RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON ABBREVIATED PROCEDURES FOR REGISTRATION OF PHARMACEUTICAL 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 in order to protect public health by increasing access and availability of essential medicines.

Considering the provisions of the technical regulations governing the registration of human medicinal products, the authority has to issue Guidelines on abbreviated procedures for registration of pharmaceutical products to be used whenever necessary.

Rwanda FDA abbreviated procedures for registration of pharmaceutical products are domesticated from the EAC joint assessment abridged procedures in order to accelerate national registration of regulated products approved by recognised reference regulatory authorities, trusted institutions and regulatory harmonisation initiatives and networks.

The aim of the abbreviated guidelines is to promote application of a risk based approach in order to avoid duplication of effort and reduce the time taken to assess and register pharmaceutical products approved in recognised reference bodies.

The implementation of these guidelines is expected to improve the efficiency and acceleration of the registration process to reduce the time taken to make decisions on pharmaceutical products registration while maintaining stringent quality assurance processes that will ensure continuous improvement of the regulatory system of Rwanda FDA.

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GUIDELINES DEVELOPMENT HISTORY

First issue date	20/04/2020
Effective date of this revision	29/02/2024

Document Revision History

Revision number	Changes made and/or reasons for revision
Rev 0	1) First Issue
Rev 1	1) Adoption of the new Guidelines template 2) Adoption of the new document number format 3) Update of application submission requirements 4) Change of mode of application submission 5) Change of the title of the document to make it clear and concise 6) Editorial changes

TABLE OF CONTENTS

FOREWORD 2
GUIDELINES DEVELOPMENT HISTORY 3
ABBREVIATIONS AND ACRONYMS 5
GLOSSARY / DEFINITIONS 6
1. INTRODUCTION 8
1.1. Background 8
1.2. Purpose of these Guidelines 8
1.3. Scope of these Guidelines 8
2. IMPLEMENTATION OF THESE GUIDELINES 8
2.1. Recognition 9
2.2. Abridged assessments 9
3. SUBMISSION REQUIREMENTS 9
4. VARIATIONS TO PRODUCTS REGISTERED VIA ABBREVIATED PROCEDURES 10
5. PROCESSING TIMELINE 10
ENDORSEMENT OF THE GUIDELINES 12

ABBREVIATIONS AND ACRONYMS

CRP	Collaborative Registration Procedure
EAC	East African community
EMA	European Medicine Agency
GMP	Good Manufacturing Practices
ICH	International Conference on Harmonisation
Rwanda FDA	Rwanda Food and Drugs Authority
SRA	Stringent Regulatory Authority
US FDA	US Food and Drug Administration
WHO	World Health Organization
WLA	World Health Organization Listed Authorities
tWLA	WHO transitional Listed Authorities
MA	Marketing Authorisation
NRA	National Rgulatory Authority
ML3	Maturity Level 3
MoU	Memorandum of Understanding
BMR	Batch Manufacturing Records

GLOSSARY / DEFINITIONS

The following definitions provided below apply to the words and phrases used in these guidelines and they are provided to facilitate their interpretation. Other terminologies can be found in the Rwanda FDA glossary of terms.

Abridged assessment:
A limited independent assessment of specific parts of the dossier, while relying on prior assessment outcomes from a reference authority or trusted institution to inform the local decision.

Applicant:
A person who applies for registration of a human pharmaceutical 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 Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under Law No. 003/2018 of 09/02/2018.

Pharmaceutical product:
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.

Recognition:
is a routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of a recognized Authority is sufficient to meet the regulatory requirements of Rwanda FDA. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.

Reliance:
The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

Reference Regulatory Authority:
In these guidelines, a Reference Regulatory Authority refers to a national, regional or international authority or a trusted institution such as WHO prequalification (WHO PQ) and WHO transitional Listed Authorities (tWLA) whose regulatory decisions and/or regulatory work products are relied upon by another regulatory authority to inform its own regulatory decisions.

Sameness of product:
For the purpose of this document, the sameness of product means that two products have identical essential characteristics (i.e., the product being submitted to the relying authority and the product approved by the reference regulatory authority). All relevant aspects applicable to medicinal products, medical devices and in vitro diagnostics have to be considered in order to confirm that the product is the same or sufficiently similar (e.g., same qualitative and quantitative composition, same strength, same pharmaceutical form, same intended use, same manufacturing process, same active pharmaceutical ingredient suppliers, etc.). Additionally, the results of supporting studies of safety, efficacy and quality, indications and conditions of use should be the same.

