**Form No. BDMCA/DPS/RN/01**

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| **DEPARTMENT OF PHARMACEUTICAL SERVICES**  **MINISTRY OF HEALTH**  **BRUNEI DARUSSALAM** | | | | | | |
| **APPLICATION FORM FOR RENEWAL OF REGISTRATION OF MEDICINAL PRODUCTS** | | | | | | |
| PRODUCT LICENCE NO.:   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **B** | **R** | **U** |  |  |  |  |  |  |  |  |  |  |  | **P** |  |  |  |  |  | | | | | | | |
| RENEWAL REFERENCE NO. (*For Official Use Only*): ( )/DRU/DRA.Renewal/20\_\_ | | | | | | |
| Instructions:   1. Only **one original copy** of the application form is to be submitted per product. Form must be typed. 2. 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, BE 4710, Brunei Darussalam. | | | | | | |
| **1.0** | **REGISTERED MEDICINAL PRODUCT PARTICULARS** | | | | | |
| 1.1 | Proprietary Name: | | | | | |
| 1.2 | Dosage Form: | | | | | |
| 1.3 | Active Ingredient (Name and Strength): | | | | | |
| 1.4 | Current Validity of Product Licence: | | | | | |
| **2.0** | **PRODUCT LICENCE HOLDER PARTICULARS** | | | | | |
| 2.1 | Name of Company: | | | | | |
| 2.2 | Address: | | | | | |
| 2.3 | Company Registration No.:  *(Please enclose a copy of Company Registration Certificate)* | | | | | |
| 2.4 | Telephone No.: | 2.5 Fax No.: | | | | 2.6 E-mail Address: |
| **3.0** | **APPLICANT PARTICULARS** | | | | | |
| 3.1 | Name (Mr/Ms/Mrs/Mdm/Dr) | | | 3.2 Designation | | |
| **4.0** | **MANUFACTURER ‘S PARTICULARS**  *Note: If more than 1 manufacturer, please write on a separate sheet of A4 paper* | | | | | |
| 4.1 | Name of Manufacturer : | | | | | |
| 4.2 | Address: | | | | | |
| 4.3 | Telephone No.: | | 4.4 Fax No.: | | 4.5 E-mail Address: | |
| **5.0** | **IMPORTER’S PARTICULARS**  *Note: For imported medicinal products only* | | | | | |
| 5.1 | Name of Importer: | | | | | |
| 5.2 | Address: | | | | | |
| 5.3 | Telephone No.: | 5.4 Fax No.: | | | | 5.5 E-mail address: |
| **6.0** | **POST-MARKETING SURVEILLANCE OF THE REGISTERED MEDICINAL PRODUCT** | | | | | |
| 6.1 | **Monitoring of Adverse Drug Reaction (ADR) Report (local)**  *Please list related reports received and actions taken:*   1. Reporting by Consumers  |  |  |  |  | | --- | --- | --- | --- | | **Type of ADR** | **Date of Report** | **Reporter** | **Action / Date of Report submitted to Pharmacovigilance Section** | |  |  |  |  | |  |  |  |  | |  |  |  |  |  1. Reporting by Pharmacovigilance Section  |  |  |  |  | | --- | --- | --- | --- | | **Type of ADR** | **Date of Report** | **Action Taken** | **Date of Action Taken** | |  |  |  |  | |  |  |  |  | |  |  |  |  | | | | | | |
| 6.2 | **Monitoring of Product Complaints (Local)**   1. Complaints by Consumers  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Type of Complaint** | **Date Received** | **Reporter** | **Action** | **Date of Complaint submitted to Pharmacovigilance Section** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  |  1. Complaints that require investigation as instructed by Pharmacovigilance Section  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Type of Complaint** | **Date Received** | **Reporter** | **Action** | **Date of Action Taken** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | | | | | |
| 6.3 | **Monitoring of Product Quality (Post-Marketing)** | | | | | |
| 6.3.1 | Has the product sample been taken for quality testing after registration? Yes / No | | | | | |
| 6.3.2 | If yes, please fill in the following information:   1. Date Sample Taken: ………………………………. 2. Date of Any Product Deficiencies Reported (*if applicable*): ……………………….   i.e. non-conformance to the registered product details such as **NO** package insert, registration no., product licence holder, different packaging, etc. | | | | | |
| **6.4** | **Punitive Action Against the Product (Local and Overseas)** | | | | | |
| 6.4.1 | Any punitive action (including warning) against the product? Yes / No | | | | | |
| 6.4.2 | If yes, please state the date, type of failure, type of action and follow-up action:   |  |  |  |  | | --- | --- | --- | --- | | **Date** | **Failure** | **Type of Action** | **Remedial Action** | |  |  |  |  | |  |  |  |  | |  |  |  |  | | | | | | |
|  | *Note: Please indicate as* ***“NONE”*** *if no punitive action is taken against the product.* | | | | | |

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| **7.0** | | **VARIATIONS TO THE REGISTERED INFORMATION** | |
| 7.1 | | Please list down variations to the registered information that have been submitted to DRU   |  |  |  |  | | --- | --- | --- | --- | | **Variation Application Ref. No. from DRU** | **Types of Variation** | **Date of Application** | **Approval Status** | |  |  |  |  | |  |  |  |  | |  |  |  |  | | |
| **8.0** | **DECLARATION** | | |
| I, on behalf of the company named in Section 2.1, hereby | | | |
| 8.1 | Declare that all particulars given in this application form are true. | | |
| 8.2 | Undertake to abide to the laws and legislations stated in the Medicines Order, 2007. | | |
| 8.3 | Undertake to notify the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam of any change in the particulars submitted in this application and of any new safety information during the course of evaluation and as long as the product remains on the market. | | |
| 8.4 | Undertake to notify the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam if a product is rejected for registration in any drug regulatory authority. | | |
| 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) | | | |
| Passport/ IC No. | | | |
| Designation | | | |
| Signature | | | Company Stamp |
| Date | | | |

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| **FOR OFFICIAL USE: PROCESSING FEE DETAILS** | | |
| Receipt No: | Amount Paid: | |
| Name of Payee: | | |
| Name & Signature of Officer receiving the Processing Fees: | | Received Date: |
| Notes: | | |