



*Regulations Governing Control of Importation and Exportation of
Pharmaceutical Products and Medical Devices*



**REGULATIONS GOVERNING CONTROL OF IMPORTATION
AND EXPORTATION OF PHARMACEUTICAL PRODUCTS
AND MEDICAL DEVICES**

(Rwanda FDA law N^o. 003/2018 of 09/02/2019, Article 9)



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REGULATION DEVELOPMENT HISTORY

DRAFT ZERO BY COUNSULTANTS	June 2018
ADOPTION BY RWANDA FDA	January 2019
STAKEHOLDERS CONSULTATION	18 th February 2019
ADOPTION OF STAKEHOLDERS' COMMENTS	12 th March 2020
DATE FOR COMING INTO EFFECT	10 th July 2020





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ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article No 9 of the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these regulations No. CBD/TRG/002 Rev. No 0, governing Control of Importation and Exportation of Pharmaceutical Products and medical devices, made this 09th day July, 2020.

Dr. Charles KARANGWA
Ag. Director General



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CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these Regulations

The purpose of these Regulations is to provide a legal framework for the effective and efficient control of importation and exportation of pharmaceutical products and medical devices and provide a transparent, non-discriminatory process their importation and/or exportation.

Article 2: Citation

These Regulations may be cited as the *“Regulations No DIS/TRG/002 Rev._0, governing authorization for importation or exportation of pharmaceutical products and medical devices.”*

Article 3: Application

These regulations shall apply to the authorization of importation or exportation of pharmaceutical products and medical devices, for public, private and non-profit organizations, including donated products, as stipulated in Article 3 of Law No 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.

Article 4: Interpretation

In these regulations, unless the context otherwise requires:

“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

“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 licences, permits, and certificates.

“Fee” means the income prescribed in the Fees Regulations in accordance with Article 9 and Article 32 of the Law No 003/2018 of 09/02/2018.



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“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.

“Law No 003/2018” means Law No 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning;

“Law No. 47/2012” means Law No 47/2012 of 14/01/2013 relating to the regulations and inspection of food and pharmaceutical products;

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

“Pharmaceutical product” means any substance capable of preventing, 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 farm houses;

“Pharmacist” means any person holding a second cycle university degree in pharmacy who is registered and licensed;

“Pharmacy” means any licensed/authorized location used for the practice of the pharmacy profession; and

“Premises” means any plot of land, buildings or boats, aircrafts, vehicles, a part of a building, channels, yards, a place of storage, annexed to a building, or part of that building, carriage or receptacle of any kind, whether open or closed.

“Licensed person” means any person who hold a licence to practice from a recognized professional council;

“Medical device” means any instrument, machine, appliance, 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;



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“Authorised person” means

- a) a person who holds a licence to operate a wholesale pharmacy issued in terms of Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning and Law No. 47/2012 of 14/01/2013 Relating to the regulation and inspection of food and pharmaceutical products.
- b) a person who holds a licence to operate a retail pharmacy issued in terms of Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning and Law No. 47/2012 of 14/01/2013 Relating to the regulation and inspection of food and pharmaceutical products; or
- c) a person who holds a licence to manufacture pharmaceutical products or medical devices issued in terms of Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning and Law No. 47/2012 of 14/01/2013 Relating to the regulation and inspection of food and pharmaceutical products; or
- d) any person approved as such by the Authority.

In these Regulations, the following verbal forms are used:

“shall” indicates a requirement;

“should” indicates a recommendation;

“may” indicates a permission; and

“can” indicates a possibility or a capability.

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CHAPTER II: IMPORTATION/EXPORTATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Article 5: Obligation to obtain an Import/export Authorization/Visa

Any person shall not import any pharmaceutical product or medical device without an Import Authorization/Visa for each consignment, issued by the Authority in accordance with the Law and these Regulations.

All the required documentation for application shall be uploaded into pharmaceutical regulatory information system in PDF for visa consideration and approval.

