RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR IMPORTATION AND EXPORTATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

JULY, 2021

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GUIDELINES DEVELOPMENT HISTORY

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FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the 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, medical devices, and diagnostics especially in articles 3, 8, and 9.

Reference to the provisions of the technical regulation No CBD/TRG/002 Rev_0 governing the control of importation and exportation of pharmaceutical products and medical devices.

These guidelines provide guidance on the information and documentation required in any application submitted to Rwanda FDA by an importer or exporter of pharmaceutical products, medical devices, and diagnostics as set in these guidelines. Adherence to the set requirements will minimize the delays in processing applications of import and export permits; hence speed up the provision of quality services to the clients.

These guidelines also provide guidance to the inspectors to minimize risks of trading sub-standard products among nations and therefore prevent dumping unfit 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. Charles KARANGWA
Ag. Director General

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ACCRONYMES AND ABBREVIATIONS

Rwanda FDA:	Rwanda Food and Drugs Authority
NGOs:	Non-Government Organizations
COA:	Certificate of Analysis
PoE:	Port of Entry
GDL:	Guideline
MoU:	Memorandum of Understanding
PRIMS:	Pharmaceutical Regulatory information system
GMP:	Good Manufacture practices
ISO:	International Organization for Standardization
Ce :	Conformité Européenne
IP :	Investigational Product

1.0. GLOSSARY

In these guidelines, unless the context otherwise states:

Authoritymeans 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 the applicant under the 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 other; Products regulated to recipients in 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 for sale;

Importermeans a person or organization that brings goods or services into a country from abroad for sale;

Manufacturer means a person who sells medical devices under their own name, or under a trade- mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf;

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;

A pharmaceutical product means a drug /medicine used to diagnose, cure, treat, or prevent disease in human and veterinary medicine;

Import Visa/Authorizationmeans a stamp marked on a proforma invoice indicating that applicants' documents have been verified and pharmaceutical products /Medical devices have

been granted permission to enter 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 permit/License means a certificate issued to the importer by Rwanda FDA authorizing him/her to import pharmaceutical products or medical devices into the country after complying with the importation requirements;

Export Permitmeans a permit issued to an exporter by Rwanda FDA, authorizing him/her to export pharmaceuticals or medical devices from the country;

Controlled substancesmean 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.

2.0. INTRODUCTION

The safety, efficacy, and quality of pharmaceutical products and medical devices 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, both nationally and internationally conforms 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, medical devices, and diagnostics 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 chapter provides for the requirements and procedures to be followed up during the importation of pharmaceuticals and medical devices while the second one outlines the requirements and procedures for the exportation of these products.

3.0. SCOPE

These guidelines apply to pharmaceutical products and medical devices 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 guideline outlines requirements for the importation and exportation of pharmaceutical products and medical devices.

MODULE I: IMPORTATION OF PHARMACEUTICAL PRODUCTS, MEDICAL DEVICES AND DIAGNOSTICS

1.1 Eligibility for imports

Eligible applicants for pharmaceutical products and medical devices authorization include:

i. A company with pharmaceutical products, medical devices, or diagnostics manufacturing Authorization.
ii. A company with pharmaceutical products, medical devices, or diagnostics wholesale Authorization.
iii. A company with pharmaceutical products, medical devices, or diagnostics retail Authorization (only on medical prescription) in case the product is not available on the market.
iv. Clinical trial investigator.
v. Persons importing medical devices or pharmaceutical products for medical purpose.
vi. Exhibitors.
vii. A beneficiary of pharmaceutical products, medical devices, or diagnostics donation.
viii. Referral Hospital.
ix. Research institutions/researchers holding a valid Clinical Trial Approval Certificate issued by the Authority or ethical committee approval/certificate or approval from government institutions (for veterinary research).
x. Non-governmental organizations (NGO) with Memorandum of Understanding (MOU) with the Ministry of Health or Government of Rwanda.
xi. Government institutions.
xii. UN organizations intervening in the Health sector.
xiii. A tourist, a visitor in the country, or any other person for justified reasons as per article 35 of law 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.
xiv. Private health facilities in special cases as per article 35 of the law N0 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.

