17 January 2025
MCA-GL-102, version 4 - 2025
MCA Technical Working Group

Guideline for Marketing Authorisation (Registration) of Medicines

Draft written and agreed by MCA Technical Working Group	16 September 2024
Release for consultation by MCA The Gambia	24 October 2024
Start of public consultation	24 October 2024
End of consultation (deadline for comments)	25 November 2024
Agreed by MCA Technical Working Group	11 January 2025
Approved by MCA Executive Director	17 January 2025
Date of coming into effect	20 January 2025

This guideline replaces version 3 dated 15 April 2020 of the MCA 'Guideline for Registration of Medicines' (MCA-GL-102).

Version #	**Effective Date**	**Reasons for Change:**
2	15 February 2018	Editorial changes, harmonisation of format for MCA guidelines, adaptation to the CTD, nutritional supplements integrated.
3	15 April 2020	Editorial changes, references to the Regulations included, information contained in other regulatory documents deleted and cross-referenced.
4	20 January 2025	Format changed to the current template; title changed; editorial changes; CTD format extended to herbal medicinal products and biologicals and reference to respective guideline deleted; some requirements deleted and references to respective MCA guidelines added; role of the local representative of MAH more detailed; data requirements more

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162 Serekunda
Telephone +220 4380632
Send a question via our website www.MCA.gm or info@mca.gm
An agency of The Gambia

		detailed.

Comments should be provided by using the template (MCA-F-021/03) for Submission of Comments and sent to info@mca.gm

Keywords	medicine, medicinal product, marketing authorisation, registration, local representative

Guideline for Marketing Authorisation (Registration) of Medicines

Table of contents

Acknowledgements

We duly thank the World Health Organization (WHO), the European Commission, the European Medicines Agency (EMA) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) for publishing their guidelines and notice to applicants that contributed in several aspects relevantly to the development of this guideline.

1 Introduction (background)

1.1. The marketing authorisation (registration) of medicines by the Medicines Control Agency (MCA) in The Gambia ensures that the products

- meet international standards of quality, safety and efficacy; and
- are manufactured and controlled to consistently meet acceptable standards.

1.2. The Agency has adapted the Common Technical Document (CTD) format to applications for marketing authorisation of medicines (medicinal products) for human use.

1.3. The CTD is an internationally agreed format for the organisation and preparation of application dossiers to be submitted to regulatory authorities

for marketing authorisation. It will be applicable for all types of marketing authorisation applications irrespective of the procedure and type of application, and for all types of medicines.

1.4. To determine the applicability of this format for a particular type of product, applicants should consult with the MCA.

Objective

1.5. This guideline presents a common format for the preparation and submission of an application to the MCA for the marketing authorisation of medicines.

1.6. The objectives of this guideline include the following:

- Ensure appropriate preparation of documentation for the authorisation of all medicines.
- Provide guidance on the technical and other general data requirements for the authorisation of medicines.
- Promote transparency and efficiency for the subsequent evaluation processes by the MCA.

2 Legal basis

2.1. The regulation of medicines in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014 ("Act"), by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products.

2.2. Part VI of the Act, Registration of Medicines and Related Products, Sections 25, 26, and 30 requires that all medicines manufactured, prepared, imported, exported, distributed, sold, supplied or exhibited for sale have been registered (authorised) by the Agency.

2.3. The Medicines and Related Products Regulations, 2020 ("Regulations") details the legal requirements.

2.4. Applicants are required to familiarise themselves with this document and the above stated law before applying for marketing authorisation (registration) of a medicine.

3 Scope

3.1. This guideline applies to medicines as defined in the Act and the Regulations, and includes herbal medicinal products, biologicals (biotherapeutics) and vaccines manufactured in country or imported into The Gambia for human and animal use.

3.2. It also applies to line extensions of medicines.

3.3. There are separate MCA guidelines for the renewal of marketing authorisation (registration) of medicines, withdrawal, revocation, suspension or cancellation of marketing authorisation of medicines, marketing authorisation under non-routine procedures (Emergency Use Authorisation of Medicines) and for variations of authorised medicines.

