15 January 2025
MCA-GL-111, version 1 - 2025
MCA Technical Working Group

Guideline for Renewal of 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	15 January 2025
Date of coming into effect	16 January 2025

This guideline replaces sections 4 of the MCA 'Guideline for Registration of Medicines' (MCA-GL-102), version 3, 15 April 2020 and MCA 'Guideline for Registration of Herbal Medicinal Products' (MCA-GL-106), version 3, 15 April 2020.

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

Keywords	medicines (medicinal products), bioequivalence, pharmacokinetics, renewal

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

Guideline for Renewal of Marketing Authorisation (Registration) of Medicines

Table of contents

Acknowledgements

We thank all members of the Joint Technical Working Group for Development of Guidelines in Marketing Authorization (TWG-MAG):

- Food and Drugs Authority (FDA, Ghana)
- Liberia Medicines & Health Products Regulatory Authority (LMHRA, Liberia)
- Pharmacy Board of Sierra Leone (PBSL, Sierra Leone)
- Global Health Protection Programme (GHPP-PharmTrain Project), Federal Institute for Drugs and Medical Devices (BfArM, Germany)

We duly thank the Food and Drugs Authority Rwanda, Food and Drugs Authority Ghana, European Medicines Agency for publishing their guidelines that contributed in several aspects relevantly to the development of this guideline.

Executive summary

The development of this guideline is based on the outcomes and consensus of the meetings convened in January/February 2020 by GHPP-PharmTrain Project team of the Federal Institute for Drugs and Medical Devices (BfArM, Germany) with participants from the national medicines regulatory authorities (NMRA) of Liberia (LMHRA, Liberia Medicines and Health Products Regulatory Authority), Sierra Leone (PBSL, Pharmacy Board of Sierra Leone), and The Gambia (MCA, Medicines Control Agency).

The document has been discussed and adapted in the exchange between LMHRA, PBSL, The Gambia MCA, Ghana (FDA, Food and Drugs Authority) and the GHPP-

PharmTrain project team from September 2021 to September 2022. Version 1 of the Guideline on Renewal for the National Medicines Regulatory Authorities of Ghana, Liberia, Sierra Leone, and The Gambia was finalised on 02 December 2022 for preparation of the NMRA's own guidelines.

This document should be read in conjunction with the relevant sections of MCA Guidelines concerning marketing authorisation (registration) of medicines and other applicable guidance.

1 Introduction (background)

1.1. Renewal of marketing authorisation (registration) of medicines (medicinal products) is required as specified in the legal provision, the Medicines and Related Products Act, 2014 ("Act").

1.2. This guideline applies to all medicines whose marketing authorisation (MA) validity is before ninety (90) calendar days to expiration. It provides guidance to marketing authorisation holders (MAH) on format and content of minimum documents and information required for renewal of authorisation of medicines. It also guides the MCA in managing applications for renewal of authorised medicines.

1.3. This guideline provides requirements to be fulfilled by MAH, including specific documents to be submitted for evaluation prior to renewal of medicines authorisation. MAHs should read this guideline in conjunction with the MCA *Guideline for Marketing Authorisation (Registration) of Medicines, Guideline for Emergency Use Authorisation, and Guideline for Labelling of Medicines for Human Use* along with other references provided in this document.

1.4. It should be noted that the MCA has the right to request any further information or documents, with a commitment that such requests are justifiable, and will be for the purpose of ensuring quality, safety, and efficacy of the submitted product.

Objective

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

1.6. The objectives of this guideline include the following:

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

2 Legal basis

2.1. Part IV of the Act stipulates the legal requirements for registration (marketing authorisation) of medicines.

2.2. In pursuance of the legal provision in section 33 of the Act this guideline is hereby promulgated for information, guidance and strict compliance by all concerned on the procedure and requirements for the renewal of authorisation of medicines in The Gambia.

2.3. In accordance with section 30 of the above stated legal provision a MA valid for five years could be granted. In order for a MA to remain valid, a renewal is required for another three years after the granting of the initial MA (irrespective of whether the MA has been suspended during that period). After that time a new application for marketing authorisation is required. The period of three years, respectively will be counted from the date of notification of the MCA to the MAH.

2.4. The MA may be renewed once upon application by the MAH least ninety (90) calendar days before its expiry. The renewal assessment must be based on a general re-evaluation of the benefit-risk balance of the product. It is the responsibility of the MAH to apply for renewal of the authorisation of the medicine.

2.5. Section 25 (5) states that where the application for renewal is made after the expiration of the marketing authorisation of a medicine, the application shall be considered as a fresh application.