1.2 General conditions for obtaining an import license

i. All pharmaceutical products, medical devices, and diagnostics must be imported by importers whose premises are licensed by Rwanda FDA or who fall within the eligible importer category.
ii. All pharmaceutical products, medical devices, and diagnostics to be imported must be registered or appear on Rwanda's FDA authorized list unless granted special approval by the Authority.
iii. The application for import license of investigational medical products and trial products for the purpose of conducting clinical trials in Rwanda must be accompanied by a valid clinical trial Approval certificate issued by the Authority.
iv. Donated pharmaceutical products must be fit for human consumption as stipulated in the ministerial instructions No 20/12 of 18/02/06 determine the guideline for donated drugs in Rwanda.
v. Eligible importers shall pay prescribed non-refundable verification fees if applicable.

vi. All imported pharmaceutical products must have at least two-thirds of their shelf life remaining when they arrive at the port of entry.

vii. The primary packaging of pharmaceutical products and or medical devices must be clearly labelled in officially recognized languages in Rwanda with the following information:

a. Trade name or brand name.
b. The generic name of the pharmaceutical products and or medical devices.
c. The quantities of the active ingredients in the finished pharmaceutical products.
d. The dates of manufacture and expiry date.
e. The batch or lot number/serial.
f. Special conditions of storage if applicable.
g. The name and address of the manufacturer.
h. The physical address of the manufacturing site.
i. The registration number of the pharmaceutical product and medical devices, where applicable.

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

ix. 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

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

1.3. Procedure for the importation of pharmaceutical products and medical devices

i. The eligible importer must apply for an import visa and import license for each consignment to the authority.

ii. All documentation requesting an import Visa and import license shall be uploaded in the product regulatory information system (PRIMS) in an appropriate format for verification and approval.

1.3.1 Visa import authorization requirements:

i. A proforma invoice signed by a technician and stamped originally showing manufacturer name, description, quantity, and value for each product in convertible currency, full address of exporter and importer companies, country of origin, and Clear description of items including brand and common names as declared in information of pharmaceutical products and medical devices submitted to Rwanda FDA, mode of shipping (air, road)

ii. Proof of compliance to the international standards or European Community standards (ISO or CE certificate) issued by a regulatory body (for medical devices and consumables)

iii. Valid good manufacturing practice certificate (GMP) for pharmaceutical products issued by the competent Regulatory Authority.

iv. A pharmaceutical product or medical device import Visa (Annexe I) shall be valid for six (6) months from the date of approval.

The application will be processed in 24 hours 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.

1.3.2 Special import visa conditions

A special case import Visa shall be issued for unregistered /unauthorized pharmaceutical products /medical devices in the following conditions:

i. If the imported pharmaceutical products/medical devices have no registered therapeutic equivalent (alternative) products available in Rwanda with reasons for import found to be valid.
ii. Applications for the importation of medicines or medical devices for personal use should be accompanied by a medical prescription from an authorized medical practitioner in Rwanda.
iii. Importation of pharmaceutical products, medical devices, or diagnostics to be used in the clinical trial shall be submitted accompanied by a valid clinical trial approval certificate issued by the Authority, or ethical committee approval/certificate or approval from government institutions(for veterinary research)
iv. An Official Certificate of importation of controlled substances will be issued to the applicant importing narcotics and psychotropic substances and precursors in a standard format as specified in the annex II and the visa will be valid for six (6) months from the date of issue.

1.3.3 Import License certificate requirements:

i. An application letter addressed to the Director-General of the Authority requesting the Import license.
ii. Commercial Invoice having the following Information:
   a) Name, full address of the supplier, and importer.
   b) Trade name or proprietary name (specialty) of medical products if applicable.
   c) International non-proprietary name or generic name, dosage form, and strength of pharmaceutical products. In the case of a product containing more than one active ingredient, the name and strength of each ingredient should be specified.
   d) The quantity to be imported for each health commodity and their respective value, name, and country of origin of the manufacturer.
   e) Name and address of the manufacturer.
iii. Certificate of donation with the total value of donated health commodity if applicable
iv. 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.
v. A packing list of the medical products with the following information:
   a) Imported quantities.
   b) Batch number or serial number for medical equipment and expiry date where applicable.
   c) The product registration number issued by the Authority where applicable.

vi. Certificate of analysis or certificates of conformity for each batch or serial number issued by the manufacturer.
vii. A Proof of Payment of verification fees as specified in the Regulation governing services fees, tariff, and fines.
viii. Certificate of origin/export license/sanitary certificate/.
ix. A Valid Visa issued by the Regulatory Authority.

The import license (Annexe III and IV) shall be valid for three (3) months from the date of approval, and it can be renewed if the time limit granted in the license is over.

1.3.4 Authorization to Import Narcotic drugs and psychotropic substances

An application for narcotic, psychotropic, and precursor substances import license is made by a person issued with an import Visa under article 8 of the regulation governing control of importation and exportation of pharmaceutical products and medical devices.