3.4. For withdrawal, suspension, revocation or cancellation of the marketing authorisation of medicines refer to the respective MCA Guideline (MCA-GL-115).

4 Timelines

4.1. The Agency shall acknowledge receipt of applications and completed payment of fees within two weeks of reception of the complete application.

4.2. If data and/or documents and/or samples are outstanding, they should be provided within 15 working days.

4.3. The Agency shall process an application for marketing authorisation (registration) of a medicine within 180 days.

4.4. The Agency may carry out an abridged review of application to authorise a medicine for marketing in The Gambia, if it has a marketing authorisation issued by a stringent regulatory authority (SRA) that applies standards for quality, safety and efficacy evaluation recommended by WHO or is prequalified by WHO. In case of an abridged review the application should be processed within 90 days.

4.5. During evaluation, additional data and/or documents and/or samples may be requested through a query letter. Once a query has been raised and issued to the applicant, the process stops until when MCA receives a written response to the query.

4.6. The applicant shall submit written responses to queries within 180 days or in case of an abridged review within 90 days from the date of their issuance. If the queries have been reissued for a second time and the applicant provides unsatisfactory responses, the product will be disqualified and the application will be rejected. The applicant will be required to apply afresh.

4.7. If no response is received within 180 or 90 days, respectively of the request, it will be deemed that the applicant has withdrawn the application and the application will be discontinued.

4.8. The marketing authorisation (registration) of a medicine, unless otherwise stated, shall be valid for a period of five (5) years. For renewal of the initial authorisation refer to the MCA *Guideline for Renewal of Marketing Authorisation (Registration) of Medicines* (MCA-GL-111).

5 General Requirements

5.1. A separate application is required for each product.

5.2. Products that differ in active pharmaceutical ingredient(s), strength, dosage form, presentation, package size or manufacturer(s) are considered to be different products and hence require separate applications.

5.3. For a fixed dose combination medicine, the applicant must provide proven evidence that the product has been shown to be safe and effective and that all of the active ingredients contribute to the overall therapeutic effect. In addition, it should be proven that there can be real clinical benefits in the form of increased efficacy and/or a reduced incidence of adverse effects and/or improved patient compliance.

5.4. Registration of innovative medicines in The Gambia shall normally not be permitted within the first two years of the initial authorisation and being placed on the market in the country of origin where there is prevalence of the disease condition. Verifiable information regarding the date of expiry of the patent should be provided.

5.5. The Agency charges non-refundable application fees for the marketing authorisation (registration) as specified in the MCA Fee Schedule published in the *Gazette*. Evidence of payment as bank transfer should be submitted alongside the application. Note that any application not accompanied by the requisite proof of completed payment will not be given consideration.

5.6. The manufacture(s) and the proposed marketing authorisation holder (MAH) responsible for the product in The Gambia shall be clearly indicated.

5.7. If the proposed MAH is not resident in The Gambia, the MAH must ~~shall~~ appoint a local representative.

5.8. The local representative shall represent the MAH at the Agency and perform functions delegated by the MAH. The designation of a local representative shall not relieve the marketing authorisation holder of his/her legal responsibility.

5.9. The local representative shall be a legal entity registered by the respective statutory body in The Gambia. The Agency may accept a regional representative residing a West African country.

5.10. An application for the authorisation of a medicine shall be made in writing via a completed application form (MCA-F-112/01) available from the MCA website www.mca.gm, dated and signed by the applicant and accompanied by a cover letter.

5.11. The duly signed cover letter shall be addressed to the Executive Director, Medicines Control Agency, Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. BOX 3162, Serekunda, The Gambia.

5.12. 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.

5.13. In case of a line extension, this should be indicated in the cover letter.

6 Documentation Required for Marketing Authorisation (Registration)

6.1. All applications shall contain the information and documents as required by the Regulations.

6.2. The dossier for application shall be submitted in the MCA Common Technical Document (CTD) format as provided by the Agency (MCA-G-112/02) including all supporting documents, unless stated otherwise in this guideline. Other CTD formats (e.g. WAHO, WHO, EU, ICH) would be accepted.

