
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.

Requirements for Import LICENSE

1. Certificate of compliance of the manufacturer or supplier (applicable for unregistered products). This is a certificate given by an authorized body confirming that the manufacturer or distributor complies with standards requirements.

Examples include but are not limited to certificates such as Good Manufacturing Practices (GMP), International Organization for Standardization (ISO), Conformité Européenne (CE), International Electrotechnical Commission (IEC, for Medical Electrical Equipment), Good Distribution Practices (GDP), Operational License from respective Regulatory bodies, etc.

If the manufacturer is from the 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.

2. Certificate of analysis (CoA) of imported products. A CoA is an official document that is meant to testify quality control data for a particular lot/batch of product. A CoA can be replaced by a Health Certificate or Phytosanitary Certificate where applicable (Other alternatives are detailed below in Notes No 1, 2, 3 & 4).
3. Commercial invoice

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) upon providing other relevant documentation.
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 the Embassy of the country of origin or representative of the diplomatic mission in Rwanda endorses the license application. The endorsement confirms that products are imported from reliable sources.
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 donations, a certificate from the donor is required.
5. For the importation of investigational products, a clinical trial approval certificate is required.
6. For the importation of health products for research purposes, ethical clearance from the Ethics Committee is required.
7. For importation of used medical devices/IVDs, imported products must have at least 80% of their lifespan.
8. The above-listed information and the products' labelling should be in any of the official languages used in Rwanda.
9. All imported products are subjected to a physical inspection at the port of entry or at the client's premise when consignments have been released under seal.
10. All applications are made through Rwanda FDA online platform (IRIMS).
11. The Authority reserves the right, when deemed necessary to request the importer to provide additional documents/information for further analysis.
12. Information related to applicable fees is given in the annex.

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

Service	Fee (FOB)
Permit for the importation of food products	0.5%
Permit for the importation of animal feed and feed ingredients	0.2%
Permit for the importation of Food supplements	2%
Permit for importation of granted products	0.2%
Permit for importation of medical devices (human)	2%
Laboratory and household chemicals	0.5%
Permit for the importation of pesticides and poisons	1%
Permit for the importation of tobacco and tobacco products	2%
Permit for importation of medical devices (animal)	1%
Permit for the importation of cosmetics	1%
Permit for the importation of raw materials 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
Permit for importation of donated products requested by the public institutions.	Free