**DEPARTMENT OF PHARMACEUTICAL SERVICES**

**For Official Use:**

**Log Ref. No.: (\_\_\_\_\_)/DRU/Log.Updates.Var/20\_\_**

**MINISTRY OF HEALTH**

**BRUNEI DARUSSALAM**

**LOG FOR THE SUBMISSION OF UPDATED DOCUMENTS FOR APPLICATION OF VARIATION TO REGISTERED MEDICINAL PRODUCTS**

|  |  |
| --- | --- |
| **Name of Product Licence Holder :**  | **Date:**  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **No.** | **Variation Ref. No.****()/DRU/DRA.Variation/20..** | **Product Name and Strength** | **Product Licence No.** | **Types of Updates1** | **Annex B2 provided** **(please tick)** | **FOR OFFICIAL USE**  |
| **Annex B provided** | **Remarks** |
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**Notes:**

***1 Please provide the types of updates including the variation code e.g. MaV-1: addition of new indication, MiV-PA2: change in product labelling, etc.***

**Date Received (For Official Use):**

***2 Completed Annex B should be attached at the front part of the updated documents upon submission to Drug Registration Unit. Failure to provide this will lead to non-acceptance of the documents.***

**DEPARTMENT OF PHARMACEUTICAL SERVICES**

**ANNEX B**

**MINISTRY OF HEALTH**

**BRUNEI DARUSSALAM**

**SUBMISSION OF UPDATED DOCUMENTS FOR APPLICATION OF VARIATION TO REGISTERED MEDICINAL PRODUCTS**

|  |  |
| --- | --- |
| **Product Licence No.** |  |
| **Variation Ref. No.****( )/DRU/DRA.Variation/20..** |  |
| **Product Name and Strength** |  |

|  |
| --- |
| **DETAILS ON THE UPDATES**  |
| **Types of Updates** | **Current Product Details**  | **Updated Product Details** | **Reasons for the Updates** | **Status of the Updates** **in DPS’s Reference Countries** | **Enclosures**  |
|  |  |  |  |  |  |

**Date Received (For Official Use):**