GUIDANCE DOCUMENT ON IMPORT/EXPORT OF MEDICINES AND OTHER HEALTH COMMODITIES

1.0 Purpose

The purpose of this guidance document is to outline the requirements related to the importation of all health products.

2.0 Scope

This guidance document applies to all health commodities as defined by the Law No. 47/2012 of 14/01/2013 relating to the Regulation and Inspection of Food and Pharmaceutical products and Law No.03/2012 of 15/02/2012 governing Narcotic drugs, Psychotropic Substances and Precursors in Rwanda. This includes medicines, medical devices and medical equipment, medical consumables and laboratory reagents, raw materials for manufacture of medicines. No person shall import and introduce into the country health commodities unless he/she has an import VISA granted in accordance with the provisions of this Law.

3.0 Definitions

Import Visa: A visa in terms of import control is a stamp marked on the applicant’s proforma invoice by the National Medicines Regulatory Authority of the country (NMRA) to indicate that the applicant's import documents have been verified and medicines detailed on the proforma invoice have been granted permission to enter into the country. The Visa gives the right to the importer to confirm an order to the supplier and this one can issue the commercial invoice of products that have been granted an Import Visa.

Import License: An import license is a certificate/ import permit addressed to the importer after complying with the import requirements. It confirms the list of imported products and help to clear them from customs office.
4.0 Eligibility for getting import/Export permit

Eligible Importers/Exporters of medicines and other health commodities are in the following categories:

1. Government Institutions (GoI), UN organizations and other international organizations intervening in Health sector.
2. Non-Governmental Organizations (NGOs) with MoU with MoH or GoR,
3. Authorized wholesale Pharmacies,
4. Authorized Retail pharmacies in special case
5. A tourist, a visitor in the country or any other person for justified reasons
6. Private Health Facilities in special cases,
7. Holders of ethical clearance certificate to conduct clinical trials in the country
8. Donations by individuals or organizations to meet specific needs of the country
9. Pharmaceutical Manufacturers importing raw materials for manufacture of medicines

5.0 Requirements for import permit of health commodities

5.1 Import Visa

1. A motivation letter addressed to Honorable Minister of Health showing the proforma invoice number and category of the products to be imported (Annex 1a)
2. Proof of eligibility to get import permit of health commodities
3. Two (2) Proforma Invoices signed by technician and stamped originally showing Manufacturer’s name, quantity for each product, full address of Exporter Company and Country of Origin.
4. Proof of Establishment License issued by the Health Regulatory Authority in the country of origin.
5. Proof of Pharmaceutical product Registration (Certificate) issued by the Health Authorities in the country of origin. [For medicines only]
6. Proof of compliance to Good Manufacturing Practices (GMP certificate) issued by Regulatory Body in the country of origin. [For medicines only]
7. Proof of compliance to International Standards or European Community Standards (ISO or CE certificate) issued by Certified Regulatory Body; [For medical equipment only]
8. Certificate of conformity and/or Quality Control Tests; [For medical equipment only]
9. Proof of Payment of verification fees (if applicable)
10. Copy of tender contract (if applicable)

5.1 Import License:

1. A motivation letter addressed to Honorable Minister of Health showing the invoice number and category of the products to be imported (Annex 1b)
2. Proof of eligibility to get import permit of health commodities
3. A well completed form of data related to health commodities’ importations (Annex 2)
4. Original Import Visa issued by the MOH
5. Definitive/Commercial Invoice having the following Information:
   - Name and full address of the supplier
   - 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 commodity
   - Name and country of origin of the manufacturer

6. Certificate of Donation with total value of donated health commodities (if applicable)
7. A Packing List of the health commodities with following information:
   - Imported quantities
   - Batch Numbers [Serial number for medical equipment]
   - Manufacturing & Expiry dates (if applicable). The expiry dates should be at
     least 2/3 of the product’s shelf life at arrival in the country.

