

Model application cover letter for the marketing authorisation (registration) of medicine

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

Dear Sir/Madam,

Subject: Submission of Application for the Marketing Authorisation (Registration) of <Product Name>.

We are pleased to submit our application(s) for the marketing authorisation of the product(s) as detailed below.

Name of the medicine:

Dosage form(s) and strength(s):

INN/Active Pharmaceutical Ingredient(s):

.....
Manufacturer name and country of origin:

Marketing Authorisation Holder Name:

.....
Please note that you will also find alongside this cover letter the following:

- Application form
- One hard copy (CTD Module 1 only)
- One USB flash drive containing all information on the product (where applicable)
- Evidence of payment of the fee(s) as stipulated in the fee schedule
- A valid Certificate of cGMP compliance
- Three commercial samples with batch certificates of analysis

I, the undersigned certify that all the information in this application and accompanying documentation is correct, complete and true to the best of my knowledge.

Yours sincerely,

<Signature>

<Name>

<Designation>

<Phone number(s)>

<Social Media Contact>

<Email address>