Article 6: Obligation to obtain a Licence/Verification certificate for import/export

- Any person shall not import into, or export from Rwanda, any pharmaceutical product and medical device without a Licence issued by Rwanda FDA.
- All the required documentation for application shall be uploaded into pharmaceutical regulatory information system in PDF for Licence consideration and approval.
- All consignments of pharmaceutical products and medical devices shall be subjected to physical inspection to ensure that they comply with claimed specifications and samples may be taken for quality control tests.
- Substandard or non-registered health commodities shall be re-exported to country of origin or incinerated. The cost related to this exercise is paid by the importer.
- No person shall obstruct or hinder Rwanda FDA inspectors in the exercise of their powers or performance of their duties as provided for in the Law.

Article 7: Requirements and eligibility for Pharmaceutical products and/or medical devices Import Authorization

1. Eligibility for imports

Eligible applicants for pharmaceutical products and medical devices import authorization include:



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- a) a company with pharmaceutical products or medical devices manufacturing authorization;
- b) a company with pharmaceutical products or medical devices wholesale authorization;
- c) a company with pharmaceutical products or medical devices retail authorization (only on medical prescription) in case not available on the local market;
- d) a beneficiary of pharmaceutical products or medical devices donation;
- e) Referral Hospitals;
- f) Research institutions/researchers with clinical trial approval in the country;
- g) Non-governmental organizations (NGOs) with MOU with Ministry of Health (MOH) or Government of Rwanda;
- h) UN organizations and other international organizations intervening in Health sector;
- i) A tourist, a visitor in the country or any other person for justified reasons as per article 35 of the Law No. 47/2012 of 14/01/2013 Relating to the regulation and inspection of food and pharmaceutical products
- j) Private Health Facilities in special cases as per article 35 of the Law No. 47/2012.

2. *The Visa/Import Authorization requirements*

- a) A Proforma Invoice signed by technician and stamped originally showing Manufacturer's name, description, quantity and value for each product, full address of Exporter and importer Companies and Country of Origin.
- b) Proof of compliance to International Standards or European Community Standards (ISO or CE certificate) issued by Certified Regulatory Body (for medical devices and consumables).
- c) Valid Good Manufacturing Practice certificate (GMP) for pharmaceutical products.
- d) Pharmaceutical products/medical devices import authorization/Visa shall be valid for a period of 3 months from the date it was issued.



3. License/Verification certificate requirements

- a) Final commercial Invoice having the following Information:
 - Name and full address of the supplier and importer
 - The International Non Proprietary name (INN) or the generic name of the health commodity and its strength. In case of a product containing more than one active ingredient, the name and strength of each ingredient should be specified.
 - The quantity to be imported for each health commodities and their respective values
 - Name and country of origin of the manufacturer
 - Name and address of the manufacturer
- b) Certificate of Donation with total value of donated health commodities if applicable
- c) A Packing List of the health commodities with following information:
 - Imported quantities
 - Batch Number or Serial number for medical equipment
 - Manufacturing & Expiry dates
- d) The product registration number issued by Rwanda FDA
- e) The port of entry
- f) Quality Control Certificate (Certificate of Analysis/conformity) for each batch or serial number issued by the Manufacturer.
- g) Proof of Payment of verification fees
- h) Certificate of origin

The Authority shall, prior to issuing a verification certificate, ascertain that the manufacturing facility from which the pharmaceutical products and/or medical devices to be imported are manufactured, complies with the internationally accepted Good Manufacturing Practice Guidelines adopted by the Authority.

An application for pharmaceutical products/medical devices import authorization shall be made using the standard form Doc. No. DIS/FOM/024- Application for Authorisation for Importation of Pharmaceutical products. (for manual applications in special cases)



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In case of a donation, the donor shall provide to the recipient of the pharmaceutical products and medical devices a certificate of donation, certified by an authorised person.

The certificate of donation shall indicate:

- i. Detailed address of the donor;
- ii. the conditions to be fulfilled by the recipient, if any;
- iii. the name of the manufacturer of the pharmaceutical products and/or medical devices;
- iv. the name of the pharmaceutical product and/or medical devices, its batch or lot number, manufacture and expiry dates;
- v. The total value of donated pharmaceutical products and/or medical devices;

The donor shall provide a detailed packing list of donated pharmaceutical products and/or medical devices.

