RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR REGISTRATION OF INNOVATIVE HUMAN MEDICAL PRODUCTS

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety, and efficacy of pharmaceutical products to protect public health by increasing access and availability of essential medicines.

In consideration of the provisions of the technical regulations No. DFAR/HMDAR/TRG/001 Rev_3 of 28th September 2022 governing the registration of medicinal products, the Authority has issued the *"Guidelines for registration of Innovative human medical products"*.

These guidelines have been developed in order to cope with the new developments in line with the requirements for marketing authorisation of Innovative human medical products. They provide guidance on the content and format of information to be presented in registration dossiers submitted to Rwanda FDA for registration of such new products emanating from R&D and innovation.

Adherence to the guidelines by all concerned will facilitate timely assessments and approval of application dossiers for marketing authorization of innovative medical products.

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

Prof. Emile BIENVENU
Director General

DOCUMENT DEVELOPMENT HISTORY

First issue date	
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DOCUMENT REVISION HISTORY

Revision number	Changes made and/or reasons for revision

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ACCRONYMS AND ABBREVIATIONS

API	Active Pharmaceutical Ingredient
FPP	Finished Pharmaceutical Product
Rwanda FDA	Rwanda Food and Drugs Authority
CTD	Common Technical Document
FIFO	First-in first-out rule
GMP	Good manufacturing practice
RMP	Risk management plan
LTR	Local technical representative
SOP	Standard Operating Procedures
WHO	World Health Organization
MAH	Marketing Authorization Holder
QPPV	Qualified person for pharmacovigilance
STC	Standard table of content

DEFINITIONS

The definitions provided below apply to the terms used in these guidelines. They may have different meanings in other contexts and documents.

Innovative product

A medical product manufactured locally or abroad but has conducted all phases of clinical trial in Rwanda, and not previously registered in Rwanda or abroad and that apply for registration in order to add a new therapeutic advantage.

This includes: breakthrough innovation which is new molecular entity either single or in combination or Incremental innovation, a novel modification that is made to already registered products.

Therapeutic advantage

An advantage that is added by the innovative product. It includes any of the following advantages:

1. An innovative product which is more effective.
2. An innovative product which ensures greater safety.
3. An innovative product which has better pharmacokinetics.
4. An innovative product which improves patient's compliance to medication.
5. An innovative product which adds a new therapeutic option.

Innovator product: The first medicinal product (containing a new chemical entity that has not been previously used in other medications) authorized for marketing, typically as a patented product based on a complete set of documentation demonstrating its quality, safety and efficacy.

Active Pharmaceutical Ingredient (API) or drug substance

A substance used in the FPP, intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.

Medical products:

Encompass a broad range of items used in healthcare, including drugs, medical devices, and biological products. These products are designed to diagnose, prevent, treat, or alleviate disease, or to restore, correct, or modify bodily functions.

Active Pharmaceutical Ingredient (API) Starting Material

A raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. An API starting material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or produced in-house.

Applicant

An applicant is a person who applies for registration of a human Medical 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

The 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.

Biobatch

The batch used to establish bioequivalence or similarity to the comparator product as determined in bioequivalence or bio waiver studies, respectively.

Final Pharmaceutical Intermediate

The last reaction intermediate in the synthetic pathway that undergoes synthetic transformation to the API or the crude API. Purification is not considered to be a synthetic transformation.

Finished Pharmaceutical Product (FPP)

A finished dosage form of a Medical product which has undergone all stages of manufacture including packaging in its final container and labelling.

In-Process Control

Check performed during manufacture to monitor or to adjust the process in order to ensure that the final product conforms to its specifications.

Manufacturer

A company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of Medicals.

Pilot-Scale Batch

A batch of an API or FPP manufactured by a procedure fully representative of and simulating that to be applied to a full production-scale batch. For example, for solid oral dosage forms, a pilot scale is generally, at a minimum, one-tenth that of a full production scale or 100 000 tablets or capsules, whichever is the larger, unless otherwise adequately justified.

Production Batch

A batch of an API or FPP manufactured at production scale by using production equipment in a production facility as specified in the application.

Local Technical Representative (LTR)

Means any registered company in Rwanda and licensed by Rwanda FDA to deal with regulated products that has received a mandate from the Applicant to act on his/her behalf with regard to matters pertaining to the registration of regulated products.

