RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON CONTROL OF IMPORTATION AND EXPORTATION OF COSMETIC PRODUCTS

DECEMBER, 2022

Doc. No.: FDISM/FDIEC/GDL/005	Revision Date: 13/12/2022	Review Due Date: 26/12/2025
Revision No.: 0	Approval date: 21/12/2022	Effective Date: 27/12/2022

FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organization and functioning. One of the functions of Rwanda FDA is to regulate matters related to quality, safety, and efficacy of cosmetic Products in order to improve access to medicated cosmetics in Rwanda.

Reference to the provisions of the technical regulation No CBD/TRG/011 governing the control of cosmetic products;

These guidelines provide guidance on the information and documentation required in any application submitted to Rwanda FDA by an importer or exporter of Cosmetic products or their raw materials, as set in these guidelines. Adherence to the set requirements will minimize the delays in processing applications of import and export authorizations; hence speed up the provision of quality services to the clients.

These guidelines also provide guidance to the inspectors to prevent risks of trading sub-standard cosmetic products among nations and therefore to prevent dumping unfit products in our country.

These guidelines will be reviewed as per Rwanda FDA Quality Manual or from time to time as the need arises.

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

Dr. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	**15/09/2022**
ADOPTION BY RWANDA FDA	**20/10/2022**
STAKEHOLDERS CONSULTATION	**11/11/2022**
ADOPTION OF STAKEHOLDERS' COMMENTS	**18/11/2022**
DATE FOR COMING INTO EFFECT	**27/12/2022**

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
13/12/2022	0	First issue

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

Rwanda FDA: Rwanda Food and Drugs Authority

NGOs: Non-Government Organizations

COA: Certificate of Analysis

PoE: Port of Entry

GDL: Guideline

MoU: Memorandum of Understanding

PRIMS: Pharmaceutical Regulatory information system/ILMS

GMP: Good Manufacture practices

ISO: International Organization for Standardization

CE : Conformité Européenne

IP : Investigation Product

DEFINITIONS

In these guidelines, unless the context otherwise states:

Authority means Rwanda Food and Drugs Authority, or its acronym "Rwanda FDA" established under article 2 of the law No 003/2018 of 09/02/2018;

Authorization means a legal document granted by Rwanda Food and Drugs Authority to the applicant under the law No 003/2018 of 09/02/2018 determining its mission, organization, and functioning, it includes licenses, permits, and certificates;

Consignment means a quantity of goods that are sent to a person or place to be sold;

Donation means an act or instance of presenting Medicated cosmetic, medical products, processed foods and other; Products regulated to recipients in emergency or as a part of development aid in non-emergency situations;

Exporter means a person, country, or organization that sends goods or services to another country for sale;

Importer means a person or organization that brings goods or services into a country from abroad for sale;

"Manufacturer" means a person who is involved in the production, processing, compounding, formulating, filling, refining, transforming, packaging, repackaging and labelling of cosmetics.

"Cosmetic" means any substance or preparation intended to be placed in contact with the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance or correcting body odours, protecting them or keeping them in good conditions.

"Medicated cosmetics "or "cosmeceuticals" are products that have both cosmetic and therapeutic effects, and are intended to have a beneficial effect on skin health and beauty. Like medicated cosmetics, they are applied topically but contain active ingredients that have an effect on skin cell function. In some cases, their action is limited to the skin surface (such as exfoliants), while others can penetrate to deeper levels, either enhancing or limiting normal skin function.

"Batch number or Lot" means the number or a combination of numbers and letters specifically given to a medicated cosmetics product which is linked to the manufacturing history of the product;

"Label": Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a container of any cosmetic product or raw material.

Import Visa means an authorization/permit issued to the importer after confirmation by the Authority that manufacturer(s)/suppliers of cosmetics or their raw materials to be imported comply with international and national standards. The Import visa gives the right to the importer to confirm an order/purchase order of the products and to apply for import license.

Import License means an authorization/permit issued to the importer by the Authority, authorizing him/her to import cosmetics or their raw materials into the country after complying with the documentary importation requirements;

Export Permit means a permit issued to an exporter by the Authority, authorizing him/her to export cosmetic products from the country;

"**Approve" or "approval**" means official consent by the Authority as an acceptance of an importation or exportation of the cosmetics to be used in the Rwandan market;

"Fee" means the regulatory service charge prescribed in the Fees Regulations in accordance with Article 9 and Article 32 of the Law No 003/2018 of 09/02/2018.