Stringent Regulatory Authority (SRA):
A regulatory Authority which is:
a) member of the International Conference on Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or
b) an ICH observer being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or
c)is associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

WHO-Listed Authority:
A regulatory authority or a regional regulatory system which has been documented to comply with all the indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process.

1. INTRODUCTION

1.1. Background

The standard registration process requires the application of equal resources and attention to details for all products. This may result in delays during the registration process. The guidelines of abbreviated Procedures for Registration of Pharmaceutical Product provide guidance for the implementation of a risk based approach to product dossier assessment and details of documentation required for products approved by Stringent Regulatory authorities (SRAs), WHO Listed Authorities (WLAs), prequalified by World Health Organization (WHO) and recommended by Continental and Regional regulatory harmonisation initiatives and networks such as EMA, AMA, and EAC, through the Joint Dossier Assessments and products registered by at least maturity level 3 (ML3) functioning regulatory Authorities having Memorandum of Understanding (MOU) with Rwanda FDA.

The Authority recognizes the scientific evaluation of Pharmaceutical Products by the above mentioned bodies which apply similarly stringent standards. This will therefore, ensure effective utilization of available resources without compromising the quality, safety and efficacy of registered pharmaceutical products.

1.2. Purpose of these Guidelines

The purpose of these guidelines is to provide information and guidance to applicants on the submission requirements and processes adopted and implemented by Rwanda FDA to accelerate the process of registration of pharmaceutical products using risk based approach without compromising the quality, safety and efficacy.

1.3. Scope of these Guidelines

These guidelines apply to pharmaceutical products approved by Stringent regulatory authorities WHO transitional Listed Authorities (B category), WHO Listed Authorities, pharmaceutical products Prequalified by World Health Organization under the framework of the WHO Collaborative Registration Procedure (CRP), products recommended by EMA, AMA, and EAC through the Joint Dossier Assessments and products registered by at least ML3 functioning regulatory Authorities having Memorandum of Understanding (MOU) with Rwanda FDA.

2. IMPLEMENTATION OF THESE GUIDELINES

Abbreviated assessment pathways for medicines applications will follow one of the following pathways:

2.1. Recognition

The authority may apply the recognition approach in granting marketing authorisation of a pharmaceutical product following confirmation of the sameness or sufficient similarity of the product to the one registered or approved by the reference regulatory authority or trusted institution.

2.2. Abridged assessments

For products approved by a reference regulatory authority or trusted institution for which confirmation of sameness cannot be made on some aspects,the authority may decide to conduct abridged assessement following a risk based approach. For example, in cases where similarity of the product may be verified for qualitative and quantitative composition, strength, pharmaceutical form, intended use, but manufacturing process not verified.

In all these cases, applicability of the assessment outcomes of reference regulatory authority or trusted institution in the Rwandan national context will be considered, where necessary; for example, in terms of legal and regulatory settings, benefit-risk assessment, co-morbidities, unmet medical needs, risk management plans, quality-related specificities such as climatic zones for product stability and suitability of information for patients/health professionals.

3. SUBMISSION REQUIREMENTS

All applications must be submitted in line with the Guidelines for Registration of Human Pharmaceutical Products. In addition, applicants are required to submit the following:

a. Proof of registration or approval of the product by the reference regulatory authority e.g. registration/ marketing authorization certificate or approval letter;
b. Where applicable, all unredacted assessment reports including quality, non-clinical, clinical and risk management plans (translated to English/French/Kinyarawanda where required);
c. A completed application form for registration including the same technical information as that submitted to the reference regulatory authority;
d. The product dossier for the pharmaceutical product to Rwanda FDA. The dossier submitted to Rwanda FDA should at the time of submission, be the same as that submitted to the reference regulatory authority during the initial submission, and subsequent variation documentation, where applicable. Variations that are under assessment by the reference regulatory authority at the time of submission of an application for registration to Rwanda FDA should not be included as the technical part

of the dossier should be identical to the current version approved by the reference regulatory authority. These should be submitted as post-approval changes after finalization by the reference regulatory authority;

e. The following country specific documentation;
    i. Executed and master batch manufacturing records
    ii. Long-term stability studies protocol and report conducted at Zone IVB conditions
    iii. Copy of the current version of Quality Information Summary (QIS)
f. Country specific labelling information
g. Rwanda FDA GMP certificates or Proof of GMP inspection application to Rwanda FDA
h. For product applications submitted under the framework of the WHO Collaborative Registration Procedure, a completed expression of interest form (Part A of Appendix 3 found on the WHO website). Further information on the documents and procedures for CRP may be found on the WHO website.)

