RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR REGISTRATION OF MEDICAL PRODUCTS FOR UNMET MEDICAL NEEDS

SEPTEMBER, 2022

Doc. No.: WWW/XXX/YYY/ZZZ	Revision Date: DD/MM/YYYY	Review Due Date: DD/MM/YYYY
Revision No.:	Approval date: DD/MM/YYYY	Effective Date: DD/MM/YYYY

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018 determining its mission, organization and functioning. One of its functions is to regulate matters related to quality, safety and efficacy of medicinal products, medical devices and IVDs in order to protect public health by increasing their access and availability.

Considering the provisions of the Regulations No. CBD/TRG/010 governing the registration of medicinal products and Regulation No. CBD/TRG/012 governing registration of medical devices including IVDs,

It is in this regard, that the Authority has developed the Guidelines No. DFAR/HMDAR/GDL… for registration of medical products for unmet medical needs.

Dr. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	
ADOPTION BY RWANDA FDA	
STAKEHOLDERS CONSULTATION	
ADOPTION OF STAKEHOLDERS' COMMENTS	
DATE FOR COMING INTO EFFECT	

DOCUMENT REVISION HISTORY

Date of revision	Revision number	Changes made and/or reasons for revision
	0	First Issue

TABLE OF CONTENTS

ACCRONYMES AND ABBREVIATIONS

IVDs: In vitro diagnostics
CBD: Chair of Board of Directors
TRG: Technical Regulations

GLOSSARY / DEFINITIONS

In these Guidelines, unless the context otherwise states: -

"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".

"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.

"Local technical representative" means any applicant who is not resident in Rwanda shall appoint a local technical representative who must be a company incorporated in Rwanda and authorized by Rwanda FDA to deal in medicinal products and must hold a wholesale operating license. The appointment shall be notified to the Authority by submitting a letter of appointment supported by original copy of power of attorney duly notarised in country of origin,

"Marketing Authorisation" means an approval from the authority necessary to market and sell a product in Rwanda. This is a legal document that establishes the detailed composition and formulation of the product and the pharmacopoeia or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.

"Medical product" means medical devices, diagnostics, and pharmaceutical products including any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal to 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, cleaning hospitals, equipment, and farm houses;

"Orphan medical product"
(a) A medical product which remains commercially undeveloped due to low commercial returns, or
(b) A medical product intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders, or
(c) A medical product intended to treat rare diseases that the sponsors are reluctant to develop them under usual marketing conditions.

"A Rare Disease" means a disease condition which occurs in a small percentage of the population.

"Unmet Medical Need"
An unmet medical need is a condition or symptom whose diagnosis, prevention or treatment is not addressed adequately by available therapy. An unmet medical need includes an immediate need for a defined population (e.g., to treat a serious condition with no or limited treatment).

INTRODUCTION

In pursuance of the Law **Nº 003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority and determining its mission, organization and functioning;

Considering the provisions of the Regulations No. CBD/TRG/010 governing the registration of medicinal products especially in its article 5 regarding application for registration of medicinal products and Regulation No. CBD/TRG/012 governing registration of medical devices including IVDs in its article 6 regarding application and requirements for registration of medical devices and in vitro diagnostic devices

The Authority has developed these guidelines to provide guidance on registration of medical products for unmet medical needs.

The Authority recognizes the need for granting special status to medical products to treat a rare disease or condition upon request of an applicant.

1. To ensure that patients suffering from rare diseases receive the same quality of healthcare as other patients.
2. To provide commercial incentives in order to encourage developing and marketing of medical products for unique individual health needs.
3. Moral responsibility of the Government to facilitate access and availability of medical products for unique individual health needs.

SCOPE

These guidelines are hereby made to provide guidance on the registration of medical products classified as unregistered medical products for chronically, seriously debilitating or life threatening diseases, with no satisfactory treatment authorised in Rwanda, orphan medical products, compassionate medical products, and other medical products for public health interest.

REQUIREMENTS FOR REGISTRATION

The following should be submitted for the registration of medical products under this scope;

1. An application may be made at any stage of product lifecycle, during development, marketing authorization or post-approval.

2. A cover letter expressing interest addressed to the Director General of Rwanda FDA.

3. A filled and signed application form.

4. 2 samples of the medical product.

5. 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.

CRITERIA FOR DRUG CLASSIFICATION UNDER THESE GUIDELINES

1. The medical product should fall under the scope of these guidelines.
2. If there is no alternative method of diagnosis, prevention or treatment of the indicated conditions.
3. If marketing of the product does not generate sufficient return to justify the investment.
4. If a medical product is registered through the normal registration, application by another applicant will be considered if the applicant is able to prove non-availability and meet the mentioned criteria.

TIMELINES FOR REGISTRATION

Applications under this category will be processed within ninety (90) working days of submission;

1. The Authority shall review the documents and inform the Applicant if the medical product fulfils the criteria under these guidelines within thirty (30) working days.
2. Evaluation shall be completed within sixty (60) working days after the applicant has submitted a complete dossier.

INCENTIVES FOR REGISTERING MEDICAL PRODUCTS UNDER THESE GUIDELINES

1. Exemption from some provisions of the Fees and Charges as per Regulations No. CBD/TRG/004 Rev_2 related to regulatory service tariffs/fees and fines Article 8;
   No application fees, no renewal fees, and no retention fees.

2. Expedited review.

3. Technical assistance in meeting regulatory requirements including but not limited to collaborative approach and real time communications regarding additional information and pending issues as well as pre-submission meetings.

VALIDITY OF THE MEDICAL PRODUCT REGISTRATION

Registration is valid for three (3) years after which renewal is required.

ENDORSEMENT OF THE GUIDELINES

	Author	**Checked by**		**Approved by**
Title	**Division manager**	**Head of Department**	**Quality Assurance Analyst**	**Director General**
Names	Mrs. Clarisse IRASABWA	Dr. Védaste HABYARIMANA	Mr. Théogène NDAYAMBAJE	Dr. Emile BIENVENU
Signature				
Date				