"Prohibited Ingredient" refers to a substance which is forbidden to be a component of a cosmetic due to its toxicity or poisonous effects to human health;

"Ingredients" means any substance that is one of the components of a medicated cosmetic and includes colouring agents, botanicals, fragrance, and flavour, but does not include substances that are used in the preparation of the medicated cosmetic. that are not present in the final product as a result of the chemical process.

"Leaflet of a medicated cosmetic" refers to a printed paper and includes any written information related to a medicated cosmetic.

INTRODUCTION

The quality, efficacy, and safety of Medicated Cosmetic products can be highly affected by the lack of adequate control on importation and exportation. It is therefore imperative that the manufacture, importation and exportation of Medicated Cosmetic products, both nationally and internationally conforms to certain set standards.

The Authority has developed these guidelines to strengthen the control of importation and exportation of these products and to assist those in the field to adhere to the legal framework during importation and exportation activities.

The main objective of these guidelines is to provide importers and exporters of cosmetics and their raw materials with the necessary information to enable them to comply with the law and regulations governing the control of importation and exportation of these products.

These guidelines are organized into two Chapters. The first chapter provides the requirements and procedures to be followed up during the importation of Cosmetics while the second one outlines the requirements and procedures for the exportation of these products.

SCOPE

These guidelines apply to cosmetic products as specified in the law No 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products, Law nº 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, Organisation, and functioning, Ministerial Order Nº20/38 of 26/02/2016 determining the list of cosmetics whose use is prohibited in Rwanda and Regulations Nº CBD/TRG/011 governing control of medicated cosmetics in Rwanda. The guideline outlines requirements for the importation and exportation of cosmetic products and their raw materials.

CHAPTER I: IMPORTATION OF MEDICATED COSMETIC PRODUCTS

I.1. REQUIREMENTS

I.1.1. General requirements

All cosmetic products must be imported by importers whose premises are licensed by Rwanda FDA or who fall within the eligible importer category.

Cosmetic products to be imported shall not be banned or contain prohibited substances including but not limited to skin bleaching/whitening ingredients or containing ingredients which have been banned in the country of origin or in Rwanda for quality or safety purpose.

All imported cosmetic products must have at least two-thirds (2/3) of their shelf life remaining when they arrive at the port of entry. Cosmetic products to be imported shall comply with labelling requirements according to related Standards.

A cosmetic product registered by Rwanda FDA shall be imported by the marketing authorization holder' Local Technical Representative or by any other company authorized by the marketing authorization holder or by the manufacturer in case he/she is the marketing authorization holder.

All consignments of cosmetic products shall pass through the gazetted ports of entry and shall be subjected to physical inspection at the port of entry or at importer's premise for the consignments released under seal before being used to ensure they comply with claimed specifications.

Apart from the specific requirements for importation/exportation, the Authority reserves the right, when deemed necessary and for justified reasons, to request the importer to provide any other document/information for further analysis.

I.1.2. Eligibility for Importation

1. Only the following shall be eligible/allowed to import cosmetic products and their raw materials:
2. A manufacturer of cosmetic products holding operational license issued by the Authority;
3. A wholesaler or retailer of cosmetic products holding operational license issued by the Authority;
4. Researchers or research institutions authorized by competent institutions to conduct research or clinical trial in the country.
5. Company importing sample for laboratory testing;
6. Persons importing cosmetic products for personal use;
7. Government institutions;
8. Non-government institutions authorized by competent institution;
9. A beneficiary of cosmetic products donation upon presentation of the donation certificate;
10. A company or individual attending exhibition upon presentation of the invitation and a commitment letter stipulating that the remaining products will be re-exported after the exhibition;

11. A tourist, a visitor in the country or any other person for justified reasons after getting authorization from the Authority.