- For generic/multisource medicines CTD Modules 1, 2 and 3 and part of Module 5 (*5.3.1 Reports of Bio-pharmaceutic Studies*) are required as safety and effectiveness of the medicine is established. For the establishing of equivalence refer to the EMA with the annotations in the MCA *Guideline on Investigation of Equivalence* (MCA-GL-121).

- For biosimilar products and medicines containing a new chemical entity (new active substance) all modules of the MCA CTD are required for an application.

6.3. For herbal medicinal products and biologicals (biotechnical products) the requirements stipulated in Volume 2B, Notice to Applicants of the European Commission 2003 will apply.

6.4. All submitted documents shall be in English, must be legibly printed and not handwritten. Documents that are in any language other than English must be accompanied by a notarised English translation.

6.5. The dossier shall be submitted as follows: one hard copy (CTD Module 1 only) and one soft copy (all CTD Modules 1, 2, 3, 4 & 5) provided as a USB flash drive.

6.6. Copies of the proposed or marketed container labels, patient information leaflet (package insert) and Summary of Product Characteristics (professional information), shall be included in the documentation.

6.7. All applications shall be accompanied by three (3) samples of the product in the commercial pack(s) with batch Certificates of Analysis (CoA). The CoA shall be issued by an authorised person with expert knowledge (qualified person) and duly signed and dated.

6.8. Although clinical trial data including bioequivalence data for generic medicines derived from studies in other countries will be considered in taking a decision with any application, the Agency reserves the right to request for clinical evaluation in The Gambia, where necessary, based on existing MCA guidelines.

6.9. The Agency may ask the applicant to provide other information as may be required to enable reaching a decision on the application.

7 Manufacturing Information

7.1. Medicines manufactured in The Gambia can only be authorised ~~registered~~ after the manufacturing premises were inspected and licensed by the Agency.

7.2. For medicines to be imported the manufacturing licence and Good Manufacturing Practice (GMP) certificate must be submitted.

7.3. Where the product is manufactured in different countries and the applicant wishes to obtain approval to use all sites of manufacture, the corresponding manufacturing licenses and GMP certificates, where applicable should be submitted from all the countries.

7.4. The manufacturer of the Active Pharmaceutical Ingredient (API) should provide a signed declaration stating that the synthesis and subsequent purification is conducted in accordance with what is presented in the Drug Master File (DMF).

7.5. All oral liquid preparations (e.g. solutions, suspensions, syrups) shall have an appropriate graduated measure included in the final package.

7.6. For all solid oral dosage forms, reports of dissolution studies are required. If the monograph used by the applicant does not require dissolution, the dissolution requirement in officially recognised pharmacopoeias shall apply.

7.7. For information about excipients refer to the MCA *Guideline on Excipients* (MCA-GL-124) with the annotations of the EMA *Guideline on Excipients in The Dossier for Application for Marketing Authorisation of a Medicinal Product*.

7.8. For stability requirements refer to the MCA *Guideline on Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products* (MCA-GL-123) with the annotations of the WHO Guideline, Annex 10, *Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products*.

7.9. The labelling requirements for medicines ~~for human use~~ must be fulfilled as detailed in the MCA *Guideline for Labelling of Medicines for Human Use* (MCA-GL-101). The requirements for medicines for animal use apply accordingly as far as they correspond.

8 Pharmacovigilance Information

Pharmacovigilance System

8.1. MAHs of medicines marketed in The Gambia shall permanently and continuously have at their disposal a person responsible for Pharmacovigilance, referred to as Qualified Person for Pharmacovigilance (QPPV). MAHs not resident in The Gambia must have a QPPV residing in The Gambia at their disposal. For further details refer to the MCA *Guideline for Safety Monitoring of Medicines (Pharmacovigilance) including Vaccines* (MCA-GL-307).

