



**GUIDELINES ON VARIATION APPLICATION OF REGISTERED
COSMETICS, VECTOR CONTROL AND PUBLIC HEALTH LABORATORY
CHEMICAL PRODUCTS**

AUGUST, 2025

FOREWORD

Rwanda Food and Drugs Authority 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 cosmetics, vector control and public health laboratory chemical products in order to improve access to quality and safety for these products on Rwandan Market.

Considering the provisions of the technical Regulations No CBD/TRG/011 Governing control of medicated cosmetics, Regulations No.: No CBD/TRG/013 Governing the registration of pesticides, laboratory chemicals and cleaning chemicals products, the authority has to issue Guidelines: No. DD/CHCR/GDL/006 for variation application of registered cosmetics, vector control and public health laboratory chemical products. These guidelines have been developed to provide guidance to the applicants and the Authority in managing applications for variation of registered cosmetics, vector control and public health laboratory chemical product.

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

Prof. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

First issue date	Refer to the approval date
Effective date of this version	Refer to the approval date

DOCUMENT REVISION HISTORY

Version number	Changes made and/or reasons for revision
1	First issue

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ACCRONYMES AND ABBREVIATIONS

CHCR:	Cosmetics and Household Chemicals Registration
CHC:	Cosmetics and Household Chemicals
DD:	Drugs Department
IRIMS:	Integrated Regulatory Information Management System
MAH:	Market Authorization Holder
QMS:	Quality Management System
Rwanda FDA :	Rwanda Food and Drug Authority
SOPs:	Standard Operating Procedures

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GLOSSARY / DEFINITIONS

All of the technical terms and terminologies used in these guidelines are referred to the related regulations and guidelines under the concerned regulated products including:

- The technical Regulations No CBD/TRG/011 Governing control of medicated cosmetics,
- Regulations No.: CBD/TRG/013 Governing the registration of Pesticides, Laboratory chemicals and cleaning chemicals,
- Regulation No.: ODDG/RES/TRG/001_Version 5 governing tariff/fees for services rendered by Rwanda Food and Drugs Authority
- Doc. No.: DD/CHCR/GDL/002 Guidelines on Submission of Documentation for Registration of Cosmetic Products,
- Doc. No.: DD/CHCR/GDL/001 Guidelines on Submission of Documentation for Registration of Vector Control Products,
- Doc. No.: DD/CHCR/GDL/005 Guidelines on Submission of Documentation for Registration of Public Health Laboratory Chemicals.

Rwanda FDA Guidelines on Variation of Registered cosmetics, vector control and public health laboratory chemical products - First Edition' is a publication by the Rwanda Food and Drugs Authority. It outlines the procedures and requirements for documenting changes to registered products. These guidelines were created to ensure the quality, safety, and efficacy of registered products.

Changes to registered products are a normal part of their life cycle, and applicants are responsible for ensuring the safety, efficacy, and quality of their products throughout their life cycle. This means that applicants must provide to the Authority any changes made to their products to accommodate technical and scientific progress or to improve or introduce additional safeguards. These changes, known as variations, require approval from the Rwanda FDA before implementation.

The guidelines provide information on how to present an application to implement a change to a registered cosmetic, vector control and public health laboratory chemical products. They also classify post-approval changes according to the level of risk inherent in each change. Applicants are encouraged to refer to these guidelines when preparing documentation for variations to registered products. However, the guidelines are not exhaustive, and applicants are encouraged to contact Rwanda FDA for advice on variations not covered in the guidelines.

Fees

Applicable fees are defined in the regulation No. ODDG/RES/TRG/001_Version 5 Governing tariff/fees and charges on services rendered by Rwanda food and drugs authority. Note that Rwanda FDA reserves the right to determine the correct interpretation of the fee payable based on the published schedule. Please note that relevant variation application fees apply to all variations. Any application not accompanied by the relevant proof of payment will not be considered.

