|  |
| --- |
| **FORM NO.: BDMCA/DPS/Vartn/02** |

|  |
| --- |
| **DEPARTMENT OF PHARMACEUTICAL SERVICES****MINISTRY OF HEALTH****BRUNEI DARUSSALAM** |
| APPLICATION FORM FOR VARIATION TO REGISTERED MEDICINAL PRODUCTS |
| VARIATION REFERENCE NO. (*For Official Use Only*): (………)/DRU/DRA.Variation/20…… |
| Instructions:1. Applicants are advised to refer to the “Guideline on Application for Variation to Registered Medicinal Products” for guidance before filling up application form.
2. Only **one original copy** of the application form is required to be submitted per product. Form must be typed.
3. The completed application form should be submitted to the Drug Registration Unit, Product Regulation Section, 2nd Floor, Department of Pharmaceutical Services, Ministry of Health, Spg 433, Kg Madaras, Mukim Gadong ‘A’, Rimba Highway, BE4710, Brunei Darussalam.
 |
| **1.0** | **REGISTERED MEDICINAL PRODUCT PARTICULARS** |
| 1.1 | Product Licence No. (s): | 1.2 Expiry Date:  | 1.3 Application Ref. No.: LOA-P/……../ ………….. |
| 1.4 | Product Name and Strength: |
| 1.5 | Active Ingredient(s): |
| **2. 0** | **PRODUCT LICENCE HOLDER PARTICULARS** |
| 2.1 | Name of Company:(*in block letters)* |
| 2.2 | Address: | 2.3 Tel No.: |
| 2.4 Fax No.: |
| 2.5 Email No.: |
| **3.0**  | **APPLICANT PARTICULARS** |
| 3.1 | Name (Mr/Ms/Mrs/Mdm/Dr): | 3.2 Designation: |

|  |  |
| --- | --- |
| **4.0** | **DECLARATION** |
| I, on behalf of the company named in Section 2.1, hereby declare that |
| 4.1 | There are no other changes than those proposed on this application form; |
| 4.2 | All the conditions for the proposed changes are fulfilled; |
| 4.3 | The supporting documents required for the proposed changes have been submitted; and |
| 4.4 | All particulars given in 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 (in block letters): |
| Signature: | Company Stamp: |
| Date: |

|  |  |
| --- | --- |
| **5.0** | **DETAILS OF PROPOSED CHANGE(S)** |
| Variation Code\* | Current Product Details  | Proposed Change(s) | Reason(s) for Change | Expected effective date | Variation Application Status in DPS’s reference countries | Enclosures\*\* |
|  |  |  |  |  |  |  |

|  |  |
| --- | --- |
| \* | Please refer to **Appendix 5 – Types of Variation** of the Guide to Application for Registration of Medicinal Products (4th Edition) for the Variation Code e.g. MaV-1, MiV-PA1 etc. |
| \*\*  | Please list and submit the documents required for each Variation Code as listed on **Appendix 5 – Types of Variation** and the supporting documents indicated in **Annex 18 (Item no. 4)**  of the Guide to Application for Registration of Medicinal Products (4th Edition) |