*Extraordinary*

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

## HERBAL MEDICINE AND RELATED PRODUCTS LABELLING REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

*Regulation* :

S. I. No. 76 of 2021

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

## HERBAL MEDICINE AND RELATED PRODUCTS LABELLING 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 Honourable Minister of Health makes the following Regulations –**

**1.** These Regulations shall apply to Labelling of Herbal Medicine and Related Products manufactured, imported, exported, distributed, advertised, displayed for sale or used in Nigeria. Scope of application.

**2.** A person shall not manufacture, import, export, distribute, advertise or sell any Herbal Medicine and its Related Products unless it is labelled in accordance with the provision of these Regulations. Prohibition.

**3.**—(1) All information required to be indicated on the label of Herbal Medicine and Related Products shall be prominent, legible and distinct. Labelling information.

(2) All statements shall appear in font size and style type that is legible, clear and placed on contrasting background without obscuring designs or vignettes or crowding within written, printed or graphic matter.

(3) All information on Herbal Medicine and Related Products shall be in English Language and may include any other language.

(4) Labelling shall be informative and accurate.

(5) Labelling shall not be false, misleading nor promotional in tone.

(6) The product name shall not be suggestive of any therapeutic claim.

(7) Each product shall have a distinct design not similar to any other registered product.

(8) All information and statements as required by these Regulations shall appear on the part or panel of the label as presented or displayed under customary conditions of purchase.

(9) The label space shall not be used to present information, statement or graphics not required by these Regulations in a manner to make the label space insufficient for information or statements required under these Regulations.

(10) The labeling shall be based on data derived from human experiences.

(11) Implied claims or suggestions of Herbal Medicine and Related Products shall not be made, where there is inadequate evidence of safety or a lack of substantial evidence of effectiveness.

(12) Where a claim of effectiveness or therapeutic indication labeling is made for any herbal medicine and related products, it shall carry boldly and in close proximity to the claim, a statement to the fact that such claim has not been evaluated by NAFDAC, unless such claim has been clinically proven and deemed satisfactory by the Agency.

Name and address of Manufacturer, Packer or Distributor.

4.—(1) The label of any herbal medicine or related products shall specify conspicuously the name and address of the manufacturer and Holder Certificate of Registration.

(2) Where an herbal medicine or related product is not manufactured by a person whose name appears on the label, the name shall reveal the connection between the person and the manufacturer, such as "Manufactured for" Distributed by...", or any other wording that expresses the facts.

(3) The label of Herbal Medicine or Related Product shall specify conspicuously in the information panel the name and address of the Holder of Certificate of Registration.

Reference to International Bodies.

5. Reference, either direct or indirect to international bodies, shall not be made on any label of herbal medicine or related products, except as prescribed by the Agency.

Declaration of Ingredients.

6.—(1) A quantitative list of ingredients of Herbal Medicine and Related Products by their botanical names or, by their common names, shall be declared conspicuously on the label.

(2) Name or index number of colour used in the preparation of Herbal Medicine and Related Products shall be declared on the label.

Brand name or Trademark.

7.—(1) Where Herbal Medicine or Related Products has a brand name or trade mark displayed on the labcl, the brand name or trade mark shall not give wrong impression of the nature, quality or substance of the Herbal Medicine and Related Products or mislead the user nor be suggestive of any therapeutic use.

(2) Where the brand name or trade mark registration is in conflict with any Regulations or requirements of the Agency, the Regulations or requirements of the Agency shall prevail.

Registration number assigned by the Agency.

8.—(1) The outer and inner label of every Herbal Medicine or Related Products shall show clearly the NAFDAC Registration Number (NAFDAC Reg. No.) assigned to it as indicated on the Certificate of Registration in a manner prescribed by the Agency.

(2) Where Herbal Medicine or Related Product has tertiary, secondary and primary packaging materials and the content of the unit pack is reasonably considered to be dispensed or sold to an end-user as a whole or is for a single use, the NAFDAC Reg. No. shall be shown on the tertiary and secondary packaging materials only.

Identification mark.

**9.**—(1) Where tablets, capsules, caplets and similar dosage forms bear identification marks, the identification marks shall be traceable to the Holder of Certificate of Registration or the manufacturer of the herbal product.

