manufacturer, Local technical representative, and expiry date of the registration certificate.

Article 18: Validity of registration

a. A certificate of full registration issued under Article 16 shall, unless earlier suspended or revoked, and subject to payment of prescribed annual retention fees, be valid for a period of five (5) years from the date of issuance and may thereafter be renewed.

b. Notwithstanding the provision in Article 18 a, a certificate of conditional registration shall be valid for a period specified in the certificate and that period shall not exceed three (3) years.

Article 19: Application for variation of a registered medicinal product

a. Any variation to registered medicinal product information shall be notified in writing to the Authority through an application in the approved format.

b. An application for variation shall be submitted as per the requirements set out in the relevant Guidelines for Variation of Registered medicinal products in force at the time of submission.

c. A distinction shall be made between major and minor variations in accordance with the relevant Guidelines for Variation of Registered medicinal products and there shall be a distinction in the payment of applicable fees.

Article 20: Retention of medicinal product on the register

a. The registered medicinal product is retained on the register annually after payment of fees.

b. Application for retention on the register shall be submitted one (1) month before the due date.

c. The medicinal product shall be removed from the register if application and payment of fees is not effected as stated in article 20 a and 20 b.

Article 21: Application for renewal of registration certificate

a. Application for renewal of registration shall be made to the Authority at least ninety (90) calendar days before its expiry.

b. A grace period for renewal shall extend to ninety (90) days after the specified expiry date.

c. Failure of renewal within the grace period, the application shall be considered as new.

d. The application shall be in the prescribed format as per Rwanda FDA guidance for renewal of registration of medicinal products

Article 22: Suspension of registered medicinal product

The Authority may suspend registered medicinal product if it is satisfied that:

a) A registered medicinal product has been advertised in manner which is false or misleading or does not comply with the provisions of the Laws and Regulations currently enforced by the Authority;
b) The marketing authorization holder has contravened these Regulations or any other provision of the Laws;
c) The marketing authorisation holder made a false or misleading statement or misrepresentation in the application;
d) the marketing authorisation holder has failed to comply with the terms and conditions of the registration as provided in certificate of registration;
e) the marketing authorisation holder has failed to pay the prescribed retention fees within the prescribed time;
f) the marketing authorisation holder has failed to submit periodic post-marketing surveillance reports;
g) the marketing authorisation holder, intentionally and without justifiable reasons has failed to submit reports on adverse effects; and
h) Renewal of registration has been defaulted beyond the specified grace period.

Article 23: Notice of suspension

Any suspension shall be effected upon a written notice thereof.

The notice for suspension of registered medicinal product shall:

a) set out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
b) Require the marketing authorisation holder to show reasons as to why the suspension should not be effected.

Article 24: Suspension or cancellation of registration without notice

a. The Authority may cancel or suspend the registration of a medicinal product without prior notice if it is necessary to do so in order to prevent injury to the health or safety of patients, users or other persons.
b. The marketing authorization holder may apply to the Authority, in writing, requesting that the cancelation or suspension be uplifted.
c. The Authority may, within thirty (30) days after the date of receiving the application review its decision.

Article 25: Restoration of a cancelled or suspended registered medicinal product

Pursuant to the provision of Articles 22, 23 and 24, the Authority may, upon satisfaction that the reasons of the suspension or cancellation of registered medicinal product has been corrected or if such reason for suspension or cancelation was unfounded, reinstate the registered medicinal product.

Article 26: Refusal to grant marketing authorisation

a. The Authority shall refuse to grant marketing authorisation of a medicinal product if it is satisfied that:
    1. after verification of the particulars and evaluation of documents submitted in accordance with Article 6 a, it appears that the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product;
    2. the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such medicine are inadequate to preserve its identity, strength, quality, and purity; or
    3. particulars or documents provided by the applicant in accordance with Article 6 a are incorrect or if the labelling and package inserts proposed by the applicant are not in accordance with relevant guidelines
    4. Any ingredient in the formulation if found to be listed as banned either in Rwanda or in any international convention for which Rwanda is signatory
b. Pursuant to the provision of Article 26 a, where the Authority refuses to grant registration to a medicinal product, the Director General shall inform the applicant in writing of such decision and the reasons thereof.
c. The refusal of a marketing authorisation shall constitute a prohibition on the placing on the market of the medicinal product concerned.
d. The information about all refusals and the reasons for such refusal may be made publicly accessible on the authority's website.

