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FOOD AND DRUGS AUTHORITY

GUIDELINE FOR REGISTRATION OF HOMEOPATHIC MEDICINES

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FOOD AND DRUGS AUTHORITY GUIDELINE FOR REGISTRATION OF HOMEOPATHIC MEDICINES

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 Homeopathic Medicines 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 – a Homeopathic Medicine.

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

Homeopathic Medicine refers to:

- I. A substance that can be attenuated to render it stronger as the potency increases and at the same time that the original substance is diluted.

Or

- II. A substance that can cause certain symptoms in a healthy person and can be used to relieve those symptoms in any other person suffering from those symptoms.

Homeopathy: means an alternative system of medicine based on the concept that diseases can be cured when a patient is treated with minute quantities of a substance that produces symptoms of the diseases on a healthy person.

For a product to meet the criteria for a homeopathic medicine, a product must be:

- Manufactured from, or contain as medicinal ingredients, only substances referenced in a homeopathic monograph in one of the following homeopathic pharmacopoeia, as they are amended from time to time:
 - *Homeopathic Pharmacopoeia of the United States* (HPUS);
 - *Homöopathische Arzneibuch* (German Homeopathic Pharmacopoeia)(HAB)
 - *Pharmacopée française* (French Pharmacopoeia) (PhF)
 - *European Pharmacopoeia* (Eur. Pharm.) • *British Homeopathic Pharmacopoeia* (BHP)
 - *Indian Homeopathic Pharmacopoeia*.
- Prepared in accordance with the methods outlined in one of the above-mentioned homeopathic pharmacopoeia, as they are amended from time to time.

3. REQUIREMENT

3.1. GENERAL REQUIREMENTS

Registration

- a. An application for the registration of Homeopathic medicine 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 Homeopathic medicine 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

- 3.2.1. 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.
- 3.2.2. All samples of oral liquid preparations (solutions, syrups) shall have an appropriate graduated plastic measure included in the final package.
- 3.2.3. All samples submitted shall conform to labelling regulations in force in Ghana (*Refer to Food and Drugs Authority Guidelines for Labeling of Products*).
- 3.2.4. If the product is manufactured on contract basis, evidence of the contract shall be submitted. This information shall be clearly stated on the product label and package insert.

3.3. QUALITY SPECIFICATIONS

The quality requirements for homeopathic medicines should include specifications for the following:

- Identity (prior to dilution);
- Microbial purity (at the finished product stage);
- Chemical purity (not required if the medicinal ingredients are diluted 2X or above).

Applicants are required to provide the specifications details at the raw material and/or at the finished product stage as outlined below.

3.4. IDENTIFICATION

Identification of the medicinal ingredients should be conducted at the raw material stage as outlined in pharmacopoeial monographs listed under reference section of this document. The medicinal ingredients used in the product should be identified at the raw material stage by identification tests such as chromatographic methods (High Performance Thin Layer Chromatography (HPTLC), HPLC, or GC), or spectroscopic methods and/or any other applicable chemical identification test.

3.5. MICROBIAL TESTING

Homeopathic medicines should be tested for microbiological contaminants at the finished product stage. Each medicinal ingredient used in the product should also be tested for the chemical contaminants at the raw material stage.

3.6. MICROBIAL CONTAMINANTS

Microbial testing is required at the finished product stage. When ethanol is not present, or the ethanol content is less than 50%, microbial testing is required on a lot-by-lot basis.

3.7. CHEMICAL CONTAMINANTS

Each medicinal ingredient used in the product must also be tested for the chemical contaminants at the raw material stage. Chemical contaminant testing at the raw material stage is not required for homeopathic potencies of 1 CH (2X) or higher because at this dilution level, under normal circumstances, any contaminants will be sufficiently diluted to fall within safety parameters. Testing of chemical contaminants is not required if the medicinal ingredient is diluted above 2X. Otherwise, testing of these should be performed as stated.

3.8. HEAVY METAL

Heavy metal tests are not required when the medicinal ingredient is a heavy metal itself. For example, if mercury is the medicinal ingredient, the raw material does not need to be tested for mercury.

4.0 The Authority in considering an application:

- a) shall satisfy itself that there is the need to have the product registered in Ghana.
 - b) reserves the right to conduct a Good Manufacturing Practice (GMP) audit inspection on the manufacturing facility for the product at a fee prescribed by the Authority.
 - c) may ask the applicant to supply such other information as may be required to enable it reach a decision on the application.
- I. An appeal for the review of an application may be made in writing to the Minister of Health within thirty (30) days of receipt of the rejection notice.
 - II. Where the Authority is satisfied that there is the need to register a product and all requirements for its registration have been satisfied, it shall do so and issue to the applicant a certificate of registration, subject to such conditions as may be prescribed by the Authority from time to time.
 - III. The registration of a product under these regulations, unless otherwise revoked, shall be valid for a period of three (3) years and may be renewed.
 - IV. No information given in this application shall be disclosed by the Food and Drugs Authority to a third party except:-
 - a) with the written consent of the licence holder; or
 - b) in accordance with the directive of the Directors of FDA; or
 - c) for the purpose of a legal process under the Public Health Act 2012, Act 851

5.0 The Authority shall cancel, suspend, or withdraw the registration of a product if:-

- a. the grounds on which it was registered is later found to be false; or
- b. the circumstances under which it was registered no longer exist; or
- c. any of the provisions under which it was registered has been contravened; or
- d. the standard of quality, safety and efficacy, as prescribed in the documentation for registration is not being complied with; or

- e. 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 Homeopathic medicine.

- f. Where the registration of a Homeopathic medicine is suspended, withdrawn or cancelled, the Authority shall cause the withdrawal from circulation of that product and shall accordingly cause the suspension, cancellation or withdrawal to be published in the Gazzette.