CHAPTER I: INTRODUCTION

I.1 Background

Rwanda Food and Drugs Authority (Rwanda FDA) was established by 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 vector control products in order to improve access to quality and safe vector control products in Rwanda.

Considering the provisions of the technical regulation N° CBD/TRG/013 governing the registration of pesticides, laboratory and cleaning chemicals, and regulation N° CBD/TRG/011 governing the control of medicated cosmetics, the authority has to issue these Guidelines DD/CHCR/GDL/006 on submission of documentation for variation of a registered cosmetic, vector control and public health laboratory chemical products. These guidelines illustrate the procedures and requirements for the implementation of variation of a registered cosmetic, vector control and public health laboratory chemical products.

Any variation of registered cosmetic, vector control and public health laboratory chemical products shall not be manufactured or imported or placed on the Rwandan market unless it has been approved in accordance with these guidelines. Unless otherwise, any manufacturer or importer of variation of registered cosmetic, vector control and public health laboratory chemical products, shall submit an application for variation approval to the national regulatory authority. The Authority has developed these guidelines to assist applicants for variation of a registered cosmetic, vector control and public health laboratory chemical products by providing required information and procedures for submission of documentation thereby facilitating assessment and subsequently approval.

Adherence to these guidelines by the manufacturers/importers/applicants will timely facilitate assessments and variation approval for the concerned cosmetic, vector control and public health laboratory chemical application dossiers by the authority for pre-marketing evaluation, marketing and post-marketing review.

I.2 Scope

These guidelines are intended to:

- Assist applicants with the classification of changes made to a registered cosmetic, vector control and public health laboratory chemical products.
- Provide guidance on the technical and other general data requirements to support changes to the quality, safety, efficacy and administrative attributes of the Finished Registered cosmetics, vector control and public health laboratory chemical products.

Therefore, these guidelines apply to applicants intending to make changes to the different sections of product dossiers for a registered cosmetic, vector control and public health laboratory chemical products. These guidelines should be read in conjunction with the Rwanda FDA Guidelines on submission of documentation for registration of cosmetics, vector control and public health laboratory chemical products as well as other related applicable guidelines.

CHAPTER II: GUIDANCE FOR THE IMPLEMENTATION

II.1 Reporting types

The following reporting types provide guidance on how to classify changes, variations can be classified as major or minor. If an application involves two or more types of variations, it will be considered a major variation. Therefore, a variation that includes both minor and major changes will be classified as a major change.

If an applicant is unsure about the classification of a change, they should contact Rwanda FDA for guidance before making any modifications. It is the applicant's responsibility to submit relevant documentation to prove that the change will not negatively affect the product's quality.

II.1.1. Minor Variation

Minor variations that could have minimal or no adverse effects on the overall safety, efficacy and quality of the finished product and must be notified to Rwanda FDA immediately before the implementation of the change.

Applicants must satisfy themselves that they meet all of the prescribed conditions for the change and submit all required documentation with the variation application and the change can only be implemented on receipt of variation approval letter from Rwanda FDA. Such variations will be handled within thirty (30) calendar days from the date of acknowledgement of the application and a variation approval letter will be issued for all minor variations when the variation is considered acceptable. Refer to annex I (Types of variations and requirements). Minor variation will not pay and it is free of charge processed.

II.1.2. Major variation

Major variations are changes that could have major effects on the overall safety, efficacy and quality of the finished products. The documentation required for the changes included in this reporting type should be submitted. Prior acceptance by Rwanda FDA is required before the changes can be implemented. Such variations will be handled within sixty (60) calendar days from the date of acknowledgement of the application. Variation approval letter will be issued for all major variations if and when the variation is considered acceptable. Refer to annex I (Types of variations and requirements).

II.1.3 New applications

Certain changes are so fundamental that they alter the terms of the accepted dossier and consequently cannot be considered as changes. In these cases, a new dossier must be submitted. Refer to annex I (Types of variations and requirements).