8. Quality Control Certificate (Certificate of Analysis) for each batch for medicines
    and certificate of conformity for medical equipment issued by the Manufacturer.
9. Copy of tender contract (if applicable)

NOTE:
1. For narcotic, psychotropic and other controlled substances, an official import
   certificate is requested (Annex 3)
2. The consignment is inspected for compliance with claimed specifications and samples
   may be taken for quality control tests.
3. Substandard or non-registered health commodities shall be re-exported or incinerated.
   The cost related to this exercise will be paid by the importer
4. All supporting documents should be in English or French

5.1 Export License:
   1. A motivation letter addressed to Honorable Minister of Health showing the invoice
      number and category of the products to be imported (Annex 1c)
   2. Proof of eligibility to get import/export permit of health commodities
   3. A well completed form of data related to health commodities’ export
   4. Proof of import license and import Visa
   5. Certificate of Donation with total value of donated health commodities if applicable
   6. Definitive/commercial Invoice having the following Information:
      - Name and full address of the local supplier
      - Name and full address of the Client
• 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 exported for each health commodity
• Name and country of origin of the manufacturer

10. A Packing List of the health commodities with following information:

• Exported quantities
• Batch Number or Serial number for medical equipment
• Manufacturing & Expiry dates (if applicable). For the Pharmaceutical products and medical consumables, the expiry dates should be at least 2/3 of the product’s shelf life at arrival in the country.

0 9 OCT 2014

Done at Kigali on,......................

Dr. Theophile DUSHIME
Director General of Clinical Services
Annex 1a

<Applicant>
<Telephone and Email address>
<Address>
<Post code> <Town>
<Country>

<Date/Month/Year>

>To Honourable Minister>
<Ministry of Health Rwanda>
<P. O. Box 84 Kigali>
<Rwanda>

Subject: Application for an Import Visa of Health commodities as detailed on the Proforma Invoice No<insert the number and date> From<Company/ country of origin>

Honourable Minister,

We are pleased to submit our Application Dossier for an import Visa of: (Tick as appropriate)

☐ Pharmaceutical products ☐ Narcotic Substances ☐ Psychotropic substances
☐ Medical consumables ☐ Other controlled substances
☐ Medical equipment
☐ Laboratory reagents
☐ Other related health commodities

We confirm to submit all requirements for getting an import Visa of health commodities as per guidance for import control of health commodities issued by Ministry of Health.

Yours sincerely,

<Signature>
>Name>
>Title>
<Phone number>
Annex 1b

<Applicant>
<Telephone and Email address>
<Address>
<Post code> <Town>
<Country>

<Date/Month/Year>

<To Honourable Minister>
<Ministry of Health Rwanda>
<P. O. Box 84 Kigali>
<Rwanda>

Subject: Application for an Import License of Health commodities as detailed on the commercial Invoice N°<Insert the number and date> From<Company/ country of origin>

Honourable Minister,

With reference to the import Visa <Insert import Visa number and date>, we are pleased to submit our Application Dossier for an import License of: (Tick as appropriate)

☐ Pharmaceutical products  ☐ Narcotic Substances  ☐ Psychotropic substances

☐ Medical consumables  ☐ Other controlled substances

☐ Medical equipment

☐ Laboratory reagents

☐ Other related health commodities

We confirm to submit all requirements for getting an import License of health commodities as per guidance for import control of health commodities issued by Ministry of Health.

Yours sincerely,

<Signature>
<Name>
<Title>
<Phone number>
Annex 1c
<Applicant>
<Telephone and Email address>
<Address>
<Post code> <Town>
<Country>

<Date/Month/Year>

<To Honourable Minister>
<Ministry of Health Rwanda>
<P. O. Box 84 Kigali>
<Rwanda>

Subject: Application for an Export License of Health commodities as detailed on the commercial Invoice No<Insert the number and date> to<Company/ country of export>

Honourable Minister,

With reference to the import License<Insert import license number and date>, we are pleased to submit our Application Dossier for an Export License of: (Tick as appropriate)

☐ Pharmaceutical products  ☐ Narcotic Substances  ☐ Psychotropic substances

☐ Medical consumables  ☐ Other controlled substances

☐ Medical equipment

☐ Laboratory reagents

☐ Other related health commodities

We confirm to submit all requirements for getting an Export License of health commodities as per guidance for import control of health commodities issued by Ministry of Health.

Yours sincerely,

<Signature>
>Name>
>Title>
<Phone number>
Annex 2 English:

REPUBLIC OF RWANDA

MINISTRY OF HEALTH

www.moh.gov.rw
P.O. Box 84 KIGALI

HEALTH COMMODITIES IMPORT DATA COLLECTION FORM

Name of Applicant Establishment: .................................................................

Import Visa No .............................................. obtained on: ........................................

Invoice No ...................................................... dated: ........................................