1.3.5. Importation of donated pharmaceutical or medical devices

i. All Donations will be in accordance with the recipient's need and should comply with the existing government policies, laws, guidelines and administrative arrangements
ii. Donation should comply with applicable standards and there will not be double standards regarding quality of donated items. Unacceptable medical devices, pharmaceutical products in the donor country shall not be allowed into the recipient's country.
iii. Any person, institution and organization intending to donate medical devices will be required to apply for import permit through Rwanda FDA Online portal.
iv. Application should be accompanied by the following documents:
    a. A support letter from the relevant authority which supports such donation (if applicable)
    b. A support letter from the importer
    c. Donation certificate
    d. Declaration of Conformity of donated medical devices or pharmaceutical products from manufacturer/donor/certified company (where applicable)
    e. certificate of analysis for sterile medical devices, pharmaceutical products (where applicable)
    f. certificate of refurbishment for used medical devices (issued by manufacturer/donor of certified company)
v. Donated medical device, or pharmaceutical products should have a shelf life of not less than 60% of the original shelf life (where applicable).
vi. If the medical device is used, it must be reconditioned, 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 order
vii. Donated medical devices shall include all essential parts, accessories and working materials

viii. For software operated medical devices, the software shall be either preloaded and/or accompanied by the software package.

ix. 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 that it shall be calibrated and inspected by a qualified Medical Physicist.

x. Damaged, outmoded, and redundant medical devices and diagnostics for which spare parts and consumables are no longer available will not be accepted.

xi. The permit issued for importation of donated medical devices, or pharmaceutical products will be valid for six (6) months.

xii. Label of the donated medical device and pharmaceutical products

Medical devices or pharmaceutical products depending on their nature and type, the label of donated medical device, pharmaceutical products should have the following minimum information:

a. The name of the medical device, in vitro diagnostic or laboratory equipment
b. Model number or serial number;
c. Manufacturing and expiry dates; (where applicable)
d. Life span or expectancy;
e. Name and address of the manufacturer;
f. Handling and storage requirement(s);
g. Technical direction for use;
h. An indication, if applicable, that the medical device, pharmaceutical products is intended to be used
i. If it is a refurbished device, an indication that the device or laboratory equipment is refurbished;

xiii. If donated medical device, in vitro diagnostic and laboratory equipment are found to be unfit, the recipient shall dispose or return the product to the country of origin at his/her own expenses.

1.3.5 Inspection of imported consignments at ports of entry

Each consignment of pharmaceutical products, medical devices, and diagnostics must be examined by a port of entry inspection specialist at the port of entry to ensure that it complies with the approved requirements and regulations before they are released. The verification of investigational products must be carefully conducted in a manner that the investigational product (IP) is not altered and where possible consignment may be released under seal in order to maintain the storage conditions of IP as specified by the sponsor or manufacturer.

The consignment must be accompanied by the following requirements:

a) A valid import license.
b) A corresponding commercial invoice.
c) A certificate of Analysis for each batch or a certificate of conformity or a test report.
d) Pharmaceutical products must have at least 2/3 of their shelf life remaining at the port of entry.

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

1.3.6 Sampling of imported products

The inspector at the port of entry may take samples of pharmaceutical products or medical devices or diagnostics for further investigation during the inspection and release of the consignment if suspected poor-quality product (Annexe V) or in case of routine sampling.
Routine samples: the consignment from which the samples have been taken shall be released to the importer for distribution.
Suspicious consignment in which sample was taken for analysis shall not be released nor shall it be distributed until the laboratory results are available for decision-making.

1.3.7 Release of consignments

A port of entry inspector shall release the consignment if it meets the requirements for the importation of pharmaceutical products, medical devices, and diagnostics by stamping the supporting documents "**APPROVED".**
In the case of a partial shipment, an inspector will write "PARTIAL SHIPMENT" on the import license and invoice, along with the quantities imported and remaining.

1.3.8 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 one month. The following are the reasons for re-export of a consignment:
   a) Pharmaceutical product or medical devices or diagnostics not registered in the country
   b) Pharmaceutical products or medical devices or diagnostics not meeting labelling specifications.
   c) Pharmaceutical product or medical devices or diagnostics not allowed or withdrawn from the Rwanda market
   d) Any other reason the authority may deem necessary.
ii. If a consignment is rejected due to quality reasons, a seizure certificate will be issued and thereafter follow procedures for safe disposal..
iii. A Destruction Certificate after completion of the destruction exercise is issued and a report is given to Rwanda FDA.
iv. Where the consignment is rejected/detained an inspector will write a PV de constat with recommendations to follow safe disposal measures.

