GUIDELINE ON APPLICATION FOR RENEWAL OF REGISTRATION OF MEDICINAL PRODUCTS

1. Applications for renewal of registration of medicinal products shall be made on prescribed form, Form No.: BDMCA/DPS/RN/01.

2. Only **one original copy** of the application form is to be submitted per product and the form must be typed.

3. All entries must be made in English. Relevant information required in the form should be supplied accordingly. Otherwise, the incomplete form may result in an undue delay in the processing of the application.

4. A separate A4-size sheet may be attached to the application form if the space provided on the form is inadequate. The attached sheets should be numbered appropriately at the top right hand corner, where each of the numbers would correspond to that in the column of the application form.

5. Application for renewal of registration of medicinal products should be submitted **at least 1 year but not more than 18 months** prior to expiry of the registration of the medicinal product.

6. Applicants are also required to submit the following documents:
   i. **Original copy** of Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin. CPP not more than 2 years old is required.

   ii. The latest Periodic Benefit-Risk Evaluation Report (PBRER) or Periodic Safety Update Report (PSUR) of the medicinal product. This document is required to be saved into a CD. If PSUR is not available, letter of justification of unavailability of PSUR from product owner / manufacturer must be submitted.

7. The renewal of the registration of the medicinal product is based on the existing approved registration information. Product Licence Holder is required to submit variation application separately if there is any change to the product information.

8. Fees
   Please refer to Section 8 Application Fees.

9. The completed application form together with the Log for the Application for Renewal of Registration of Medicinal Products and required supporting documents should be submitted by appointment basis to:

   Drug Registration Unit
   Product Regulation Section
   2nd Floor, Department of Pharmaceutical Services
   Ministry of Health
   Spg 433, Kg Madaras, Mukim Gadong 'A'
   Rimba Highway, BE4710
   Brunei Darussalam

10. For application enquiries or more information, please contact the Product Regulation Section at tel: +67322393298/ 2393301 / 2393230 Ext 225.