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| **DEPARTMENT OF PHARMACEUTICAL SERVICES****MINISTRY OF HEALTH****BRUNEI DARUSSALAM****MEDICINES ORDER, 2007****MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) REGULATIONS, 2010****APPLICATION FORM FOR IMPORT LICENCE AND WHOLESALER’S LICENCE** **FOR MEDICINAL PRODUCTS** |
| **SECTION 1: INSTRUCTIONS** |
| 1. Please fill out this application form in CAPITAL LETTERS.
2. Please tick (✓) the appropriate boxes or write “N/A” for any item that is not applicable to your application.
3. When the symbol **\*** appears, please strikethrough the wording that is not applicable.
4. The complete application form with the relevant fee should be submitted to the **Compliance and Licensing Section, 1st Floor, Department of Pharmaceutical Services, Kg Madaras, Mukim Gadong ‘A’, Brunei Darussalam**.
5. Payment of fees can either be made in the forms of cash or cheque only. Fees paid are non-refundable. Please note that payments can only be made from **Monday to Thursday, 8am to 11.30am** (8am to 10.30am for Ramadhan month) during government working days.

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| Fees: |  |  |
| 1. **Application** for **Import Licence**
 | – | **$50** |
| 1. **Application** for **Wholesaler’s Licence**
 | – | **$100** |
| 1. **Renewal** of **Import Licence**
 | – | **$50** |
| 1. **Renewal** of **Wholesaler’s Licence**
 | – | **$100** |

***Note:*** *Only complete application forms (one original and one photocopy) submitted with confirmed payment will be processed.* |
| **SECTION 2: CHECKLIST FOR SUPPORTING DOCUMENTS** |
| 1. This checklist is to be filled in by the applicant.
2. The application form should be submitted with the list of supporting documents.
3. Please tick (✓) the appropriate boxes if the documents are attached.
4. For New Application, please proceed to **Section 2(A)** whereas Application for Licence Renewal, please proceed to **Section 2(B)**.
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| **List of Supporting Documents** |
| 1. **NEW APPLICATION**
 | 🞎 | *For official use only* |
| 1. A copy of applicant’s **Identity Card** issued in Brunei Darussalam.
 | 🞎 | 🞎 |
| 1. A copy of **Business Certificate of Registration** (Sections 16 & 17); or

**Certificate of Incorporation and Memorandum of Article & Association**. | 🞎 | 🞎 |
| 1. Layout plan of the **storage area**.
 | 🞎 | 🞎 |
| 1. List of **registered medicinal products** *(arranged alphabetically in hard and soft copies)*.
 | 🞎 | 🞎 |
| 1. Copy of each of the **Product Licences**.

*(Note: These will be returned to the applicant after completion of the screening process.)* | 🞎 | 🞎 |
| 1. **Authorisation letter** issued by the Product Licence holder if its **company is not the product licence holder**.
 | 🞎 | 🞎 |
| 1. **Authorisation letter** issued by the company authorising the applicant to apply for the licence on its behalf, if **applicant is not the company owner**.
 | 🞎 | 🞎 |
| *Additional documents required from applicant:* |

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| 1. **APPLICATION FOR LICENCE RENEWAL**
 | 🞎 | *For official use only* |
| 1. A copy of previous \*Import/Wholesaler’s licence.
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| 1. A copy of applicant’s **Identity Card** issued in Brunei Darussalam.
 | 🞎 | 🞎 |
| 1. Layout plan of the **storage area** *(only required if there was any change made to previous layout plan)*.
 | 🞎 | 🞎 |
| 1. List of **registered medicinal products** *(arranged alphabetically in hard and soft copies)*.
 | 🞎 | 🞎 |
| 1. Copy of each of the **Product Licences** *(only required for additional medicinal products).*