2.6. In the case where a MAH does not submit the renewal application, the MA will expire by law.

3 Scope

3.1. This guideline is developed in pursuance of the legal provision of the Act and shall apply to all medicines authorised by MCA.

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

3.3. MAs approved under routine as well as non-routine are covered by this guideline.

3.4. MAHs are encouraged to familiarise themselves with this document and the above law before completing the application form for the renewal of authorisation of medicine.

4 Timelines

4.1. By the MCA's laws and regulations in place, MAHs must apply for renewal of authorisation to the MCA at least ninety (90) calendar days before its expiry.

4.2. Application submission, validation and processing should be done at least 3 months before the expiration of the validity of an authorised medicine. Following which, the new validity period of the renewed medicine would commence just before or at about the same time of the product's expiry.

4.3. The MCA will perform the validation of the content of the application and may request supplementary information in order to finalise the validation. Upon

receipt of a technically valid and complete application for renewal, MCA will start the procedure and will inform the MAH of the outcome of the assessment. A renewal application will be processed within 3 months of receipt of the application.

4.4. For any question regarding the submission of the renewal application, the MAH can contact the MCA.

5 General Requirements

The renewal constitutes a crucial step in the lifecycle of a medicine, where a re-evaluation of the benefit-risk balance of the medicine takes place. The documentation presented hereafter should be submitted within the renewal application.

5.1 Administrative requirements for submission of application

5.1.1. The application should be submitted by the MAH directly to the MCA or through the authorised local representative. A cover letter should be addressed to the Executive Director, Medicines Control Agency, Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. BOX 3162, Serekunda, The Gambia. A model application cover letter for the renewal of authorisation of medicines (MCA-T-111-02) is available from the MCA website: www.mca.gm.

5.1.2. The application should be submitted in English. All submitted documents that are in any language other than English must be accompanied by a notarised English translation.

5.1.3. Data should be presented in clear and readable format (preferably Verdana, font size 11 or Arial or Times New Roman font size 12). Every page shall be numbered sequentially (x of y). Extension sheets, tables, diagrams, and other supporting documents shall, where possible, be of the same size, clear, well annotated, numbered, and appropriately cross-referenced.

5.1.4. All required technical data shall be presented in the Common Technical Document (CTD) format required in the MCA *Guideline for Marketing Authorisation (Registration) of Medicines*.

5.1.5. One USB flash drive should be provided containing all information on quality and pharmacovigilance data of post market surveillance of the product.

5.1.6. The Agency charges non-refundable application fees for the renewal of marketing authorisation (registration) as specified in the MCA Fee Schedule. Evidence of payment as bank transfer at the time of submission should be submitted alongside the application for renewal. Note that any application not accompanied by the requisite proof of payment will not be given consideration. Also, the MCA reserves the right to determine the correct interpretation of the fee payable based on the fee schedule published in the *Gazette*.

5.2 Content of the application; technical data requirements

5.2.1. Applications for the renewal of authorised medicines shall be accompanied by the following data documentation/requirements:

- An application for the renewal of medicine authorisation shall be made in writing via a completed application form (MCA-F-111-03) available from

the MCA website www.mca.gm, dated and signed by the MAH or local representative and accompanied by the cover letter.

- All currently authorised strengths, dosage forms, product presentations, pack sizes and manufacturer(s) for which renewal is sought should be listed in the cover letter as well as those that the MAH does not wish to renew should be clearly indicated.
- A list of all variations accepted by the MCA over the authorisation period of the products to be renewed, where applicable. Any variation has to be approved prior to the submission of the renewal application and no variation can be applied for until renewal authorisation.
- A list of all countries where the product has been reviewed and approved over the authorisation period of the product, the authorisation/registration numbers, and copies of authorisation/registration certificates if available.
- Three (3) commercial samples including Patient Information Leaflet (PIL) and copies of coloured mock up labels of the product as marketed in The Gambia.
- Current versions of Summary of Product Characteristics (SmPC), inner and outer labelling, as applicable, and Patient Information Leaflet (PIL) in line with the approved MCA templates in both Microsoft Word and PDF format clearly expressed in English. For labelling of medicines for human use refer to the MCA *Guideline for Labelling of Medicines for Human Use.*
- The updated Risk Management Plan (RMP) and where relevant, the new RMP. Where there are no new data justifying changes to the latest approved RMP, the MAH should provide in the clinical overview declaration and confirm that the current approved RMP remains unchanged and applicable. Where there is no RMP for the medicine, this should be stated in the cover letter.

