

**GUIDELINES FOR IMPORTATION AND EXPORTATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES**

**OCTOBER 2022**

# GUIDELINES DEVELOPMENT HISTORY

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| --- | --- |
| **DRAFT ZERO**  | 2nd June 2021 |
| **ADOPTION BY RWANDA FDA** | 11th June 2021 |
| **STAKEHOLDERS CONSULTATION**  | 18th June 2021 |
| **ADOPTION OF STAKEHOLDERS’ COMMENTS** | 25th June 2021 |
| **DATE FOR COMING INTO EFFECT**  |  |

## DOCUMENT REVISION HISTORY

| Date of revision | Revision number | Changes made and/or reasons for revision |
| --- | --- | --- |
| 14th July 2021 | 0 | First issue |
| …/…./2022 | 1 | 1. Requirements for import visa: for 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, if a product is from a country with stringent regulatory authority, COAs is no longer required and GDP can replace GMP where the product is from a country with stringent regulatory authority.
3. The application processing time have been updated
4. The validity for import/export license have been updated
5. The procedure and condition for re-exportation of rejected consignment have been added
6. The application processing chart/diagram was added
 |

# FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by Law N° 003/2018 of 09/02/2018. One of the functions of the Rwanda FDA is to regulate the import and export of pharmaceuticals, and medical devices/IVDSs, especially in articles 3, 8, and 9.

Reference to the provisions of the technical regulations No CBD/TRG/002 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/IVDSs and their respective 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 speeding up the provision of quality services to the clients.

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**

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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

# Glossary

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 law No 003/2018 of 09/02/2018;

***Authorization*** means a legal document granted by Rwanda Food and Drugs Authority to the applicant under 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 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*** meansa person, country, or organization that sends goods or services to another country;

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

***Manufacturer means*** a person or a firm that is engaged in the manufacturing of medical products;

***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.

***A pharmaceutical product*** means a [drug](https://en.wikipedia.org/wiki/Drug) /medicine used to [diagnose](https://en.wikipedia.org/wiki/Medical_diagnosis), [cure](https://en.wikipedia.org/wiki/Cure), [treat](https://en.wikipedia.org/wiki/Therapy), or [prevent](https://en.wikipedia.org/wiki/Preventive_medicine) [disease](https://en.wikipedia.org/wiki/Disease) in human and veterinary medicine;

***Raw materials*** means any substance of a defined quality used in the production of a

pharmaceutical product and medical devices, but excluding packaging materials;

***Import Visa*** *is an authorization* that gives permission to the applicant to bring pharmaceutical products or medical devices/IVDs into the country. The Import visa gives the right to the importer to confirm an order of the products that he has been granted that Import visa;

***Import License*** means an *authorization* issued to the importer authorizing him/her to import pharmaceutical products or medical devices/IVDs into the country after complying with the importation requirements. The importer will present this document during the physical inspection of the imported products.

***Export Permit*** means an *authorization* to an exporter, authorizing him/her to export pharmaceuticals or medical devices/IVDS from the country;

***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.

# 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 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 importation and exportation of these products.

These guidelines are organized into two modules.

The first module provides for the requirements and conditions to fulfil during the importation of pharmaceuticals and medical devices/IVDS while the second module outlines the requirements and conditions for the exportation of these products.

# 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 the law No 03/2012 of 15/02/2012 governing Narcotic drugs, Psychotropic substances, and precursors in Rwanda.

The guidelines outline requirements for the importation and exportation of pharmaceutical products and medical devices/IVDS.

# Module I: Importation of Pharmaceutical Products and Medical Devices/IVDs

## Requirements

### 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 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 labelling and packaging requirements.

The product information leaflet/catalogue enclosed in or accompanying the pharmaceutical product, medical devices/IVDS, shall be in officially recognized languages in Rwanda.

The importation of a pharmaceutical product labelled 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.

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:

1. Licensed manufacturers and wholesale companies of pharmaceutical and medical devices/IVDS.
2. Licensed retail of pharmaceutical and medical devices/IVDS (only on medical prescription) in case the product is not available on the market.
3. Public and private health facilities.
4. Hatcheries
5. The beneficiary of a donation.
6. Non-governmental organizations (NGOs) with Memorandum of Understanding (MOU) with the Ministry of Health or Government of Rwanda.
7. Government institutions and Embassies.
8. UN organizations intervening in the Health sector.
9. Clinical Trial Sponsors and Principal Investigators.
10. A tourist, a visitor in the country, or any other person for justified reasons.

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

1. The trade or brand name;
2. The generic name of the pharmaceutical products and/or medical devices where applicable;
3. The quantities of active ingredients in the pharmaceutical products/or medical devices where applicable;
4. The dates of manufacture and expiry where applicable;
5. The batch or lot number/serial or model number;
6. Special storage conditions and handling requirements where applicable;
7. The name and address of the manufacturer where applicable;

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

### Specific requirements

### 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 of the products to be imported.

The following requirements are mandatory to apply for an import visa:

### Registered pharmaceutical products and medical devices/IVDS

1. 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
2. The operational license of the importer (if applicable)

### Special import 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 emergence 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.
1. 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 size as it appears on Rwanda FDA registers of medicinal products.
	* Quantity and value for each product in convertible currency
2. The operational license of the importer (if applicable)
3. **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.
4. **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.
5. 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.