(2) Exemptions request shall be made in writing to the Agency giving reasons why a waiver is justified.

Adequate Labelling.

**10.** Herbal Medicine or Related Products shall be properly labelled and displayed on the principal display panel or information panel as the case may apply on the inner and outer package labels—

(*a*) the brand name, botanical or common name, if any, shall be qualified as herbal, homeopathic, animal or mineral medicinal product and or admixture of it ;

(*b*) quantitative list of ingredients of the product by their botanical or common names ;

(*c*) the net content of the product in terms of weight, measure, or numerical count and shall be in metric unit ;

(*d*) the name and factory location, address of the manufacturer ;

(*e*) adequate directions as to safe use of the product, including amount for usage in specific age groups ;

(*f*) the lot or batch number ;

(*g*) manufacture and expiration dates ;

(*h*) the storage condition requirement ;

(*i*) dosage, route and frequency of administration ;

(*j*) indication for the product ; and

(*k*) any other requirements as may be specified by the Agency.

Labelling of bulk package.

**11.** Where an Herbal Medicine or Related Product is sold in bulk for further manufacturing, the provisions of these Regulation shall not apply, provided that the label of the bulk product contains the following information—

(*a*) the proprietary or brand name of the Herbal Medicines and Related Product ;

(*b*) the botanical or common name of the Herbal Medicines and Related Product ;

(*c*) a statement of net contents ;

(*d*) an identifying lot or batch number ;

(*e*) the manufacture and expiration dates ; and

(*f*) statement of caution such as "manufacturing purpose only".

Labelling Information for Practitioners.

**12.** All Herbal Medicine or Related Products may be accompanied by an outer label and package insert with relevant information to practitioners for the safe use of the products.

Information on Package insert.

**13.** Relevant information required to appear on the package for Practitioners guide, shall include the—

(*a*) product name ;

(*b*) description ;

(*c*) Clinical Pharmacology or as applicable ;

(*d*) indications and usage ;

(*e*) contraindications ;

(*f*) warnings ;

(*g*) precautions ;

(*h*) dosage and administration ;

(*i*) side effects and adverse reactions ;

(*j*) drug abuse and dependence or as may be applicable ;

(*k*) symptoms of over dosage and treatment ;

(*l*) presentation ; and

(*m*) storage conditions ;

Prohibition of Labelling of Herbal Medicine and Related Products for certain treatments.

**14.**—(1) A person shall not label Herbal Medicine or Related Products as a treatment, preventive or cure for any of the diseases, disorders or abnormal states as specified in the Schedule to these Regulations.

(2) A person shall not sell, advertise, display or orally present any Herbal Medicine or Related Products to the general public whose label contains such words as "for vitality".

Herbal medicine and related products not for use in pregnancy & children (below 5 years).

**15.** Inner and outer labels of all Herbal Medicine and Related Products shall carry warning statement directing pregnant women and children, below 5 years of age, not to use them, except there is adequate evidence of safety in pregnancy and children under 5 years of age.

Warning for children.

**16.** The label of all Herbal Medicine or Related Products shall carry a warning "Keep this medicine out of the reach of children".

Misleading information and misinformation.

**17.**—(1) A person shall not sell, advertise, display or use any Herbal Medicine or Related Product with a name suggestive of the symptom, disorders, diseases or abnormal states that it is supposed to treat, prevent or cure.

(2) The label of Herbal Medicine and Related Products with antipyretic and analgesic property shall not bear the indication "for fever" but shall be labelled "for feverish conditions" or "feverish feeling".

Offences and Penalties.

**18.**—(1) Any person who contravenes any of the provisions of these Regulations commits an offence and 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 ₦800,000.00 or to both ; and

(*b*) a body corporate, to a fine not exceeding ₦5,000,000.00.

(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 ;

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

(*c*) trustee of the body concerned ;

(*d*) person involved 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 that 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.

**19.** A 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 instrumentalities used in any manner to commit or to facilitate the commission of the offence.

Revocation.

**20.**—(1) The Herbal Medicine and Related Products Labelling Regulations 2005 is revoked.

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

Enforcement of these Regulations.