The donor shall also provide quality control certificate or certificate of analysis for pharmaceutical products and/or medical devices and ISO or CE for medical devices and equipment.

The recipient of the pharmaceutical products and/or medical devices for donation shall:

- i. Submit a written undertaking to the authority, not to sell the donated pharmaceutical products and/or medical devices;
- ii. not to transfer the pharmaceutical products and/or medical devices without the written permission of the Authority; and
- iii. to make returns to the Authority showing how the pharmaceutical products and/or medical devices is distributed and used.

Labels and Leaflets for all imported pharmaceutical products and/or medical devices shall be in recognised official languages in Rwanda.

Article 8: Authorisation for importation of narcotic drugs and psychotropic substances.

- 1) Any person shall not import narcotic drugs or psychotropic substances unless an authorization is issued by the Authority.



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- 2) The import authorization for narcotics or psychotropic substances shall be in the standard format (Doc. No. DIS/FMT/027- Authorisation for Importation of Narcotics, Psychotropic substances or Precursors)
- 3) An application for a narcotics import authorization shall be made by a person issued with an import authorization under Article 7 of these Regulations.
- 4) Where the application is made by a manufacturer of a pharmaceutical product, the applicant shall furnish the Authority with evidence showing that the reason for the importation of the narcotic drugs or psychotropic substances is for the use of the narcotic drugs or psychotropic substances as a raw material for the manufacture of a finished or intermediate pharmaceutical product.
- 5) The Authority shall issue a narcotic or psychotropic substances import authorization where it is satisfied that the applicant meets the requirements set out in these Regulations and any applicable national and/or international laws.
- 6) Any person granted an authorization to import a narcotic drug or psychotropic substance shall provide quarterly reports to the Authority.

Article 9: Packaging for imported/exported pharmaceutical products and/or medical devices

- 1) The primary packaging of pharmaceutical product and/or medical devices shall be clearly labelled in officially recognized languages in Rwanda with the following information:
 - a) the trade or brand name;
 - b) the generic name of the pharmaceutical products and/or medical devices;
 - c) the quantities of active ingredients in the pharmaceutical products;
 - d) the dates of manufacture and expiry;
 - e) the batch or lot number/serial number;
 - f) special conditions of storage applicable;
 - g) the name and address of the manufacturer;
 - h) the physical (location) address of the manufacturing site;



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- i) the registration number of the pharmaceutical product and/or medical devices, where applicable;
- 2) The product information leaflet enclosed in or accompanying the imported pharmaceutical product shall be in officially recognized languages in Rwanda
- 3) A pharmaceutical products labelled “for sale only in specified countries” shall not be imported into Rwanda except where Rwanda is one of the specified countries.
- 4) The Authority may, in special circumstances, authorise the importation of a pharmaceutical product and/or medical device labelled “for sale only in specified countries” where Rwanda is not one of the specified countries.
- 5) Where the label of a pharmaceutical product and/or medical device shows evidence of alteration, it shall be deemed to be adulterated and shall not be allowed entry into Rwanda or shall be returned to the country of origin at the cost of the importer.
- 6) Evidence of alteration in the label includes circumstances where:
 - a) the entire label or a part of the label with the details such as the batch number or the date of manufacture of the pharmaceutical products and/or medical devices is removed;
 - b) there is evidence of removal of the original label and evidence of attaching another label or evidence of placing a label over the original label; or
 - c) there is evidence of erasing or concealing the original details of the label and replacing the details with other details.

Article 10: Container closure system

The inner primary package of an imported pharmaceutical product shall have tamper-evident seal designed in such a way that the pharmaceutical product cannot be opened without permanently damaging or breaking the seal.

Article 11: Verification of pharmaceutical products and/or medical devices by the Authority at ports of entry into Rwanda

The Authority shall inspect each batch or lot on arrival at a designated port of entry into Rwanda to confirm that:



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- a) the product complies with the relevant specifications;
- b) each batch is accompanied by a certificate of analysis, or a certificate of conformity or a test report.
- c) the pharmaceutical product has at least two third (2/3) of its shelf life.
- d) Valid import/export license
- e) Commercial invoice

Note: The imported products that are released under seal shall wait for inspection by the inspectors from the Authority before being used.

