RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR THE CANCELLATION/ SUSPENSION OF MARKETING AUTHORISATION FOR MEDICAL PRODUCTS

SEPTEMBER, 2022

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 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, Rwanda FDA issues the guidelines for the cancellation/suspension of marketing authorization for medical products.

It is in this regard, that the Authority has developed *Guidelines No: DFAR/HMDAR/GDL/016 for the cancellation/suspension of marketing authorization for medical products*.

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

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Director General

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	12/08/2022
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ACRONYMS 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 this guideline, 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" means a company incorporated in Rwanda and authorized by Rwanda FDA to deal in medicinal products and holds 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 ~~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.

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 articles 24,25,26,27 and 29 concerning cancellation/suspension of marketing authorization and Regulations No. DFAR/HMDAR/TRG/002 governing registration of medical devices including IVDs in its articles 24,25,26,27 and 28 concerning cancellation/suspension of marketing authorization of medical devices including IVDs;

The Authority has developed these guidelines to provide guidance on the cancellation/suspension of marketing authorization for medical products.

SCOPE

These guidelines are hereby made to provide guidance on the cancellation or suspension of the Marketing Authorization of human/veterinary medicinal products, vaccines and biological products for human and animal use, herbal medicinal products, disinfectants and antiseptics, medical devices and IVDs.

1. SUSPENSION OF A MARKETING AUTHORIZATION BY THE AUTHORITY

The Authority may suspend a registered medical product if it is satisfied that:

a) A registered medical product has been advertised in a 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 the Laws and Regulations currently enforced by the Authority;
c) The Marketing Authorization Holder made a false or misleading statement or misrepresentation in the application;
d) The Marketing Authorization Holder has failed to comply with the terms and conditions of the registration as provided in certificate of registration;
e) The premises in which the product or part thereof is manufactured, packaged or stored by or on behalf of the holder of the certificate of registration is unsuitable for the manufacturing, packaging or storing of the product;
f) The Marketing Authorization Holder has failed to pay the prescribed retention fees within the prescribed time;
g) The Marketing Authorization Holder has failed to submit periodic post-marketing surveillance reports;
h) The Marketing Authorization Holder, intentionally and without justifiable reasons has failed to submit reports on adverse effects; and
i) Renewal of product registration has been defaulted beyond the specified grace period.

Any suspension shall be effected upon a written notice thereof. The notice for suspension of a registered medical 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 Authorization Holder to show reasons as to why the suspension should not be effected.

2. CANCELLATION OF A MARKETING AUTHORIZATION BY THE AUTHORITY

The Authority may cancel the marketing authorization of a registered medical product

if:

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

A written notice of cancellation shall then be issued to the Marketing Authorization Holder, stating the reason(s) for cancellation**.**

3. SUSPENSION OR CANCELLATION WITHOUT NOTICE

The Authority may cancel or suspend the marketing authorization of a medical 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 cancellation or suspension be uplifted.

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

Where the registration of a product is suspended/cancelled based on safety or quality issues, the Authority shall withdraw the circulation of that product from the market.

4. CANCELLATION/WITHDRAWAL OF AN APPLICATION

a) In the event that the responses to the queries are not submitted within ninety (90) calendar days from the date they were issued, it will be considered that the applicant has withdrawn the application unless the applicant has requested an extension of the deadline to Rwanda FDA. The Authority will notify the applicant in writing.

b) The applicant may withdraw an application for a medical product willingly at any stage of the registration process. This may be done by submitting a written letter to the Director General of Rwanda FDA.

c) The Authority shall act on this request and amend its records within 30 working days.

Thereafter, registration of the product may only be considered upon submission of a new application.

5. CANCELLATION OF A MARKETING AUTHORIZATION BY AN APPLICANT

a) An applicant may cancel the marketing authorization of a product by submitting a letter addressed to the Director General of the Authority giving reason(s) for the cancellation of the marketing authorization of the medical products.

b) The Authority shall act on this request and amend its records within 30 working days.

An applicant may at any time after the cancellation of a registration, resubmit a new application dossier for registration of the medical product, complying with the current requirements for registration.

ENDORSEMENT OF THE GUIDELINES

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