I.1.3. Specific requirements

I.1.3.1. Requirements to apply for Import Visa

The following are requirements to apply for an import visa:

a. Application letter where applicable
b. A proforma invoice showing:
    i. Invoice number and date,
    ii. Name of the manufacturer
    iii. Name and full address of exporter and importer,
    iv. Country of origin of the product,
    v. A clear description of each product including brand and common names,
    vi. Quantity, value for each product and the currency.
c. The operational license of the importer where applicable
d. Certificate of compliance of the manufacturer or the supplier;

The certificate of compliance includes but not limited to the followings: ISO Certificate, Good Manufacturing Practices certificate (GMP), Good Distribution Practices certificate (GDP), Operational License from respective Regulatory body, or Health certificate, permit to use standardization mark (Ex: TBS, KEBS…), etc.

Note:

- Certificate of compliance may not be a mandatory requirement only for a justifiable reason approved by the Authority. Ex: If the manufacturer is located in a country with Stringent Regulatory Authority.
- Products imported from countries with Stringent Regulatory Authorities will be exempted from providing the above quality documents.
- Products imported from countries where quality documents can't be provided, will be allowed to be imported if and only if the embassy of the countries of origin endorse the application. The endorsement confirms that products are imported from reliable sources.

I.1.3.2. Requirements to apply for Import License

After getting an Import Visa, the second step is to apply for an Import License. It is an authorization that permits the applicant to import the approved cosmetic products and is granted for a single consignment. The following are requirements to apply for an import license:

a. Import Visa
b. Commercial invoice having the following information:
    i. Invoice number and date,
    ii. Name of the manufacturer,

iii. Name and full address of exporter and importer,
iv. Country of origin of the product,
v. Clear description of each product including brand and common names,
vi. Quantity, value for each product and the currency.

c. A packing list (if applicable) with the following information: Imported products and their quantities, Batch/lot number, Manufacturing and expiry date.
d. Certificate of analysis issued by the manufacturer or a designated laboratory, for each batch number, indicating the following information:
   i. Name and address of the manufacture
   ii. Brand and common name of the cosmetic product,
   iii. Product description,
   iv. Batch/lot number
   v. Manufacturing and expiry date (or Best before date),
   vi. Tested Parameters and their results (specification and qualitative/quantitative results)
   vii. Specification limit
   viii. Document traceability references (e.g. document number, revision, etc.)
   ix. Signed by authorized personnel.
e. A Proof of Payment of verification fees as specified in the Regulations CBD/TRG/004 related to regulatory service tariff/fees and fines.

Note:

- Certificate of Analysis may not be a mandatory requirement only for a justifiable reason approved by the Authority. Ex: Products manufactured in EAC member states, or if the manufacturer is located in a country with stringent regulatory Authority.
- Products imported from countries with Stringent Regulatory Authorities will be exempted from providing the above quality document.
- Products imported from countries where quality documents can't be provided, will be allowed to be imported if and only if the embassy of the countries of origin endorse the application. The endorsement confirms that products are imported from reliable sources.
- In case of donation, Certificate of donation and Donation acceptance letter will be required.

I.1.3.3. Requirements to apply for importation of registered Cosmetic products

To import cosmetic products registered by Rwanda FDA, the applicant shall submit the following requirements:

a. Commercial invoice,
b. Operational license,
c. Certificate of analysis for each batch except for products originating from EAC countries and countries under Mutual Recognition with Rwanda FDA).
d. Proof of payment of verification fees as specified in the Regulations CBD/TRG/004 related to regulatory service tariff/fees and fines.

I.1.3.4. Authorization to import cosmetic products for special cases

a. Requirements to apply for importation of cosmetic products for research purpose:
   i. Application letter addressed to the Director General of the Authority,
   ii. Authorization to conduct research issued by competent institution,
   iii. Invoice with description of the products.
b. Requirements to apply for importation of cosmetic products for sample registration:
   i. Application letter addressed to the Director General of the Authority,
   ii. Invoice with description of the products.
c. Requirements to apply importation of cosmetic products for exhibition
   i. Application letter addressed to the Director General of the Authority,
   ii. Commercial Invoice,
   iii. Certificate of compliance of the manufacturer,
   iv. Certificate of analysis for each batch number of the products to be exhibited
   v. Commitment letter agreeing to re-export the remaining products after exhibition.
d. Requirements to apply for importation of Cosmetic products declared as personal effects: a tourist, a visitor in the country or any other person who wants to import Cosmetic products for personal use, not for sale, shall request for an authorization by providing information described in the Guidelines No: FDISM/FDIEC/GDL/003 related to importation and exportation of regulated products declared as personal effects.

