DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

# GUIDE TO APPLICATION FOR AN IMPORT PERMIT OF A MEDICINAL PRODUCT ON CONSIGNMENT BASIS

1) This application form is used in the application of a permit required for the importation of one consignment of a medicinal product that is solely intended for use in human. A separate application form is necessary for each product.

2) All entries must be made in English. Relevant information required in the form should be supplied accordingly. Otherwise, the incomplete form may result in an undue delay in the processing of the application.

3) A separate A4-size sheet may be attached to the application form if the space provided on the form is inadequate. The attached sheets should be numbered appropriately at the top right hand corner, where each of the numbers would correspond to that in the column of the application form. All attachments should be noted down in the "List of Attachments" enclosed.

4) An import permit shall be issued in the name of the local company registered with the Registry of Companies & Businesses. The company should authorize a responsible person to apply for the permit.

5) The holder of the permit shall comply with all the legal requirements relating to the importation, sale and supply of the product.

6) The product to be imported must be the same in all respects to the medicinal product registered in Brunei Darussalam.

7) Applications are also required to submit the following documents for evaluation:

a) A copy of the Business Registration Certificate for Company OR Certificate of Incorporation for Private Ltd Company & Memorandum and Articles of Association;
b) Statement from the exporter that it is a registered pharmaceutical dealer in the exporting country;
c) Documentary evidence to show that the product is registered in the exporting country;
d) Certificate of analysis of the product to be imported from the manufacturer or from an approved local testing laboratory; or documentation on Good Distribution Practice compliance throughout the supply chain from the source of manufacture to importation;
e) An undertaking from the applicant that it will be responsible for the quality, safety and efficacy of the product;

f) The proposed product and locally registered product packaging and labeling materials such as inserts, brochures, etc. to be used for the imported product, but which shall be exempted from generic labelling requirements; and
g) A copy of the invoice from the exporting agent, indicating the batch number and expiry date of the product to be imported.

8) Sufficient samples for use in assessing the product conformity and as retention samples for future reference.

9) The following shall be printed or shall appear on a stick-on label: the phrase, "Imported by (name of company)", the import permit reference number and other labelling requirements, if they are not already present on the immediate label or box.

10) The completed application form together with the required supporting documents should be sent to:

**DRUG ADMINISTRATION SECTION**
**Block 2G:8:03, 8th Floor,**
**Ong Sum Ping Condominium,**
**Bandar Seri Begawan BA1111**
**Brunei Darussalam**

11) For application enquiries or more information, please contact the Drug Administration Section (DAS) officer at telephone/fax no: +673 2230001.