CHAPTER ONE: INTRODUCTION

Rwanda Food and Drugs Authority (Rwanda FDA) is established by the Law N° 003/2018 of 09/02/2018. Considering the provisions of the Regulations Governing the Registration of Human Pharmaceutical Products which gives the power to issue guidelines, the Authority has issued *Guidelines for Registration of Innovative Human Medical Products*.

The Purpose of issuing this regulatory guideline is to define the concept of the innovative products and to stipulate their registration procedures by the Rwanda FDA. In addition, it provides guidance to applicants preparing a Common Technical Document (CTD) for the Registration of Medicines for Human Use.

The authority recognises the following differences between Innovator and Innovative medical products.

Feature	**Innovator**	**Innovative**
Definition	The first authorized version authorized medicines developed with full data of quality, safety and efficacy	A medicinal product that introduces significant novelty such as anew chemical entity, mechanism or therapeutic
Regulatory basis	Approved based on complete (full)registration dossier	May be newly developed or significantly modified/improved compared to existing therapies
Example	The original brand –name drug(eg-Lipitor by Pfizer	Anew gene therapy or a novel mRNA Vaccine
Patent status	Usually patented or protected	May or may not be Patented-the focus is on therapeutic Novelty
Role in drug life cycle	Serves as the reference for generics or Biosimilar	May later become the Innovator if it is the first in the class
WHO/ICH content	Basis for Generic product comparison	Recognized in the priority review, orphan drug or breakthrough therapy designations

For Innovator product, we have guidelines for Registration of Pharmaceutical products as well as Guidelines for Registration of human biological products that apply based on the type of products.

Based on the above outlined differences, it necessitated the development on a separate guideline for registration of Innovative medical products

SCOPE

This Guideline shall apply to human medical products that have not previously been registered by Rwanda FDA or abroad which apply for registration in order to add a new therapeutic advantage.

The principles in these guidelines would also apply to chemical combinations and complexes that comprise more than one active ingredient including fixed dose combinations (FDC).
More details on the scientific principles applicable to the assessment of FDC products is stipulated in the *Rwanda FDA guidance on registration of fixed dose combination (FDC) for human pharmaceutical products*

CHAPTER TWO: ORGANISATION OF REGISTRATION PROCESS

2.1 ELIGIBILITY CRITERIA FOR INNOVATIVE PRODUCT REGISTRATION PROCEDURE

Products that meet the following criteria are eligible for the Innovative medical product registration procedure at Rwanda FDA:

a) The product (Break-through innovation) is not registered by any regulatory authority at the time of submission to Rwanda FDA;
b) The product (Incremental innovation) offers a significant advantage over currently approved products;

2.2 REGISTRATION PROCEDURE AND DESIGNATION OF INNOVATIVE MEDICAL PRODUCTS STATUS

2.2.1. Inquiry request

Applicant notifies Rwanda FDA of the intention for registration and submits a cover letter, application form accompanied by the supporting documentation indicated in the Appendix No. (1) via official communication channels
(eg : info@rwandafda.gov.rw)

Rwanda FDA committee for Scientific Evaluation of Innovative Products shall review the request within 10 working days from the date of receiving a complete request and notify the applicant of the status of the submitted request in terms of the acceptance or rejection. The applicant shall be invited to the pre-submission meeting in the next 10 working days prior to the meeting.

2.2.2. Pre-submission meeting.

The Authority shall convene the pre-submission meeting to discuss with applicant the application requirements, and provide additional guidance in line with upcoming application dossier.

2.2.3. Submission of the application dossier

2.2.3.1. Application requirements

The applicant shall be required to submit the scientific data of the innovative product in line with CTD format (with exception of medical devices) and other documentations requested during the pre-submission meeting for evaluation through IRIMS; Rwanda FDA online portal (https://www.irims.rwandafda.gov.rw/portal)

The following are the application requirements:

a) Application Cover letter
b) Evidence of appointment of LTR and Qualified person for pharmacovigilance

c) Proof of payment, made in accordance to regulations related to regulatory services tariffs/ fees and charges
d) Technical dossier, CTD format in (PDF), QOS and QIS in MS-Word or STED/STC for medical devices

e) Physical samples of the product packaged in the primary packaging and other needed materials for testing.
f) Risk management plan.
g) Application for GMP Inspection/Quality audit for sites that have not been inspected by Rwanda FDA

Note:

The application should be typed in **English, French or Kinyarwanda**. Any document which is in any language other than English, French, or Kinyarwanda must be accompanied by a certified or notarized translation.

