FORM NO.: BDMCA/DPS/Vartn/02

DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

APPLICATION FOR VARIATIONS TO A REGISTERED MEDICINAL PRODUCT

Variation Screening Ref. No. (for official use only): (……)/DRU/DRA.Variation/20……

Instruction:

1. Applicants are advised to refer to the "Guideline on application for variations to a registered medicinal product" for guidance before filling up application form.
2. Only **one original copy** of the application form is required to be submitted per product. Form must be typed.
3. Completed form is to be sent to the Drug Registration Unit, Drug Administration Section, Department of Pharmaceutical Services, Block 2G:8:04, 8th Floor, Ong Sum Ping Condominium, Bandar Seri Begawan, BA1111, Brunei Darussalam.

1.0	**DETAILS OF MEDICINAL PRODUCT REGISTRATION**		
1.1	Product Licence No. (s):	Expiry Date:	Application Ref. No.: LOA-P/……../S……..
1.2	Product Name and Strength:		
1.3	Active Ingredient(s):		

2. 0	**DETAILS OF PRODUCT LICENCE HOLDER**	
2.1	Name of Company : (in block letters)	
	Address:	Tel No.:
		Fax No.:
		Email No.:

3.0	**APPLICANT PARTICULARS**	
3.1	Person authorised to submit and handle application on behalf of the company:	
	Name (Mr/Ms/Mrs/Mdm/Dr):	Designation:

4.0	DECLARATION

I, on behalf of the company named in Section 2.1, hereby declare that

4.1 There are no other changes than those proposed on this application form;

4.2 All the conditions for the proposed changes are fulfilled;

4.3 The supporting documents required for the proposed changes have been submitted; and

4.4 All particulars given in this application form and the supporting documents attached to this form are true.

I understand that a wilfully false statement is an offence under the Medicines Order 2007 and that all documents submitted for evaluation are not returnable.

Name (in block letters):

Signature: Company Stamp:

Date:

AMENDMENT FEE DETAILS (For Official Use)	
Receipt No:	Amount Paid:
Name of Payee:	
Name & Signature of officer receiving the Amendment Fees:	Received date:
Notes:	

5.0 DETAILS OF PROPOSED CHANGE(S)						
Variation Code*	Current Product Details	Proposed Change(s)	Reasons for Change	Expected effective date	Variation Application Status in DPS's reference countries	Enclosures**

* Please refer to **Appendix 4 – Types of Variations** of the Guide to Application for Registration of Medicinal Products (3rd Edition) for the Variation Code e.g. MaV-1, MiV-PA1 etc.

** Please list and submit the documents required for each Variation Code as listed on **Appendix 4 – Types of Variations** and the supporting documents indicated in **Annex 13 (Item no. 4)** of the Guide to Application for Registration of Medicinal Products (3rd Edition)