8.2. The MAH is required to provide a summary of its pharmacovigilance system that records the system that will be in place and functioning at the time of granting of the marketing authorisation and placing of the product on the market.

8.3. MAHs of herbal medicinal products are not required to submit the summary, but they are required to operate a pharmacovigilance system and prepare, maintain and make available on request a PSMF.

8.4. The summary of the pharmacovigilance system should be provided in the application dossier for marketing authorisation (see Module 1.8.1 of the EU Notice to Applicants, Pharmacovigilance System) and include the following elements:

- proof that the applicant has at his disposal a qualified person responsible for pharmacovigilance (QPPV);
- the location in which the QPPV resides and carries out his/her tasks;
- the contact details of the QPPV;
- a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks; and
- a reference to the location where the pharmacovigilance system master file (PSMF) for the medicines is kept.

8.5. The MAH may combine this information in one single statement to confirm the obligation to have the necessary means to fulfil the tasks and responsibilities listed in this document.

8.6. Such statement should be signed by an individual who can act on behalf of the legal entity of the applicant/MAH and by the QPPV. The title, role and responsibility of each individual signing the statement should be clearly specified in the document.

8.7. The requirement for the summary of the pharmacovigilance system is the same for any marketing authorisation application, independent of the legal basis for the application.

8.8. Although the PSMF is not part of the marketing authorisation dossier, the applicant may be requested to provide a copy of the PSMF to the Agency for review during the evaluation of a marketing authorisation.

8.9. The PSMF has to describe the pharmacovigilance system in place at the time of the application. Information about elements of the system to be implemented in the future may be included, but these should be clearly described as planned rather than established or current.

8.10. The pharmacovigilance system will have to be in place and functioning at the time of placing the product on the market.

Risk Management Plan

8.11. The MAH and representatives of MAHs should provide a detailed description of a risk management system in the form of a Risk Management Plan (RMP) for

- any product containing a new active substance;
- a similar biological medicine;
- a generic medicine where a safety concern requiring additional risk minimisation activities has been identified with the reference medicinal product.

8.12. For details of the RMP refer to the MCA *Guideline for Safety Monitoring of Medicines (Pharmacovigilance) including Vaccines*.

9 Decision on Marketing Authorisation (Registration)

9.1. The Agency in considering an application for marketing authorisation (registration):

- shall verify the quality, safety and efficacy of the medicine;
- may consult with other bodies and experts with knowledge of the medicine;
- may take into account and give significant weight to assessments performed and decisions made by reference institutions in accordance with the MCA Guideline for Reliance on decisions, reports, or information from other national medicines regulatory authorities (NMRAs) or regional and international bodies; and
- reserves the right to conduct a GMP inspection on the manufacturing facility for the product at a fee prescribed by the Agency.

9.2. Decisions on marketing authorisation by MCA shall be based on the dossier evaluation, quality control results of the samples and inspection on compliance to GMP, if applicable.

9.3. An appeal for the review of an application may be made in writing to the Executive Director within sixty (60) days of receipt of the rejection notice.

9.4. Where all requirements for the marketing authorisation of a medicine have been met, the Agency shall issue to the applicant a certificate of marketing authorisation (registration), subject to such conditions as may be prescribed by the Agency.

9.5. The Agency shall gazette annually the authorised products.

9.6. No confidential information given in this application shall be disclosed by the MCA to a third party except:

- with the written consent of the applicant/marketing authorisation holder; or
- by the directive of the Governing Board of MCA; or
- for a legal process under the Medicines and Related Products Act, 2014.

Definitions

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: **www.mca.gm.**

The definitions provided below apply to the terms used in this guideline. They may have different meanings in other contexts and documents.

The interpretation of terms provided in the Act and Regulations apply, unless further defined in this guideline.

Active Pharmaceutical Ingredient (API)
Any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals. Synonym is "active substance".

Composition
In relation to a medicine means an ingredient of which it consists, proportions, degree of strength, quality, and purity in which those ingredients are contained.

Excipient
Any constituent of a pharmaceutical form that is not an active pharmaceutical ingredient.

