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

DRUG AND RELATED PRODUCTS ADVERTISEMENT REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 63 of 2021

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

DRUG AND RELATED PRODUCTS ADVERTISEMENT REGULATIONS, 2021

[7*th 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 advertisements or promotion of drug products manufactured, imported, exported, sold, distributed or used in Nigeria. Scope of application.

2.—(1) A person shall not— Prohibition.

(*a*) advertise any drug or related product unless it has been registered by the Agency ;

(*b*) advertise any drug product unless the advertisement has the approval of the Agency ; and

(*c*) engage in consumer promotions of any kind, including but not limited to gifts or free samples of drug or related products to the consuming public.

(2) Product launch for drug or drug products shall be approved by the Agency.

(3) Without prejudice to subregulation (2) of Regulation 2—

(*a*) claims made for prescription only medicines shall be published in Medical or Scientific Journals only ; and

(*b*) press releases stating the product name and indications, shall be provided by the Agency.

3.—(1) The advertisement of a drug or drug related product shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health care practitioners. Nature of advertisement.

(2) Statements, illustrations or pictures used in an advertisement shall not mislead directly or by implication.

4. Advertisement of a drug or related product shall not— Non-referential advertisement.

(*a*) imitate the general layout, text, slogan or visual presentation of another drug product in a manner likely to mislead or confuse the consumer ; or

(*b*) be framed in such a manner as to exploit any superstitions or be calculated to induce fear among consumers causing them to purchase the drug product being advertised.

Application for the Approval of Advertisement.

5. Advertisement materials including scripts, story-boards, artwork, radio scripts and any other advertisement material shall be submitted along with an application, in the manner prescribed by the Agency.

Particulars of Application.

6.—(1) Every application shall contain the following information—

(*a*) the brand name of the drug product, if any ;

(*b*) the generic name of the drug product ;

(*c*) the dosage form available ;

(*d*) the place of importation or local manufacturer ;

(*e*) the name and address of the manufacturer ;

(*f*) the name and address of the local distributor ;

(*g*) the name and address of the advertising company ;

(*h*) the date of first introduction of the drug product to the Nigerian market ;

(*i*) previous advertisement of the drug product in Nigeria ;

(*j*) a copy of the old script, if any ;

(*k*) the proposed media for the advertisement ;

(*l*) a copy of the Certificate of Registration of the drug product ;

(*m*) a copy of the registration certificate of the premises of the sponsors ;

(*n*) scripts and recording ;

(*o*) justification for any special claims on the drug product ; and

(*p*) any other requirement that the Agency may from time to time prescribe.

(2) Materials submitted under these Regulations shall be authenticated by the Chief Executive or authorised technical person of the company sponsoring the product.

(3) The advertisement materials on the drug product shall be authenticated by the Superintendent Pharmacist and the Chief Executive of the drug product company sponsoring the drug product advertisement.

Validity of approval.

7.—(1) An approval for advertisement of drug product shall be valid for a period of 1 year at first instance from the date of the approval and may be renewed.

(2) Subsequent advertisement applications shall be valid for 2 years provided no alteration is made and conditions of renewal of approval remain the same.

(3) Notwithstanding the provision of sub-regulation (1) of this regulation, consumer promotions shall have validity period of 15 weeks..

Withdrawal of an approval.

8. The Agency shall withdraw the approval for an advertisement, where—

(*a*) the grounds on which the approval was granted was later found to be false or incomplete ;

(*b*) any of the conditions under which the approval was granted has been contravened ;

(*c*) there is a new scientific evidence against claims contained in the advertisement ; or

(*d*) there is a court order.

Advertisement to effect caution in drug product usage.

9. Drug product advertisements shall reflect an overall attitude of the caution in respect to the drug product usage with emphasis on national drug product therapy and shall also provide sufficient and balanced information to permit assessment of risk or benefit.

Boxed warning.

10.—(1) Drug products that have special safety warnings, particularly ones that may lead to death or serious injury, shall have the warning information displayed within a box in the advertisement.

(2) Where the special safety warnings on drug products is discovered post-registration, the Box-warning shall be this warning information also displayed within a box in the advertisement.

Drug product advertisement claims.

