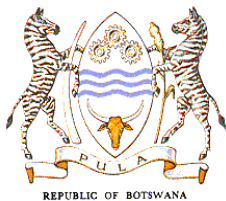


GUIDELINES ON APPLICATION FOR REGISTRATION OF COMPLEMENTARY/ALTERNATIVE MEDICINES IN BOTSWANA

Third Edition

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I. INTRODUCTION

A. BACKGROUND

The broad policy of the Ministry of Health aims at ensuring that all drugs manufactured, imported or exported, distributed or sold in Botswana are of acceptable quality, safety and efficacy. The process of drug registration forms an important basis for evaluating and assuring drug safety, efficacy and quality. Therefore, all drugs manufactured, imported/exported, distributed or sold in Botswana should be registered.

These guidelines have been developed to guide applicants to correctly fill the application forms when applying for registration of their products.

B. DEFINITIONS

For the purpose of these guidelines the following definitions shall apply.

- 1) **Act:** The Drugs and Related Substances Act, 1992 and as subsequently amended.
- 2) **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.
- 3) **Product:** This refers to the complimentary/alternative medicine.
- 4) **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.
- 5) **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.
- 6) **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.

II. GUIDELINES

A. KEY NOTE

- 1) Where applicants are unsure whether a product falls within the definition of a drug in terms of the Drugs and Related Substances Act, 1992 the following information should be forwarded to the DRU:
 - a) The proposed name of the product;
 - b) The composition (especially active ingredients and the quantities thereof) and formulation of the product;
 - c) The intended use
 - d) The intended marketing/promotional strategy and material.

- 2) A written reply will be issued by DRU as to whether the product is a Drug or Complementary product.
- 3) If the product applied for, has medicinal indications (such as treats, alleviates, improves, enhances, prevents, restores, protects, relieves, corrects, cures, antiviral, analgesic etc), the product will be rejected as complimentary medicine
- 4) The name of a product should not be suggestive of a medical condition or an indication for a medical condition otherwise it will not be accepted.
- 5) Preparations other than oral will not be accepted as complimentary medicines
- 6) Vitamins and minerals should be applied for by following Application of a Medicine Guideline.

B. SUBMISSION REQUIREMENTS

1. Submission of applications

- The applicant shall submit one hard copy of the completed application including all required attachments.
- The Soft copy (Word Format on the CD) of the application must be typed in font New Times Roman, font size 12. Attachments should be scanned and included in the CD.

The Completed application shall be submitted with a covering letter. To expedite unpacking of documents the covering letter should itemise the contents of the submission.

2. Samples

Sealed samples (at least one samples), in the actual distribution container shall be submitted. DRU may request for more samples for testing.

3. Promotional material

Copies of existing and proposed promotional material should be submitted.

4. All documents must be in English.

C. THE DRUG ADVISORY BOARD

The Drug Advisory Board is a statutory body appointed by the Minister of Health, and it is responsible for the registration of drugs of acceptable safety, efficacy and quality and in the interest of the public.

Application evaluation

- 1) The Drugs Regulatory Unit evaluates applications for registration. The recommendations are submitted to the Board for the final resolution;
- 2) Board meetings are at intervals of approximately six to eight weeks;

- 3) Applicants are notified in writing about Board resolutions regarding their applications.

APPLICATION FOR REGISTRATION

The following guidelines are intended to familiarise the applicants with the type of information to be submitted with applications.

In order to substantially address these areas the application form comprises of:

- Page 1, Administrative. (Applicant and Product details);
- Page 2, Composition;
- Page 3, Package insert;
- Page 4, Pharmaceutical documentation;
- Page 5, Evidence of Health Claim

1. ADMINISTRATIVE Page 1 of 5

1.1 Applicant and product details

a) Applicant details

This part requires general information about the applicant, the product and the manufacturer (the applicant may or may not be the actual manufacturer). The name and address (both postal and physical) of the applicant should be provided.

b) Product details

The details of the product should include:

- The approved name
- Dosage-form (tablets, capsules, mixture etc)
- Colour;
- Strength per dosage unit;

- Package size(s)
- Name and physical address of all the manufacturers. Provide Good Manufacturing Procedures (GMP) Certificate, Manufacturing license or ISO certificates.
- List all the countries where the product is marketed and provide certificates or authorization letters of such.
- Authorization letters from the applicant to the agent/local representative indicating the responsibility of the agent/representative.

Different dosage-forms (e.g. solution, suspension, emulsion, ointment etc) should have different applications.

All the various package sizes intended for marketing should be submitted. Any distinguishing unique characteristics of each package should be described. A sample label bearing all the labelling information (in English) as would appear on the immediate container should be attached to the application.

1.2 Declaration Form

The declaration form must be completed and signed by the responsible person in the manufacturing facility and applicant as specified.

2. COMPOSITION (Page 2 of 5)

This section should be presented in a table as shown on the Form.

For ingredients

- Approved name;
- Quantity per dosage unit or other suitable unit of mass or of volume of the product.
- Purpose of inclusion, i.e active or inactive.
- Uses of the ingredient. On this column it must be stated what the particular ingredients are used for in the final product. E.g. *Helps in weight loss, diluent etc*

3. PACKAGE INSERT (Page 3 of 5)

Please note that all items on the Package insert page are required. If there is any reason to omit any of the parameters, a justification must be given.

4. PHARMACEUTICAL DOCUMENTATION (Page 4 of 5)

Information required in the pharmaceutical documentation should indicate details of the following:

4.1 Comments on Specifications for Excipients

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.

4.2 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.

4.3 Stability studies, and expected shelf life. Submit results of real time and accelerated stability studies. On the application form, complete the table of summary of stability studies and indicate the proposed storage conditions and shelf life. Refer to the Stability guideline on the Ministry of health website.

4.4 Manufacturing procedures. These should be presented in a form of a flow diagram.

4.5 Container Closure System; Describe the materials of the immediate container (e.g. HDPE, amber glass bottle) and of other components of the packaging (e.g. stopper, secondary container (box).

5. EVIDENCE OF HEALTH CLAIM (Page 5 of 5)

A brief summary of expected outcome from product administration should be given. Evidence-based Data should be submitted.

Label text matter

- 1) A sample label as would appear on the immediate container should be attached bearing information in English
 - a) Approved name;
 - b) Local name;
 - c) Package size;
 - d) Quantity of the active ingredient per dosage unit;
 - e) Batch number;
 - f) Expiry date;
 - g) Storage conditions;
 - h) Warnings and precautions;
 - i) Directions for use;
 - j) Manufacturer's name and address.

References

List all the references used