1.3.9 Authorized ports of entry

Air	Land(road)
1. Kigali International Airport	1. Kagitumba 2. Rusumo 3. Rusizi 1, 2 4. La Corniche 5. Poids lourds 6. Dubai port

MODULE II
EXPORTATION OF PHARMACEUTICAL PRODUCTS, MEDICAL DEVICES, AND DIAGNOSTICS

2.1 Eligibility for Export

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

i. A company with pharmaceutical products or medical devices or diagnostics manufacturing Authorization.
ii. A company with pharmaceutical products or medical devices or diagnostics wholesale Authorization.
iii. A beneficiary of pharmaceutical products or medical device donation.
iv. Non-governmental organizations (NGO) with MOU with the Ministry of Health or Government of Rwanda.
v. Government Institutions.
vi. UN organizations intervening in the Health sector.
vii. A tourist, a visitor in the country, or any other person for justified reasons as per article 35 of law 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.
viii. Clinical trial sponsors and investigators;
ix. Persons authorized by Rwanda FDA

2.2 Specific Conditions for export

i. All pharmaceutical products, medical devices, and medical devices must be exported by importers whose premises are licensed by Rwanda FDA or who fall within the eligible importer category.
ii. NGO or faith-based institutions shall be required to submit MOU with the ministry of health.
iii. Exporters of pharmaceutical products and medical devices should have a valid export permit issued by the Authority (Annexe VI).
iv. All consignments of pharmaceutical products /medical devices to be exported must go through the authorized PoE.

2.3. Procedure for Exportation of pharmaceutical products, medical devices, or diagnostics.

i. An eligible exporter who wishes to export pharmaceutical products or medical devices should apply info@rwandafda.gov.rw along with a letter addressed to the Director-General, Rwanda FDA, stating the category of products to be exported, the destination (country), and the port of exit.
ii. All application for an export license shall be accompanied by the following documents:
   a) Application letter addressed to the Director-General of Rwanda FDA includes the category of the products to be exported, destination (country), port of exit.

b) Proforma Invoice shall have a signature and stamp of exporter including the following information: name and address of the exporting and full address of importing company, date of the proforma, and items with the quantity to be exported and their respective values.
c) Certificate of analysis from the authorized laboratory for every batch with details of tested parameters if applicable.
d) A Packing List with the following details: Batch Number or Serial number for medical equipment and Manufacturing & Expiry dates, quantity and value of the category item to be exported.
e) Operational authorization of the importer.
f) Operational authorization of the exporter.
g) Proof of Payment of verification fees as specified in the Regulation governing services fees, tariff, and fines.

iii. An export permit shall not be transferable and shall be issued to cover only one shipment and the permit will be valid for three (3) months from the date of issuance.
iv. 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.
v. Exporting wholesale pharmacies will be required to provide evidence of the source of the exported products.
vi. All applications for export will be processed within 1 day (working day).

3. REVIEW AND APPEAL PROCEDURE

i. Any person aggrieved by the decision of the Authority in relation to any application for importation or exportation of devices may appeal for review of the decision to the Director General within a period of 14 days from the date of receipt of the decision.
ii. The Authority may review its decision, reject or vary the condition of approval.
iii. 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.

4. REFERENCES

i. The law N0 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.
ii. Ministerial instructions No 20/12 of 18/02/06 determine the guideline for donated drugs in Rwanda.
iii. The regulation governing control of importation and exportation of pharmaceuticals and devices.
iv. 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.

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ENDORSEMENT OF THE GUIDELINES

	Author	**Authorized by**	**Approved By**
Title	Division Manager of Food and Drugs Import & Export Division	Head of Food and Drugs Inspections & Safety Monitoring Department	Director General
Names	**Theobald HABIYAMBERE**	**Alex GISAGARA**	**Dr Charles KARANGWA**
Signature			
Date	14/07/2021	14/07/2021	14/07/2021

ANNEXES

ANNEXE I: PRIMS IMPORT APPROVED VISA

RWANDA FOOD AND DRUGS AUTHORITY
Telephone: +250788223004
Email: info@rwandafda.gov.rw
Address: NYARUTARAMA BLOCK, KG 4 AVE
Kigali, Rwanda
Website: rwandafda.gov.rw

Special Case Import

Visa No : .....
Name of firm / Individual : .....
TIN :
Premise No : .....
Postal Address :
Physical Location :
Total Product Value : .....

This certificate authorizes the above named firm / individual to import Rwanda FDA regulated products specified in Proforma Invoice number .....

