RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING REGISTRATION OF MEDICINAL PRODUCTS

(Rwanda FDA Law Nº 003/2018 of 09/02/2018, Article 9)

Doc. Ref. No.: DFAR/HMDAR/TRG/001 Rev_3

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO BY COUNSULTANTS	09/09/2019
ADOPTION BY RWANDA FDA	04/02/2020
STAKEHOLDERS CONSULTATION	31/08/2022
ADOPTION OF STAKEHOLDERS`COMMENTS	31/09/2022
DATE FOR COMING INTO EFFECT	28/09/2022

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
20/04/2020	0	First Issue
08/06/2021	1	1. The Article on reliance is included 2. The article on authorization for emergency use included 3. The article on Donation of medicinal products included 4. Interline is changed from 1.5 to 1.15 as per SOP on internal document control.
07/10/2021	2	1. Article 16 on Authorization for Emergency Use was revised 2. Article 33 on Exemption revised to include a statement on Authorisation for Emergency Use 3. Article 34 on Advisory or Scientific Committee included 4. Inclusion of French and Kinyarwanda as application language 5. Editorial changes
09/09/2022	3	1. Formulate the article 15 on conditional registration of medicinal product by merging the article 15 on conditional registration of medicinal products and article 16 on Authorization for Emergency Use 2. Editorial changes

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, hereby ADOPTS and ISSUES these Regulations No:CBD/TRG/010 Rev_3 Regulations Governing Registration of Medicinal Products on this 23 / 09 / 2022.

Dr Emile BIENVENU
Director General

ARRANGEMENT OF THE REGULATIONS

CHAPTER ONE: GENERAL PROVISIONS

Article One: The Purpose of the Regulations

The purpose of these Regulations is to put in place a 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 all medinal products regulated by Rwanda Food and Drugs authroity.

Article 2: Scope

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. The regulations apply to all medicinal products to be registered in Rwanda.

Article 3: Citation

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

Article 4: Definitions

In these regulations, unless the context otherwise requires:

1. "**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".
2. "**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
3. "**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.
4. "**Certificate of registration**" means a certificate issued by the authority after its approval to market and sell a product in Country;
5. "**Composition**" means the ingredients of which the product consists, proportions, degree of strength, quality and purity in which those ingredients are contained;

6. **"Emergency circumstances"** means situations that occur when the country is faced with disasters, pandemics, war and any other national public health emergency declared by the Ministry of Health or ;
7. "**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;
8. "**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;
9. "**Manufacture**" means all operations that involve preparation, processing, filling transforming, packaging, and repackaging and labelling of medicinal products;
10. "**Manufacturer**" means a person or a firm that is engaged in the manufacture of medicinal products;
11. "**Marketing authorization**" Means approval from the authority necessary to market and sell a product in Country
12. **"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.
13. **" Unapproved product"** means any regulated product marketed without prior approval by the Authority
14. **"Unmet medical needs"** means a condition for which there exists no satisfactory method of diagnosis, prevention or treatment authorised in Rwanda or, even if such a method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected.

CHAPTER II: ASSESSMENT AND REGISTRATION OF MEDICINAL PRODUCT

Article 5: Application for registration of medicinal products

All medicinal products shall be registered by the Authority before they are placed on Rwanda market. A person who intends to manufacture, sell, distribute, import or export a medicinal product shall ensure it is done in compliance with the provisions of this regulations

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

Application for registration of medicinal product shall be made in hard or electronic copies as detailed in relevant Guidelines.

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.

Notwithstanding the requirement stated above, all parenteral preparations in different pack sizes shall require separate applications as provided for under the Guidelines.

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 made in **English, French or Kinyarwanda.** Where some documents are submitted in a language different from English, French or Kinyarwanda, the applicant shall submit translated copies to expedite the review process.

Article 9: Authenticity of documents

Any document submitted to the Authority shall be authentic when approved by the applicant or by the authorized person.
The Authority may 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 authorization holder

The applicant shall be accountable for all information supplied in support of his/her 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, where 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 raisedby 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

The Authority shall ensure safe custody of information related to the registration of medicinal products submitted by applicants.

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

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.

a. 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.

b. Where the Authority requires additional samples, documents, information, and data and or clarification pursuant to paragraph c of this Article, the processing of the application shall not proceed until the applicant makes the additional submission.

c. Where the applicant fails to submit requested information according to paragraph b of this Article, within the period of ninety (90) days from the date of request, the application shall be considered withdrawn.

d. Pursuant to the requirements of parapgraph c of this Article, 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.

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

f. An application withdrawn pursuant to paragraph c and an application rejected pursuant to paragraph e of this Article 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 announced on-site inspection or an announced 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:

a. The medicinal product dossier is assessed and product found to have fulfilled the requirements of safety, quality and efficacy,
b. The manufacturing site of the medicinal product is compliant to the Good Manufacturing Practices,
c. Medicinal product fulfils the requirements of laboratory quality tests.

