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 Form for Renewal of Authorisation of Medicine

(To be submitted in duplicate electronic copies)

Cover letter addressed to:

Executive Director, Medicines Control Agency, Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia

Submission should always be done by the MAH directly to the MCA or through the authorised local representative.

Note: Samples can be forwarded to the MCA directly or through the local representative; customs duty and clearance are to be effected by the marketing authorisation holder (MAH) in all instances.

1. Product Details
Existing MCA Registration (marketing authorisation) Number: Full Name of Product (proprietary name): Human or Veterinary (if veterinary, state target species):
International Non-Proprietary Name (INN): Is this product registered in other countries? ☐ Yes ☐ No If yes, list countries and authorisation/registration numbers: WHO prequalification status (*please provide PQ date*):
Pharmacological classification ATC Code(s): Pharmaceutical form: Formulation type: Route of Administration: Concentration/Strength: Appearance/Colour: Therapeutic indications: Active pharmaceutical ingredient(s):
Dispensing Category: Proposed distribution network, if applicable:
Country of origin:

Manufacturer: Marketing authorisation holder: Marketing authorisation/registration number & date (country of origin):
2. MAH Contact Information
Full name of MAH: Manufacturing company and manufacturer's licence number (*including accessory companies):* Name of contact person(s): Title and / or designation:
Physical address (MAH):
Postal address (MAH):
E-mail (MAH): Telephone number (MAH): Website (MAH):
3. Name and Contact Details of the Qualified Person for Pharmacovigilance (QPPV) Responsible for the Finished Product in The Gambia
Name: Registration number with the applicable Council in The Gambia: Address: Telephone number: E-Mail:
4. Name and Contact Details of the Local Representative
Note: Only a body incorporated in The Gambia can be appointed as a local representative for this application
Full name of local representative (*must be a registered company*):
Business registration number: Name of contact person: Title and /or designation:
Postal address (local representative):
Physical address (local representative):
E-mail (local representative): Telephone number (local representative): Fax number (local representative):

Full name of Supervising Pharmacist: Registration number of Supervising Pharmacist:
Correspondence about this application is to be addressed to: ☐ MAH ☐ local representative

5. Product Data
Data must be accompanied by a table of content; information shall be provided in soft copy-DUPLICATE (an electronic format saved on a USB flash drive).
Data may include, but not limited to the following: • Supporting documentation for any variations since the product was last registered • Certificate of analysis of the finished product • Certificate of Pharmaceutical Product (CoPP) issued by the statutory national medicines regulatory authority, in accordance with the World Health Organization (WHO) Certification Scheme for Pharmaceutical Products Moving in International Commerce • Long-term/Real-time and real condition stability studies for three (3) production batches (protocol and report) • Method of analysis (Protocol and Report) • Analytical Method Validation (Protocol and Report) • Evidence of Good Manufacturing Practice (GMP) • Batch release documents • Reference Standard/ Product • Certificate of Analysis of the Reference Standard/Reference Product • Risk management plan and pharmacovigilance data of post market surveillance
6. Variation(S) Made to Packaging/Presentation/Formulation
List all variations made to the primary and/or secondary packaging/presentation/formulation since initial authorisation/registration
7. List of all Change(s) in the Conditions of Use, Labelling or Registration Conditions for the Product
8. Distinct Prescribed Uses
List all proposed therapeutic indications (for veterinary, state target species and situation)

9. Manufacturers' Details

The manufacturer must be licensed to manufacture the product for which this renewal application applies. Include the name and address of all facilities involved in any step of manufacture, including packaging & labelling, contractors and analytical laboratories where applicable.

Company name	**Company's registration number**	**Physical address of manufacturing site**	**Extent/Stage of manufacture** (attach flow diagram)
1.			
2.			
3.			
4.			
5			

Provide details of responsible person performing 'Release for Supply':

Name of responsible person:
Position:
Title:
Company name:
Physical Address:
E-mail:
Telephone number:
Fax number:

10. Container and Pack Size Details

Proposed pack size(s)	**Brief description of the packaging material, including that which is in direct contact with the product (*i.e.* primary and secondary packaging).**	**Method of label attachment**

Provide details of product presentation (e.g. single glass bottle inside individual cardboard carton with enclosed leaflet).

11. Storage Stability Details

The proposed shelf life from the date of manufacture:	
Proposed in-use shelf life:	
Proposed storage conditions: (e.g. between 2°C and 8°C. Refrigerate. Do not freeze).	
Submit a comprehensive stability study protocol, data and report on three (3) consecutive batches to support the storage stability of the product:	
For products in multiple dose containers: Submit an in-use stability study to support the in-use shelf life of the product:	
Submit a detailed storage temperature profile of the product (i.e. transportation and excursions):	

12. MAH's Checklist

Tick the appropriate boxes to verify that required documentation is attached:

- ☐ Application Overview completed including outline of exact purpose of application (and all relevant attachments)
- ☐ Appropriate fee
- ☐ Application form signed in ink and completed all relevant sections
- ☐ Completed batch release records, if applicable

Attachments (where applicable) should be indicated in the table of attachments and attached to this Application Form.

Table of attachments

Attachment	**Attached?**	
Product label in appropriate format	☐ Yes	☐ No
Product Data	☐ Yes	☐ No
GMP certificates/documentation	☐ Yes	☐ No
MCA import clearance permit for samples, if applicable	☐ Yes	☐ No

Evidence of purchase of reference product (if applicable)	☐ Yes ☐ No
Other (specify)	

Note: The entire application should be submitted with a table of contents. The total number of pages in the application, and total number of pages of attachments and appendices should be clearly stated.

I declare that the information provided with this application is complete and correct.

Signature (MUST be in ink): ..... Date: .....
Official stamp:

False declaration may lead to prosecution.

FOR OFFICIAL USE ONLY
Application tracking number:
MCA Authorisation (Registration) number: