**DEPARTMENT OF PHARMACEUTICAL SERVICES**
**MINISTRY OF HEALTH**
**BRUNEI DARUSSALAM**

## CHECKLIST FOR SUBMISSION OF APPLICATION OF RENEWAL OF REGISTRATION OF MEDICINAL PRODUCTS

| | | |
|---|---|---|
| **Application Ref. No.** *(For Official Use)* | : | **(_____) / DRU / DRA.Renewal / 20_____** |
| **Product Name** | : | |
| **Name Of Company** | : | |

| No. | Items | Applicant[1] | DRU *(For Official Use)* |
|---|---|---|---|
| 1. | **Application form (Form No. BDMCA/DPS/RN/01)** | | |
| | 1.1 Form signed by applicant | | |
| 2. | **Certificate of Pharmaceutical Product (CPP)** | | |
| | 2.1 Original copy of CPP issued by the competent authority in the country of origin, not more than 2 years from the date of issue | | |
| | 2.2 Notification letter / email correspondence from the relevant authority verifying the issuance of electronic CPP *(if applicable)* | | |
| | 2.3 Declaration letter from manufacturer / product owner verifying the product in CPP is the same as the registered product in Brunei Darussalam in cases where the product names are inconsistent *(if applicable)* | | |
| 3. | **Periodic Benefit-Risk Evaluation Report (PBRER) or Periodic Safety Update Report (PSUR)** | | |
| | 3.1 The latest PBRER or PSUR of the medicinal product in CD format. | | |
| | 3.2 Letter of justification of unavailability of PSUR / PBRER from product owner / manufacturer *(if applicable)* | | |
| 4. | **Product Labelling** | | |
| | 4.1 The latest approved version of product labelling (i.e. *outer carton*, *inner label* and *package insert*) of products for which a **BDMCA Directive** has been issued such as, but not limited to Salicylic Acid Derivatives, Domperidone, Promethazine, Camphor, Dextromethorphan, Guaifenesin, Pholcodine, Topical Diclofenac, Pseudoephedrine and Triprolidine and Warfarin containing preparations *(if applicable)* | | |
| | 4.2 The latest approved version of the *outer carton* and *inner label* for medicinal products of **capsule** form *(if applicable)* | | |
| 5. | **Remarks** *(For Official Use)*: | **Date Received** *(For Official Use)*: | |

[1] *Please tick (✓) if the document is provided or write "N/A" for any item that is not applicable to your application.*
***Note: Please attach this checklist at the front of each application form.***