I.1.4. Processing applications

An application for import visa or for import license, fulfilling all requirements, will be processed in 3 working days. The applicant will be notified by the Authority, in writing, about the decision either approval or rejection. An authorization is issued to an applicant, for a particular consignment, and shall not be transferable.

I.1.5. Validity of an Authorization

The import visa shall be valid for six (6) months from the date of issuance.
The import license shall be valid for six (6) months from the date of issue.6. Renewal of an import license
In case an import license is expired before being used, the applicant shall apply for renewal by submitting the following documents:

- Application letter addressed to Director General of Rwanda FDA,
- Operational license of the importer,
- Expired import license,
- Commercial invoice, and
- Payment proof of inspection fees for the previous application.

I.1.6. Inspection of imported consignments at ports of entry

Each consignment of cosmetic products must be inspected by the Authority at the port of entry or at importer's premise for the consignments released under seal, before being used to ensure they comply with applicable regulations and claimed specifications.
The consignment must be accompanied by the following requirements:

a) A valid import license issued by the Authority,
b) A corresponding commercial invoice,
c) A certificate of analysis for each batch, except for products originating from EAC countries and countries under Mutual Recognition with Rwanda FDA). The imported cosmetic products must have at least two-thirds (2/3) of their shelf life remaining when they arrive at the port of entry.

The appearance of the imported cosmetic product shall reflect its true nature for example, free from foreign matters, damaged packaging, discoloured, etc.
The primary packaging of cosmetic products must be clearly labelled in officially recognized languages in Rwanda with the following information:

i. Trade name or brand name;
ii. Intended use of cosmetic products;
iii. Instructions for use
iv. Country of origin
v. Net content(weight/volume);
vi. Name and physical address of the manufacturer site;
vii. List of ingredients (International Nomenclature Cosmetic Ingredients name);
viii. Manufacturing dates;
ix. Expiry dates
x. The batch or lot number;
xi. Storage conditions
xii. Precautions and warnings;

The primary packaging of imported cosmetic shall be clearly labelled in at least one of the official languages used in Rwanda and the labelling shall comply with the relevant cosmetic labelling standard. If any message on the label is not in one of the official languages, a supplementary label translated in one of the official languages shall be used and available to consumers. The translated information shall fully and accurately reflect the one on the original label.
The translation shall be signed and stamped by the manufacturer or the Embassy of the country having the original language on the label as their official language or stamped by a Notary who knows that language.

Cosmetic products with labels which show evidence of alteration, will be regarded as substandard. Such alterations include:
Entire label or parts with details such as batch number, dates of manufacturer and expiry cut off,
Evidence of labels being removed or new ones attached or new labels being pasted over old ones,

Details of being erased or painted out and replaced with new details,

Counterfeiting. The primary package shall be sealed in such a way that the product cannot be reached or tempered without damaging the seal.

I.1.7. Sampling of imported products

During physical inspection, if any cosmetic product is suspected for poor quality or whenever deemed necessary, the inspector may take samples for further investigation and the consignment shall not be released until the laboratory results are available for decision-making. The inspector shall fill out the Report of findings (PV de constat). In case of routine sampling, the consignment from which the samples have been taken shall be released to the importer for distribution.

I.1.8. Release of consignments

Once satisfied that all importation conditions have been fulfilled as required, the Inspector shall release the consignment with approved stamp. For the partial shipment, the importer will write "PARTIAL SHIPMENT" on the import license and invoice, along with the quantities imported.

I.1.9. Release underseal

When a consignment is not physically inspected at port of entry or needs further inspection, for instance intra-region consignments, consignments that require special storage conditions, consignments that cannot be offloaded at the port of entry, or any other reason as may be decided by the Authority shall be released under seal and inspected at owner's premise before being used.

I.1.10. Rejection of consignments

If the physical inspection finds out that the consignment doesn’t comply with related cosmetic standards, the products shall be rejected. The importer shall implement the decisions taken and incur the cost.

