RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR IMPORTATION AND EXPORTATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

NOVEMBER, 2022

FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drug Authority and determining its mission. One of the functions of the Rwanda FDA as per the law is to regulate the import and export of pharmaceuticals, and medical devices/IVDs, especially in articles 3, 8, and 9.

Reference to the provisions of the technical regulations No FDISM/FDIEC/TRG/001 Rev_2 governing the control of importation and exportation of pharmaceutical products and medical devices/IVDs.

These guidelines guide the information and documentation required in any application submitted to Rwanda FDA by an importer or exporter of pharmaceutical products, medical devices/IVDs, and their respective raw materials as set in these guidelines. Adherence to the set requirements will speed up the provision of quality services to clients and ensure the quality and safety of pharmaceutical products and medical devices/IVDs.

These guidelines also provide guidance to the inspectors to minimize risks of trading sub-standard and falsified products among nations and therefore prevent dumping these products in our country.
These guidelines will be reviewed 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	02/06/2021
ADOPTION BY RWANDA FDA	11/06/2021
STAKEHOLDERS CONSULTATION	18/06/2021
ADOPTION OF STAKEHOLDERS' COMMENTS	25/06/2021
DATE FOR COMING INTO EFFECT	30/11/2022

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
13/07/2021	0	First issue
17/10/2022	1	1. Requirements for import visa of registered products: certificates of compliance to international standards such as GMP, ISO, IEC, CE, etc. are not required. 2. Requirements for import visa and license for non-registered products: COAs is no longer required if the manufacturer is located in a country with stringent regulatory authority and GDP or Operational license of the supplier can replace certificates of compliance to international standards such as GMP, ISO, IEC, CE, etc. 3. The application processing time has been updated 4. The validity for import/export license has been updated 5. The validity for official certificate of importation of controlled substances has been updated 6. The conditions for re-exportation of rejected consignment have been added 7. The application processing chart/diagram was added

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ACRONYMS AND ABBREVIATIONS

CE : Conformité Européenne
COA: Certificate of Analysis
GDL: Guideline
GDP: Good Distribution Practice
GMP: Good Manufacture practices
IEC: International Electrotechnical Commission
ISO: International Organization for Standardization
IVDs: In-Vitro Diagnostics
ME: Medical Electrical
MoU: Memorandum of Understanding
NGOs: Non-Government Organizations
PoE: Port of Entry
PEMS: PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS
PRIMS: Pharmaceutical Regulatory information system
RESW: Rwanda Electronic Single Window
Rwanda FDA: Rwanda Food and Drugs Authority
RFID: Radio Frequency Identification

Definitions

In these guidelines, unless the context otherwise states:

Authority means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under Article 2 of the Law No 003/2018 of 09/02/2018 establishing Rwanda Food and Drug Autority and determining its mission.

Authorization means a legal document granted by Rwanda Food and Drugs Authority to an applicant under the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization, and functioning; it includes import visas, import/export licenses, permits, certificates, and other types of approval as may be issued by the Authority.

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

Donation means an act or instance of presenting medical products, processed foods, and others;
Products regulated to recipients in an 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;

Export License means an authorization/permit issued to an eligible exporter by Authority, authorizing him/her to export pharmaceuticals or medical devices or their respective raw materials from the country;

Good Manufacturing Practice means that part of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorisation, Clinical Trial Authorisation, or product specification. Good Manufacturing Practice is concerned with both production and quality control.

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

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

Import Visa means an authorization/permit issued to the importer after confirmation by the Authority that the manufacturer(s)/suppliers of pharmaceutical products or medical devices or their respective 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 an import license.

Manufacturer means a person or corporation, or other entity engaged in the business of manufacturing pharmaceutical products and/or medical devices/IVDs;

Medical device/IVDs 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. A medical device is an in vitro diagnostic device (IVDs) if it is a reagent, calibrator, control materials, kit, specimen receptacle, software, instrument, apparatus, equipment, or system, whether used alone or in combination with other diagnostic good for in vitro use which is used during the examination of specimens derived from the human body.