11.—(1) Advertisement for Over-the-Counter drug products shall state or imply in absolute terms or by quotation taken out of context, that a drug product is "safe" or has "guaranteed efficacy" or special status.

(2) Any statement claiming or implying a superlative function such as "most effective", "least toxic", "best tolerated", or special status such as "the drug product of choice", or any such statements, for a drug product shall not be used unless it can be adequately substantiated and shall not imply superior efficacy to other products in same category.

(3) "*Best-selling*" claims when used shall not imply superior efficacy to other products in same category.

(4) Where an advertisement portrays a drug product as "fast", "immediate" "instant" or "rapid" in action, or any similar descriptions, such claims must be substantiated using studies based on the rate of absorption of the drug product.

(5) "*Duration of action*" claims in drug product advertisements shall be allowed provided the claim can be supported by the pharmacokinetic attributes of the drug products, particularly plasma half-life.

(6) Where claims on efficacy are made in the advertisement of a drug product, such claims shall be substantiated using efficacy studies carried out in actual patients, absorption data alone are not enough to substantiate efficacy claims.

(7) Superiority claims may be used only when a product proves to be superior to an identified comparator or to all products in same category.

(8) Top parity claims and 'Natural' claims may be permitted provided they are adequately substantiated.

Restrictions.

12.—(1) Advertisement of any drug or related product shall not contain—

(*a*) any false or misleading information ;

(*b*) false information, inadequate qualification and limitations regarding safety or effectiveness of the drug product ;

(*c*) vague, unsubstantiated statements, or suggestion of superiority over other competing drug products ; or

(*d*) any false impression that the advertised drug product is for universal cure or should be regarded as a more effective and safer alternative to other related drug products.

(2) Prescription only Medicines shall not be advertised through Out-of-Home, Television, Radio, SMS, online media or any such media.

Labelling advertisement for prescription drug products.

13.—(1) Notwithstanding the provision of regulation 12 (2), prescription drug products shall be advertised in accordance with the provisions of these Regulations via scientific and medical journals, "Leave Behind", pamphlets or scientific literature on health newsletters which shall be used for distribution to healthcare professionals only, provided that such materials have been vetted and approved by the Agency.

(2) Prescription drug products for advertisement shall be properly labelled in accordance with the Agency's Drug Labelling Regulations.

Data comparison misrepresentation for prescription drug products.

14.—(1) A comparison on drug or related product package shall be supported by current scientific data and shall not be misleading, directly or by implication.

(2) Reference to a competitive manufacturer or their specialities shall be restricted to factual comparisons without the use of identifiable products or brand names.

(3) Data illustration presented in the advertisement including charts, graphs, tables, extracted from reference studies or other sources or reproduced by artwork shall be accurate, complete and clear with their source specifically identified.

(4) Data illustrations shall not be misleading, ambiguous or distort the originally intended meaning or interpretation either directly or by implication.

Side effect and contra-indications for prescription drug products.

15.—(1) Advertisement for drug products shall present information that is reasonably balanced, between indications, effectiveness, safety, side effects and contra-indications.

(2) Advertisement of drug products for use during pregnancy shall state any known effects of the drug product on a pregnant woman, foetus and lactation.

Contents of advertisements with specific therapeutic claims for prescription drug products.

16. Advertisement of drug products containing specific therapeutic claims shall contain within the advertisement—

(*a*) the brand or generic name of the drug product ;

(*b*) the therapeutic classification of the drug product ;

(*c*) a quantitative list of the actual medical ingredients contained in each dose or unit ;

(*d*) the indication for use ;

(*e*) the recommended dosage, methods of use and routes of administration for all stated indications ;

(*f*) a list of adverse reactions (with some indication or expected incidence, if known), the precaution to be taken by any member of the health profession and the contra-indications and warning of the drug product ;

(*g*) a statement that the product monograph or full prescribing information is readily available ; and

(*h*) the full name and location address of manufacturer and the Holder Certificate of Registration.

Accurate interpretation of research findings for prescription drug products.

17.—(1) Advertisement materials including scripts, story-boards, artwork, radio scripts and any other advertisement material for drug or related products shall be written as to accurately interpret valid and representative research findings.

(2) Statistics in an advertisement of drug products shall be written as to reflect only their true validity and significance.

