



**NATIONAL AGENCY FOR FOOD AND DRUG  
ADMINISTRATION AND CONTROL (NAFDAC)**

**HERBAL MEDICINES AND RELATED PRODUCTS  
REGISTRATION REGULATIONS 2019**

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### **Commencement:**

**In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honourable Minister of Health hereby makes the following Regulations:-**

#### **1. Scope:**

These Regulations shall apply to the registration of all herbal medicines and related products that are manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

#### **2. Prohibition.**

- (1) No Herbal Medicine and related product shall be manufactured, imported, exported, distributed, advertised, sold or used in Nigeria unless it has been registered in accordance with the provisions of these regulations.
- (2) No person to whom a certificate of registration has been issued under these Regulations shall lend, hire, sell, transfer or otherwise dispose of the certificate of registration to any other person without the approval of the Agency.

#### **3. Exceptions:**

Notwithstanding the provisions of Regulation 2, the Agency may grant a permit for the importation or manufacture of samples of Herbal Medicine and related products for the purpose of clinical trial or any such process as may be approved by the Agency and the importation or manufacture shall be in accordance with the conditions specified in the permit.

#### **4. Application for Registration .**

- (1) Application for the registration of a Herbal Medicine and related products shall be made by filing an application and accompanied with relevant documents in such form as the Agency may, from time to time, prescribe and shall-
  - (a) contain the particulars and description of the Herbal Medicine and related products, in respect of which the application is made;

- (b) be accompanied by such fee as the Agency may, from time to time, prescribe.
- (2) The product particulars and description shall be detailed enough to consist of all administrative and technical information in sufficient details as may be required to enable the Agency make an informed judgment about the product.
- (3) The Agency, in considering an application-
  - (a) may ask the applicant to supply such other information as it may require to enable it to reach a decision on the application;
  - (b) shall satisfy itself that there is need to have the Herbal Medicine and related products registered in Nigeria.
- (4) The registration of a Herbal Medicine and related products under these Regulations shall, unless cancelled earlier, be valid for a period of two or five years as the Agency may deem appropriate and may be renewed.
- (5) The Agency shall, from time to time, publish the list of registered products on the Agency's official website.
- (6) The Agency may refuse to register a product under Regulation 3(2) of these Regulations for any of the following reasons, unless the requirement have been waived;
  - (a) if the outcome of review of information provided by the applicant in support of the product registration application showed that the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the herbal medicine or related product are inadequate to ensure and preserve its identity, strength, quality, and purity consistently.
  - (b) if the laboratory report of the product under review is unsatisfactory;
  - (c) if the GMP inspection report of the product under review is unsatisfactory;
  - (d) product labelling is in contravention of the Agency's Herbal Medicine and related products Labelling regulations;
  - (e) or any other reasons as the Agency may deem fit.

## 5. **Penalty.**

- (1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :
  - (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N50,000 or to both such imprisonment and fine; and
  - (b) a body corporate, to a fine not exceeding N100, 000.

- (2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every:-
- (a) director, manager, secretary or other similar officer of the body corporate; or
  - (b) partner or officer of the firm or
  - (c) trustee of the body concerned ;or
  - (d) person concerned in the management of the affairs of the association ;or
  - (e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

#### 6. Forfeiture after conviction

- (1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-
- (a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence;
  - (b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.
- (2) In this section, **"proceeds"** means any property derived or obtained, directly or indirectly, through the commission of the offence.

#### 7. Interpretation.

In these regulations, unless the context otherwise requires:

**"Agency"** means National Agency for Food and Drug Administration and Control; and

**"GMP"** means Good Manufacturing Practice

**"Herbal Medicine and related products"** means:

- (a) finished medicinal product containing plant and their preparation presented with therapeutic or prophylactic claim and includes all preparations containing a plant material in part or wholly.
- (b) preparation or admixture of herbal medicinal products presented with prophylactic or therapeutic claim; and

(c) preparation or admixture used for restoring, correcting or modifying organic functions in man or in animal.

**8. Repeal of Herbal Medicine and Related Products (Registration) Regulations 2005**

- (1) The Herbal Medicine and Related Products (Registration) Regulations 2005 is hereby repealed.
- (2) The repeal of these Regulations specified in Regulation 8.1 shall not affect anything done or purported to be done under the repealed Regulations.

**9. Citation**

These Regulations may be cited as the Herbal Medicine and related products (Registration) Regulations 2019.

**MADE at Abuja this.....day of.....2019**

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**Inuwa Abdulkadir Esq  
Chairman Governing Council**

**National Agency for Food and Drug Administration and Control (NAFDAC)**