In situations where the applicant wishes to apply Abbreviated Procedures to an application which is already pending with Rwanda FDA, the applicant should first update the dossier to ensure that the technical part of the information is the same as that submitted to the reference regulatory authority.

The Authority reserves the right to choose and confirm the appropriate assessment pathway and to shift from an abbreviated assessment to a full assessment pathway at any stage in the assessment process, if the manufacturer or applicant fails to submit satisfactory evidence supporting the Safety, Efficacy and Quality of products as approved by the reference regulatory authorities.

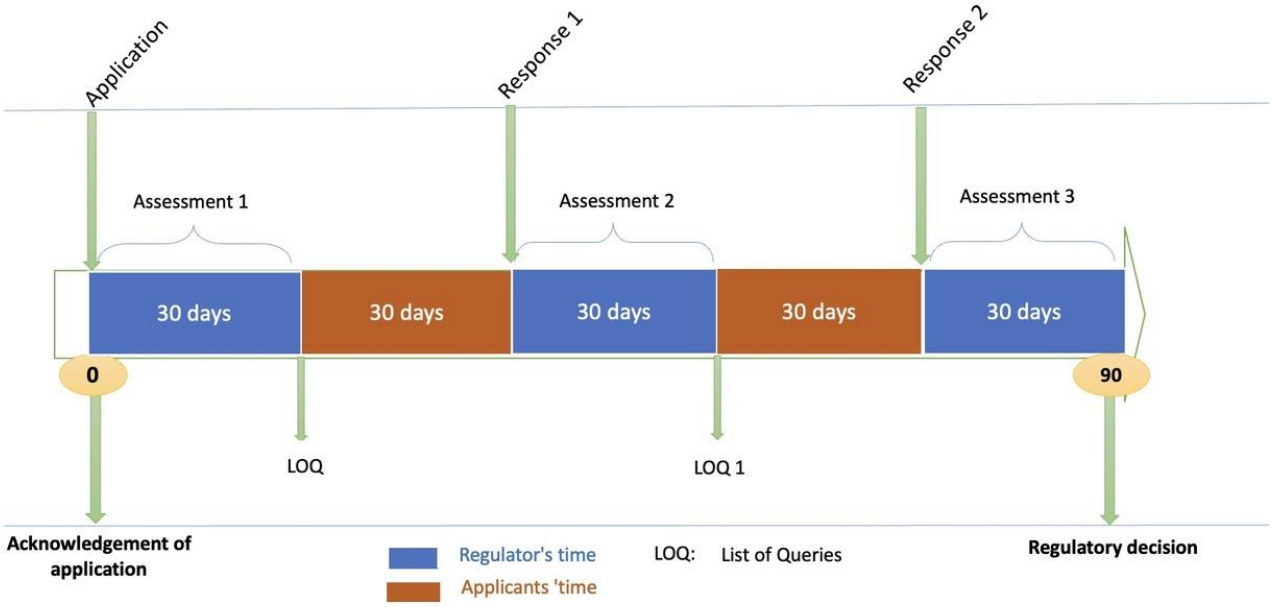
4. VARIATIONS TO PRODUCTS REGISTERED VIA ABBREVIATED PROCEDURES

Any variation (post-approval changes) to the products shall follow the applicable Rwanda FDA guidelines on variations to registered products. Reliance can also be applied for assessing post-approval changes already approved by reference regulatory authorities. Proof of approval of these variations should be included in the application to facilitate such assessments.

5. PROCESSING TIMELINE

The Authority shall process the application and communicate its decision on the product to the applicant within ninety (90) calendar days.

Illustration of timelines



ENDORSEMENT OF THE GUIDELINES

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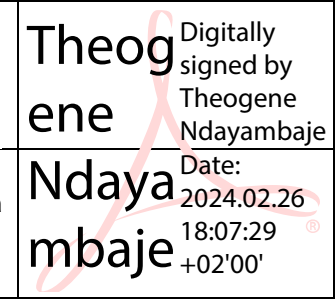
Signature				
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