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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.

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| 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)* |  |
|  |
| 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.
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| **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.
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| **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** |  |