	Title: GUIDELINES FOR THE REGISTRATION OF COMPLEMENTARY/ALTERNATIVE MEDICINES	
Rev No: 02	**Doc No: PBSL/GL/031**	Version no. 03
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Agreed by QMS committee	
Approved by Board	

Pharmacy Board of Sierra Leone,

PMB 322

Central Medical Stores Compound

New England Ville

Freetown

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ACKNOWLEDGEMENTS

EXECUTIVE SUMMARY

1.0 INTRODUCTION

In pursuance of Section 44 of the Pharmacy and Drugs Act, 2001, this Guideline is hereby developed to provide information, guidance and strict compliance by all concerned on the procedure and requirements for the registration of nutritional agents in Sierra Leone. It is applicable to all complementary/alternative medicines for use in humans as well as for veterinary use, where applicable.

Complementary/alternative medicines are vital agents in supporting good health and quality of life. Complementary/alternative medicines must be of good quality, safe, effective and manufactured in premises that comply with the requirements of current good manufacturing practices (cGMPs). An appropriate regulatory framework is, therefore, required to ensure that these are adequately assured.

This guideline describes the requirements for registration of complementary/alternative medicines and explains how applications are made to the PBSL for such registration.

2.0 OBJECTIVE

This guideline has been designed to assist in the following;

- Provide guidance on the technical and other general data requirements for the registration of complementary/alternative medicines by the Pharmacy Board of Sierra Leone.
- To help facilitate the processes and procedures involved in the registration of complementary/alternative medicines.
- Promote effective and efficient processes for the evaluation of these applications and the subsequent issuance of Marketing Authorization.

3.0 SCOPE

In pursuance of Section 44 of the Pharmacy and Drugs Act 2001, this Guideline is made to provide guidance to applicants on the procedure for registering a Herbal Medicinal Product in
Sierra Leone. Applicants are encouraged to familiarize themselves with this document and the above law before completing the registration form.

4.0 REQUIREMENT

4.1 GENERAL REQUIREMENTS

Registration

a. An application for the registration of Complementary/Alternative medicines shall be made in writing.

b. An application form shall be completed in accordance with the sequence of appendices dated, signed and stamped by the applicant/license holder.

All certificates accompanying registration documents shall be submitted in English.

c. This shall be submitted in duplicate (hard and (or) soft copy) and accompanied by:

I. A covering letter addressed to the Registrar of the Authority,

II. Samples of the product as specified in the Authority's samples Schedule, packed in the final package ready for sale.

III. A non-refundable fee prescribed in the Authority's approved fees Schedule.

Registration Variation

a) An application for the variation of registration of a product prior to re-registration shall be made to the Authority. This variation shall be approved by the Authority before any importation of the product shall be made into the country.

b) The application shall be accompanied by:

I. Supporting documentation for the variation.

II. Samples reflecting the variation as specified in the Authority's samples Schedule.

III. Non-refundable variation fee as specified in Authority's approved fees Schedule.

Re-Registration

a. An application for the re-registration of Herbal medicinal product should be made 3 (three) months before the expiration of the registration.

b. The application shall be accompanied by:

I. Supporting documentation for any changes since the product was last registered

II. Samples as specified in the Authority's Sample Schedule.

III. A non-refundable application fee as specified in the Authority's Fee Schedule.

4.2 SPECIFIC REQUIREMENTS

a. The presentation of the product shall not have any resemblance in spelling and pronunciation of name, or packaging to another product, that has been previously registered by the Authority.

b. All samples submitted should conform to existing labeling regulations as specified in the Authority's guidelines for product labeling.

c. The list of all excipients used and their quantities per dosage units used in the preparation shall be submitted. For excipients obtained from

sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), a letter of attestation with supporting documentation should be provided confirming that the material is not from a BSE/TSE affected country/area.

d. The indications for which the herbal medicinal product is being presented for registration shall be unambiguously stated.

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

f. Four (4) copies of the labels and leaflet inserts, conforming to existing labeling regulations in Sierra Leone shall be included in the documentation

g. If the product is produced on contract manufacture, evidence of the contract agreement shall be produced in the documentation submitted.

4.3. QUALITY SPECIFICATIONS

In order to ensure quality of the finished products, manufacturers of Complementary/Alternative Medicines should specify and implement quality requirements at every stage of manufacture.

A certificate of analysis for each medicinal ingredient should be provided with detailed information as to the testing performed to confirm the identity and purity of the medicinal ingredient.

Finished product specifications must be provided for every Complementary/Alternative medicine. 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. Specifications of the finished product e.g. description, disintegration etc. Attach Certificates of Analysis for Final product. The CoA must include Control for Heavy Metals.

Stability studies shall be conducted for 3 (three) trial batches of production and the proposed shelf-life and storage conditions must be determined, based on these results.

a) WHO Zone IV B climatic conditions

Condition	Accelerated	Real Time
Storage Temperature	40 + 2 °C	30 °C
Relative Humidity	75 + 5 %	70 %
Duration	6 months	Until end of shelf life

b) The stability study shall be conducted in the container closure system in which it will be marketed in Sierra Leone.

Where applicable, a Certificate of Pharmaceutical Product (CPP) in accordance with the

WHO Certification scheme/or Free sale certificate and issued by the statutory regulatory authority in the country of origin of the product, shall be submitted along with a certificate of analysis

4.3.1 Physical/chemical identification tests

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.).

