RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON CONTROL OF IMPORTATION AND EXPORTATION OF REGULATED PRODUCTS DECLARED AS PERSONAL EFFECTS

MARCH, 2023

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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 the Rwanda FDA is to regulate the import and export of pharmaceutical products, food products, and cosmetics, especially in articles 3, 8, and 9.

These guidelines provide guidance on the information and documentation required in any application submitted to Rwanda FDA by an importer or exporter of regulated products declared as personal effects. Adherence to the set requirements will minimize the delays in processing applications for import and export permits; hence speeding up the provision of quality services provided to the clients.
These guidelines will be reviewed from time to time as the need arises.

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

Digitally signed by Rwanda FDA (Director General)
Date: 2023.03.13 19:36:53 +02'00'

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Director General

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	**16/05/2022**
ADOPTION BY RWANDA FDA	**07/06/2022**
STAKEHOLDERS CONSULTATION	**NA**
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Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
28/10/2022	0	First issue
15/02/2023	1	1) Section of Glossary/ Definitions: Amendment of the definition of "Personal effect" and addition of the definition of "Specialized company/institution" 2) Section 3.1.1: addition of general requirements for specialized company/institution 3) Section 3.1.5: Quantity exceeding 90 days' supply may be authorized for justified reasons 4) Section 3.2.2: Addition of specific requirements for a specialized company/institution importing personalized/customized regulated products before starting the importation and on arrival of the imported products at the port of entry Removal of section 4 of review and appeal procedure to comply with QMS requirements.

ACRONYMS AND ABBREVIATIONS

Rwanda FDA	:	Rwanda Food and Drugs Authority
PoE	:	Port of Entry /Exit

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GLOSSARY / 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 determining its mission, organization, and functioning;

"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;

"Food product" means any animal or plant products that have been processed or transformed from their original state and are intended for human or animal consumption with the exception of pharmaceutical products, tobacco, food additives and food fortificants;

"Port of Entry and Exit" refers to all approved inland ports and gazetted borders.

"Personal effect/product for personal use" means any Rwanda FDA-regulated product imported by an individual or a group of individuals for their own use or use for a person or animal under one's own care or use by a person or animal one is traveling with, and not meant for sale to the public. It also means regulated products imported by a specialized company/institution for specific clients and not for open market or sale to the public.
For pharmaceutical products and medical devices, the imported quantity shall not exceed 90-day supply or a single course of treatment based on the product's direction for use, or its use shall not require direct oversight or administration by a trained operator. For food products, cosmetics, and household chemical substances, the imported quantity shall also not exceed 90-day supply whichever is applicable. Any import beyond these specified quantities shall not be approved as a personal effect but for commercial purposes.

"Specialized company/institution" refers to a company/institution authorized by Rwanda FDA to import or export regulated products categorized as personalized products for specific treatment of its clients and not meant for sale to the public.

"Regulated products" refers to a human and veterinary drug, processed food for humans and animals, food supplements and fortified foods, poisonous substances, herbal medicines, medicated cosmetics, human and veterinary medical devices, tobacco and tobacco products, and laboratory and cleaning chemicals and pesticides.

"Controlled substances" mean any narcotic drug, psychotropic substance, or precursor as described under the Law n° 03/2012 of 15/02/2012 governing narcotic drugs, psychotropic substances, and precursors in Rwanda.

"Medical device" means any instrument, machine, appliance, or material intended by the manufacturer to be used alone or in combination for the purpose of diagnosis, testing, vaccination, cure, surgery or for human or animal health protection.
"Pharmaceutical product" means a drug /medicine used to diagnose, cure, treat, or prevent disease in human and veterinary medicine.

Import Permit /License means an authorization issued to the importer by the Authority, authorizing him/her to import regulated products into the country after complying with the documentary importation requirements;

Export Permit /License means an authorization issued to an exporter by the Authority, authorizing him/her to export regulated products from the country;

Visitor means any person who is not a citizen or permanent resident of Rwanda arriving in Rwanda;

1. INTRODUCTION

The safety, efficacy, and quality of regulated 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 regulated products both nationally and internationally conform to certain set standards.

Effective regulation of the importation and exportation of regulated products is key in ensuring the protection of the health and safety of consumers. Clearance of products meant as personal effects, as carried out by Rwanda FDA, typically involves authorization issuance and inspection.

