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|  | FORM NO.: DPS/DRS/05  **PRODUCT REGULATION SECTION**  **DEPARTMENT OF PHARMACEUTICAL SERVICES**  **MINISTRY OF HEALTH**  **BRUNEI DARUSSALAM**  **APPLICATION TO IMPORT A REGISTERED MEDICINAL PRODUCT BY NON-PRODUCT LICENCE HOLDER (ON CONSIGNMENT BASIS)** | | | | | | | | |
| **APPLICATION REF. NO. (*For Official Use Only*)**: (………)/DPS/IL/Reg.MP/20……  Instructions: Applicants are advised to refer to the DPS ‘Guideline for Submission of Application to Import a Registered Medicinal Product by Non-Licence Holder (on Consignment Basis)’ for guidance before filling up the form. | | | | | | | | | |
| **SECTION 1: PRODUCT DETAILS** | | | | | | | | | |
| 1.1 | | Product Name (*Including Dosage Form and Strength*):  Click or tap here to enter text. | | | | | | | Quantity:  Click or tap here to enter text. |
| 1.2 | | Name and Strength of Active Ingredient(s):  Click or tap here to enter text. | | | | Route of Administration:  Click or tap here to enter text. | | | Pack Size:  Click or tap here to enter text. |
| 1.3 | | Batch Number(s):  Click or tap here to enter text. | | | | Expiry Date(s):  Click or tap here to enter text. | | | |
| 1.4 | | Brunei Product Licence Number of the Locally Registered Product:  Click or tap here to enter text. | | | | Product Licence Holder in Brunei Darussalam:  Click or tap here to enter text. | | | |
| 1.5 | | Name and Address of Manufacturer: Click or tap here to enter text.  Click here to enter text. | | | | | | | |
| 1.6 | | Name and Address of Exporter (*One Exporter Per Application*): Click or tap here to enter text. | | | | | | | |
| 1.7 | | Registration Status in Exporting Country (Please attach documentary evidence to show that the product is registered in the exporting country):   |  |  |  |  | | --- | --- | --- | --- | | **Country** | **Product Registration No.** | **Date of Registration** | **Approved Forensic Classification** | | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | | | | | | | |
| 1.8 | | Purpose of Import (*Please Tick Where Applicable*):  For Supply To:  Ministry of Health via:Tender/Quotation Reference Number\*……………………………………………  Name of Private Hospital/Clinic: ……………………………………………..  Others, Please State: ……………………………………………..  *\*Please delete where applicable* | | | | | | | |
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| **SECTION 2: IMPORTER PARTICULARS** | | | | | | | | | |
| 2.1 | | Name and Address of Importer: Click or tap here to enter text. | | | | | | Name of Applicant: Click or tap here to enter text. | |
| Designation: Click or tap here to enter text. | |
| Passport/IC No.: Click or tap here to enter text. | |
| 2.2 | | Telephone No.:Click or tap here to enter text. | | Fax No.: Click or tap here to enter text. | | | | Email Address: Click or tap here to enter text. | |
| 2.3 | | I, on behalf of the company named in Section 2.1, hereby declare that/ undertake to/ confirm that:   1. All particulars given in this application are true and that the documents enclosed are authentic or true copies. 2. Comply with all legal requirements relating to the import, sale and/or supply of the medicinal product to which this consignment approval relates including, the display of the approval number assigned to this product on the product packaging, and your company’s name and address and other labelling requirements prior to sale in Brunei Darussalam. 3. Responsible for the quality, safety and efficacy of the product to be imported.   I understand that a wilfully false statement is an offence under the Medicines Order, 2007.  Signature of Applicant Company Stamp & Date Company Registration No.: Click | | | | | | | |
| **SECTION 3: TO BE COMPLETED BY REQUESTING HEALTH INSTITUTION** | | | | | | | | | |
| 3.1 | | Full Product Name:Click or tap here to enter text. | | | | | Unit Quantity Required: Click or tap here to enter text. | | |
| 3.2 | | Name and Designation of Requestor:Click or tap here to enter text. | | | | | | | |
| 3.3 | | Name and Address of Health Institution:Click or tap here to enter text. | | | | | | | |
| 3.4 | | Telephone No.:Click or tap here to enter text. | Fax No.:Click or tap here to enter text. | | | | Email Address:Click or tap here to enter text. | | |
| 3.5 | | Signature of Requestor: | | | | | Date:Click or tap here to enter text. | | |
| **SECTION 4: APPROVAL** | | | | | | | | | |
| 4.1 | | **Approval no.: PCB /20­­\_­­­\_** | | | | **Date:** | | | |
| 4.2 | | This approval is given on the understanding that the importer is responsible for the quality, safety and efficacy of the product to be imported and that it is in all aspects equivalent to the medicinal product registered in Brunei Darussalam.  This approval is valid for **ONE CONSIGNMENT** of the **listed item** only and it must be imported **within 6 months** from the date of this approval subject to the following conditions:   1. All records of the import and supply of the medicinal product shall be made readily available for inspection by the authority. 2. The following must be printed or must appear on a stick-on label: the phrase ‘Imported by (name of company)’, the approval number on the immediate label or outer carton prior to sale. This activity must be in accordance with the approved Standard Operating Procedures by your relevant department. Please take note that tampering of the security seal to paste the stick- on label is not allowed. 3. The import licence holder must comply with all legal requirements relating to the import, sale and supply of the medicinal product. 4. For Narcotic and Psychotropic drugs, the import is subject to the provisions of Misuse of Drug Regulations and/or legal requirements of exporting country.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Chair of Brunei Darussalam Medicines Control Authority*  Please ensure that the **ORIGINAL** copy of this permit is attached to the Import Declaration of this consignment and submitted for endorsement to Compliance & Licensing Section, Department of Pharmaceutical Services. | | | | | | | |
| **FOR OFFICIAL USE** | | | | | | | | | |
| **PROCESSING FEE DETAILS**  Receipt No.: ………………………………………..  Amount Paid: ………………………………………  Name of Payee:…………………………………… | | | | | Name & Signature of Officer Receiving the Processing Fees:  ………………………………………………………………  Received Date: ………………………………………….. | | | | |