MEDICINES CONTROL AGENCY

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GUIDELINE FOR REGISTRATION OF HERBAL MEDICINAL PRODUCTS

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1 INTRODUCTION

1.1 LEGAL BASIS

1.1.1. The regulation of herbal medicinal products 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

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

Herbal Medicinal Product (Herbal Medicine): means any finished medicinal product that contains active ingredients, aerial or underground parts of a plant or other plant material or combination used for the purposes of treatment or prevention of a disease or altering normal physiological function, permanently or temporarily in any way in humans or animals.

1.3 PURPOSE

1.3.1. In pursuance of the law this document provides guidance to applicants on the procedures for registrations of herbal medicinal products in The Gambia, for variations of registered herbal medicinal products and renewals of registrations.

Note: The registration, variation and renewal of registration of herbal medicinal products 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 herbal medicinal products 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 finished herbal medicinal products as defined in this guideline whether manufactured in country or imported into The Gambia.

1.4.2. It does not apply to traditional herbal remedies prepared for individual patients.

2 REGISTRATION OF HERBAL MEDICINES

2.1 GENERAL REQUIREMENTS

2.1.1. A separate application is required for each product.

2.1.2. Products that differ in 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.

2.2 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. For any registration the application form (MCA-F-116/01) must be completed by the applicant for each herbal medicinal product. 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. All documentation submitted shall be in English, and must be legibly printed and not handwritten.

2.2.9. The documents shall be submitted both as one hard copy and one soft copy.

2.2.10. 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.

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

2.2.12. The CoA for the finished herbal medicinal product shall be issued by an authorised person with expert knowledge (qualified person).

2.3 MANUFACTURING INFORMATION

2.3.1. Finished herbal medicinal products manufactured in The Gambia can only be registered after the manufacturing premises is inspected and licensed by the Agency.

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

2.3.3. 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.

2.3.4. Scientific and/or botanical names, including genus and species of the plants used should be given to ensure correct identification of a plant, as well as the parts of plants used and the quantity of active ingredients used in the preparation, shall be submitted.

2.3.5. The manufacturing procedure for the plant preparation should be described in detail.

2.3.6. The manufacturing procedure and formula for the finished product, including the amount of excipients per dosage units, should be described in detail.

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

2.3.8. 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.

2.3.9. 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

2.3.10. The stability study shall be conducted in the container-closure system in which the product 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 QUALITY REQUIREMENTS

2.4.1. In order to ensure quality of the finished products, manufacturers of herbal medicines should specify and implement quality requirements at every stage of manufacture.

2.4.2. A Certificate of Analysis (CoA) for the active ingredient(s) should be provided with detailed information as to the testing performed to confirm the identity and purity of the medicinal ingredient. The CoA shall be issued by the authorised person with expert knowledge (qualified person).

2.4.3. Finished product specifications must be provided for every herbal medicinal product. The specifications should indicate which tests are carried out routinely on each batch of the finished product, and for those which are not carried out routinely, the frequency of the testing should

be stated on the specification sheet.

2.4.4. For herbal medicinal products manufactured in country, toxicological-test reports shall be submitted from MCA recognised laboratories or research institutions.

Physical/chemical identification tests

2.4.5. Physical identification tests should be done on the final dosage form and should be documented in the finished product specifications. Tests for physical identification of the finished product might include tests such as organoleptic evaluation (sensory characteristics e.g., taste, odour, feel, appearance (colour and shape of the capsule or tablet), etc.).

2.4.6. Where the medicinal ingredient is a defined chemical entity, or where a marker is present, chemical identification tests should be used.

Microbial tests

2.4.7. Microbial testing of the under listed parameters should be done according to Pharmacopoeia (USP, Ph.Eur. etc.), WHO methods or any other internationally recognized methods:

- Total viable aerobic plate count
- Contaminating fungus (yeast and mould)
- *Salmonella* spp.
- *Escherichia coli*
- *Staphylococcus aureus*

Heavy Metals (i.e., arsenic (inorganic), cadmium, lead and mercury):

2.4.8. These should be tested individually or as total heavy metals expressed as lead at the finished product stage or at the raw material stage if all medicinal and non-medicinal ingredients are tested. Testing should be done according to Pharmacopoeia or any other internationally accepted methods.