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

4.3.2 Microbial test: 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

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

4.3.4 Pesticide Residues: Testing for pesticides in Complementary/Alternative Medicines should be done according to WHO methods for pesticide screening. 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.

4.3.5 Foreign matter: Testing should be done according to internationally recognized methods.

4.3.6 Toxicological Requirement

Acute, chronic and sub-chronic toxicity test reports of the finished product shall be submitted.

4.4. EVIDENCE OF CLAIM

Substantial evidence of the clinical effectiveness of the Complementary/Alternative Medicines for the indications stated shall be required. All indications and claims based on scientific evidence require human studies. For those rare occasions where only non-human data exist,

indications and claims may be allowed on a case-by-case basis. Supporting evidence may be used in conjunction with primary evidence to strengthen the wording of a claim.

In a claim based on scientific evidence, 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 claim is being made. When the evidence is based on an active constituent, qualification may be necessary according to how other constituents in the product may affect the activity of that constituent in the product.

Although foreign clinical data is acceptable, the Authority may request for local clinical trials based on the Authority's Guidelines for Clinical Trials in Humans at its own discretion. The cost of such a trial shall be borne by the applicant.

5.0 GLOSSARY

In this guideline, unless the context otherwise states: -

"**Authority"** means Pharmacy Board of Sierra Leone

"**Product"** means Complementary/Alternative Medicines

"Applicant" means the product owner or license holder. Representatives of license holders may not hold themselves as applicants unless they own the product.

"**Complementary/Alternative Medicines":** This refers to a substance or mixture of substances used in supporting good health and without any reference to alleviation, treatment, modification or prevention of ill health.

Shelf life: The period that product is expected to remain safe and of good quality. The expiry date of an individual batch is based on the known shelf life.

Stability: The capacity of an active ingredient or product or dosage form to remain safe and of good quality and maintain its identity, purity, strength.

Storage Condition: The storage condition, which shall guarantee the maintenance of the quality of the product in relation to its safety, acceptability throughout the shelf life.

"Variation" means a change in the indication(s), dosage recommendation (s), drugs classification and / or patients group(s) for a previously registered Herbal medicinal product been marketed under the same name in Sierra Leone. A variation also includes, but not limited to, a change in the product name, site of manufacture and / or source of ingredients.

6.0 REFERENCES

- Complementary Medicines – DisciplineSpecific – Safety and Efficacy 7.01_CMs_SE_DS_Jun16_v3 MCC
- Complementary Medicines – Road Map 7.02_Roadmap_for_CAMs_Dec13_v1
- Complementary Medicines – ZA-CTD Format 7.03_CAMs_ZACTD_Jun16_v3 MCC
- Complementary Medicines – Health Supplements – Safety and Efficacy 7.04_SE_Health_Supplements_Jun16_v2 MCC
- Complementary Medicines – Quality 7.05_CMs_Quality_Jun16_v1 MCC

7.0 APPENDICES

APPENDIX I

1.0 Criteria for applicant

The local agent for product registration must be a company incorporated in Sierra Leone.

1.1 Responsibility of applicant

The applicant shall be responsible for the product and all information supplied in support of his application for registration of the product.

APPENDIX II

4.0 TIMELINES

All new applications and applications for renewal would be processed within a minimum period of six months, unless:

4.1 The application is for expedited review where the process would be shorter; or

4.2 Where queries have been raised for the attention of the applicant, which queries have not been addressed or not been addressed adequately, for which reason the process would be longer.

APPENDIX III

4.0. SANCTIONS AND PENALTIES

4.1 The Authority may cancel the registration of a product, if:

(i) the grounds on which the product was registered is later found to be false or incomplete.

(ii) the circumstances under which the product was registered no longer exist.

(iii) any of the provisions under which the product was registered has been contravened.

(iv) the standard of quality, safety and efficacy, as prescribed in the documentation for registration, is not being complied with.

(v) the premises in which the product, or part thereof, is manufactured, assembled, packaged or stored by, or on behalf of the holder of the certificate of registration, are unsuitable.

APPENDIX IV

6.0 FILING AN APPEAL FOR A REJECTED APPLICATION

The final decision for the issuance of MAC rests with the Pharmacy Board of Sierra Leone, in line with Section 44 of the Pharmacy and Drugs Act 2001. However, in the event that the PBSL during the registration process decides to reject an application, the applicant may submit a notice of appeal within four (4) weeks following the date of issuance of the letter of rejection.

The appeal representation shall be made in writing to the Authority addressed to:

The Registrar Pharmacy Board of Sierra Leone

Central Medical Stores Compound

New England Ville

Freetown

Sierra Leone

Upon submission of the notice of appeal, it will be subjected to internal scrutiny by the PBSL. Decisions on outcome of appeals shall be communicated to applicants within four (4) weeks after receipt of an appeal.

If the PBSL is satisfied with the notice of appeal submitted, it may approve the registration of the medical product (s); otherwise the notice of appeal shall be rejected.

Where the registration of a product is suspended or cancelled, the Authority shall cause its recall from circulation and shall accordingly cause the suspension, cancellation or recall to be published in the Gazette.

Prepared by	***Reviewed by***	***Approved by***
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