Pharmaceutical product means any substance in its finished dosage form, or as a starting material for use in such a dosage form, capable of preventing, or treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises where food and pharmaceutical products are manufactured, prepared, or stored, cleaning hospitals, equipment, and farmhouses.

Raw materials mean any substance of a defined quality used in the production of a pharmaceutical product and medical devices, but excluding packaging materials; 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.

Special import authorization refers to an import authorization issued for unregistered /unauthorized pharmaceutical products / medical devices/IVDs.

1. Introduction

The safety, efficacy, and quality of pharmaceutical products and medical devices/IVDs 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 pharmaceutical products and medical devices/IVDs, both nationally and internationally conform to certain set standards.
The Authority has developed these guidelines to strengthen the control of the 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 pharmaceuticals and medical devices/IVDs with the necessary information to enable them to comply with the law and regulations governing the control of the importation and exportation of these products.
These guidelines are organized into two modules.
The first module provides for the requirements and conditions to fulfill during the importation of pharmaceuticals and medical devices/IVDs while the second module outlines the requirements and conditions for the exportation of these products.

2. Scope

These guidelines apply to pharmaceutical products, medical devices/IVDs, and their respective raw materials as specified in the law N0 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products and law No 03/2012 of 15/02/2012 governing Narcotic drugs, Psychotropic substances, and precursors in Rwanda.
These guidelines outline requirements for the importation and exportation of pharmaceutical products and medical devices/IVDs for human beings or animals.

Chapter 1. Importation of Pharmaceutical Products and Medical Devices/IVDs

1.1 Requirements

1.1.1 General requirements

All pharmaceutical products, medical devices/IVDS to be imported must be registered or granted special approval by the Authority.
Any import application passes through two mandatory phases; Visa and License whereby Visa is the starting phase.

All applications of importation/ exportation of pharmaceutical products and medical devices/IVDs for personal use is guided by Guidelines NO FDSIM/FDIEC/GDL/004 Importation and Exportation of regulated products declared as personal effects.

All imported pharmaceutical products and medical devices/IVDs (where applicable) must have at least two-thirds of their shelf life remaining when they arrive at the port of entry and must comply with applicable labeling and packaging requirements.
The product information leaflet/catalog enclosed in or accompanying the pharmaceutical product, medical devices/IVDs, shall be in officially recognized languages in Rwanda.

The importation of a pharmaceutical product labeled for sale in a specified country is prohibited in Rwanda except where Rwanda is one of the specified countries.
All applications for import authorization shall be submitted using a platform defined by the Authority.

All consignments of pharmaceutical products and medical devices/IVDs shall pass through the approved port of entry.

All imported consignments of pharmaceutical products and medical devices/IVDs shall be subjected to physical inspection at the port of entry or at the importer's premise (for the consignments released under seal) before being used, to ensure that 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.

1.1.2 Eligibility for Import Authorization

All pharmaceutical products and medical devices/IVDs must be imported by importers whose premises are licensed by Rwanda FDA or who fall within the eligible importer category. Only the following shall be allowed to import pharmaceutical products and medical devices/IVDs:

a) Licensed manufacturers and wholesale companies of pharmaceutical and medical devices/IVDs.
b) Licensed retail of pharmaceutical and medical devices/IVDs (only on medical prescription) in case the product is not available on the market.
c) Public and private health facilities.
d) Hatcheries
e) The beneficiary of a donation.
f) Non-governmental organizations (NGOs) with a Memorandum of Understanding (MOU) with the Ministry of Health or Government of Rwanda.
g) Government institutions and Embassies.
h) UN organizations intervening in the Health sector.
i) Clinical Trial Sponsors and Principal Investigators.
j) A tourist, a visitor in the country, or any other person for justified reasons.

