RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FDA GUIDELINES FOR APPEAL AGAINST REGULATORY DECISIONS

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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, specifically in article 8, paragraph 7 and 12 to regulate and inspect clinical trials.

Reference to the provisions of that Law, especially in its chapter 2 determining missions powers of the Authority, different regulatory decisions may/or can be appealed by stakeholders.

In this regards, the Authority Issues *Guidelines N°* QMS/GDL/025 on appeals against Regulatory decisions for their smooth handling.

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

Dr Charles KARANGWA
Ag. Director General

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INTRODUCTION

This guideline has been developed to provide guidance to applicants who are aggrieved by any regulatory decision of the Authority with regards to the services provided by the Food and Drugs Authority (FDA).

If any person is aggrieved by a regulatory decision of Rwanda FDA, it is his/her right to appeal against the decision in line with the provisions in the Rwanda FDA Quality Manual and these guidelines.

The purpose of this guideline is to provide guidance on the appeal process to applicants.

Scope

These guidelines have been developed to give guidance to persons aggrieved by decisions of the Authority in the following regulatory functions;

1. Marketing authorization or Registration
2. Inspection and Licensing of manufacturers, importers, exporters and wholesalers and retailers of regulated products
3. Regulatory enforcement actions, such as:
    a. Detention and/or seizure of medical products
    b. Recall and withdrawal of medical products
    c. Disposal of medical products
    d. Fines imposed
4. Control of clinical trials of medical products
5. Control of promotion and advertisement of regulated products
6. Laboratory testing of regulated products
7. Any other decision made by the Authority

Definitions

"**An Appeal":** Is a formal request for a review of a regulatory decision and/or an outcome of an application.

GENERAL REQUIREMENT

1. Any person who is aggrieved by a regulatory decision made by Rwanda FDA may formally request in writing for Rwanda FDA to reconsider/review the initial decision within 60 days after the date of notification of the decision.
2. All appeal requests shall be made in writing, and addressed to:

    THE DIRECTOR GENERAL
    RWANDA FOOD AND DRUGS AUTHORITY
    P.O BOX: 1948 KIGALI_RWANDA

3. The aggrieved person shall ensure that the appeal request includes the following:
   - the appeal letter, dated and signed by the aggrieved person requesting for the review;
   - a copy of the initial decision notification letter (or other evidence of notification) stating clearly the regulatory decision for which the appeal is requested;
   - any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why review is requested;
   - a description of how the interests of the aggrieved person are affected by the regulatory decision (only applicable if the notification of an initial decision was not issued to the aggrieved person).

It is important to ensure that all information and documentation that you wish Rwanda FDA to consider is provided with the request to the Authority since it shall not consider any information provided after the submission of the request unless the information is provided in response to a request.

In the event that the aggrieved person whose interests are affected is a third party (i.e. the applicant was not the person to whom the regulatory decision was issued by the Authority), Rwanda FDA shall also notify in writing, the person to whom the regulatory decision was issued (e.g. the Market Authorization Holder (MAH) of the product, Sponsor of a Clinical Trial, etc.) advising that a request for review has been received by the Authority.

All appeals received by Rwanda FDA shall be acknowledged and adequately investigated by the responsible *Division/Department* with inputs from the Legal *Service/Department* where applicable.

The Head of the responsible Division/Department shall make presentation to an Administrative Appeal Committee that shall be established to hear and determine appeals lodged by persons aggrieved by the decisions of the Authority. The committee shall consider new information submitted with the appeal application.

REVIEWING AN APPEAL APPLICATION

Upon review of the appeal application, the Authority shall give response in writing of the outcome of the appeal application, which shall include a statement of reasons (i.e. findings, references to evidence and reasons for the decision). The response shall be addressed to the aggrieved person within 30 days after submitting an appeal application.

If the initial decision is one of which is required to be published on Rwanda FDA's website (such as a decision to register a product or revoke/cancel/suspend a product registration, facility license,

etc.), and Rwanda FDA upon revision of the regulatory decision decides to revoke and substitute the regulatory decision, the particulars of the current decision shall be published.

An appeal of a regulatory decision will result in one of the under listed outcomes:

1. Endorse the regulatory decision;
2. Revoke the regulatory decision;
3. Revoke and substitute the regulatory decision with a new decision.

Endorsing the regulatory decision

Where upon review the Authority decides to uphold the regulatory decision, the regulatory decision shall remain unchanged.
It is however possible that upon review, the Authority may have come to the same conclusion as the regulatory decision but for different reasons. The committee may assess evidence in support of the regulatory decision differently or come to another conclusion on the basis of available evidence (which might be additional to what was available when making the regulatory decision).

Revoking the regulatory decision

Where upon review the Authority decides to overturn a regulatory decision, the regulatory decision would be reversed as though the regulatory decision was never made.

Revoking and substituting the regulatory decision with a new decision

Where upon review, Rwanda FDA decides to vary all or part of the regulatory decision; the regulatory decision would be partially or entirely replaced (substituted) by a new decision.
Upon review of the initial decision, the Authority may decide that a variation (to one or more specific aspects) of the initial decision is, under certain circumstances, the correct outcome.

The Authority may assess the initial decision as being partially or entirely incorrect at the time it was made or as being partially or entirely incorrect in light of additional information made available to the Authority upon review of the initial decision. **The decision of the Administrative Appeals Committee is final.**

Withdrawing an Appeal Application

An aggrieved person may withdraw his/her request at any time before the Authority convenes a committee to review the regulatory decision. Withdrawal of an appeal application should be notified in writing to the Director General

Nonetheless, the committee shall work independently of the office associated with the appeal and the Chair of the committee shall document and maintain records of all engagements related to the appeal process.

The Authority shall suspend all routine evaluation activities related to the appeal pending the completion of the appeal review process and pending confirmation that the client wishes to proceed with the regulation.

Timelines

Request for appeal against decision(s) made by the Authority must be made within 60 days after the date of notification of the decision.
Feedback from the Authority to the aggrieved person shall be made within 45 days after submitting an appeal application.
Withdrawal of an appeal application from the Authority should be made within ten (30) working days after submission.

Appeal to the supervising Authority.

In case the feedback on the decision appealed does not satisfy the aggrieved person, he/she may appeal the supervising Authority of Rwanda FDA, Honourable Minister of Health currently.

Appendix 1: ENDORSEMENT OF THE GUIDELINES

	Author	Authorized Person	Approved by
Title	**Quality Management Systems Specialist**	**Chief Finance officer**	**Director General**
Names	Théogène NDAYAMBAJE	Françoise BERWA	Dr. Charles KARANGWA
Signature			
Date			

Change history

SN	Date	Version Number	Description of Change
1		01	Initial issue