MEDICINES CONTROL AGENCY

54 Kairaba Avenue, Pipeline, The Gambia. Tel.no. +220 4380632, www.mca.gm

GUIDELINE FOR REGISTRATION OF MEDICINES

Document number and version:	MCA-GL-102, version 3
Date of implementation:	15 April 2020

TABLE OF CONTENTS

1 INTRODUCTION

1.1 LEGAL BASIS

1.1.1. 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.

1.1.2. 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 has been registered by the Agency.

1.1.3. The Medicines and Related Products Regulations, 2019 (“Regulations”) details the legal requirements.

1.1.4. The Agency charges non-refundable application fees for registrations, variations and renewals as specified in the MCA Fee Schedule.

1.1.5. Applicants are required to familiarise themselves with this document and the above stated law before applying for a registration, variation or renewal.

1.2 INTERPRETATION AND ABBREVIATIONS

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

1.3 PURPOSE

1.3.1. In pursuance of the law this document provides guidance to applicants on the procedures for registrations of medicines in The Gambia, for **Variations** of registered medicines and for **Renewals** of registrations.

Note: The registration, variation and renewal of registration of medicines should be approved by the Agency before importation into the country, except of those used as samples for the purpose of this application.

1.3.2. The registration of medicines by the Agency ensures that they

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

1.4 SCOPE

1.4.1. This guideline applies to medicines as defined in the Act and the Regulations, including nutritional supplements manufactured in country or imported into The Gambia.

1.4.2. There is a separate guideline for registration of herbal medicinal products.

2 REGISTRATION OF MEDICINES

2.1 GENERAL REQUIREMENTS

2.1.1. A separate application is required for each product.

2.1.2. Products that differ in active pharmaceutical ingredient(s), strength, dosage forms, proprietary names though containing the same ingredients or from different manufacturers, are considered to be different products and hence require separate applications.

2.1.3. 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 pharmaceutical 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 adherence.

2.1.4. 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.

2.2 PROCESS OF APPLICATION

2.2.1. The application fee shall be paid at the time of submission of an application.

2.2.2. The accompanying cover letter shall be duly signed and addressed to **Executive Director, Medicines Control Agency, 54 Kairaba Avenue, K.S.M.D, The Gambia**.

2.2.3. An application form (MCA-F-112/01) must be completed by the applicant for each medicine. The application form shall be dated, signed and stamped by the applicant and indicate the local agent, where applicable. The application form is available on the MCA website: www.mca.gm.

2.2.4. If the applicant is not resident in The Gambia, he/she shall appoint a contact person or company residing in The Gambia as local agent being responsible for facilitating communication with the applicant unless exempted by the Agency.

2.2.5. The designation of a local agent shall not relieve the marketing authorisation holder of his/her legal responsibility.

2.2.6. The proposed marketing authorisation holder and manufacture(s) shall be clearly indicated.

2.2.7. All applications for registration shall contain the information and documents as required by the Regulations.

2.2.8. The dossier for application for registration 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, ICH) would be accepted.

2.2.9. All documentation submitted shall be in English, and must be legibly printed and not handwritten.

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

2.2.11. Copies of the proposed or marketed labels, patient information leaflet (package inserts) and professional information (Summary of Product Characteristics), conforming to the Regulations shall be included in the documentation.

2.2.12. 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, based on existing MCA guidelines for clinical trials, or bioequivalence data for generic medicines based on existing WHO guidelines for bioequivalence studies, where necessary. The cost of this trial shall be borne by the applicant.

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

2.2.14. All applications shall be accompanied by three (3) samples of the product in the commercial pack(s) with batch Certificates of Analysis (CoA).

2.2.15. The CoA for the medicine shall be issued by an authorised person with expert knowledge (qualified person).

2.3 DOCUMENTATION REQUIRED FOR REGISTRATION

2.3.1. For generic/multisource medicines CTD Modules 1, 2 and 3 and part of Module 5 (5.3.1) are required as safety and effectiveness of the medicine is established.

2.3.2. The bioequivalence of the generic medicine must be demonstrated in comparison to the reference medicine. The reference medicine must be authorised by a stringent RA as indicated by WHO, accompanied by a confirmation that the reference medicine is or has been authorised together with the full composition of the reference medicine and if necessary other relevant documentation.