Any medical/IVDs device and pharmaceutical products shall be clearly labeled depending on their nature and type. The label should have the following minimum information:

- The trade or brand name;
- The generic name of the pharmaceutical products and/or medical devices where applicable;
- The quantities of active ingredients in the pharmaceutical products/or medical devices where applicable;
- The dates of manufacture and expiry where applicable;
- The batch or lot number/serial or model number;
- Special storage conditions and handling requirements where applicable;
- The name and address of the manufacturer where applicable;
- Any other safety information, depending on the nature of the product.

The labeling information may be provided in a human-readable code or through automatic identification technology such as barcodes or Radio Frequency Identification (RFID)

1.1.3 Specific requirements

1.1.3.1 Import visa requirements

Any import application starts from a step called import visa. The import visa gives the right to the importer to confirm an order for the products to be imported.
The following requirements are mandatory to apply for an import visa:

a) Registered pharmaceutical products and medical devices/IVDs

i) A Proforma invoice showing:
- Invoice number and date,
- Manufacturer name,
- Address of exporter and importer companies,
- Country of origin of the manufacturing site for each product,
- A clear description of each product including brand and common names as they appear on Rwanda FDA registers of medicinal products or medical devices/IVDs.
- Quantity and value for each product in convertible currency

ii) The operational license of the importer (if applicable)

b) Special import authorization approval

The special import authorization is issued for unregistered /unauthorized pharmaceutical products / medical devices/IVDs in the following conditions:

- If the imported pharmaceutical products/ medical devices/IVDs have no registered/authorized therapeutic equivalent (alternative) products available in Rwanda with valid reasons for import (orphan medicines, medicines for emergency use, and medicines for specific treatment including but not limited to cancer).
- The importation of pharmaceutical products and medical devices/IVDs to be used in the clinical trial.

i) A proforma invoice showing:
- Invoice number and date,
- Manufacturer name,
- Address of exporter and importer companies,
- Country of origin of the manufacturing site for each product,
- A clear description of each product including brand/trade and common names, strength, dosage form, and pack.
- Quantity and value for each product in convertible currency

ii) The operational license of the importer (if applicable)

iii) **For pharmaceutical products:** Valid Good Manufacturing Practices certificate (GMP) if the manufacturer is not located in a country with stringent regulatory authority or Valid Good Distribution Practices certificate (GDP) or Operational License of the supplier if the manufacturer is located in a country with a stringent regulatory authority.

iv) **For medical devices/IVDs**: Proof of compliance to the international standards or European Community standards (ISO or CE certificate or IEC) issued by an accredited certifying/notified body or Valid Good Manufacturing Practices certificate (GMP) if the manufacturer is not located in a country with stringent regulatory authority or Valid Good Distribution Practices certificate (GDP) or Operational License of the supplier if the manufacturer is located in a country with stringent regulatory authority or certificate of

refurbishment(for used medical devices/IVDs) issued by the manufacturer or certified company.

v) Clinical trial approval certificate or ethical committee approval/certificate or approval from government institutions (for veterinary research) in case of investigational products and related trial products, an application form [FDISM/FDIEC/FOM/003] shall be filled and submitted during application.

The application will be processed in 3 working days, and any application which does not meet any of the importation requirements will be rejected. An applicant will be notified by the Authority stating clearly the reason(s) for rejection.

The import visa, for a specific consignment, shall be valid for six (6) months from the date of issue.
The official certificate of importation of controlled substances [DIS/FMT/119] is valid for twelve (12) months from the date of issue.

