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# **FOOD AND DRUGS AUTHORITY**

## **GUIDELINE FOR REGISTRATION OF HERBAL MEDICINAL PRODUCTS IN GHANA**

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**TABLE OF CONTENT**

- 1. SCOPE .....3
- 2. INTERPRETATION .....3
- 3. REQUIREMENTS .....4
  - 3.1. GENERAL REQUIREMENTS .....4
  - 3.2. SPECIFIC REQUIREMENTS .....5
  - 3.3. QUALITY SPECIFICATIONS .....5
  - 3.4. EVIDENCE OF CLAIM .....7
- 4. SANCTIONS.....8
- 5. PENALTIES.....9

# **GUIDELINE FOR THE REGISTRATION OF HERBAL MEDICINAL PRODUCTS IN GHANA**

## **1. SCOPE**

In pursuance of Section 118 of the Public Health Act 2012, Act 851 this Guideline is made to provide guidance to applicants on the procedure for registering a Herbal Medicinal Product in Ghana. Applicants are encouraged to familiarize themselves with this document and the above law before completing the registration form.

## **2. INTERPRETATION**

In this guideline, unless the context otherwise states: -

“**AUTHORITY**” means Food and Drugs Authority

“**PRODUCT**” means Herbal medicinal product

“**APPLICANT**” means the product owner or license holder. Representatives of license holders may not hold themselves as applicants unless they own the product.

“**HERBAL MEDICINAL PRODUCT**” means any finished labeled medicinal product that contains active ingredients, aerial or underground parts of the 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

Includes plant-derived material preparations with therapeutic or any other human health benefits which contain raw or processed ingredients from one or more plants and materials of organic or animal origin.

“**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 Ghana.

A variation also includes, but not limited to, a change in the product name, site of manufacture and / or source of ingredients.

### **3. REQUIREMENT**

#### **3.1 GENERAL REQUIREMENTS**

##### **Registration**

- a. An application for the registration of Herbal medicinal product 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 CEO 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.

### **3.2 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. Scientific and/or botanical names of the plants used, as well as the parts of plants used and the quantity of active ingredients used in the preparation, shall be submitted.
- d. The list of all excipients used and their quantities per dosage units used in the preparation shall be submitted.
- e. The indications for which the herbal medicinal product is being presented for registration shall be unambiguously stated.
- f. All documentation submitted shall be in English, and must be legibly printed and not handwritten.
- g. Four (4) copies of the labels and leaflet inserts, conforming to existing labeling regulations in Ghana shall be included in the documentation
- h. If the product is produced on contract manufacture, evidence of the contract agreement shall be produced in the documentation submitted.

### **3.3. QUALITY REQUIREMENT**

In order to ensure quality of the finished products, manufacturers of Herbal Medicinal Products 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 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.

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 Ghana.

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

### 3.2.1.1 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.

**3.2.1.2 MICROBIAL TEST:** Microbial testing of the underlisted 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*

**3.2.1.3 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.

**3.2.1.4 Pesticide Residues:** Testing for pesticides in plant or plant materials, algae, fungi, should be done according to WHO methods for pesticide screening I. 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.

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

### **3.2.1.5 Toxicological Requirement**

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

For locally manufactured Herbal medicinal products, toxicological test reports shall be submitted from but not limited to any of the under listed institutions:

- I. Centre for Scientific Research Into Plant Medicine, Mampong,
- II. Noguchi Memorial Institute for Medical Research, University of Ghana, Legon.
- III. Kwame Nkrumah University of Science and Technology, Kumasi (KNUST).
- IV. The Pharmacology Department, University of Ghana Medical School, Korle-Bu.

## **3.4. EVIDENCE OF CLAIM**

Substantial evidence of the clinical effectiveness of the Herbal medicinal product 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.

**4. The Authority**, in considering an application,

- I. may ask the applicant to supply such other information as may be required to enable it reach a decision on the application.
- II. shall satisfy itself that there is the need to have the Herbal medicinal product registered.
- III. may consult with other bodies and experts with knowledge in the Herbal medicinal product.
- IV. may request for the agreement from the manufacturer to register the Herbal medicinal product.
- V. may request the applicant to satisfy the Authority that he has the resources and facility to execute an effective recall of the product if the need arises.
- VI. Where the Authority is satisfied that there is the need to register a drug, and all requirements for its registration have been satisfied, it shall issue to the applicant a certificate of registration, subject to such conditions as may be prescribed by the Authority from time to time.
- VII. The registration of a Herbal medicinal product under these regulations, unless otherwise revoked, shall be valid for a period of 3 (three) years and may be renewed.
- VIII. The Authority shall, from time to time, publish a notice in the Gazette notifying the registration of drugs under these regulations.
- IX. No person shall disclose any information supplied to the Authority in pursuance of these Regulations, except under the following conditions:
  - (i) With the written consent of the person who supplied the information; or
  - (ii) In accordance with the directive of the Authority; or
  - (iii) For the purpose of a legal process under the Public Health Act, 2012 (Act 851)

**5. The Authority** may cancel, suspend or withdraw the registration of herbal medicinal product if:

- (a) The grounds on which the drug was registered is later found to be false

- (b) The circumstances under which the herbal medicinal product was registered no longer exist
- (c) Any of the provisions under which the drug was registered has been contravened
- (d) The standard of quality, safety and efficacy, as prescribed in the documentation for registration, is not being complied with
- (e) The premises in which the herbal medicinal product, or part thereof, is manufactured, packaged or stored by, or on behalf of, the holder of the certificate of registration are unsuitable for the manufacture, packaging or storage of the Product.
- (f) Where the registration of a Product is suspended, withdrawn or cancelled, the Authority shall cause the withdrawal from circulation of that Herbal medicinal product and shall, accordingly, cause the suspension, cancellation or withdrawal to be published in the Gazette.
- (g) Where a Product registration is suspended, withdrawn, or cancelled, an appeal for the review of an application can be made in writing to the Authority, and this shall be accompanied with an application fee, as may be determined by the Authority from time to time.