Article 27: Cancellation or revocation of marketing authorisation

a. The Authority may cancel or revoke the marketing authorization of a registered medicinal product if:
    1. it is not in the public interest that the registered medicinal product should be made or continue to be made available;
    2. the medicinal product has been banned in Rwanda;

3. the medicinal product no longer meets the quality, safety and effectiveness requirements; and
4. the marketing authorisation has been suspended for a period of more than 12 months.

b. Pursuant to the provision of Article 27 a, a written notice of cancellation shall then be issued to the marketing authorisation holder, stating the reasons for cancellation.

Article 28: Labelling and Package insert

a. Labelling: Every container of a medicinal product intended to be marketed in Rwanda shall be labelled in at least one of the official language used in Rwanda according to the relevant Guidance on Format and Content of Labels.
b. Package inserts: The package insert aimed at medical practitioners and other health professionals shall be drawn up in accordance with the summary of product characteristics as determined in the relevant Guidance on Format and Content of Patient Information Leaflets.

CHAPTER III: RESTRICTION FOR SALE OF UNREGISTERED MEDICINAL PRODUCT

Article 29: Prohibitions

No person shall manufacture, prepare**,** store, export, sell, dispense, distribute or import medicinal products by either manufacturer, wholesale or retail unless it is in accordance with the provisions of these Regulations, and that person holds the appropriate registration certificate issued by the Authority.

Article 30: Exemption

a. Notwithstanding the provision of Article 29, these Regulations shall not apply to:
    1. any medicinal product prepared in a pharmacy and is done by or under the supervision of a pharmacist in accordance with a prescription given by a licensed medical practitioner, dentist;
    2. any product prepared in a hospital pharmacy in accordance with the formulas of a pharmacopoeia, and intended to be supplied directly to patients served by the concerned pharmacy and commonly referred to as the official formula;
    3. medicinal products intended to be used in research and development studies, without prejudice to the provisions of the Regulations on clinical trials in force;
    4. any medicinal products prepared and stocked in a hospital pharmacy by or under the supervision of a pharmacist with the view to dispensing as mentioned in paragraph (2); or

5. any preparation made by a traditional health practitioner registered under Laws and Regulations currently enforced related to a traditional medicine specifically prepared for administration or supply to a particular patient.

b. Any person who prepares any preparation shall be duly bound and shall be held liable for any harm to the patient brought by the medicine.

c. The authority may issue an expression of interests where the product is or are intended for treatment of rare diseases

CHAPTER IV: MISCELLENIOUS PROVISIONS

Article 31: Appeals and review

a. Any person aggrieved by a decision of the Authority may apply to the Authority for review of the decision showing grounds for dissatisfaction within thirty (30) days from the date of notice.

b. The Authority shall, within fifteen (15) days from the date of receiving the application, review, reject or vary its own decision.

c. Notwithstanding the provision of Article 31a the applicant shall not be barred from appealing to the Minister without applying to the Authority for review.

d. If a person is dissatisfied with the decision after review, he may appeal to the Minister whose decision shall be final.

Article 32: Power to issue guidelines

The authority shall issue guidelines, SOPs, forms necessary for the implementation of these Regulations

Article 33: Offences and penalties

A person contravening a provision of these regulations commits an offence and shall be liable to any of the penalties as stipulated in the regulation related to regulatory service tariff/ fees and charges in force at the time of application issued by the Authority.

Article 34: Commencement and repealing

a. This regulation shall enter into force on date of its signature and publication.

b. All prior contrary provisions to these regulations are hereby repealed.

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