1.1.3.2 Import license requirements

a) The commercial invoice has the following information:
   - Invoice number and date,
   - Manufacturer name,
   - The address of exporter and importer companies,
   - Country of origin of the manufacturing site for each product,
   - A clear description of each product including brand and common names as they appear on Rwanda FDA registers of medicinal products.
   - Quantity, and value for each product in convertible currency

b) Donation certificate/letter with the total value of donated health commodity where applicable

c) Clinical trial approval certificate or ethical committee approval/certificate or approval from government institutions (for veterinary research) in case of investigational products and related trial products, an application form [FDISM/FDIEC/FOM/003] shall be filled and submitted during application.

d) A packing list of the medical products (if applicable) with the following information:
   - Imported quantities.
   - Batch/lot number or the Model number for medical device /IVDs and expiry date where applicable.

e) Certificate of analysis for pharmaceutical products or Medical devices/IVDs (where applicable) certificates of conformity for each batch /model of medical devices/IVDs if the manufacturer is not located in a country with a stringent regulatory authority.

f) A Proof of Payment of verification fees as specified in the Regulations governing services fees, tariffs, and fines.

The application will be processed in 3 working days, and any application which does not meet any of the importation requirements will be rejected. An applicant will be notified by the Authority stating clearly the reason(s) for rejection.

The import license[DIS/FMT/122]is granted for a single consignment, valid for six (6) months from the date of issue and it is renewable for 3 months in case it has not been used.

1.1.3.3 Import license of controlled substances

An application for a narcotic, psychotropic, and precursor substances import license is made by a person issued with an official certificate of importation/exportation of controlled substances[DIS/FMT/119] under article 10 of the regulation governing control of importation and exportation of pharmaceutical products and medical devices/IVDs. For cannabis and cannabis products, requirements and eligibilities are indicated in regulations for the importation and exportation of cannabis and cannabis products [CBD/TRG/020 Rev_0]

In the case of controlled drugs (narcotics, psychotropics, and precursors), a proforma invoice will be accompanied by an import certificate from a drug regulatory authority of an importing country.
Note that the requirements to apply for an official certificate of importation of controlled substances are the same as those required to get an import visa for pharmaceutical products.

1.1.3.4 Conditions for the importation of donated pharmaceutical products or medical/IVDs.

In addition to the above-mentioned requirements to apply for an import visa and import license, the following conditions shall be fulfilled for the importation of donated pharmaceutical products and medical devices/IVDs:

a) All applicants intending to export donated pharmaceutical products and medical devices/IVDs to Rwanda, apart from registered products or those granted special approval by the authority, shall apply first for a donation acceptance letter as per the guidelines No DAR/GDL/040 for Donation of Medical Products.
b) All Donations will be in accordance with the recipient's need and should comply with the existing government policies, laws, guidelines, and administrative arrangements.

c) Donations should comply with applicable standards and there will not be double standards regarding the quality of donated items. Unacceptable medical devices/IVDs, and pharmaceutical products in the donor country shall not be allowed into the recipient's country.

d) Any person, institution, or organization intending to import donated pharmaceutical products, and medical devices/IVDs will be required to apply for import permit authorization.

e) The application for an import visa should be accompanied also by the following documents:
A supporting document from the relevant institution which supports such donation (if applicable).

i) A donation certificate/letter from the donor to the beneficiary.
ii) Donation acceptance letter issued by the Authority, the corresponding requirement can be found in Guidelines for Donation of Medical Products [DAR /GDL/ 0 40]
iii) Certificate of refurbishment (for used medical devices/IVDs) issued by the manufacturer or certified company.

f) Donated medical devices/IVDs, or pharmaceutical products should have a shelf life of not less than 2/3 of the original shelf life or 80% for products with a shelf life of less than 24 months.

g) If the medical equipment/instrument is used, it must be reconditioned and tested and all essential parts, accessories, and working materials included before shipment together with the relevant supporting documents to indicate that the device is in good state

h) For software-operated medical devices/IVDs, the software shall be either preloaded and/or accompanied by the software package.

i) For medical electrical equipment, the electrical needs of the equipment shall be set to the standard voltage of 220V/50Hz, and for X-ray emitting equipment it shall be calibrated and inspected by a qualified Medical Physician.

j) Damaged, outmoded, and redundant medical devices/IVDs for which spare parts and consumables are no longer available will not be accepted.

k) Donated medical devices/IVDs and pharmaceutical products must meet the labeling requirements.