5.3 Quality Requirements

5.3.1. The MAH should incorporate a signed declaration stating that the quality of the product, in respect of the methods of preparation and control, has been regularly updated by variation procedures to take account of technical and scientific progress, and that the product conforms with current MCA quality guidelines. For allopathic medicines the following is required:

Active Pharmaceutical Ingredient(s) (API(s))

- 3.2.S.2 Names and complete addresses of all current suppliers of active pharmaceutical ingredient(s) along with manufacturing and current Good Manufacturing Practices (GMP) certificates of the active pharmaceutical ingredient(s) manufacturing site issued by the competent regulatory authorities and indicating the date, and, where applicable, inspection team and outcome.
- 3.2.S.4 Copy of current signed and dated specifications (with version number) along with change history, where applicable and analytical procedures used for testing of the API(s) by the finished product manufacturing site.

Finished Pharmaceutical Product (FPP)

- 3.2.P.1 Description of qualitative and quantitative composition of the unit dosage form and of the commercial batch size(s) as approved by the NMRA

including excipients (where applicable) in a manner provided for in the MCA *Guideline for Marketing Authorisation (Registration) of Medicines*.

- 3.2.P.3.1 MAH should submit valid GMP certificate, for the finished product manufacturing site indicating the date, and, where applicable, inspection team and outcome.
- 1.3.2 The MAH should provide a valid Certificate of Pharmaceutical Product (CPP) with the importing country specified.
- 3.2.P.5.1-2 A copy of current signed, dated and version numbered release and shelf life specifications of the finished products along with change history, where applicable, and standard testing procedures.
- 3.2.P.8 Data on current long term stability of the finished product should be provided. Studies should be conducted according to requirements stipulated under section 3.2.P.8 of the MCA *Guidance for the Application in the Common Technical Document (CTD)* and specific guidelines on Stability Testing Requirements for Active Pharmaceutical Ingredients and Finished Pharmaceutical Products.
- 3.2.R A copy of batch manufacturing record (BMR) for the largest production batch manufactured within six months before the date of submission of the renewal application.
- 3.2.R Report on annual product quality review (APQR) as stated in Annex 3 of this guideline for all batches of the finished product manufactured in the past 60 months before the date of application of the renewal.
- 3.2.R Copies of Certificate of Analyses (CoAs) for the finished products batches submitted as samples.
- 3.2.R Completed Quality Information Summary (QIS)

5.3.2. For herbal medicinal products a copy of the most recent annual product quality review, prepared according to the requirements of the NMRA of the manufacturing country, is required.

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.

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 chemical substances including the active pharmaceutical ingredient, are combined to produce a final pharmaceutical product.

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

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.

The term "medicines or medicinal products" in the context of this guideline includes finished pharmaceutical products, herbal medicinal products, biologicals (biotherapeutics) and vaccines 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

- European Medicines Agency, Guidelines on the processing of renewals in the centralized procedure, July 2016, EMEA/CHMP/2990/00 Rev.5.
- European Medicines Agency, Reflection Paper Criteria for requiring one additional five-year renewal for Centrally Authorised Medical Products, November 2007, EMEA/131973/2006.
- Ghana FDA, Guidelines for registration of biosimilar products, March 2019, FDA/SMC/BPD/GL-RBS/2013/02.
- Ghana FDA, Registration renewal application form for innovator biological products, March 2015, FDA/SMC/BPD/A-RBP/2016/02.
- Rwanda FDA, Guidelines No. DHT/GDL/022 on submission of documentation for registration of Veterinary medicinal products.
- Rwanda FDA, Guidelines No DHT/GDL/001 on submission of documentation for registration of human medicinal products.
- Saudi Food and Drug Authority SFDA, Data Requirements for the Renewal of Marketing Authorizations for Herbal and Health Products; May 2012.
- Tanzania Medicines and Medical Devices Authority TMDA, Guidelines on submission of documentation for renewal of registration of human and Veterinary Medicinal products, March 2020.
- Uganda NDA, Guidelines for submission of renewal of registration of pharmaceutical product for human use, February 2020.
- WHO, Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products: A manual for National Medicines Regulatory Authorities (NMRAs), 2011.
- Medicines and Related Products Act, 2014, The Gambia

Annex

Annex 1: Model application cover letter for the renewal of authorisation of medicine (MCA-T-111/02)

Annex 2: Application form for renewal of authorisation of medicine (MCA-F-111/03)

Annex 3: Content of the annual product quality review report (MCA-L-111/04)