
REQUIREMENTS FOR ACQUIRING AUTHORIZATION TO IMPORT REGULATED PRODUCTS

These requirements are extracted from the following guidelines on control of importation and exportation of regulated products:

- Guidelines N°: *FDSIM/FDIEC/GDL/001* for Importation and Exportation of Pharmaceutical Products and Medical Devices.
- Guidelines N°: *FDISM/FDIEC/GDL/002_Rev1* for Importation and Exportation of food products.
- Guidelines N°: *FDISM/FDIEC/GDL/005* for Importation and Exportation of cosmetic products.

Step 1: Requirements for Import VISA

Import Visa is a permit issued after verifying whether products to be imported comply with applicable legal and regulatory requirements (standards) for quality, safety, and effectiveness.

1. Proforma Invoice
2. Operational license of the importer provided by Rwanda FDA
3. 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 region, a Bureau of Standards permit to use standardization mark (Ex: TBS, KEBS, etc) shall be presented to prove compliance of the manufacturer to quality standards.

NB: Applicant shall provide **one** of these certificates depending on product category and registration status of the products to be imported.

Step 2: Requirements for Import LICENSE

Import License authorizes imported regulated products to enter the Country after complying with all importation requirements:

1. Import VISA
2. Commercial invoice
3. Certificate of analysis (CoA) of imported products. A CoA is an official document that meant to testify quality control data for a particular lot/batch of product. A CoA can be replaced by Health Certificate or Phytosanitary Certificate. (Other alternatives are detailed below in Notes N° 1,2 &3).

Notes:

1. Products imported from countries with **Stringent Regulatory Authorities (SRAs)** may be exempted from providing the certificate of compliance and/or certificate of analysis (CoA).
2. Products imported from countries where quality documents cannot be provided, and which are not SRAs will be allowed to be imported if and only if the Embassy of the country of origin or representative of diplomatic mission in Rwanda endorses the visa application. The endorsement

confirms that products are imported from reliable sources. As this concerns only quality documents, it doesn't refrain Rwanda FDA from conducting other importation processes as stated in regulations and guidelines.

3. Eligible importers who may import food products without certificates of analysis or fail to acquire them prior to importing food products, shall consent to incur the cost for laboratory testing for each batch of imported products. The tests shall be done in accredited laboratories or designated laboratories. Importers must allow Inspectors to randomly take needed samples from the consignment.
4. For donation of registered products, provide the donation certificate from the donor. If the donated products are not registered, apply for the donation acceptance letter before applying for the importation authorization.
5. In case of importation of investigational products, provide a clinical trial approval certificate
6. In case of importation of health products for research purpose, provide ethical clearance from Ethics Committee.
7. In case of importation of used medical devices/IVDs, imported product must have at least 80% of its lifespan.
8. Ensure the above listed information and the products' labelling are in any of the official languages used in Rwanda. Otherwise adhere to language requirements as stipulated in Rwanda FDA regulations and guidelines.
9. Apart from the above-mentioned requirements for importation, 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.
10. Any imported product is subjected to a physical inspection while reaching the port of entry or at the client's premise for the case of consignments that have been released under seal.
11. The application is made using Rwanda FDA online platform.

Dr. Emile BIENVENU
Director General

ANNEX: Product types (category), payable fees, and Rwanda FDA's bank accounts

Service	Fee (FOB)	Account Numbers
Permit for importation of donated products in case of official request from government	Free	<ul style="list-style-type: none"> • BNR:1000047658/RWF • BNR :1000047666/USD • Swift Code: BNRWRWRW • BK:100025143684/RWF • BK:100025143765/USD • Swift Code: BKIGRWRW
Food products	0.5%	
Animal feed, Donated products, Raw materials and Packaging materials	0.2%	
Food Supplement	2%	
Permit for importation of grants products	0.2%	
Permit for importation of medical devices (human)	2%	
Laboratory and household chemicals	0.5%	
Pesticides and poisons	1%	
Permit for importation of medical devices (animal)	1%	
Medicated Cosmetic Products	1%	
Raw material for cosmetics production	0.2%	
Permit for importation of therapeutic and imaging equipment	1%	
Permit for importation of donated products	0.2%	
Verification of consignments for disasters, emergency and outbreaks officially declared by competent Authority	Free	