Pesticide Residues:

2.4.9. Testing for pesticides in plant or plant materials, algae, fungi, should be done according to WHO methods for pesticide screening l. Multi-residue pesticide screening is preferential. The pesticide residues that are routinely tested should be those pesticides which were used in treatment of the plant or any pesticides where residues are suspected and may carry over to the final dosage form.

Foreign matter:

2.4.10. Testing should be done according to internationally recognised methods.

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. 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.

2.5.3. The presentation of the product shall not have any resemblance in

spelling, pronunciation and layout of name or packaging to another product from a different manufacturer or MAH.

2.6 SAFETY OF THE PRODUCT

2.6.1. Documented experience of long-term use without evidence of safety problems should form the basis of the risk assessment.

2.6.2. The applicant should provide proof of long period use by different communities including folklore, anthropological studies, etc.

2.6.3. If long-term traditional use cannot be documented or there are doubts on safety, toxicity data should be submitted.

2.6.4. The applicant should provide a report on pharmaco-toxicological data which should include pharmacological activity, acute, sub-acute, chronic and sub-chronic tests submitted from laboratories or research institutions recognised by the Agency.

2.7 EVIDENCE OF CLAIMED INDICATION

2.7.1. Evidence of the clinical effectiveness of the herbal medicinal product for the indications stated shall be required.

2.7.2. The information of proof of efficacy should include any of the following:

- Individual experiences recorded in reports from registered medical practitioner; or
- Experiences from herbal practitioners; or
- Experiences from treated patients.

2.7.3. Clinical evidence will be required in cases where traditional use has not been documented by scientific literature validated by clinical trials.

2.7.4. The recommended dosage of the product needs to be consistent with the evidence used to make the claim. The evidence must relate to the whole product or the same active constituent(s) with similar dosage regimen, dose form and route of administration to the product for which a claimed indication is being made.

3 REGISTRATION OF VARIATION

3.1. If the applicant makes changes to the details of the registered herbal medicinal product, 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. An application for variation registration of a product 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.**

3.3. The application form for product variation (MCA-F-112/03) registration must be completed by the applicant for each dosage form and/or strength.

3.4. 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 herbal medicinal product registration shall be made 90 days before expiration of the existing registration.

4.2. The application for renewal of a registration of a product 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-116/01) must be completed by the applicant for each herbal medicinal product. The application form is available from the MCA website: www.mca.gm.

4.4. The applicant shall submit

- Report of additional adverse reactions, if any
- 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.
- Any other requirements that the Agency may determine.

4.5. Three (3) samples of the product in the commercial pack(s) shall be provided with batch CoAs.

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 herbal medicinal product within 180 days.

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

5.4. 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.

5.5. When the applicant fails to submit written responses to queries within 180 days or if the queries have been reissued for a second time and the applicant provides unsatisfactory responses, the application will be rejected and the applicant will be required to apply afresh.

5.6. The registration of a herbal medicinal product, 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 herbal medicinal product;
- 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.

6.2. Decisions on registration by MCA shall be based on the documentation that should show that MCA requirements are met, 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 product 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 product if:

- the basis on which the product was registered is later found to be false; or
- the circumstances under which the product was registered no longer exist; or
- any of the provisions under which the product 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 product 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 product 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 GUIDELINE

Document No	**Title** (as referenced on the document)
MCA-F-116/01	Herbal Medicines 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 Medicines (MCA-GL-102)
- MCA Guideline for Importation of Medicines and Related (MCA-GL-103)

11 DOCUMENT HISTORY

Version #	**Implementation Date**	**Reasons for Change**
1	25 July 2017	New document
2	12 February 2018	Editorial changes and harmonisation of format for MCA guidelines.
3	15 April 2020	Editorial changes, references to the Regulations included, information contained in other regulatory documents deleted and cross-referenced.