Product Category :

No. Product	Pack Size	Quantity	Unit Value	Total Value
.. ..	.....	.....	.....	.....
			Total	.....

Name of Supplier / Exporter / Consignee : .....

Address :

Date : .....

This Special Case Import Visa is valid for only, 6 months from the issue date

Rwanda Food and Drugs Authority

ANNEXE II: OFFICIAL CERTIFICATE OF IMPORTATION OF CONTROLLED SUBSTANCES

RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 84 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

OFFICIAL CERTIFICATE OF IMPORTATION OF CONTROLLED SUBSTANCES Nº: ...../YEAR

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 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 Milligrams (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 N°:	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 six (6) months from date of its signature

Done at Kigali, on .....

By Authority Delegation

.....

HoD Food and Drugs Inspection and Safety Monitoring

ANNEXE III: IMPORT LICENCE FORM

RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 84 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

Ref N°: DIS/……./FDA/YEAR

IMPORT LICENSE OF …… (PRODUCT CATEGORY).

Reference made to your request **N° ……./YEAR** dated **DAY/MONTH/YEAR, IMPORTER NAME** based in **……**, 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 beverages, 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…… RWF

AGREEMENT FOR REMOVAL
Port of entry is □……
Done at Kigali on ……
By Authority Delegation
……
HoD Food and Drugs Inspection and Safety Monitoring

Doc. No.: …/GDL/0..	Revision Date: …/…/….	Review Due Date: …/…/….
Revision No.: 0	Effective Date: …/…/….	

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ANNEXE IV: PRIMS IMPORT APPROVED LICENSE

IMPORT/EXPORT APPROVED LICENSE

Date:

Application Details

License No: ....

Visa No: ....

Invoice No: ....

Consignee Details

Name: ....

Supplier Details

Name: ....

Physical Address: ....

Physical Address: ....

Postal Address: P.O BOX ....

No.	Product Name	Batch Details	Quantity	Amount	Status
..	....	....	....	....	....
..	....	....	....	....	....
..	....	....	....	....	....
..	....	....	....	....	....
..	....	....	....	....	....

Total Value: ....

This License is valid for only 3 months from the issue date

ANNEXE V: SUSPECTED POOR QUALITY PRODUCT REPORTING FORM

PSM/FOM/009

P O. Box 84 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

SUSPECTED POORQUALITYPRODUCT REPORTING FORM

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 N^{O}		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
☐OthersSpecify) ……

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? YESNO☐ ☐

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 completed please send it to Rwanda FDA.

ANNEXE VI: EXPORT LICENSE FORM

RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 1948 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

Ref N°: DIS/ /FDA/YEAR

EXPORT LICENSE OF ..... (PRODUCT CATEGORY)

Reference made to your request **N° ...../YEAR** dated **D/M/YEAR, EXPORTER NAME** based in ....., 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 consumables, food and beverage products the exported products are detailed below:

Product Name	**Quantity**	**BATCH N°**	**Manufacture Date**	**Expiration Date**

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

AGREEMENT FOR REMOVAL

Port of exit is □ .....

Done at Kigali on .....

By Authority Delegation

.....

HoD Food and Drugs Inspection and Safety Monitoring

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ANNEXE VII: APPLICATION FORM FOR IMPORATION OF INVESTIGATIONAL MEDICAL PRODUCT

Date of application		
Title of the study		
Clinical Trial Approval Certificate Number		
Date of issuance		
Date of Expiration		
Sample size/Participant to be recruited		
Name of Investigational Product (IP) Proprietary Product Name (if relevant)		
International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API), strength, pharmaceutical form.		
Name (s) and complete address (es) of the manufacturer (s) of the Investigational product (s), including the final product release if different from the manufacturer.		
IP Therapeutic Classification		
IP Route of Administration		
Quantity needed for entire Trial		
Quantity to be imported		
Storage conditions		
Special Precautions		
Name's placebo or comparators (if applicable		
Quantity to be imported		
Storage conditions		
other		
DECLARATION OF THE APPLICANT		

I DECLARE THAT:

- ✓ The information provided on the application is correct,
- ✓ The imported Investigational products will be distributed to the approved clinical trial sites approved by Rwanda FDA
- ✓ I confirm that the investigational products are manufactured in accordance with good manufacturing practices (GMP) and that they will be stored / distributed under appropriate conditions
- ✓ I will inform the Authority the quantity of investigational products and/or Placebos destroyed according to the Rwanda FDA requirements

SIGNATURE OF APPLICANT

Applicant names	**Phone number**	**Signature**