Ministry having Health in its attributions

"Article No 34 & 35 LAW N° 47/2012 OF 14/01/2013 relating to the Regulation and Inspection of Food and Pharmaceutical products"
Annex 2 French:

REPUBLIQUE DU RWANDA

MINISTERE DE LA SANTE

www.moh.gov.rw
B.P. 84 KIGALI

FICHE DE COLLECTE DES DONNEES RELATIVES AUX IMPORTATIONS

Nom de l’établissement demandeur: ........................................................................................................

Visa d’importation No ................................obtenu le : ...........................................................................

Facture definitive N° : ........................................date : ...........................................................................

Office douanier de: .................................................................................................................................

Fournisseur : ...........................................................................................................................................

Pays d’origine : ...........................................................................................................................................

Valeur de la facture en devise : ..................................................................................................................

Valeur en Frw (Taux moyen BNR, cours du jour) : ..................................................................................

Fait à ........................................................................................................................le............................

Nom, signature du Technicien responsable et cachet de l’Etablissement demandeur

N.B :
Toute opération d’importation des produits de Santé nécessite un visa d’importation préalable délivré par le Ministre ayant la santé dans ses attributions.

« Article No 34 et 35 de la Loi N° 47/2012 du 14/01/2013 Portant Réglementation et Inspection des produits alimentaires et pharmaceutiques »
CERTIFICAT OFFICIEL D'IMPORTATION DES PRODUITS LICITE STUPEFIANTS PSYCHOTROPES N° …………..

Convention unique sur les stupéfiants de 1961
Convention de 1971 sur les substances psychotropes

Le Ministère de la Santé charge de l'application des lois et règlements relatifs aux stupéfiants et aux substances psychotrope visés par les conventions et protocoles internationaux, autorise par la présente l'importation de :

<table>
<thead>
<tr>
<th>Nom commercial de la préparation</th>
<th>Dénomination commune internationale</th>
<th>Forme Pharmaceutique et quantité</th>
<th>Contenu unitaire en principe actif</th>
<th>Quantité total a importé</th>
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</table>

Source :

<table>
<thead>
<tr>
<th>Importateur</th>
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</thead>
<tbody>
<tr>
<td>Nom :</td>
</tr>
<tr>
<td>Profession :</td>
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<tr>
<td>Adresse :</td>
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<th>Exportateur</th>
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<tr>
<td>Nom</td>
</tr>
<tr>
<td>Adresse :</td>
</tr>
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</table>

Sous réserve des conditions suivantes :

✓ Mode d’expédition :
✓ Bureau de douane d’entrée :
✓ Raisons d’importation (médicales ou scientifiques) :

L'envoi ne sera en aucun cas adressé à une boîte postale ou un entrepôt de douane sauf (pour ce dernier cas) autorisation expresse préalable (cette autorisation ne peut être donnée dans le cas des substances ou des préparations du tableau I de la Convention sur les substances psychotropes de 1971).

Fait à Kigali ..............................................

Pour le Ministre de la Santé

Titre du fonctionnaire habilité: ..............................................

Signature: ...........................................................................
Official Certificate of importation of illicit Narcotic and Psychotropic substances N° ..........................

Single Convention on Narcotic Drugs, 1961
1971 Convention on Psychotropic Substances

The Ministry of Health responsible for the implementation of laws and regulations relating to narcotic drugs and psychotropic substances covered by international conventions and protocols, hereby authorize the importation of

<table>
<thead>
<tr>
<th>Brand name of the substances</th>
<th>International Nonproprietary Name</th>
<th>Pharmaceutical form and quantity</th>
<th>Content of active ingredient per unit</th>
<th>Total quantity to be imported</th>
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Source :

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<tr>
<td>Name:</td>
<td>Profession:</td>
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<tr>
<td>Address:</td>
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<table>
<thead>
<tr>
<th>Exporter</th>
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<tbody>
<tr>
<td>Name:</td>
<td>Address:</td>
</tr>
</tbody>
</table>

Subject to the following conditions:
- Shipping:
- Customs office of entry:
- Reasons import (medical or scientific):

The shipment will in no case addressed to a P O Box or a bonded warehouse except (in this latter case) express permission (authorization may not be given in the case of substances or preparations in Schedule I of the Convention on psychotropic Substances of 1971)

Date .................................................

Validity :

For the Minister of Health

Title of authorized official: .........................................................

Signature: .....................................................................................