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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

HERBAL MEDICINES AND RELATED PRODUCTS (REGISTRATION) REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 00 of 2021

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

HERBAL MEDICINES AND RELATED PRODUCTS (REGISTRATION) REGULATIONS, 2021

[*7th Day of July*, 2021] Commencement.

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap N1 LFN) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and all other 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 Minister of Health makes the following Regulations—

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

2.—(1) A herbal medicine and related product shall not be manufactured, imported, exported, distributed, advertised, sold or used in Nigeria unless it has been registered in accordance with the provisions of these Regulations. Prohibition.

(2) Any person to whom a certificate of registration has been issued under these Regulations shall not lend, hire, sell, transfer or otherwise dispose of the certificate of registration to any other person without the approval of the Agency.

3. Notwithstanding the provisions of regulation 2 of these Regulations, the Agency may grant a permit for the importation or manufacturing of samples of herbal medicine and its related products for the purpose of clinical trial or any such process as may be approved by the Agency and such importation or manufacturing shall be in accordance with the conditions specified in the permit. Exceptions.

4.—(1) Application for the registration of any herbal medicine and its related products shall— Application for Registration.

(*a*) be made by filing an application and accompanied with relevant documents in such form as the Agency may, from time to time, prescribe ;

(*b*) contain the particulars and description of the herbal medicine and related products, in respect of which the application is made ; and

(*c*) be accompanied with the fee as the Agency may, from time to time, prescribe.

(2) An applicant shall submit particulars and description, consisting of administration and technical information in sufficient details as may be required to enable the Agency make an informed decision about the product.

(3) The Agency, in considering an application—

(*a*) may ask the applicant to supply such other information as may be required, to enable the Agency to reach a decision on the application ; and

(*b*) shall satisfy itself that there is need to have the herbal medicine and its related products registered in Nigeria.

(4) Where the is satisfied that there is need to register the Herbal Medicine and its related product, it shall do so and issue the applicant a Certificate of Registration.

(5) The Agency shall, from time to time, publish the list of registered herbal medicine and its related products on the Agency's official website.

(6) The Agency may refuse to register a product under regulation 4 (1) (2) (3) of these Regulations for any of the following reasons, unless the requirements have been waived—

(*a*) where the outcome of reviewing 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*) where the laboratory report of the product under review is unsatisfactory ;

(*c*) where the Good Manufacturing Practice (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 ; and

(*e*) any other reasons as the Agency may deem fit.

Power to seal.

5. The Agency shall have power to seal up any premises used or being used in connection with any offence under these Regulations until such time as the regulated product is removed or such reasonable time as the Minister responsible for health may determine.

Offences and Penalties.

6.—(1) Any person who contravenes any of the provisions of these Regulations commits an offence and shall be liable on conviction, in the case of—

(*a*) an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding N800,000.00 or to both ; and

(*b*) a body corporate, to a fine not exceeding N5,000,000.00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every of its—

(*a*) director, manager, secretary or other similar officer of the body corporate ;

(*b*) partner or officer of the firm ;

(*c*) trustee of the body concerned ;

(*d*) person concerned in the management of the affairs of the association ; or

(*e*) person who purports to act in a capacity referred to in paragraphs (*a*) to (*d*) of this sub-regulation,

is liable to be proceeded against and punished for the offence in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction.

7. Any person convicted of an offence under these Regulations shall forfeit to the Federal Government of Nigeria—

(*a*) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence ; and

(*b*) any of the person's property or instrument used in any manner to commit or to facilitate the commission of the offence.

Revocation.

8.—(1) The Herbal Medicine and Related Products (Registration) Regulations, 2005 is revoked.

(2) The revocation of the Regulations specified in sub-regulation (1) of this regulation shall not affect anything done or purported to have been done under the revoked Regulations.

Enforcement of these Regulations.

9. The Agency shall be responsible for the enforcement of these Regulations.

Interpretation.

10. In these regulations—

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

"*Good Manufacturing Practice*" (GMP) means that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Certificate of Registration.

"*Herbal medicine and related products*" mean—

(*i*) 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,

(*a*) director, manager, secretary or other similar officer of the body corporate ;

(*b*) partner or officer of the firm ;

(*c*) trustee of the body concerned ;

(*d*) person concerned in the management of the affairs of the association ; or

(*e*) person who purports to act in a capacity referred to in paragraphs (*a*) to (*d*) of this sub-regulation,

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"*Herbal medicine and related products*" mean—

(*i*) 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,

(*ii*) preparation or admixture of herbal medicinal products presented with prophylactic or therapeutic claim, and

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

Citation.

11. These Regulations shall be cited as the Herbal Medicine and Related Products (Registration) Regulations, 2021.

MADE at Abuja this 7th day of July, 2021

DR. OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health