1.1.3.5 Inspection of imported consignments at ports of entry

Each consignment of pharmaceutical products and medical devices/IVDS must be inspected by the authority at the port of entry to ensure that it complies with the approved requirements and applicable regulations.
The consignment must be accompanied by the following requirements:

- A valid import license issued by the Authority.
- A corresponding commercial invoice.
- A certificate of analysis for each batch or a certificate of conformity (if applicable).

The imported pharmaceutical products and medical devices/IVDs (if applicable) must have at least 2/3 of their shelf life remaining on arrival at the port of entry.

If the consignment contains controlled substances, it must be accompanied by an export authorization from a competent authority.

a) Sampling of imported products

The inspector at the port of entry may take samples of pharmaceutical products or medical devices/IVDS for further investigation during the inspection and release of the consignment in case of suspected poor-quality product reporting form[FDISM/PVSM/FOM/016] or in case of routine sampling.
In the case of routine sampling, the consignment from which the samples have been taken shall be released to the importer for distribution if they meet all the quality requirements.
Suspicious consignment in which a sample was taken for analysis, shall not be released and shall not be distributed until the laboratory results are available for decision-making.
An inspection report will be written for that purpose.

b) Release of consignments

At the port of entry, the inspector shall release the consignment if it meets the quality, documentary, and physical verification requirements for the importation of pharmaceutical products, medical devices/IVDs, and diagnostics by stamping the supporting documents "**APPROVED**".
In case the physical inspection cannot be conducted at the port of entry for example: for intra-region consignments, consignments that require special storage conditions, or consignments that cannot be offloaded at the port of entry, the inspector releases the consignment underseal (by stamping supporting documents "**RELEASED UNDERSEAL**" and filling the form [DIS/FOM/151] for further inspection at importer's premise.
For the partial shipment, an inspector will write "**PARTIAL SHIPMENT**" on the import license and invoice, along with the imported and remaining quantities.

c) Rejection of consignments

i) If the consignment does not meet importation requirements, it shall be rejected and follow the procedure for re-export and the exercise will be done within 90 days. The following are the reasons for the re-export of a consignment:

- Pharmaceutical products or medical devices/IVDs not meeting the labelling specifications.
- Pharmaceutical products or medical devices/IVDs are not allowed or withdrawn from the Rwanda market.
- Any other reason the authority may deem necessary.

ii) If a consignment is rejected due to quality and/or safety reasons, the applicant will proceed for safe disposal. The application for safe disposal shall be done within one month. The Rejected product will get a full release in the Rwanda electronic single window (Resw) after the submission of the destruction/disposal certificate.

iii) Where the consignment is rejected/detained, an inspector will fill minutes of inspection findings /PV de constat [FDISM/FDIC/FOM/004] with recommendations to follow safe disposal measures where applicable.

Chapter 2: Exportation of Pharmaceutical Products and Medical Devices/IVDs

2.1 General requirements

Exporters of pharmaceutical products and medical devices/IVDs should have a valid export authorization issued by the Authority.
All consignments of pharmaceutical products / medical devices/IVDs to be exported must go through the authorized port of entry (PoE)/Exit.

2.2 Eligibility for Export Autorization

Eligible applicants to export pharmaceutical products and medical devices/IVDS include:

a) A manufacturer of pharmaceutical products or medical devices/IVDS;
b) A wholesaler of pharmaceutical products or medical devices/IVDS;
c) A donor of pharmaceutical products or medical devices/IVDS;
d) Referral Hospitals, Government institutions;
e) Private Health Facilities with justified reasons;
f) Research institutions/researchers with clinical trial or research approval in the country;
g) Non-governmental organizations (NGOs) with MOU with the Ministry of Health (MOH) or Government of Rwanda;
h) UN organizations and other international organizations intervening in the health sector;
i) A tourist, a visitor in the country, or any other person for justified reasons.