The following shall apply for such consignments:

a. The inspector shall not release the consignment and rejection shall be applied.
b. Cosmetics that contains prohibited ingredients
c. Cosmetic products not meeting labelling specifications

Cosmetic products rejected because of safety and quality reasons shall be disposed. The application for safe disposal shall be done by the owner within one month. For protection of public health, the Authority has power to destroy, by its own discretion, the substandard rejected product at the products owners cost he Rejected product will get a full release in the Rwanda electronic single window (Resw) after the submission of the destruction/disposal certificate.

Where the consignment is quarantined, the inspector shall issue a report of findings (PV de constat) clearly stating the quarantined products and the reason. Cosmetic products rejected for reasons other than their composition safety and quality shall be rejected and follow the procedure for re-export.

The following are the reasons for re-export of a consignment:

a. Cosmetic products which are not allowed or withdrawn from the Rwanda market.
b. Medicated cosmetics that contains ingredients prohibited in Rwanda.
c. Any other reason the authority may deem necessary.

The importer shall re-export them in the country of origin or to a third country within a period of three months from the date of rejection and incur the cost. Copies of export documents stamped at the exit port shall be submitted to Rwanda FDA as evidence of re-exportation exercise.

CHAPTER II: EXPORTATION OF COSMETIC PRODUCTS

II.1. General requirements

Exporters of cosmetic products should have a valid Export License issued by the Authority
All cosmetic products must be exported by exporters whose premises are licensed by Rwanda FDA or who fall within the eligible exporter category. On pre-packaged cosmetic products to be exported shall comply with specifications and/or requirements prescribed by the Authority.

Cosmetic products to be exported shall comply with relevant cosmetic standards.
All consignments of cosmetics products to be exported must exit through gazetted ports of exit and shall be subjected to physical inspection at the port of exit or at exporter's premise to ensure they comply with claimed specifications.

II.2. Eligibility for Export

Only the following shall be allowed to export cosmetic products;

a) A manufacturer of cosmetic products holding operational license issued by the Authority;
b) A wholesaler or retailer of cosmetic products holding operational license issued by the Authority;
c) Researchers or research institutions authorized by competent institution to conduct researches;
d) An individual or company exporting a sample for laboratory testing;
e) Government institutions;
f) Non-government institutions authorized by competent institution;
g) A company or individual attending exhibition
h) A tourist, a visitor in the country or any other person for justified reasons after getting authorization from the Authority

II.3. Requirement for Exportation of cosmetic products

All applications for an export license shall be accompanied by the following documents:

a) Operational authorization of the exporter;
b) Invoice of the product to be exported including the following information:
    i. Invoice number and date,
    ii. Manufacturer name
    iii. Name and full address of exporter and importer,
    iv. Country of origin of the product,
    v. Clear description of each product including brand and common names,
    vi. Quantity, value for each product, and the currency.
c) A packing list (if applicable) with the following information:
    i. Exported products name and their quantities
    ii. Batch/lot number,
    iii. manufacturing
    iv. and expiry date.
d) Certificate of analysis issued by the manufacturer or a designated laboratory, for each batch number, indicating the following information:
    i. Name and address of the manufacturer,
    ii. Brand and common name of the cosmetic product,
    iii. Product description,
    iv. Batch/lot number,
    v. Manufacturing and expiry date (or Best before date),
    vi. Tested parameters and their results (qualitative/quantitative) results and specifications,
    vii. Specifications limit,
    viii. Document traceability references (e.g. document number, revision, etc.)
    ix. Signed by authorized personnel.
e) A Proof of Payment of verification fees as specified in the Regulations CBD/TRG/004 related to regulatory service tariff/fees and fines.

An export license is issued to an applicant, for a particular consignment, and shall not be transferable.
The export license will be valid for three (3) months from the date of issuance.
Applications for export license, fulfilling all requirements, will be processed within 3 working days.

ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved By
Title	**Division Manager of Food and Drugs Import & Export Division**	**Head of Food and Drugs Inspections & Safety Monitoring Department**	**Quality Assurance Analyst**	**Director General**
Names	Theobald HABIYAREMYE	Dr. Eric NYIRIMIGABO	Théogène NDAYAMBAJE	Dr. Emile BIENVENU
Signature				
Date	14/12/2022	14/12/2022	16/12/2022	21/12/2022