II.1.4. Consequential Variations

Some variations may require the submission of additional consequential variations. Applicants should consider whether multiple variations need to be submitted for a given change.

Alternative approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate scientific justification. It is also important to note that Rwanda FDA may request information or material, or define conditions not specifically described in these guidelines, in order to adequately assess products 'safety, efficacy and quality.

CHAPTER III: REQUIREMENTS

III.1 Requirements for application for minor variation

- a. Cover letter: A cover letter should be included with the application, providing a brief description of the proposed variation and the reason for the variation.
- b. Application form: The application form should be completed and submitted. The form should provide details of the product and the proposed variation.
- c. Labelling: Any changes to labelling should be submitted along with the application.
- d. Certificate of analysis of the final product (where applicable)
- e. Samples reflecting the variation as specified in the authority sample schedule (where applicable).

III.2. Requirements for application for major variation

- a. Cover letter: A cover letter should be included with the application, providing a brief description of the proposed variation and the reason for the variation.
- b. Application form: The application form should be completed and submitted. The form should provide details of the product and the proposed variation.
- c. Stability data: Stability data should be submitted to demonstrate that the proposed variation will not affect the stability of the product. the stability studies should cover the shelf-life. period. If any stability issues occur during storage, inform Rwanda FDA immediately.
- d. Labelling. any changes to labelling should be submitted along with the application.
- e. Certificate of analysis of the final product.
- f. Fees: The relevant fees should be paid upon submission of the application according to the regulation No.: ODDG/RES/TRG/001_Version 5 governing tariff/fees for services rendered by Rwanda Food and Drugs Authority.
- g. Samples reflecting the variation as specified in the authority sample schedule (where applicable)

It's important to note that these requirements may vary depending on the specific type of variation being submitted and the specific regulatory requirements in Rwanda. For all changes it remains the responsibility of the applicant to provide all necessary documents to demonstrate that the change does not have a negative effect on the safety, efficacy or quality of the finished products.

It should be noted that Rwanda FDA reserves the right to request further information not explicitly described in these guidelines.

Detailed information of variation types and requirements are summarized in the annex I. For application form, refer to the annex II.

CHAPTER IV: APPLICATION AND APPROVAL PROCESS

The application dossier shall be submitted to Rwanda FDA through Integrated Regulatory Management System (IRIMS) available at <https://irims.rwandafda.gov.rw/portal/>.

All variations must be approved by Rwanda FDA before implementation and variation approval letter is issued to the applicant.

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ENDORSEMENT OF THE GUIDELINES

	Prepared by	Checked by		Approved by
Title	Division Manager/CHCR	Head of Drugs Department	Division Quality Assurance Management	Director General
Names	Dr. Janvier MUKIZA	Dr. Védaste HABYALIMANA	Mrs. Marie Ange UWASE	Prof. Emile BIENVENU
Signature				
Date				

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ANNEXES

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ANNEX I: COVER LETTER

Letter header of the applicant/manufacturer/LTR

< Applicant>
< Address>
<Postal Code>
< Town>
<Country>
<Date>

<Rwanda FDA>
<P.O.BOX 1948> <Kigali>
< Rwanda >

Dear Sir/Madam,

Subject: Submission of variation application for registered product <Brand Name(s), Common Name (s) and product form(s)

We are pleased to submit our Application Dossier(s) for variation of registered product that details are as follows:

Name the product as follow:

Brand name (s):
Proprietary (Common Name (s):
Name and strength/purity of active ingredient(s):
.....
Product form:
Intended use(s):
Manufacturer:

You will find enclosed the submission dossier as specified hereafter:

- The relevant fees for this application have been paid (where applicable)
- Two commercial samples of the product
- The electronic submission contains the following sections:

Section 1: Administrative information and product information requirement

Section 2: Technical data requirements

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We confirm that the electronic submission has been checked with up-to-date and state-of-the-antivirus software.