The summaries (Quality Information Summary, Quality Overall Summary, should be formatted as word document following templates downloadable on Authority's website.

All other documents shall be in, selectable and searchable PDF
All pages of the application should be numbered in the style: ***page x of y***.

A separate application is required for each product. The following products will be regarded as either being the same product or separate product applications.

The application must contain a complete index to the various appendices.

2.2.3.2 Officially Recognized References

The official recognized pharmacopoeias by the Authority are British Pharmacopoeia (BP), European Pharmacopoeia (Ph.Eur.), The International Pharmacopoeia (Ph.Int), Japanese Pharmacopoeia (JP) and United States Pharmacopeia (USP). References should be cited in accordance with the current edition of compendia.

When reference is made to specifications, quality control procedures and test methods in official recognized compendia or scientific publications, full references and copies of relevant pages shall be enclosed.

2.3. REVIEW OF SUBMITTED DOSSIER AND COMMUNICATION TO THE APPLICANT:

2.3.1. Screening of Innovative products applications

The Innovative Medical Products Applications submitted to the authority are not considered valid until they have been screened for completeness. All applications shall undergo screening and full assessment conducted.

The application shall then be screened for completeness and compliance with the regulatory requirements **within thirty (30) working days** from the submission date.

In case the applicant has provided incomplete information after screening, the Authority communicates through the system and request missing regulatory requirements.

The applicant submits missing requirements through the system, within **fifteen (15) working days** unless she/he requests for extension before deadline. Incomplete application will be subjected to resubmission.

2.3.2. Review of Application

The application is thoroughly reviewed to ensure transparency and quality assurance.

The review follows the first-in first-out rule (FIFO), except for applications that are conducted in public health emergencies such as disease outbreaks.
The application is assessed by different experts to ensure safety, efficacy and quality of innovative medical products applications as per the relevant SOPs.
After the review, Rwanda FDA committee for Scientific Evaluation of Innovative Products will be convened to review the outcome of evaluations.

2.3.2.1. Timelines for review

The routine review of new Innovative medical products application does not exceed 36months for emergency use, accelerated (intensive work) assessment will be done within 8 months

These timelines shall not include the time taken by the applicant to respond to any request for additional information or clarification from the Authority. A stop-clock mechanism shall thus apply each time the Authority requests for additional information. This will help to monitor timelines for each application from the date application to the final approval.

The application response to queries or clarifications from the applicant shall not exceed ninty (90) working days unless she/he requests for extension in writing before deadline.

2.3.2.2. Types of review

a) Routine Reviews

This is a comprehensive review (full assessment) of all modules of the CTD to establish quality, safety and efficacy of submitted, including risk management plan, GMP and clinical trials

b) Non-routine reviews

The non-routine review process is a pathway for accelerating the review and approval of innovative medical products application decision-making under certain circumstances (e.g., public health emergencies).

c) Expert Reviews

The expert reviews apply when the Authority hires/invites the external reviewers following to the internal procedures depending on the complexity of innovative medical applications that require special expertise. The experts will sign a confidentiality agreement with the Authority to ensure the protection of information.

d) Joint Reviews

The joint reviews of Applications are carried out jointly by the Authority with other relevant regulatory bodies at regional or international level. The applications are reviewed by experts from each participating regulatory body and the coordination is done by a designated regulatory authority. Therefore, a regulatory decision will be taken at national level once all the requirements are fulfilled.

2.3.2.3. Review of additional data

Rwanda FDA reviews the query responses/clarifications provided and if the information is satisfactory marketing authorisation certificate is issued. In case the applicant provides non satisfactory query responses for three consecutive times, the application shall be rejected.

2.3.2.4. Presentation of the report to the Technical Scientific Committee

The division in charge of registration shall present the registration report of the product to the Technical Scientific Committee, in order to take the appropriate decision (Approval/additional information /Rejection) within 20 working days.

2.3.2.5. Post Approval changes

The validity of marketing authorisation, Emergency use authorisation, Renewal, variations, publications Cancellation or Suspension will follow applicable relevant guidelines.

ENDORSEMENT OF THE GUIDELINES

	Prepared by	Checked by		Approved by
Title	**Division Manager**	**Head of Department**	**QMS Division Manager**	**Director General**
Names				
Signature				
Date				

APPENDICES

Appendix (1) Request inquiry for registration of innovative product.
Appendix (2) Template for scientific evaluation of innovative product