PRODUCT REGULATION SECTION
DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

GUIDELINE FOR SUBMISSION OF APPLICATION TO IMPORT A REGISTERED MEDICINAL PRODUCT BY NON-PRODUCT LICENCE HOLDER (ON CONSIGNMENT BASIS)

1) This document provides a guide to the applicant on the procedures & requirements for the application to import a registered medicinal product by non-product licence holder (on consignment basis) under Regulation 3 of the Medicines (Licensing, Standard Provisions and Fees) Regulations, 2010. Each application is restricted to ONE medicinal product and is valid for ONE consignment only.

2) All applications by a non-product licence holder to import a registered medicinal product must be made using **Form No: DPS/DRS/05** - *"Application Form for a Licence to Import a Registered Medicinal Product by Non Product Licence Holder (on Consignment Basis)"*. This form is available from Product Regulation Section (PRS) or can be downloaded from the MOH website.

3) All entries (Sections 1 to 3) must be made in English. Relevant information required in the form should be provided accordingly. Incomplete forms shall result in the rejection of the application.

4) Applicant MUST enter details in full for Sections 1 and 2; and also be responsible for obtaining the required information for Section 3.

5) Section 2 of the application form shall only be signed by the Import Licence holder or their authorized pharmacist(s). A letter from the Import Licence holder authorizing the appointed pharmacist(s) to act as the applicant must be submitted to PRS.

6) Section 3 of the application form must be filled in and signed by the requestor. Requestor may be the doctor/pharmacist/procurement officer of the requesting health institution.

7) The Import Licence Holder shall be fully responsible for the quality, safety and efficacy of the product.

Reference 1 - https://www.incb.org/incb/en/index.html

8) The application to import a registered medicinal product by non-product licence holder (on consignment basis) should only be made in pursuant to the request made by a health institution. The unit quantity for import must MATCH the unit quantity required by the health institution.

9) Buffer stocks without any request from a health institution is not allowed.

10) Only ONE exporter is allowed per application. You are advised to submit another application should there be any changes to the exporter.

11) Approval is granted to a single consignment of the batch(es) of the medicinal product intended to be imported and is valid for 6 months from the date of approval, subject to the validity of the corresponding Import Licence, (whichever comes first).

12) The company granted approval must comply with all the legal requirements relating to the importation, sale and supply of the product to which the consignment approval relates; including the display of the **approval number (PCB XX/20XX)** and the phrase '**Imported by (Name of Company)**' on the product packaging, as designated by the Authority. This labelling activity must be in accordance with the approved Standard Operating Procedures by the company's relevant department. Please take note that tampering of the security seal to adhere label(s) is not allowed.

13) The product to be imported on consignment basis must be identical in all aspects, to that already registered in Brunei Darussalam.

14) In addition to the consignment approval, the company must have a valid Import Licence and a Wholesaler's Licence for the import and supply of the medicinal product. If the medicinal product contains any substance in whole or part as per listed under either the "*Yellow List – List of Narcotic Substances Under International Control*"[1] *and "Green List – List of Psychotropic Substances Under International Control*"[1] -, then the import of the medicinal product shall also be subjected to the provisions of Misuse of Drug Regulations and/or any legal requirements of the exporting country.

15) Applicants shall be required to submit the following documents for evaluation:

a) A copy of the Business Registration Certificate of the intended importing Company; OR Copy of Import Licence
b) Statement from the exporter that the exporting company is a registered pharmaceutical dealer in the exporting country
c) Documentary evidence to show that the product is registered in the exporting country

Reference 1 - https://www.incb.org/incb/en/index.html

d) Certificate of Analysis of the product to be imported from the manufacturer or from any recognised testing laboratory (with the corresponding batch number of the batch intended to be imported)
e) A copy of the invoice from the exporter (with the corresponding batch number and expiry date of the batch(es) intended to be imported)
f) Clear digital image of product labelling (with the corresponding batch number and expiry date of the batch(es) intended to be imported)
   - Outer Carton
   - Inner Label / Blister (where applicable)
   - A copy of the Package Insert

16) The completed application form together with the required supporting documents are to be submitted to:

Product Regulation Section
Department of Pharmaceutical Services
Ministry of Health
2nd Floor, Spg 433, Rimba Highway,
Kg. Madaras, Mukim Gadong 'A'
BE 4710
Brunei Darussalam

For application enquiries or more information, please contact the Product Regulation Section (PRS) at telephone no: (+673) 2393298, 2393301, 2393230 ext 225, 218 or email: drugregistration@moh.gov.bn