Finished Pharmaceutical Product (FPP)
A product that has undergone all stages of production, including packaging in its final container and labelling. A FPP may contain one or more active pharmaceutical ingredients.

Formulation
The process by which different substances including the active ingredient, are combined to produce a final medicine.

Label
A descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a packaging of any medicine.

Local representative

A legal entity registered by the respective statutory body in The Gambia appointed by the marketing authorisation holder (MAH) to represent the MAH at the Agency and perform functions delegated by the MAH.

Marketing Authorisation (MA)
Approval to market a medicine in the NMRA's country. MA is issued by the NMRA with a legal document for marketing or distribution of a product within the country after evaluation for safety, efficacy and quality in the marketing authorisation assessment process.

Marketing Authorisation Holder (MAH)
A company or other legal entity that has the authorisation by a regulatory authority to market a medicine or related product and who is responsible for its quality, efficacy and safety and for compliance with conditions of authorisation (registration).

Manufacture/Manufacturing
Any total or partial operation of producing, preparing, formulating, treating, processing, filling, decanting, packaging, labelling and releasing of medicines and the related controls.

Manufacturer
Any person or entity with responsibility in manufacturing activities including implementation of oversight and controls over the manufacture of the medicine or active pharmaceutical ingredients or excipients to ensure quality.

Manufacturing site
The location where the manufacturing process of a medicine is undertaken.

Medicine/Medicinal Product
Any substance or combination of substances prepared, sold or presented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it or restoring, correcting or modifying organic functions in human beings and animals.

The term "medicines or medicinal products" in the context of this guideline includes finished pharmaceutical products, biologicals (biotherapeutics), vaccines and herbal medicinal products for human and animal use. Not included are medical devices, in-vitro diagnostics and blood products, if not indicated otherwise.

Renewal
The process of extending the validity of a marketing authorisation based on an application by the marketing authorisation holder when the validity of the current authorisation is due to expire.

Specifications
A document describing in detail the requirements such as physical, chemical, biological and microbiological test requirements with which the products or materials used or obtained during manufacture have to conform.

Shelf life
The period of time during which a medicine, if stored correctly, is expected to comply with the specifications as determined by stability studies on a number of batches of the product; the shelf life is used to establish the expiry date of each batch.

Variation

A change to the terms of a marketing authorisation. There are different types of variations with different regulatory requirements and procedures.

References

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2020
- MCA Guideline for Reliance on decisions, reports, or information from other national medicines regulatory authorities (NMRAs) or regional and international bodies (MCA-GL-109)
- MCA Guideline on the Investigation of Bioequivalence (MCA-GL-121)
- MCA Guideline on Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products (MCA-GL-123)
- MCA Guideline on Excipients in the Dossier for Application for Marketing Authorisation of Medicines (Medicinal Products) (MCA-GL-124)
- MCA Fee Schedule
- European Commission Volume 2B, Notice to Applicants, Medicinal products for human use, Presentation and format of the dossier, Common Technical Document (CTD), 2003
- EMA/CPMP Guideline on the Investigation of Bioequivalence, Doc. Ref.: CPMP/EWP/QWP/1401/98 Rev. 1/ Corr **, 20 January 2010
- EMA/CPMP Guideline on Excipients in The Dossier for Application for Marketing Authorisation of a Medicinal Product, EMEA/CHMP/QWP/396951/2006, 19 June 2007
- WHO Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products, Annex 10, WHO Technical Report Series, No. 1010, 2018
- WHO Guidelines on submission of documentation for a multisource (generic) finished product. General format: preparation of product dossiers in common technical document format, Annex 15, WHO Technical Report Series, No. 961, 2011
- WHO Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities, Annex 5, WHO Technical Report Series No. 986, 2014

Annex

Annex 1: Application form for Authorisation of Medicine (MCA-F-112/01)

Annex 2: Guidance for the Application in the CTD Format (MCA-G-112/02)

Annex 3: Model cover letter (MCA-T-112/03)