Guideline for Importation of Medicinal Products and Health Supplements

DRA-G-D1-IA-10

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Drug Regulatory Authority

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Version History

Version	Release Date	Version History	Revised By
00	31-05-2022	Original Release	

Contents

Background

As per the provisions of the Medicines Act of the Kingdom of Bhutan 2003, applicants for importation of the medicinal product shall apply to the Authority in the prescribed form before importing the medicinal products into the country.

Medicinal products include human and veterinary allopathic medicines, traditional medicines, vaccines, medical devices and blood & blood products.

To ensure the availability of safe, quality and efficacious medicinal products in the country, the Authority draws this guidance document for the importers and officials of the Authority aimed at providing general guidance and laying down basic requirements for importing medicinal products and health supplements.

1. Objective

1. To guide importers and relevant officials while applying for import of medicinal products and health supplements in the country
2. To ensure the medicinal products and health supplements imported are safe and are of quality.
3. To ensure the medicinal products and health supplements imported are from genuine sources.

2. General principle

2.1. Import of all medicinal products and health supplements require prior approval from the Drug Regulatory Authority.

2.2. Products can be imported for personal use, sale and distribution through retail pharmacies and for institutional supply.

2.3. Market Authorization Holders (MAHs) and government agencies can apply for import of medicinal products.

2.4. Any person/patient can also apply for import of medicinal products for personal use.

2.5. It shall be the responsibility of the importer to ensure that medicinal products to be imported are sourced from genuine manufacturers.

2.6. The importer shall ensure that all the imported registered medicinal products conform to the sample medicinal products or packaging specification submitted at the time of product registration. In case of non-conformity, it shall be the responsibility of the importer to remove the products from the market.

2.7. In case of imported medicinal products that conformed with the product registration conditions but are proven to be defective products based on drug testing reports, it shall be the responsibility of the importer to remove such products from the market

2.8. The importer shall be responsible for timely removal in case of product recall

2.9. In case the importer is different from the MAH, a No Objection Letter from the MAH should be sought.

2.10. The importer shall provide unhindered access to the Inspectors to inspect the premises where imported products are stored.

3. Definitions

3.1. **Authority** refers to the Drug Regulatory Authority.

3.2. **Health Supplements** refers to the product that is used to supplement a diet, with benefits beyond those of normal food, and or to support or maintain the healthy functions of the human body.

3.3. **Import Authorization (IA)** refers to the permit to import medicinal products and will be verified at the Point of Entry (POE) by the Customs Officials.

3.4. **Market Authorization Holder (MAH)** refers to the entity having technical authorization for sale and distribution by wholesale or the manufacturer or government agency, in whose name the medicinal products are registered with the Authority.

3.5. **Medical Device** refers to all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

a. diagnosis, prevention, monitoring, treatment or alleviation of disease;
b. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
c. investigation, replacement, modification, or support of the anatomy or of a physiological process;
d. supporting or sustaining life;
e. control of conception;
f. disinfection of medical devices; or
g. providing information by means of in-vitro examination of specimens derived from the human body.

3.6. **Medicinal Product** refers to:

a. All substances intended for internal or external use of human beings or animals and intended to be used in the diagnosis, treatment, mitigation or prevention of disease of any disorder in human beings or animals including vaccines and biologicals;
b. Such substances intended to affect the functioning of any structure found in the human being and animal body; and
c. Active Pharmaceutical Ingredients.

4. Exemption from Import Authorizations

4.1. A person may be exempted from obtaining Import Authorization in the following cases:

a. the products are accompanied by the person who has a prescription from a qualified and registered medical practitioner;

b. the medicinal products that are included under schedule A1 and A2 of the Regulation where the quantity does not exceed the required dose for one month;

c. for import of medicinal products as samples for registration or tendering purposes and the Authority is accordingly notified in advance; and

d. medical devices not notified by the Authority.

5. Requirements for import authorization of medicinal products

5.1. **Registered products**

5.1.1. Application form;

5.1.2. List of registered product with their details;

5.1.3. Proforma Invoice; and

5.1.4. Evidence of route of import (Airway bill OR Transport consignee note) whichever is applicable.

5.2. **Non-registered products**

5.2.1. Application form;

5.2.2. Supply/purchase order

5.2.3. Proforma invoice

5.2.4. Certificate of Analysis (CoA) or performance data/report (in case of medical devices);

5.2.5. Manufacturing license;

5.2.6. cGMP certificate;

5.2.7. Specimen of packaging (package, label and insert); and

5.2.8. Route of import permit (Airway bill OR Transport consignee note) whichever is applicable.

6. Procedure for issuance of import authorization for medicinal products

6.1. Fill in the application as per **Annexure I** for medicinal products and as per **Annexure III** for Transfusion Transmissible Infection (TTI) Test Kits;

6.2. Submit the application form along with the relevant required documents as per Section 5 of this guideline;

6.3. Import Authorization for medicinal products will be issued within a Turn Around Time (TAT) of 7 working days;

6.4. One-time import authorization will be issued for all registered products with validity of one year or till the validity of the product registration certificate if the product validity is less than one year;

6.5. One-time import authorization with validity of six months will be issued for non-registered medicinal products.

7. Requirement for import authorization of health supplements

7.1. Listed health supplements

7.1.1. Application form;

7.1.2. List of health supplements along with its details; and

7.1.3. Proforma invoice.

8. Procedure for issuance of import authorization for health supplements

8.1. Fill in the application as per A**nnexure II;**

8.2. Submit the application form for import of health supplements along with relevant documents as per Section 7 of this guideline

8.3. The Import Authorization should be issued within a TAT of 7 working days after submission of complete documents;

8.4. One-time import authorization with validity of one year or till the validity of the health supplements listed, if shorter than one year, will be issued for all listed supplements.