2.3.3. For biosimilar products all modules of the MCA CTD are required for an application.

2.3.4. For medicines containing a new chemical entity (new active substance) or major line extension (see 3.4) all modules of the MCA CTD are required for an application.

2.3.5. For innovator products verifiable information regarding the date of expiry of the patent should be provided.

2.3.6. The Agency may carry out an abridged review of application to register a medicine that has a marketing authorisation issued by a regulatory authority that applies standards for quality, safety and efficacy evaluation recommended by WHO (reference RA) or is prequalified by WHO.

2.3.7. For registration of medicines in public health emergencies the Agency shall decide on the required documentation on a case-by-case basis.

2.4 MANUFACTURING INFORMATION

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

2.4.2. For medicines to be imported the manufacturing license and GMP certificate must be submitted.

2.4.3. 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.

2.4.4. 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).

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

2.4.6. 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 the USP or equivalent shall apply.

2.4.7. When excipients of animal or human origin are used, (e.g. Stearic acid, Magnesium stearate and other stearates, Gelatine, Phosphates from animal origin) a TSE/BSE free certificate shall be provided; for Talc an Asbestos free certificate is required.

2.4.8. Stability study reports conducted for three (3) trial batches of the product, and suited to the conditions (WHO Zone IV A climatic) specified below, shall be submitted:

Study	Temperature	Relative Humidity	Minimum Time*
Accelerated	40 ± 2° C	75 ± 5 %	6 months
Long-term	30 ± 2° C	65 ± 5 %	12 months

* Period covered by data at submission

2.4.9. The stability study shall be conducted in the container-closure system in which the medicine will be marketed in The Gambia. Where the product is to be registered in more than one container-closure system, stability data shall be provided for each presentation.

2.4.10. Real-time stability data are required for all biologicals.

2.4.11. The results of the stability tests shall be presented in both tabular and graphical forms and the proposed shelf-life and storage conditions shall be determined on the basis of these results.

2.5 LABELLING AND PRESENTATION

2.5.1. The labelling requirements are detailed in the MCA Guideline for Repackaging and Labelling of Medicines (MCA-GL-101).

2.5.2. Statements required to appear on the label should be clear, prominent, indelible and legible to the consumer under normal conditions of purchase and use.

2.5.3. The label should not be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its use in any respect either pictorially or in words.

2.5.4. The presentation of the product shall not have any resemblance in spelling, pronunciation and layout of brand name or packaging to another product from a different manufacturer or MAH.

3 REGISTRATION OF VARIATIONS

3.1. If the applicant makes changes to the details of the registered medicine, such changes, whether administrative or substantive, are referred to as variations and may be subject to acceptance by the Agency prior to implementation.

3.2. Changes that may have minor effects on the overall safety, efficacy and/or quality of the medicine are considered as minor variation and can be implemented, if no objection letter has been issued within 30 calendar days

by the Agency.

3.3. Major variations are changes that could have major effects on the overall safety, efficacy and/or quality of the medicine. Prior acceptance by MCA is required before the changes can be implemented. A letter of acceptance will be issued for all major variations if and when the variation is considered acceptable.

3.4. If changes to an authorised medicine are sufficiently great that it cannot be considered as a simple variation to the original product, it is a major line extension that requires a new product authorisation. Such changes include major new therapeutic indications or new disease states, extension to new patient populations (e.g. paediatrics), a new route of administration or a novel drug delivery system.

3.5. An application for variation registration of a medicine should be submitted to the Agency by a duly signed cover letter addressed to **Executive Director, Medicines Control Agency, 54 Kairaba Avenue, K.S.M.D, The Gambia.**

3.6. The application form for product variation (MCA-F-112/03) registration must be completed by the applicant for each dosage form and/or strength of the medicine. The application form is available from the MCA website: www.mca.gm.

3.7. All documentation in support of the variation shall be provided with reference to the respective CTD sections, where applicable.

3.8. If applicable, three (3) samples of the product in the commercial pack(s) with batch Certificates of Analysis (CoA) reflecting the variation shall be provided.

4 RENEWAL OF REGISTRATION

4.1. An application for renewal of a medicine registration shall be made 90 days before expiration of the existing registration.

