**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** |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |

**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):**