9. Health supplements for personal use

9.1. Category I health supplements can be imported for personal use in any quantity taking into consideration the minimum health risk to the consumers posed by this category of products;

9.2. Category II and III health supplements that claim health benefits can be imported for personal use in the quantity as specified below:

- Maximum of 100 units (capsule/tablets) per person for a maximum of 10 individuals;
- Maximum of 600 ml of liquid health supplements (eg. 10 bottles of 60ml) per person for a maximum of 10 individuals;
- Maximum of 300 g of powdered health supplements (eg. 30 sachets of 10g) per person for a maximum of 10 individuals;

9.3. In the event of an individual importing a quantity exceeding the specified quantities (deviating from the eligible quantity mentioned under 9.2) without prescription, the excess quantity will be embargoed by the Authority. The embargoed products may be released only upon presentation of a valid prescription by the importer/patients within one month from the date of the embargo.

10. References

10.1. Medicines Act of the Kingdom of Bhutan 2003

10.2. Bhutan Medicines Rules and Regulation 2019

BMRR XV-IAA
APPLICATION FOR AUTHORIZATION TO IMPORT MEDICINAL PRODUCT(S) FOR SALE/DISTRIBUTION

I/we …… hereby apply for authorization to import for following medicinal products in Bhutan for sale and distribution.

SN	Product Name	Registration No.	Registration validity	Manufacturer	Pack size

Address of the premise(s)/Store(s):

Is the product registered by the applicant? Yes ☐ No ☐

(*Please tick the appropriate box)*

(*Please attach the following Documents*)

Documents required for registered medicinal products	Documents required for non-registered medicinal products
1. List of registered products 2.Proforma Invoice; 3.Evidence of route of import (Airway bill OR Transport consignee note) 4.No Objection letter from the Market Authorization holder in case the importer is different from the Market Authorization holder.	1. Proforma invoice 2. supply/purchase order 3.Certificate of Analysis (CoA) or performance data/report(incase of medical devices); 4.Manufacturing license; 5.cGMP certificate; 6.Specimen of packaging (package, label and insert); and 7.Route of import permit (Airway bill OR Transport consignee note)

Declaration (please tick the boxes):

☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravene the provision(s) of the act and regulations made there under.

☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Date: Signature of Applicant
Name, Address, Contact details

Annexure II: Application form for IA of health supplements

BMRR XV-IA
APPLICATION FOR AUTHORIZATION TO IMPORT MEDICINAL PRODUCT(S) FOR SALE/DISTRIBUTION

I/we …… hereby apply for authorization to import for following medicinal products in Bhutan for sale and distribution.

SN	Product Name	Registration No.	Manufacturer	Pack size

Address of the premise(s)/Store(s):

Is the product registered by the applicant? Yes ☐ No ☐

(*Please tick the appropriate box)*

(*Please attach the following Documents*)

a. Copy of proforma invoice or evidence for source of distribution (if the product is not registered)
b. No Objection letter from the Market Authorization holder in case the importer is different from the Market Authorization holder.

Declaration (please tick the boxes):

☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravene the provision(s) of the act and regulations made there under.

☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Date: Signature of Applicant
Name, Address, Contact details

Annexure III: Application form for IA of TTI test kits

BBPR Regulation No: 24 d (vii)

APPLICATION FOR AUTHORIZATION TO IMPORT TRANSFUSION TRANSMISSIBLE INFECTION TEST KITS IN BHUTAN

I/we……..hereby apply for authorization to import following TTI test kits in Bhutan for Sale and distribution.

Sl. No.	Product Name	Pack size (tests)	Manufacturer	Quantity

Attach a separate list in case of multiple products

Address of the premises/Store:
Is the product registered by the applicant? Yes □ No □ (*Please tick the*

appropriate boxes). Registration No: Validity:

To import non-registered TTI test kits, following documents should be submitted

a.Copy of Proforma invoice or evidence for the source of distribution
b.Supply order from the relevant government agency

If the TTI test kit is registered

*a.*No Objection letter from the Market Authorization holder in case the importer is different from the Market Authorization holder.
*b.*Letter of No Objection for importing if the importer is different from the Market Authorization Holder

Declaration (please tick the boxes):

□ I hereby declare that the documents submitted above/all information provided is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading. □ If my application is granted, I shall abide by the Medicines Act and Blood and Blood Products Regulations and any other standards set by the Authority.
□ I /we shall submit a record of TTI test kits imported half yearly in the prescribed format.

Signature of applicant:

Date:

We commit to provide consistent regulatory operations with risk based planning and continual improvement in compliance with the recognized standards to meet our consumers' satisfaction and confidence.

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