2.3 Requirements for exportation of pharmaceutical products and medical devices/IVDS

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

a) Invoice of the product to be exported including the following information:
   - Name and address of the exporting and address of importing companies,
   - Invoice number and date,
   - A clear description of items with the quantity and values of the product to be exported.

In the case of controlled drugs (narcotics, psychotropics, and precursors), the invoice will be accompanied by an import certificate from a drug regulatory authority of an importing country.

b) Certificate of analysis for every batch with details of tested parameters, if applicable.
c) A Packing List with the following details: Batch Number or model number for medical equipment and Manufacturing & Expiry dates, quantity, and value of the category item to be exported.
d) Operational license of the exporter.
e) Proof of Payment of verification fees as specified in the Regulation governing services fees, tariffs, and fines.

f) Evidence of the source of the products to be exported, if applicable.

An export license [DIS/FMT/125] shall not be transferable and shall be issued to cover only one shipment and the license will be valid for six (6) months from the date of issuance.
NB: All applications for export License shall be submitted using a platform defined by the Authority and will be processed within 3 working days.

2.4 Application processing flow chart

Upon submission of the application via email or the online portal, the Authority will verify the eligibility and completeness of the application dossier. The application screening is done as indicated in the diagram of Figure 1.

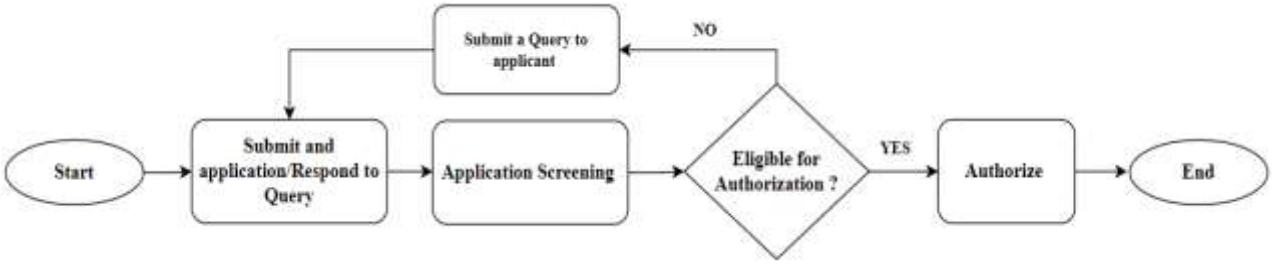

Figure 1: Application processing scheme

In the event that the application does not comply with guidelines and regulations, a query will be submitted back to the applicant.
A regulatory decision is made based on the outcome of the assessment of the submitted dossier. Based on the type of application, a processing period has been allocated (as indicated in sections 4.3 and 3.1). However, the stop-clock starts whenever a query is raised and ends when a satisfactory response is received from the applicant. Applicants are reminded to ensure the application fulfills **ALL** the eligibility criteria and that all the required information is entered correctly and accurately. Any application which fails to fulfill **ALL** the eligibility criteria specified under these guidelines will be queried.

References

1. Law N0 47/2012 of 14/01/2013 relates to the regulation and inspection of food and pharmaceutical products.

2. Ministerial instructions No 20/12 of 18/02/06 determine the guideline for donated drugs in Rwanda.

3. The regulation governing control of importation and exportation of pharmaceuticals and devices.

4. 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.

5. International Electro-technical Commission, IEC 60601-1 Edition 3.1 2012-08

6. Stringent Regulatory Authority: https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs#

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	Mr. Theobald HABIYAREMYE	Dr. Eric NYIRIMIGABO	Mr. Theogene NDAYAMBAJE	Dr. Emile BIENVENU
Signature		For		
Date	10/11/2022	21/11/2022	22/11/2022	24/11/2022

RWANDA FOOD AND DRUGS AUTHORITY • RWANDA FDA

ANNEXES

RWANDA FDA
Rwanda Food and Drugs Authority
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www.rwandafda.gov.rw

Ref. No: DIS/……../FDA/2021

EXPORT LICENSE OF PRODUCT CATEGORY.

