****

**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.

|  |  |  |
| --- | --- | --- |
| **PRESENT** | **PROPOSED** | **CTD Section** |
|  |  |  |

**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  Conditional approval  Rejection Other specify | |
|  | |
| Comments | |