I, the undersigned, certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>

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ANNEX II: TYPES OF VARIATIONS AND THEIR CORRESPONDING REQUIREMENTS

I.1 Minor variation	
Variation	Documents required
Change in the name and/or corporate address of the (MAH)	<ol style="list-style-type: none"> 1. A cover letter addressed to DG 2. Variation Application form 3. Notarized transfer documents 4. Company registration certificate from the relevant jurisdiction
Change of MAH from one company to another	<ol style="list-style-type: none"> 1. A cover letter addressed to DG 2. Variation Application form 3. Notarized transfer documents 4. Company registration certificate from the relevant jurisdiction
Change in the name and/or address of a manufacturer of the Final product.	<ol style="list-style-type: none"> 1. A cover letter addressed to DG 2. Variation Application form 3. Copy of the modified manufacturing authorization or a formal document from a relevant official body (e.g. NRA) in which the new name and/or address is mentioned. 4. Two (2) commercial samples of the product. However, if a commercial sample is not available, an artwork label—is acceptable, with a commitment letter that the samples will be submitted prior to distribution.
Change of Local Technical Representative (LTR).	<ol style="list-style-type: none"> 1. A cover letter addressed to DG 2. Variation Application form

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	<ol style="list-style-type: none"> 3. Letter of appointment of new LTR from the product Marketing Authorization Holder 4. Letter of acceptance from the proposed LTR and proof of communication for termination notice with the previous LTR. 5. List of affected products, including registration numbers. Affected products should appear on the current Public Health Chemical Product Register.
<p>Change of Proprietary/Product name</p>	<ol style="list-style-type: none"> 1. A cover letter addressed to DG 2. Variation Application form 3. Artwork label Revised product information 4. Two (2) commercial samples of the product or an artwork label with a commitment letter that the sample will be submitted prior to distribution.
<p>Change in the storage conditions of the finished product</p>	<ol style="list-style-type: none"> 1. Application letter 2. Variation Application form 3. Stability results to support the change to the storage conditions. 4. An artwork label with a commitment letter that the sample will be submitted prior to distribution.
<p>Change of the layout/artwork without altering meaning.</p> <p>Addition/deletion/replacement of pictures, diagrams, bar code, logos and/or texts that do not imply an unapproved intended use.</p>	<ol style="list-style-type: none"> 1. A cover letter addressed to DG 2. Variation Application form 3. Current approved and previous product labelling. 4. Relevant document/reference to support the changes (where applicable).

<p>Change in the package size</p>	<ol style="list-style-type: none"> 1. Application letter 2. Variation Application form 3. Justification for the new pack-size, indicating that the new size is consistent with the duration of use. 4. An artwork is acceptable, with a commitment letter that the sample will be submitted prior to distribution.
<p>Change of secondary packaging material</p>	<ol style="list-style-type: none"> 1. Cover letter 2. Application form 3. An artwork label 4. Information on the proposed secondary packaging material (e.g. description, materials of construction of secondary packaging components, specifications).
<p>I.2. Major variations</p>	
<p>VARIATION</p>	<p>DOCUMENTS REQUIRED</p>
<p>Reduction or increase of one or more components of the colouring or the fragrance system</p>	<ol style="list-style-type: none"> 1. Cover letter 2. Filled application form 3. Two (2) commercial samples of the product 4. Certificate of Analysis of Final Product detailing tested specifications as per the related guidelines 5. Results of stability testing for long-term and accelerated studies.