Reference made to your request **Nº ……./2021** dated **D/M/2021**, **EXPORTER NAME** based in KIGALI CITY, is hereby authorized to export PRODUCT CATEGORY, NOT containing narcotic and psychotropic substances, to **CONSIGNEE.**

In accordance with export license requirements of pharmaceutical products, medical equipment, devices and consumables, food products and other products regulated by Rwanda FDA, the exported products are detailed below:

Product Name	Quantity	BATCH N^{O}	Manufacture Date	Expiration Date

This license is valid for three (3) months only.

AGREEMENT FOR REMOVAL

Port of exit is □**MAGERWA**

Done at Kigali on ……

By Authority Delegation

……
Deputy Director General

RWANDA FDA
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P.O. Box 1948 Kigali
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Ref. No: DIS/……../FDA/2021

IMPORT LICENSE OF PRODUCT CATEGORY.

Reference made to your request **Nº ……./2021** dated **DAY/MONTH/2021, IMPORTER NAME** based in KIGALI CITY**,** is hereby authorized to import into **RWANDA, PRODUCT CATEGORY** , NOT containing narcotic and psychotropic substances, from **SUPPLIER NAME.**

In accordance with import license requirements of pharmaceutical products, medical equipment, devices and consumables, food products and other products regulated by Rwanda FDA, the imported products are detailed on the invoice mentioned below:

Invoice No	Date	Amount in USD	Chargeable amount/USD	Chargeable amount/RWF	Supplier	Country of Origin
Total						

This license is valid for three (3) months only. Exchange rate used: 970.089998 RWF

AGREEMENT FOR REMOVAL

Port of entry is □**MAGERWA**

Done at Kigali on ……

By Authority Delegation

……..
Deputy Director General

RWANDA FDA
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OFFICIAL CERTIFICATE OF IMPORTATION OF CONTROLLED SUBSTANCES Nº: ……/2021

Adopted from the Single Convention on Narcotic Drugs, 1961 and Convention on Psychotropic Substances 1971

Reference made to the Law Nº 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning especially in its article 8, Rwanda FDA is responsible for the implementation of laws and regulations relating to narcotic drugs and psychotropic substances covered by international conventions and protocols, hereby authorizes the importation of controlled substance (s) listed below:

SNº	Brand name of the substances	International Nonproprietary Name	Pharmaceutical dosage form	Quantity	Content per unit in (mg)	Total quantity in grams (g)
1						
2						

Details of Importer (Name, Location, Tel, Fax, Postal Address, E-mail.)	Details of Exporter (Name, Location, Tel, Fax, Postal Address, E-mail.)
Shipping information/Method:	Name of the Port of entry in Rwanda:
Reasons of import (Medical or scientific research, registration purposes):	
Reference Proforma/ Invoice Nº:	Date**:**

This certificate is subjected to the following conditions:

1. *This certificate is valid for one (1) shipment only.*
2. *This certificate is only valid for substances or preparations as specified above.*
3. *This certificate is valid for importer and exporter as specified above.*
4. *It is not permitted to import quantities greater than those specified in this certificate.*

Validity: This certificate is valid only for twelve (12) months from date of its signature
Done at Kigali, on …….
By Authority Delegation

…….
Deputy Director General

RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 1948 Kigali
info@rwandafda.gov.rw
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RELEASE UNDER SEAL FORM

I, ……, inspector of food, drugs and other regulated products in Rwanda food and drugs authority (**RWANDA FDA**) at ……Port of entry, hereby **RELEASE UNDER SEAL** this/these consignment(s) after physical inspection and/or other regulatory documentation requirements.

