



## MEDICINES CONTROL AGENCY

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia, Website: [www.mca.gm](http://www.mca.gm); E-mail: [info@mca.gm](mailto:info@mca.gm); Tel. No.: +2204380632

### APPLICATION FOR VARIATION

**Reporting Type:**     **AN**                       **IN**                       **Vmin**                       **Vmaj**  
                                  **Single Variation**                       **Grouping of Variations**

### Product(s) concerned by this application

MCA Product Registration Number .....
Proprietary name of the product .....
International Non-Proprietary Name (INN) .....
.....
Active Substance(s) .....
Pharmaceutical form and Strength .....

*Please repeat table for each product*

### Marketing Authorisation Holder (MAH)

Name.....
Premises/Business Address .....
.....
Tel .....
Email .....
Website .....

### Local Representative (if applicable)

Name .....
Address + Full Contact Details .....
.....
.....
Tel .....
Email .....
Website .....

**Status of Applicant** (please tick)

- |   |   |
|---|---|
| <input type="checkbox"/> Marketing Authorisation Holder | <input type="checkbox"/> Local Representative |
| <input type="checkbox"/> Other (please specify)         |   |

**Applicant** (if other)

Name .....
Address + Full Contact Details; .....
.....

**Classification of Changes**

Specify the precise present and proposed wording or specification with reference to the Variation Code(s) in the respective Annex of the MCA Guideline for Variations and the CTD Section(s), where applicable

For changes of the Summary of Product Characteristics, labelling and package leaflet, underline or highlight the changed words in the table below or in a separate attachment.

<b>Description of Change</b>		<b>Variation Code</b>	<b>CTD Section</b>
<b>Previous</b>	<b>Change</b>		

If the same changes were communicated to other Regulatory Authorities (RA), list the countries, names of the RAs and dates of submission in the table below. MCA may apply its Reliance Policy and recognise decisions of other RAs.

<b>Country</b>	<b>Name of RA</b>	<b>Date of submission</b>

**For Annual Notification (AN):**

Change(s) was/were implemented on: \_\_\_\_\_ Date: \_\_\_\_\_

**For Immediate Notification (IN) and Application of Minor Variation (Vmin):**

Next production run/next printing

Date: \_\_\_\_\_

**For Major Variation (Vmaj)** The date for the implementation of need to be agreed with the MCA.

**Declaration of the Applicant:**

I, the undersigned hereby submit an application for the above Marketing Authorisation(s) to be varied in accordance with the proposals given above. I declare that (*Please tick the appropriate declarations*):

- There are no other changes than those identified in this application;
- Where applicable, all conditions as set for the variation(s) concerned are fulfilled;
- The required documents as specified for the changes concerned have been submitted;
- Where applicable, samples have been provided;
- The fees have been paid by bank transfer in accordance with the Fee Schedule.

Name ..... Position .....

Signature: ..... Date: .....

**OFFICIAL USE**

Date of Receipt: .....	Variation no: .....
<input type="checkbox"/> Accepted <input type="checkbox"/> Additional data required <input type="checkbox"/> Rejected	
Comments	