These guidelines outline the processes and procedures involved in the application for and issuance of authorizations as well as the inspection and release of items meant for personal use.
These guidelines are hereby promulgated for information, guidance, and strict adherence by all concerned.

2. SCOPE

In exercise of the powers conferred to Rwanda FDA by the Law Nº 003/2018 of 09/02/2018 and in order to ensure the safety and quality of the products for personal use, these guidelines apply to all imported or to be exported products for personal use and not for sale. These products may be carried in baggage or shipped.

3. REQUIREMENTS

3.1. GENERAL REQUIREMENTS

3.1.1. Individuals, a group of individuals or a specialized company/institution authorized to import/export, shall be permitted to import/export products declared as personal effects.

3.1.2. The products declared as personal effects shall not be put on the shelves for sale or distribution to the public.

3.1.3. The product shall fit the purpose for which it was manufactured and meet all the requirements of labelling. Imported products or products to be exported must be kept in their original packaging with all dispensing labels intact.

3.1.4. Suspended, recalled and/or banned regulated products or containing a suspended, recalled and banned ingredient, shall not be allowed to be imported/exported.

3.1.5. Quantities exceeding 90 days' supply may be considered as personal effects for justified reasons after the Authority assessment.

3.2. SPECIFIC REQUIREMENTS AND OBLIGATIONS

3.2.1. For individual or group of individuals

a. Fill out the form No FDISM/FDIEC/FOM/002 (Appendix I) about imported or to be exported product information:
   i. Product name including Brand/trade name
   ii. Product quantities, value, batch/serial numbers, and where applicable indicate expiry dates.
   iii. Name, phone number, and Email addresses of both importer/exporter and the supplier (if applicable)
   iv. Reason for importation/exportation
   v. Importer/exporter identification card or passport Number
   vi. This form is available at the ports of entry

b. Invoice from a licensed premise dealing with regulated products

c. Valid prescription or written letter/declaration from an authorized practitioner for pharmaceutical products

d. Copy of Identification card or Passport of the importer / exporter

e. A payment proof of prescribed fees as stipulated in Regulations Doc. No: ODG/IMPO/TRG/001 governing tariff/fees and charges on services rendered by Rwanda Food and Drugs Authority in case of a consignment other than medical devices or pharmaceutical products valued at above 100 USD.

f. Importation/exportation of personal effects by an individual or a group of individuals shall not exceed four imports/exports per year.

3.2.2. For specialized company/institution importing personalized /customized products

3.2.2.1 Before starting the importation, the importer shall submit the application for one-year authorization (recommendation) to import products for personal use by providing the following documents:
   a. Operational license of the importer
   b. List of the products to be imported for a period of one year with the following information: full name (including brand name) of the products, name of the manufacturer and its country of origin, name of the supplier and its country of origin.
   c. Certificate of compliance of the manufacturer or supplier; it is a certificate given by an authorized body confirming that the manufacturer or distributor complies with standards requirements. Examples include but not limited to: Good Manufacturing Practices (GMP) Certificate or International Organization for Standardization (ISO) Certificate or

Conformité Européenne (CE) Certificate or International Electrotechnical Commission (IEC, for Medical Electrical Equipment) Certificate or Good Distribution Practices (GDP) Certificate or Operational License from respective Regulatory bodies, etc.

If the manufacturer is from EAC, a Bureau of Standards permit to use standardization mark (Ex: TBS, KEBS, etc.) can be presented to prove compliance of the manufacturer to quality standards.
NB: Provide **one** of these certificates depending on product category and registration status of the products to be imported.

3.2.2.2 Starting importation of products for personal use after obtaining one-year authorization to import products for personal use. On arrival of the products at the port of entry the importer shall provide:

a. A valid one-year authorization to import products for personal use issued by Rwanda FDA
b. A filled online form corresponding to each patient. This form can be filled and be submitted to Rwanda FDA prior to arrival of the products using a platform defined by the Authority. Each application must be accompanied with patient 's identification details.
c. A payment proof of service fees based on product category as stipulated in Regulations Doc. No: ODG/IMPO/TRG/001 governing tariff/fees and charges on services rendered by Rwanda Food and Drugs Authority. If requested, a company can use a pre-payment method for a given period.