4.2. The application for renewal of a registration of a medicine should be submitted to the Agency by a duly signed cover letter addressed to **Executive Director, Medicines Control Agency, 54 Kairaba Avenue, K.S.M.D, The Gambia.**

4.3. The application form (MCA-F-112/01) must be completed by the applicant for product. The application form is available from the MCA website: www.mca.gm.

4.4. All documentation in support of the renewal shall be reference to the respective CTD sections, where applicable.

4.5. The applicant shall submit:

- A copy of the most recent annual product quality review, prepared according to the requirements of the RA of the manufacturing country, should also be provided.
- Batch Manufacturing (Production) Record of a real batch manufactured within at most six months before the submission of the application.
- Periodic Benefit Safety Update Reports (PBSUR) or Periodic Safety

Update Reports (PSUR).

- Any other requirements that the Agency may determine.

4.6. Three (3) samples of the product in the commercial pack(s) with batch Certificates of Analysis (CoA) shall be provided.

5 TIMELINES

5.1. The Agency shall acknowledge receipt of all applications and payment of fees at submission.

5.2. The Agency shall process an application for registration of a medicine within 180 days. In case of an abridged review the application should be processed within 90 days. The Agency may consider an abridged review for medicines prequalified by WHO or, on a case-by-case basis, for medicines authorised by a Regulatory Authorities (RA) recognised by MCA.

5.3. For registration of medicines in public health emergencies the Agency shall decide on the timeline on a case-by-case basis.

5.4. Applications for major variations and renewals shall be processed by the Agency within 90 days.

5.5. During evaluation, additional data 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.

5.6. The applicant shall submit written responses to queries within 180 days or in case of an abridged review, major variations or renewals 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.

5.7. 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.

5.8. The registration of a medicine, unless otherwise stated, shall be valid for a period of five (5) years and may be renewed for a period of not more than three (3) years.

6 DECISION ON REGISTRATION

6.1. The Agency in considering an application for registration:

- shall verify the therapeutic value of the medicine;
- shall have proven evidence in case of a fixed dose combination medicine, that the product is clinically rational;
- may consult with other bodies and experts with knowledge of the medicine;
- reserves the right to conduct a Good Manufacturing Practice (GMP) inspection on the manufacturing facility for the product at a fee prescribed by the Agency; and

- may request the applicant to satisfy the Agency that he/she has the resources and facility to execute an effective recall of the product if the need arises.

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

6.3. 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.

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

6.5. The Agency shall gazette annually the registered products.

6.6. 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
- in accordance with the directive of the Governing Board of MCA; or
- for the purpose of a legal process under the Medicines and Related Products Act, 2014.

7 REVOCATION, WITHDRAWAL OR SUSPENSION OF REGISTRATION

7.1. The Agency shall revoke, withdraw or suspend the registration of a medicine if:

- the basis on which the medicine was registered is later found to be false; or
- the circumstances under which the medicine was registered no longer exist; or
- any of the provisions under which the medicine was registered has been contravened; or
- the standard of quality, safety and/or efficacy, as prescribed in the documentation for registration is not being complied with; or
- the premises, in which the medicine or part thereof is manufactured, packaged or stored by or on behalf of the holder of the Certificate of Registration is unsuitable for the manufacture, packaging or storage of the medicine.

7.2. Where the registration of a medicine is revoked, withdrawn or suspended, the Agency shall withdraw from circulation that medicine in accordance with the Regulations and shall cause the revocation, withdrawal or suspension to be published in the Gazette.

8 FINAL PROVISIONS

8.1. This guideline is the third version published by the MCA and will become effective on 15 April 2020.

8.2. This guideline will be reviewed within 5 years of becoming effective.

9 DOCUMENTS NEEDED FOR THIS GIIDELINE

Document No	**Title** (as referenced on the document)
MCA-F-112/01	Medicines Registration Application - Form
MCA-G-112/02	Guidance for the Application in the Common Technical Document (CTD) Format
MCA-F-112/03	Medicines Variation Registration Application – Form

10 REFERENCES

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2019
- MCA Fee Schedule
- MCA Guideline for Registration of Herbal Medicinal Products (MCA-GL-106)
- 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
- WHO Guidelines on variations to a prequalified product, Annex 3, WHO Technical Report Series No. 981, 2013.

11 DOCUMENT HISTORY

Version #	**Implementation Date**	**Reasons for Change:**
1	25 July 2017	New document
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.

12 FLOW CHART: REGISTRATION OF MEDICINE