**DEPARTMENT OF PHARMACEUTICAL SERVICES**

**MINISTRY OF HEALTH**

**For Official Use:**

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

**BRUNEI DARUSSALAM**

**LOG FOR THE SUBMISSION OF UPDATED DOCUMENTS FOR APPLICATION FOR REGISTRATION OF MEDICINAL PRODUCTS**

|  |  |
| --- | --- |
| **Name of Company:** | **Date:** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **No.** | **Ref. No. for Company’s Covering Letter** | **Product Name and Strength** | **LOA-P/\_/\_\_** | **Types of Updates1** | **Annex A2 provided**  **(please tick)** | **For Official Use** | |
| **Annex A provided** | **Remarks** |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |
|  |  |  |  |  | 🞏 | 🞏 |  |

**Notes:**

***1 Please provide the types of updates e.g. addition of new indication, addition of manufacturing site for drug product, PSUR etc.***

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

***2 Completed Annex A 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 A**

**MINISTRY OF HEALTH**

**BRUNEI DARUSSALAM**

**SUBMISSION OF UPDATED DOCUMENTS FOR APPLICATION FOR REGISTRATION OF MEDICINAL PRODUCTS**

|  |  |
| --- | --- |
| **Application Reference No. (LOA-P/\_\_/S\_\_\_)** |  |
| **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):**