(3) Any claim or quotation from a scientific literature concerning the efficacy, safety and adverse reaction, use in children or during pregnancy or any such precautionary statements with the constraints of the accepted products monograph, shall specify the scientific source of the claim or quotation.

(4) Copy of any reference cited by an applicant or in the advertisement of drug products shall be provided to the Agency for verification.

Claims and quotations from scientific literature to be mentioned for Prescription drug products.

18.—(1) Claims and quotations from the scientific literature concerning the efficacy, safety and adverse reactions, use in children, pregnancy, or any such precautionary statements with the constraints of the accepted products monograph, shall specify the scientific source of information.

(2) Copies of all references cited shall be submitted to the Agency for verification.

Scientific articles and literature to contain both positive features and negative findings for Prescription drug products.

19.—(1) Claims based on, or quotations that have been selected from a scientific article or series of articles which emphasise only the positive features other than negative findings of the drug product, shall not be acceptable.

(2) Claims and quotations shall contain both negative and positive findings and shall be verifiable.

Restriction or selection of quotation for prescription drug products.

20. Selected quotation shall not refer to another brand of the same active ingredient, or to a different formulation of the same active ingredients.

Prohibition of advertisement for certain diseases for prescription drug products.

21. A person shall not advertise a drug or related product as a treatment, prevention or cure for any disease, disorder or abnormal physical state specified in the Schedule to these Regulations.

Product launch and Press release for prescription drug products.

22. Product launch materials or press release of the drug product shall be as approved by the Agency for the purpose of the product advertising materials.

Exemption for prescription drug products.

23. Notwithstanding the provisions of regulation 21 of these Regulations prescription only medicine advertisements directed at healthcare professionals for the treatment, prevention or cure for any disease, disorder or abnormal physical state shall be exposed only in scientific and medical journals.

Labelling particulars and information for over-the-counter drug products.

24.—(1) The package and advertisement of an Over-the-Counter drug product in Nigeria shall be properly labelled in accordance with the Agency's Drug Labelling Regulations.

(2) Where all the information required on the package of any Over the Counter Medicine cannot be contained on the labels, such Over the Counter Medicines shall carry package leaflets with complete label information, in addition to the contra-indications, and the labelling shall not contain any statement, which is false, misleading as to amount to a misinterpretation.

(3) Where the bottle, jar or other "immediate container" of the drug product has an outer wrapper or carton, such outer wrapper or carton shall bear all the information required to be specified on the label.

Advertisement to contain certain information for Over-the-Counter drug products.

25. The advertisement of a drug product shall contain the following information—

(*a*) the name of the drug product ;

(*b*) the pack size being promoted ;

(*c*) the different forms in which the drug product is available, (where applicable) ; and

(*d*) the name and address of the manufacturer and the sellers.

26. Over-The-Counter drug products advertisement shall not—

Restriction on use of advertisement for Over-the-Counter drug products.

(*a*) contain such words as "magic", "miracle", or an exotic description such as "upper potency" or such other words as to induce the daily or continuous use of the drug product ;

(*b*) imply that if the reader, viewer or listener is suffering from any ailment or disease, he shall suffer more severely from the illness, ailment or disease on failure to use that particular drug product ;

(*c*) over dramatise any symptoms or unfairly attack any competitive products.

Advertisement of Over-the-Counter (OTC) drug products in mass media.

27. A person shall not advertise any OTC drug product unless such advertisement states clearly both the generic and brand names (where applicable), of the drug product.

Offences and Penalties.

28.—(1) Any person who contravenes any of the provisions of these Regulations commits an offence and is 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, or other association of individuals, the—

(*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.

29. 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.

Revocation.

30.—(1) The Drug Products Advertisement Regulations 1995 is revoked.

(2) The revocation of these 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.

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

Interpretation.