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<p>Deletion, addition or replacement of one or more components of the colouring or the fragrance system</p>	<ol style="list-style-type: none"> 1. Application letter/Cover letter 2. Filled application form 3. Two (2) commercial samples of the product 4. Certificate of Analysis of Final Product detailing tested specifications as per the related guidelines 5. Results of stability testing for long-term and accelerated studies.
<p>Addition or replacement of a manufacturing site for part or all of the manufacturing process for a Finished Product</p>	<ol style="list-style-type: none"> 1. Cover letter 2. Filled application form 3. Two (2) commercial samples of the product 4. Certificate of Analysis of Final Product detailing tested specifications as per the related guidelines 5. Results of stability testing for long-term and accelerated studies. 6. Manufacturing license for the new site
<p>Removal or Replacement or addition of a primary packaging type</p>	<ol style="list-style-type: none"> 1. Cover letter 2. Application form 3. An artwork label is acceptable, with a commitment letter that the sample will be submitted prior to distribution. 4. Information on the proposed primary packaging type (e.g. description, materials of construction of primary packaging components, specifications). 4. Stability data.
<p>Change in the shelf-life of the Finished Product involving: reduction and extension</p>	<ol style="list-style-type: none"> 1. Cover letter 2. Variation Application form 3. Proposed shelf-life, a summary of long-term stability testing results 4. An artwork is acceptable with a commitment letter that the sample will be submitted prior to distribution.
<p>Change(s) to the intended use (Addition of an intended use or modification of an approved one or Deletion of an intended use)</p>	<ol style="list-style-type: none"> 1. Cover letter 2. Variation Application form 3. Supporting data for the proposed changes

II. CHANGES THAT MAKE A NEW APPLICATION NECESSARY	
1. Change of the Finished Product Composition (product formulation)	Documents required in the registration of new products as per related guidelines
2. Change in product form	

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ANNEX III: APPLICATION FORM FOR VARIATION FOR A REGISTERED COSMETIC, VECTOR CONTROL PRODUCTS AND PUBLIC HEALTH LABORATORY CHEMICAL PRODUCTS

1. Administrative information	
1.1	<p>Particulars of Applicant/Registrant</p> <p>Company name.....</p> <p>Physical address.....</p> <p>Postal address.....</p> <p>Country.....</p> <p>Telephone.....</p> <p>Telefax.....</p> <p>E-mail.....</p>
1.2.	<p>Particulars of the Manufacturer</p> <p>Name:.....</p> <p>Physical address:.....</p> <p>Postal address.....</p> <p>Country.....</p> <p>Telephone.....</p> <p>E-mail.....</p>
1.3	<p>Particulars of Local Technical Representative/distributor (if applicable):</p> <p>Name.....</p> <p>Physical address.....</p> <p>Postal address.....</p> <p>Country.....</p> <p>Telephone.....</p> <p>E-mail.....</p>

2. Finished Product (FP)	
	Registration Certificate Number:..... Brand Name:..... Active Ingredient and strength:..... Date of Market Authorization issuance:..... Registered pack size and packaging material:..... Registered shelf life:.....
	Registered storing condition:..... Intended use:.....
3. Application details	
	Variation Type: (tick applicable option)
3.1	Minor Variation Major Variation:
3.2	Summary of proposed variation
3.2.1	Current product details:
3.2.2	Proposed product new details:
3.2.3	Reason for change:
4. Variation type: (tick all applicable options)	

4.1	Minor variation (Justification summary):
4.2	Major variation (Justification summary):
5. Submission checklist	
	<ul style="list-style-type: none"> <input type="checkbox"/> Application letter/Cover letter <input type="checkbox"/> Copy of the existing Market Authorization <input type="checkbox"/> Appointment letter of the LTR <input type="checkbox"/> Letter of acceptance from the proposed LTR and a copy of termination notice of the previous LTR (where applicable) <input type="checkbox"/> List of affected products with their registration numbers <input type="checkbox"/> A copy of manufacturing/premise license (where application) <input type="checkbox"/> Revised Artwork label (where applicable)

6. Declaration

Please check all declarations that apply. I declare that:

- For each change all conditions as stipulated in the Rwanda FDA Guidelines for variation application of registered medicated cosmetic, cleaning chemical, household pesticide and laboratory chemical product for the change requested are fulfilled.
- There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.
- The information submitted is true and correct.

Name: _____ Title/Designation _____

Signature: _____ Date: _____