



**MEDICINES CONTROL AGENCY**

Kairaba Avenue, K.S.M.D. Pipeline, The Gambia. Telephone: (+220)4380632, [www.mca.gm](http://www.mca.gm)

**MEDICINES VARIATION REGISTRATION APPLICATION**

**Variation Type:** Minor  Major  Other .....

**MCA Product Registration Number:** .....

Brand Name .....

Generic Name .....

**CHANGE(S) CONCERN(S) (TICK ALL CHANGES APPLICABLE):**

Indication  Safety  Quality

Other  (please specify) .....

**APPLICANT**

Name .....

Address + Full Contact Details; .....

**STATUS OF APPLICANT (mark as X)**

Manufacturer  Marketing Authorisation Holder  Pharmaceutical Company

Importer  National Representative  Other  (please specify)

**MARKETING AUTHORISATION HOLDER (if different from applicant):**

Name .....

Address + Full Contact Details; .....

Specify the precise present and proposed wording or specification with reference to the MCA CTD number(s), where applicable

For Professional Information/SmPC, container labelling and patient information leaflet changes, underline or highlight the changed words presented in the table below or provide as a separate Annex.

<b>PRESENT</b>	<b>PROPOSED</b>	<b>CTD Section</b>

**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 in accordance with the Fee Schedule.

Change(s) will be implemented from:

- Next production run/next printing

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

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

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

**OFFICIAL USE**

Date of Receipt: .....	Variation no: .....
Approval <input type="checkbox"/> Conditional approval <input type="checkbox"/> Rejection <input type="checkbox"/> Other <input type="checkbox"/> specify	
Comments	