Article 12: Obligation to obtain an Export Authorization

No person shall export pharmaceutical products/medical devices from Rwanda without an export Authorization issued by the Authority.

Article 13: Requirements and eligibility for Pharmaceutical products and/or medical device export Authorization

Eligible applicants for pharmaceutical products and medical devices export authorization include:

- a) a company with pharmaceutical products or medical devices manufacturing authorization;
- b) a company with pharmaceutical products or medical devices wholesale authorization;
- c) a company with pharmaceutical products or medical devices retail authorization (only on medical prescription) in case not available on the local market;
- d) a beneficiary of a pharmaceutical products or medical devices donation;
- e) Non-governmental organizations (NGOs) with MOU with Ministry of Health (MOH) or Government of Rwanda;
- f) UN organizations and other international organizations intervening in Health sector;
- g) A tourist, a visitor in the country or any other person for justified reasons.



License/Verification certificate requirements

- a) Final commercial Invoice with the following Information:
 - i. Name and full address of the exporter and consignee
 - ii. The International Non Proprietary name (INN) or the generic name of the health commodity and its strength. In case of a product containing more than one active ingredient, the name and strength of each ingredient should be specified.
 - iii. The quantity to be exported for each health commodities and their respective values
 - iv. Name and address of the manufacturer
- b) Certificate of Donation with total value of donated health commodities if applicable
- c) A Packing List of the health commodities with following information:
 - i. Exported quantities
 - ii. Batch Number or Serial number for medical equipment
 - iii. Manufacturing & Expiry dates
- d) The product registration number issued by Rwanda FDA for products manufactured in Rwanda
- e) The port of export
- f) Quality Control Certificate (Certificate of Analysis/conformity) for each batch or serial number issued by the Manufacturer.
- g) Proof of Payment of verification fees

How to apply for export authorization?

An application for pharmaceutical products/medical devices export authorization shall be made using the standard form *Doc. No. DIS/FOM/021- Application for Authorisation for exportation of Pharmaceuticals products/medical devices.* (For manual applications in special cases)



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In case of a donation:

- a. the donor shall provide to the recipient of the pharmaceutical products and medical devices a certificate of donation, certified by an authorised person. The certificate of donation shall indicate:
 - i. Detailed address of the donor;
 - ii. the conditions to be fulfilled by the recipient, if any;
 - iii. the name of the manufacturer of the pharmaceutical products and/or medical devices;
 - iv. the name of the pharmaceutical product and/or medical devices, its batch or lot number, manufacture and expiry dates;
 - v. The total value of donated pharmaceutical products and/or medical devices;
- b. The donor shall provide a detailed packing list of donated pharmaceutical products and/or medical devices.
- c. The donor shall also provide quality control certificate or certificate of analysis/conformity for pharmaceutical products and/or medical devices.

Article 14: Authorisation for exportation of narcotic drugs and psychotropic substances.

- a) Any person shall not export narcotic drugs or psychotropic substances without an authorization issued by the Authority.
- b) The export authorization for narcotics or psychotropic substances shall be in the standard format (Doc. No. DIS/FMT/027- Authorisation for exportation of Narcotics or Psychotropic substances)
- c) An application for a narcotics export authorization shall be made by a person issued with an export authorization under Article 13 of these Regulations.
- d) The Authority shall issue a narcotic and psychotropic substances export authorization where it is satisfied that the applicant meets the requirements set out in these Regulations and any applicable national and/or international laws.



- e) Any person granted an authorization to export a narcotic drug or psychotropic substance shall provide quarterly reports to the Authority.