**21.** The Agency is exclusively responsible for the enforcement of these Regulations.

Interpretation.

**22.** In these Regulations, unless the context otherwise requires—

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

"*Botanical name*" means the formal scientific name conforming to the International Code of Nomenclature by which the plant is identified ;

"*Common name*" means, with reference to herbal medicine and related products, the name in English language or other such language by which the product is commonly known ;

"*Expiration date*" means any date after which herbal medicine and related products are not recommended for use ;

"*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*) finished medicinal product containing only animal material in part or wholly and their preparation presented with therapeutic or prophylactic claim,

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

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

"*Label*" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a package (container) of a herbal medicine or related product ;

"*Manufacturer*" means the person who performs all of the following operations that are required to produce the product ;

"*Package*" includes any suitable container in which any herbal medicine and related products is wholly or partly contained, placed or packed ;

"*Principal display panel*" means—

(*a*) the part of a package or label that is most likely to be displayed, presented, shown or examined under customary conditions of display for display for retail sale,

(*b*) in the case of a container that is mounted on a display card, that part of the label applied to all or part of the principal display surface of the container ; or part of the side of the display card that is displayed or visible under normal or customary conditions of sale or use ; or to both such parts of the container and the display card,

(*c*) in the case of an ornamental container, that part of the label applied to all or part of the bottom of the container ; or to all or part of the principal display surface ; or to all or part of a tag that is attached to the container,

(*d*) in the case of all other containers, that part of the label applied to all or part of the principal display surface ;

"*Practitioners*" means any person authorized by the appropriate governmental body to practice herbal medicine and related products ;

"*Proceeds*" means any property derived or obtained, directly or indirectly, through the commission of the offence ; and

"*Sell*" includes sell, offer for sale, expose for sale, and have in possession for sale.

**23.** These Regulations shall be cited as the Herbal Medicine and Related Products Labelling Regulations, 2021. Citation.

(1) Acquired immune deficiency syndrome ;
(2) Alcoholism ;
(3) Appendicitis ;
(4) Arteriosclerosis ;
(5) Asthma ;
(6) Blood Disorders ;
(7) Cancer ;
(8) Cataract ;
(9) Cholera ;
(10) Diabetes ;
(11) Diphtheria ;
(12) Disorders of Menstrual Flow ;
(13) Disorders of Prostate Gland ;
(14) Dysentery ;
(15) Encephalitis ;
(16) Enteric Fever ;
(17) Epilepsy ;
(18) Erysipelas ;
(19) Filariasis ;
(20) Gallstones, Kidney Stones, and Bladder Stones Gangrene ;
(21) Any genital or urinary diseases not mentioned elsewhere in this schedule ;
(22) Glaucoma ;
(23) Goitre ;
(24) Hay Fever ;
(25) Heart Disease ;
(26) Hernia ;
(27) High Blood Pressure ;
(28) Infective Hepatitis ;
(29) Influenza ;
(30) Jaundice ;
(31) Kidney Disease ;
(32) Leprosy ;
(33) Loco motor ataxis ;
(34) Loss of Youth ;
(35) Measles ;
(36) Meningitis ;
(37) Mental Conditions ;
(38) Mumps ;
(39) Nervousness ;
(40) Nutritional disorders ;
(41) Obesity ;
(42) Onchocerciasis ;

(43) Paralysis ;
(44) Plague ;
(45) Pleurisy ;
(46) Pneumonia ;
(47) Poliomyelitis ;
(48) Rabies ;
(49) Rheumatic Fever ;
(50) Schistosomiasis ;
(51) Sexual impotence, loss of virility or sterility ;
(52) Sleeping sickness ;
(53) Small pox ;
(54) Snake bite ;
(55) Syphilis ;
(56) Tetanus ;
(57) Trachoma ;
(58) Tuberculosis ;
(59) Tumors ;
(60) Typhoid Fever ;
(61) Undulant fever ;
(62) Ulcers of the gastro-intestinal tract ;
(63) Veneral Diseases ;
(64) Yaws ; and
(65) Yellow Fever.

MADE at Abuja this 7th day of July, 2021

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