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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.  |  |  |  | | --- | --- | --- | | 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)**. | | |
| **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. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 🞎 | | | 🞎 | |
| 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 that   1. 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 that   1. 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.** |  | |
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| **Signature** | |
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| *Additional notes (for official use only):* |