Article 15: Re-export of imported pharmaceutical products/medical devices not allowed into Rwanda

1. Where the Authority rejects imported pharmaceutical products/medical devices for reasons other than their quality, the importer of the rejected pharmaceutical product shall re-export them in the country of origin, within a period of one month from the date of the rejection.
2. Where the Authority rejects imported pharmaceutical products/medical devices, due to reasons of poor quality, they shall be destroyed by the Authority at the cost of the importer.
3. The reasons for re-export of pharmaceutical products/medical devices include
 - a) Pharmaceutical products/medical devices not registered in the country
 - b) Pharmaceutical products/medical devices not meeting specifications of labelling requirements
 - c) Pharmaceutical products/medical devices not allowed/withdrawn from Rwanda market
 - d) Any other reason that the Authority may deem necessary

Article 16: Procedure for re-export of pharmaceutical products/medical devices not allowed into Rwanda

1. For the purposes of Article 15, the person who re-exports pharmaceutical products/medical devices that are not allowed in Rwanda, shall make an application for verification, to the Authority.
2. The application shall be accompanied by the relevant invoices and other documents related to the pharmaceutical products/medical devices including the exact their point of destination and evidence of payment of the prescribed fees.
3. The Authority shall inspect the consignment to confirm the contents.



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4. The Authority shall issue a re-export permit to the person to re-export the pharmaceutical products/medical devices.
5. The Authority shall witness the loading of the pharmaceutical products/medical devices for re-export.
6. The person who re-exports the pharmaceutical products/medical devices shall submit to the Authority a written document of re-export issued by the relevant authorities at a port of exit from Rwanda, certifying that the pharmaceutical products/medical devices was allowed to be re-exported.

Article 17: Gazetted/approved ports of entry and exit

Pharmaceutical products/medical devices shall be imported or exported only through Gazetted ports of entry and exit.

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CHAPTER III: REFUSAL, VALIDITY, SUSPENSION AND WITHDRAWAL OF AN IMPORT/EXPORT AUTHORIZATION

Article 18: Refusal to grant an Authorization

1. An authorization to Import/export shall not be granted where the Authority finds the applicant not complying with the minimum requirements prescribed in these Regulations.
2. The refusal letter shall be issued to the applicant in the standard format (*Doc. No. DIS/FMT/019- Refusal to Grant Authorization*).

Article 19: Validity of an Authorization

1. An authorization shall be valid for 3months from the date of its issuance.
2. An authorization is issued to an applicant and shall not be transferable.

Article 20: Suspension or withdrawal of an authorization

1. An authorization may be suspended or withdrawn where the Authority finds that the applicant violated any of the conditions under which authorization was granted for; or has ceased to be fit to carry out the business.
2. The notice of suspension or withdrawal shall be issued by the Authority in the following standard format:
 - a. *Doc. No. DIS/FMT/024-Notification of Suspension of Authorization*; and
 - b. *Doc. No. DIS/FMT/025-Notification of Revocation/Withdrawal of Authorization*.

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CHAPTER IV: RENEWAL AND VARIATION OF AN AUTHORIZATION

Article 21: Renewal of an authorization

An authorization shall be renewed after three months from the date it was issued, upon submission of an application for renewal and after meeting all requirements.

Article 22: Variation of an authorization

1. Whenever the Authority varies, amends, or imposes any new condition on the authorization requirements, the Authority shall communicate the return of such authorization to be duly endorsed within reasonable time.
2. An application shall be made to the Authority for review and approval of any variation made on the details of the issued authorization.

A large, semi-transparent watermark of the Rwanda FDA logo is centered on the page. It features a stylized figure holding a staff, surrounded by a wreath and a sunburst, with the text "RWANDA FDA" and "Rwanda Food and Drugs Authority" below it.

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CHAPTER V: MISCELLANEOUS

Article 21: Compliance with other requirements

A company that has been granted with an authorization shall comply with any other requirements as may be specified by the Authority.

Article 22: Penal Code provision

Any person who Imports or exports any pharmaceutical product or medical device without a permit issued in terms of Articles 7 and 13; or Fails to comply with the conditions of a permit issued to him or her; shall be guilty of an offence and Rwanda FDA may impose administrative sanction and fine or cause the prosecution of offending parties as the case may be.

Article 23: Commencement

These regulations come into force on the date of signature and publication by the Authority.

Article 24: Repealing Provisions

All Provisions contrary to these regulations are hereby repealed.

End of Document

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