The application will be processed in 4 working days, and any application which does not meet any of the importation requirements, will not be approved. An applicant will be notified by the Authority stating clearly the reason(s) for rejection.

The import visa shall be valid for six (6) months from the date of issue.

The official certificate of importation/exportation of controlled substances is valid for twelve (12) months from the date of issue.

### Import license requirements

1. Commercial invoice having 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
2. Donation certificate/letter with the total value of donated health commodity where applicable
3. 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.
4. 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 /IVDSs and expiry date where applicable.
1. Certificate of analysis for pharmaceutical products or certificates of conformity for each batch /model of medical devices/IVDS issued by the manufacturer if the manufacturer is not located in a country with a stringent regulatory authority.
2. A Proof of Payment of verification fees as specified in the Regulations governing services fees, tariffs, and fines.

The application will be processed in 4 working days, and any application which does not meet any of the importation requirements, will not be approved. An applicant will be notified by the Authority stating clearly the reason(s) for rejection.

The import license is granted for a single consignment, valid for six (6) months from the date of issue and it is renewable.

## 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 under article 10 of the regulation governing control of importation and exportation of pharmaceutical products and medical devices/IVDs.

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.

## 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:

1. 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.
2. All Donations will be in accordance with the recipient’s need and should comply with the existing government policies, laws, guidelines, and administrative arrangements.
3. 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.
4. Any person, institution, and organization intending to import donated pharmaceutical products, and medical devices/IVDs will be required to apply for import permit authorization.
5. 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).
* A donation certificate/letter from the donor to the beneficiary.
* Donation acceptance letter issued by the Authority
* certificate of refurbishment (for used medical devices/IVDs) issued by the manufacturer or certified company.
1. 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 less than 24 months.
2. 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
3. For software-operated medical devices/IVDs, the software shall be either preloaded and/or accompanied by the software package.
4. For 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.
5. Damaged, outmoded, and redundant medical devices/IVDs for which spare parts and consumables are no longer available will not be accepted.
6. Donated medical devices/IVDs and pharmaceutical products must meet the labelling requirements.

## 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:

1. A valid import license issued by the Authority.
2. A corresponding commercial invoice.
3. 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.

### 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 (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 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.

### Release of consignments

At port of entry, the inspector shall release the consignment if it meets the quality 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**”) 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.

###  Rejection of consignments

* + - 1. 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 one month. The following are the reasons for re-export of a consignment:
* Pharmaceutical products or medical devices/IVDS not meeting the labelling

 specifications.

* Pharmaceutical products or medical devices/IVDS which are not allowed or withdrawn from the Rwanda market.
* Any other reason the authority may deem necessary.
	+ - 1. If a consignment is rejected due to quality 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 certificate. how about applications sent on email
			2. Where the consignment is rejected/detained, an inspector will write a “PV de constat ”with recommendations to follow safe disposal measures where applicable.

## Authorized ports of entry

All gazetted Ports of Entry/Exit

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# Module II: Exportation of Pharmaceutical Products and Medical Devices/IVDs

## General requirements

Exporters of pharmaceutical products, 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.

##  Eligibility for Export

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

1. A manufacturer of pharmaceutical products or medical devices/IVDS;
2. A wholesaler of pharmaceutical products or medical devices/IVDS;
3. A donor of pharmaceutical products or medical devices/IVDS;
4. Referral Hospitals, Government institutions;
5. Private Health Facilities with justified reasons;
6. Research institutions/researchers with clinical trial or research approval in the country;
7. Non-governmental organizations (NGOs) with MOU with Ministry of Health (MOH) or Government of Rwanda;
8. UN organizations and other international organizations intervening in health sector;
9. A tourist, a visitor in the country or any other person for justified reasons.

## Requirements for exportation of pharmaceutical products andmedical devices/IVDS

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

* + - 1. 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.

1. Certificate of analysis for every batch with details of tested parameters, if applicable.
2. 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.
3. Operational authorization of the exporter.
4. Proof of Payment of verification fees as specified in the Regulation governing services fees, tariff, and fines.
5. Evidence of the source of the products to be exported, if applicable.

An export license 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 4 working days

## Application process flow

Upon submission of application via recommended channel, 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 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 fulfils ALL the eligibility criteria and that all the required information is entered correctly and accurately. Any application which fails to fulfil ALL the eligibility criteria specified under these guidelines will be queried.

#  Review and appeal procedure

1. Any person aggrieved by the decision of the Authority in relation to any application for importation or exportation of pharmaceutical products and medical devices/IVDS may appeal for review of the decision to the Director General within 30 days from the date of receipt of the decision.
2. The Authority may review its decision, reject or vary the condition of approval.
3. After reconsideration of the application, if the applicant is not satisfied by the decision of the review, may appeal to the Minister responsible for Health.

# References

1. The law N0 47/2012 of 14/01/2013 relating 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

# Endorsement of the Guidelines

|  |  |  |  |
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