RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR REGISTRATION OF MEDICAL PRODUCTS FOR UNMET MEDICAL NEEDS

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by Law N° 003/2018 of 09/02/2018 determining its mission, organization and functioning. One of its functions is to regulate matters related to the 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 Regulations No. DFAR/HMDAR/TRG/001 governing the registration of medicinal products, and Regulation No. DFAR/HMDAR/TRG/002 governing registration of medical devices including IVDs.

It is in this regard, that the Authority has developed *Guidelines No. DFAR/HMDAR/GDL/018 for registration of medical products for unmet medical needs.*

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Dr Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	12/08/2022
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STAKEHOLDERS CONSULTATION	31/08/2022
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DOCUMENT REVISION HISTORY

Date of revision	Revision number	Changes made and/or reasons for revision
08/09/2022	0	First Issue

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ACCRONYMES AND ABBREVIATIONS

DAFR: Drugs and Food Assessment and Registration Department
HMDAR: Human Medicines and Device Assessment and Registration Division
IVDs: In vitro diagnostics
MA: Marketing authorization
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 Authorization Holder".

"Authority" means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under article 2 of Law No. 003/2018 of 09/02/2018.

"Local Technical Representative" a company incorporated in Rwanda and authorized by Rwanda FDA to deal in medicinal products and holding a wholesale operating license, which is appointed by any applicant who is not resident in Rwanda to become his/her Local Technical Representative. The appointment shall be notified to the Authority by submitting a letter of appointment supported by an original copy of power of attorney duly notarized in a country of origin,

"Marketing Authorization" means 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, in vitro 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 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" means:

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 under usual marketing conditions.

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

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 a major therapeutic advantage to those affected.

INTRODUCTION

In pursuance of Law **Nº 003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority and determining its mission, organization and functioning, especially in article 9;

Considering the provisions of Regulations No. DFAR/HMDAR/TRG/001 governing the registration of medicinal products especially in its article 5 regarding application for registration of medicinal products, article 15 regarding conditional authorization of medicinal products and Regulation No. DFAR/HMDAR/TRG/002 governing registration of medical devices including IVDs in its article 6 concerning application and requirements for registration of medical devices and in vitro diagnostic devices.

The Authority has developed these guidelines to provide guidance on the 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 encourage the development and marketing of medical products for unmet medical needs.
3. To facilitate access and availability of medical products for unmet medical needs for the moral responsibility of the Government.

SCOPE

These guidelines are hereby made to guide 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.

1. REQUIREMENTS FOR REGISTRATION

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

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

b. A filled and signed application form;

c. Two (2) samples of the medical product, where applicable;

d. Medical product dossier complying with the technical requirements as determined by the Authority in relevant guidelines and accompanied by data to demonstrate quality, safety and efficacy.

   The dossier shall also include a discussion on the scientific rationale to establish a medically plausible basis for the use of the medical products for the rare disease or condition, including all relevant data from in vitro laboratory studies, preclinical efficacy studies conducted in an animal model for the human disease or condition, and clinical experience with the medicine in the rare disease or condition that is available to the applicant, whether positive, negative, or inconclusive. Copies of pertinent unpublished and published papers shall also be submitted;

e. Registration status of medical products in other countries.

An application may be made at any stage of the product lifecycle, during development and marketing authorization.

All applications and supporting documents shall be submitted in **English, French or Kinyarwanda**. otherwise, the applicant shall submit translated copies to expedite the review process.

2. CRITERIA FOR DRUG CLASSIFICATION UNDER THESE GUIDELINES

The medical product should fall under the scope of these guidelines.

a. If there is no alternative method of diagnosis, prevention or treatment of the indicated conditions;
b. If the marketing of the product does not generate sufficient return to justify the investment;
c. If a medical product is registered through the normal registration, and the applicant wishes to propose new therapeutic indications that meet the above criteria.

3. TIMELINES FOR REGISTRATION

Applications under this category will be processed upon submission as per the timelines below:

a. 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.
b. The evaluation shall be completed within sixty (60) working days after the applicant has submitted a complete dossier.

4. INCENTIVES FOR REGISTERING MEDICAL PRODUCTS UNDER THESE GUIDELINES

a. 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.

b. Expedited review.

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

5 VALIDITY OF THE MEDICAL PRODUCT REGISTRATION

Registration shall be valid for a period specified in the certificate and that period shall not exceed three (3) years after which the renewal is required.

ENDORSEMENT OF THE GUIDELINES

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Date	23/09/2022	23/09/2022	23/09/2022	23/09/2022