3.2.3. Importation/exportation of pharmaceutical products or medical devices for personal use should be accompanied by a medical prescription from an authorized medical practitioner where applicable. For the product that requires direct oversight or administration by a trained operator, in addition to medical prescription, the importer shall provide the address and/or the contact information of the health facilities/ healthcare provider that will be in charge of the product administration/use.

3.2.4. Controlled substances declared as personal effects can only be imported for medical purposes. Controlled substances can only be brought into the country when a returning resident or visitor arrives with them in Rwanda and should always be accompanied by a prescription or an authorization letter from a registered practitioner in the country of origin. Online purchase or importation of controlled substances using a courier is not allowed.

3.2.5. Personal use importation or exportation of prescription-only medicines, is allowed for up to 90 days' supply (for medicines, at the maximum dose recommended by the manufacturer or the competent healthcare provider) and 30 days for controlled substances.

3.2.6. All incoming and outgoing consignments of personal effects shall be physically inspected at the Port of Entry and Exit and the inspector may sample imported products for further investigations.

3.2.7. All consignments declared as personal effects shall attract verification fees as follows:

a. All the consignments of pharmaceutical products and medical devices for personal use imported are exempted from verification fees.
b. Consignments other than pharmaceutical products and medical devices valued at below 100 USD will be exempted from verification fees.

c. Consignments other than pharmaceutical products and medical devices valued at above 100 USD will pay verification fees as stipulated in Regulations Doc. No: ODG/IMPO/TRG/001 governing tariff/fees and charges on services rendered by Rwanda Food and Drugs Authority

3.3. RELEASE /REJECTION OF PERSONAL EFFECTS CONSIGNMENT

3.3.1. Consignments in compliance with these guidelines shall be released to the importer.

3.3.2. Consignments that cannot be reasonably brought into conformance, will not be released to the importer. The importer shall either re-export (if the Authority rejects imported regulated products for reasons other than their quality) or dispose of them safely (if the Authority rejects imported regulated products for reasons of poor quality) under Rwanda FDA supervision, at his/her own expense.

REFERENCES

1. The law N0 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.

2. Regulations No FDISM/FDIEC/TRG/002 governing control of importation and exportation of pharmaceutical products and medical devices.

3. Regulations No FDISM/FDIEC/TRG/004 governing control of importation and exportation of food products.

4. Regulations No. CBD/TRG/011 governing control of medicated cosmetics

5. Guidelines for Importation and Exportation of Medical Devices Including in Vitro Diagnostics and Laboratory Equipment, Second Edition, April 2020. Tanzania Medicines and Medical Devices Authority.
6. Guidelines No FDISM/FDIEC/GDL/002 for Importation and Exportation of food.

7. Guidelines for the importation and exportation of products declared as personal effects, August 2021.Ghana Food and Drugs Authority.

ENDORSEMENT OF THE GUIDELINES

	Author	**Checked by**		**Approved By**
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Date	08/03/2023	08/03/2023	08/03/2023	13 / 03 /2023

APPENDIX I: INSPECTION REPORTING FORM OF REGULATED PRODUCTS FOR PERSONAL USE

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	Food and Drugs Import and Export Control Division
Document Type: **Form**		Doc. No : FDISM/FDIEC/FOM/002
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Inspection reporting form of regulated products for personal use**	Revision Number : 0 Revision Date: : 28/10/2022 Effective Date : 07/11/2022 Review Due Date :06/11/2022 Ref Doc. : FDISM/FDIEC/GDL/003

I, ……, inspector of food, drugs and other regulated products in Rwanda Food and Drugs Authority (**RWANDA FDA**) at ……Port of Entry, hereby **RELEASE** ☐ **REJECT** ☐ this/these consignment(s) after physical inspection and/or other regulatory documentation requirements.

Details of the consignment:

Importer/Exporter/Representative names: ID or passport No:

Telephone and email address:

Supplier/country of origin: Product category:

Invoice No/RRA declaration No:

Reason for importation: Total Value:

S/N	Full name (including brand name) of the products	Batch No & Expiry date(if applicable)	Quantity

Reason for rejection (if rejected):

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Note: The importer is responsible for the proper use of the imported product.

Rwanda FDA Inspector (s) *(Name, phone, Date and Signature)*	For the Importer/Exporter/Representative *(Name, phone, Date and Signature)*