Article 15: Conditional authorization of medicinal product

The Authority, in duly justified cases may grant conditional marketing authorization for medicinal products intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, to meet unmet medical needs of patients and animals as prescribed by competent medical authority within the country

The power to grant an authorisation subject to conditions may be exercised only;

1. In emergency circumstances; and

2. When the applicant can show that he is unable to provide comprehensive data on the efficacy and safety of the medicinal prodct under normal conditions of use.

The Authority may issue the authorization for emergency use when a national public health and/or animal health emergency has been declared by the competent institutions. The emergency use authorization may also be granted for an unregistered medicinal product, or an unapproved use of a registered medicinal product for public health interest and/or animal health interest

Conditional marketing authorisation for such medicinal products may be granted prior to the submission of comprehensive pre-clinical, clinical or pharmaceutical data provided that the benefit of the immediate availability outweighs the risks. The applicant shall be able to provide comprehensive data after authorization.

Article 16: Reliance

The Authority may rely on regulatory decisions from regional, international and other Stringent Regulatory Authorities' decisions in regard to product market authorization when it deems necessary.

Article 17: 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 applicant a certificate of full or conditional registration as per prescribed format.

Article 18: 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 19: Validity of Registration Certificate

A certificate of full registration issued under Article 18 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.

Notwithstanding the provision in first paragraph of this Article, 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 20: Application for variation of a registered medicinal product

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

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.

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 21: Retention of medicinal product on the register

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

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

The medicinal product shall be removed from the register if application and payment of fees is not effected as stated in the first and second paragraphs of this Article.

Article 22: Timeframes for Application for renewal of registration certificate

Application for renewal of registration shall be made to the Authority at least ninety (90) calendar days before its expiry. A grace period for renewal shall extend to ninety (90) days after the specified expiry date.
Failure to renew the marketing authorization within the grace period, the application shall be considered as new .

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

Article 23: 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 24: 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 25: Suspension or cancellation of registration without notice

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.

The marketing authorization holder may apply to the Authority, in writing, requesting that the cancelation or suspension be uplifted.

The Authority may, within thirty (30) days after the date of receiving the application review its decision.

Article 26: Restoration of a cancelled or suspended registered medicinal product

Pursuant to the provision of Articles 23, 24 and 25, 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 27: Refusal to grant marketing authorisation

The Authority shall refuse to grant marketing authorisation of a medicinal product if it is satisfied that:

a. after verification of the particulars and evaluation of documents submitted in accordance with Article 6a, it appears that the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product;
b. 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
c. 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
d. 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.

Pursuant to the provision of the first paragraph of this Article, where the Authority may not grant registration to a medicinal product, the Director General shall inform the applicant in writing of such decision and the reasons thereof as stated below:

a. The refusal of a marketing authorisation shall constitute a prohibition on the placing on the market of the medicinal product concerned.

b. The information about all refusals and the reasons for such refusal may be made publicly accessible on the authority's website.

Article 28: Cancellation or revocation of marketing authorisation

The Authority may cancel or revoke the marketing authorization of a registered medicinal product if:

a. it is not in the public interest that the registered medicinal product should be made or continue to be made available;
b. the medicinal product has been banned in Rwanda;
c. the medicinal product no longer meets the quality, safety and effectiveness requirements; and
d. the marketing authorisation has been suspended for a period of more than 12 months.

A written notice of cancellation shall then be issued to the marketing authorisation holder, stating the reasons for cancellation.

Article 29: Labelling and Package insert

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.

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.

Article 30: Donation of medicinal products

Medicinal products to be donated shall comply to the relevant established Guidelines for donation of medical products.

CHAPTER III: RESTRICTION FOR SALE OF UNREGISTERED MEDICINAL PRODUCT

Article 31: 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 32: Exemption

Notwithstanding the provision of Article 31, these Regulations shall not apply to:

a. 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;

b. 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;

c. medicinal products intended to be used in research and development studies, without prejudice to the provisions of the Regulations on clinical trials in force;

d. 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

e. 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.

f. Any medicinal product granted Authorization for Emergency Use by the authority following the declared public health emergency.

g. 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.

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

CHAPTER IV: MISCELLENIOUS AND FINAL PROVISIONS

Article 33: Advisory or Scientific Committee

The Authority shall appoint an advisory or scientific committee, including external experts, to assist the Authority in making decisions, particularly in cases when greater knowledge is required or when a public health emergency occurs.

Article 34: Appeals and review

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.

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

Notwithstanding the provision of first paragraph of this Article, the applicant shall not be barred from appealing to the Minister without applying to the Authority for review.
If a person is dissatisfied with the decision after review, he may appeal to the chairperson of the Board of Directors of the Authority or the Minister whose decision shall be final.

Article 35: Power to issue guidelines

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

Article 36: Admnistrative Sanctions

A person who manufactures, sells, distributes, imports or exports an unapproved medicinal product commits an administrative fault. He/She shall be liable for administrative fines equivalent to double the value of condemned products plus tests related costs, when testing is compulsory.

Article 37: Commencement and repealing

This Regulation shall enter into force on date of its signature and publication. All prior contrary provisions to these regulations are hereby repealed.

End of Document