 *(Note: These will be returned to the applicant after completion of the screening process.)* | 🞎 | 🞎 |
| 1. **Authorisation letter** issued by the Product Licence holder if its **company is not the product licence holder**.
 | 🞎 | 🞎 |
| 1. **Authorisation letter** issued by the company authorising the applicant to apply for the licence on its behalf, if **applicant is not the company owner**.
 | 🞎 | 🞎 |
| *Additional documents required from applicant:* |
| **SECTION 3: DETAILS OF APPLICATION** |
| **Type of Licence** | 🞎 | **Import Licence** | 🞎 | **Wholesaler’s Licence** |
| Details of previous licence*(if applicable)* | Licence No. | : |  |
| Validity Period | : |  |
| **SECTION 4: DETAILS OF COMPANY** |
| Name of Company |  |
| Company Registration No. |  |
| Business Address |  |
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| Store Address *(if different from above)* |  |
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| Correspondence Address *(if different from above)* |  |
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| Telephone |  | Fax |  | Official E-mail |  |
| **Details of Two Responsible Persons (contactable 24 hours)** |
| Title | 🞎 | Dr | 🞎 |  Mr | 🞎 |  Mrs | 🞎 | Ms | 🞎 | Miss | Gender | 🞎 |  Dr | 🞎 |  Mr | 🞎 |  Mrs | 🞎 |  Ms | 🞎 |  Miss |
| Name |  | Name |  |
| I.C. No. (Colour) |  | I.C. No. (Colour) |  |
| Designation |  | Designation |  |
| Telephone (Office) |  | Telephone (Office) |  |
| Handphone |  | Handphone |  |

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| **SECTION 5: DETAILS OF APPLICANT** |
| Title | 🞎 | Dr | 🞎 |  Mr | 🞎 |  Mrs | 🞎 | Ms | 🞎 | Miss |
| Name |  |
| I.C. No. (Colour) | 🞎 |  Yellow | 🞎 |  Red | 🞎 |  Green |
| Designation |  |
| Telephone (Office) |  | Handphone |  | Official E-mail |  |
| **SECTION 6: DECLARATION OF APPLICANT** |
| I hereby declare that1. I understand and undertake to comply with all the provisions of the **Medicines Order 2007** and its related Regulations, **Poisons Act 1956** and **Misuse of Drugs Regulations**.
2. All particulars and attachments given in/with this application form are true.
3. There have been no changes to the information and attachments provided previously *(only applicable for licence renewal application)*.

I undertake to notify the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam of any change in the particulars submitted in/with this application form. |
| **Name of Applicant** | **Signature** | **Date** |
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| **SECTION 7: CERTIFICATION BY COMPANY** |
| I hereby declare that1. The applicant is an \*employee/owner of the above-mentioned company.
2. The \*Import/Wholesaler’s licence applied is only for the purpose of business of the above-mentioned company.
3. All of the information provided is true and complete.

I understand that a wilfully false statement is an offence under the Medicines Order 2007 and that all documents submitted for evaluation are not returnable. |
| **Name of \*Company Owner / Manager / Director** | **Signature** | **Date** & **Company Stamp** |
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| **SECTION 8: DETAILS OF REGISTERED MEDICINAL PRODUCTS FOR \*IMPORT / WHOLESALE** |
| **Notes:**1. Please list the registered medicinal products in an **alphabetical** order.
2. Please attach **additional pages** if the space provided is insufficient.
 |
| **No.** | **Product Name** | **Pack Size** | **Name** & **Country** of**Manufacturer** | **Product Licence Number** | **Validity Period** |
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| **SECTION 9: FOR OFFICIAL USE ONLY** |
| **Application Ref. No.** |  |
| 1. **APPLICATION FORM RECEIVED BY:**
 | 1. **APPLICATION FEE**
 |
| **Name** |  | **Name of Payee** |  |
| **Signature** |  | **Amount paid** |  |
| **Date** & **Stamp** |  | **Receipt No.** |  |
| **Received by** | **Name** |
| **Signature** |
| **Date** |  |

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| *Additional notes (for official use only):* |