Details of the consignment:

S/N	Importer Name	Import License Nº	Country of origin	Invoice Nº	RRA Declaration Nº/ if applicable	Product Category
1						
2						
3						

Reason of Underseal Release:

……..

.....

Place of inspection: ……...

Proposed date of inspection: ……/……/…..

Note: This consignment/ product should be used or sold after the final release by Rwanda FDA. The Importer is recommended to Notify/confirm the date of final Inspection one day before.

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

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	FDISM/PVSM
Document Type: **Form**		Doc. No : FDISM/PVSM /FOM/016
RWANDA FDA Rwanda Food and Drugs Authority	**Title:** **SUSPECTED POOR QUALITYPRODUCT REPORTING FORM**	Revision Number : 2 Revision Date: : 05/08/2022 Effective Date : 12/08/2022 Review Due Date : 05/08/2025 Ref Doc. :FDISM/PVSM/GDL/003

I. PRODUCT CATEGORY (Tick as appropriate)

Medicinal product ☐Vaccine ☐ Other Biological Products ☐Herbal product ☐Other *(Please Specify):*

……

II. PRODUCT DETAILS

Brand name				Generic Name			
Batch/Lot Nº		Manufacturing Date		Expiry date		Date of receipt	
Name of manufacturer				Physical Address and Country of Origin			
Name of Distributor/Supplier				Distributor/ Supplier's Address			

III. PRODUCT FORMULATION

☐ Tablets /capsules
☐ Suspension/Syrup
☐ Injectable/Infusions
☐ Creams/Ointment/Liniment/Paste
☐ Pessaries
☐ Suppository
☐ Powder for reconstitution of oral suspension
☐ Powder for reconstitution of injection
☐ Ear/Eye drops
☐Diluents
☐Nebulizing solutions
☐Other *(Please Specify)* ……

IV. DESCRIPTION OF PRODUCT COMPLAINT

☐Color/odor change
☐Molding
☐Turbidity
☐Mislabelling
☐Poor Packaging/ lack of patient leaflet/ lack measuring devices
☐Therapeutic ineffectiveness
☐Particulate matter
☐Seal Integrity of packs and/ or Leakage
☐Caking
☐Separating
☐ Incomplete packs
☐Powdering/crumbling
☐ Suspected falsified/ Substandard
☐Others*Specify)* ……

Describe the Complaint in details:

……
……

V. PRODUCT STORAGE CONDITIONS

Does product require refrigeration? **YES☐NO☐**
Does product require protection from light? **YES☐NO☐**
Does product require protection from Moisture? **YES☐NO ☐**
Was it stored following manufacturer/Rwanda FDA guidelines?**YES☐ NO☐**

Other Storage details *(if necessary):*

VI. CIRCUMSTANCE AND TIME OF THE POOR-QUALITY DETECTION

When did you notice the poor-quality problem?
☐Before taking/administering the product
☐While taking/administering the product
☐After taking/administering the product
☐When the patient returned the product

☐After a complaint of the patient
☐After Visual inspection
☐After quality control
☐Other(specify)…….

VII. ACTION TAKEN

☐ Stop Taking/Administration of the product
☐Quarantining the product
☐ Returning the product to the supplier
☐Other (specify):…….

Have you experienced any adverse event after taking this medicine? **YES** ☐ **NO** ☐If **YES,** please complete the ADR/AEFI Reporting Form.

VIII. REPORTER INFORMATION

Name of reporter:		Qualification:		Phone number:	
Name of Health Facility		District:		Report Reference No:	
E-mail Address:		Contact/Tel No:		Date of report:	

All information is held in strict confidentiality and will not disclose reporter's identity in response to any public request. Information supplied will contribute to the improvement of safety and vigilance of Medical Products in Rwanda. Once this form is completed please send it to Rwanda FDA via the following email: ***pv_sm@rwandafda.gov.rw***