



MEDICINES CONTROL AGENCY

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

APPLICATION FOR MARKETING AUTHORISATION (REGISTRATION) OF MEDICINES

- Generic Medicine** **New Chemical Entity (New Active Substance)**
 Biological **Herbal Medicinal Product** **Veterinary Medicine**

Proprietary name of the product

International Non-Proprietary Name (INN):

Route of Administration

Dosage form / strength

MANUFACTURER

Name.....

Premises/Business Address

Tel

Email Website

MARKETING AUTHORISATION HOLDER (MAH)

Name.....

Premises/Business Address

Tel

Email Website

LOCAL REPRESENTATIVE (if applicable)

Name

Address + Full Contact Details

Tel
Email Website

QUALIFIED PERSON FOR PHARMACOVIGILANCE (QPPV)

Name
Address + Full Contact Details
Tel
Email Website

STATUS OF APPLICANT

<input type="checkbox"/> Manufacturer	<input type="checkbox"/> MAH	<input type="checkbox"/> Local Representative	<input type="checkbox"/> Importer
<input type="checkbox"/> Other (specify)			

**COMPOSITION OF PRODUCT:
(name and quantity of active (pharmaceutical) ingredients & excipients)**

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INDICATIONS AND DOSAGES:

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**PHARMACOLOGICAL CATEGORY/PHARMACOTHERAPEUTIC GROUP/ATC
CODE:**

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**MARKETING AUTHORISATION (MA)/REGISTRATION IN OTHER COUNTRIES
(Pending or approved):**

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PACKAGE SIZES AND PRESENTATION

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DISPENSING CATEGORY (tick as applicable):

- | | |
|--|--|
| <input type="checkbox"/> Prescription Only Medicines (POM) | <input type="checkbox"/> Pharmacy Only Medicine (PM) |
| <input type="checkbox"/> Over The Counter Medicines (OTC) | <input type="checkbox"/> Controlled Drug (CD) |

MISCELLANEOUS (Special Conditions, etc.)

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ENCLOSURES (tick what is applicable)

- | | | |
|--|--|--|
| <input type="checkbox"/> CTD Dossier | <input type="checkbox"/> Manufacturing Licence | <input type="checkbox"/> GMP Certificate |
| <input type="checkbox"/> Container labels | <input type="checkbox"/> SmPC | <input type="checkbox"/> Package insert |
| <input type="checkbox"/> MA/Registration certificate(s) from country of origin and others, as applicable | | |
| <input type="checkbox"/> Risk management plan (if applicable) | | |
| <input type="checkbox"/> Samples # | <input type="checkbox"/> Other | |

DECLARATION:

I, the undersigned certify that the information in the accompanying documentation concerning the application for marketing authorisation (registration) of the medicine indicated herein is true and reflects the total information available.

I also agree that I am obliged to comply with the requirements of the Agency related to the stated product at any time in the future.

Name of Applicant:

Position/Designation and relation to MAH:

Address and Contact Details:

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Signature of Applicant: Date:

OFFICIAL USE

Application no:
Comments