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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 AMENDMENT TO AN IMPORT LICENCE AND WHOLESALE DEALER’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 should be submitted to the **Compliance & Licensing Section, 1st Floor, Department of Pharmaceutical Services, Kg Madaras, Mukim Gadong ‘A’, Brunei Darussalam**. 5. An amendment fee is payable upon collection of the licence. Payment can either be made in the forms of cash or cheque only. Fees paid are non-refundable. Payment of fees can either be made in the forms of cash or cheque only. Fees paid are non-refundable. Please note that payments are received **every Monday to Thursday, 8am to 11.30am** (8am to 10.30am for Ramadhan month) during government working days.  |  |  |  | | --- | --- | --- | | Amendment fees: |  |  | | 1. Site Inspection **required** | – | **$35** | | 1. Site Inspection **not required** | – | **$25** |   ***Note:*** *Only complete application form (one original and one photocopy) submitted with a confirmed payment will be processed.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **SECTION 2: DETAILS OF LICENCE** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Type of Licence** | | | | | | 🞎 **Import Licence** | | | | | | | | | | | | | | | | | | | | | 🞎 **Wholesale Dealer’s Licence** | | | | | | |
| Licence No. | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Validity Period | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **SECTION 3: 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 | | |  | | |
| **SECTION 4: 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 5: DETAILS OF PROPOSED CHANGES** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Notes:**   1. Any amendment on Addition of Registered Medicinal Product, please also fill out Section 6 of this application form. 2. Please refer to Section 7 of the Guideline on Application for An Import Licence and Wholesale Dealer’s Licence for Medicinal Products for further guidance. 3. Please attach **additional pages** if the space provided is insufficient. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **No.** | **Type of Amendment** | | | | | | | **Current Details** | | | | | | | **Proposed Change(s)** | | | | | | | | | **Reasons for Change** | | | | | | **Expected Effective Date** | | | **Documents Attached** |
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| **SECTION 6: DETAILS OF ADDITIONAL REGISTERED MEDICINAL PRODUCTS** | | | | | |
| **Note:**   1. This section is only applicable for amendment on Addition of Registered Medicinal Product. 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 7: DECLARATION OF APPLICANT** | | |
| I, on behalf of the company named in Section 3, hereby declare that:   * 1. There are no other changes with respect to the licence detailed in Section 2 than those proposed on this application form;   2. All the conditions for the proposed changes are fulfilled;   3. The supporting documents required for the proposed changes have been submitted; and   4. All particulars given on this application form and the supporting documents attached to this form are true.   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 Applicant** | **Signature** | **Date** & **Company Stamp** |
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| **SECTION 8: 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** |  |