32. In these Regulations—

"*Address*" means a place where the business of the manufacturer, sale, distribution, storage and display of drug and related products are carried out, which includes the house number, plot number, street name town or city, state and country ;

"*Advertisement*" means a form of communication through the media about products, services or ideas by an identified sponsor which is used to encourage, persuade or manipulate an audience (viewers, readers or listeners), to continue with or take some new action ;

"*Advertising*" means the publicity of goods and description of all products (which includes any form of notices in circulars, handouts, labels, wrappers,

catalogues and price lists, bill boards, posters, newspapers, magazines, digital and social media, and any other documents) made orally, online or otherwise or by means of projected light and sound recordings ;

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

"*Claim*" means any representation which states, suggests or implies that the drug product has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality ;

"*Drug*" includes any substances of vegetable, animal or mineral origin or any preparation or admixture thereof manufactured, sold or advertised for use in—

(*i*) the diagnosis, treatment, mitigation, in man or animal,

(*ii*) restoring, correcting or modifying organic function in man and animal,

(*iii*) disinfections or the control of vermin, insects or pest, or

(*iv*) contraception ;

"*Fast*" means the claimed effect of drug product is demonstrated to be observed 'within 30 minutes ;

"*Immediate*" or "*Instant*" means there must be evidence of claimed effects "within 10 seconds" ;

"*Justification*" means written explanation in respect of any claim, which shall be in the light of current knowledge acceptable to the Agency ;

"*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 drug or related product ;

"*Labelling*" means any written, printed or graphic matter that is present on the label, accompanying the drug or related product, including that for the purpose of promoting its sale or disposal ;

"*Media*" means newspaper, magazine, medical journal, television, radio, the Internet ; Out of home, vehicle branding, posters, handbills, cinema, point of sale material, online, digital and social media, any form of projected light and sound recordings or any of such means of communication ;

"*Prescription drug product*" means a drug product which can only be made available to a patient through a written prescription signed by a duly qualified and registered medical practitioner and dispensed by a registered and licensed Pharmacist; such drug product shall not be made available or sold directly to the general public without the said prescription and shall be identified by chemical or generic name ;

"*Prescribing information*" means information generally drafted by the drug product company and approved by the Agency; it includes the details

and directions healthcare providers need to prescribe the drug product properly; it is also the basis for how the drug product company can advertise its drug product which includes such details about the drug product as—

(*i*) its chemical description,

(*ii*) how it works,

(*iii*) how it interacts with other drug products, supplements, foods, and beverages,

(*iv*) what condition(s) or disease(s) it treats,

(*v*) who should not use the drug product,

(*vi*) serious side effects, even if they occur rarely,

(*vii*) commonly occurring side effects, even if they are not serious, and

(*viii*) effects on specific groups of patients, such as children, pregnant women, or older adults and how to use it in these populations ;

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

"*Rational drug product therapy*" means appropriate therapy recommended or prescribed which logically may be expected to remedy or ameliorate a disordered state of physical or mental health, and shall include logical use for a diagnostic and prophylactic purpose to prevent or lower the incidence of illness ;

"*Therapeutic classification of drug product*" means either the accepted pharmacological classification such as anxiolytic, diuretic, analgesic, antibiotic, or the identity of the purpose for which the drug product is intended or both ; and

"*Top Parity*" means a situation where several products within the same category are of equal efficacy and the evidence shows that no product is superior to the one being advertised ; a top parity claim may be used.

Citation.

33. This Regulation shall be cited as the Drug Products Advertisement Regulations, 2021.

SCHEDULE

[*Regulation* 21]

(1) Alcoholism ;
(2) Appendicitis ;
(3) Arteriosclerosis ;
(4) Asthma ;
(5) Blood disorders ;
(6) Cancer ;
(7) Cataract ;
(8) Cholera ;
(9) Diabetes ;
(10) Diphtheria ;
(11) Disorders of menstrual flow ;
(12) Disorders of prostate gland ;
(13) Dysentery ;
(14) Ebola infection and other haemorrhagic fevers ;
(15) Encephalitis ;
(16) Enteric fever ;
(17) Epilepsy ;
(18) Erysipelas ;
(19) Filariasias ;
(20) Gallstones, kidney stones and bladder stones ;
(21) Gangrene ;
(22) Any genital or urinary diseases not mentioned elsewhere in the Schedule ;
(23) Glaucoma ;
(24) Goitre ;
(25) Hay fever ;
(26) Heart disease ;
(27) Hernia ;
(28) High blood pressure ;
(29) Infective hepatitis ;
(30) Influenza and flu ;
(31) Jaundice ;
(32) Kidney disease ;
(33) Leprosy ;
(34) Locomotor ataxis ;
(35) Loss of youth ;
(36) Measles ;
(37) Meningitis ;
(38) Mental conditions ;
(39) Mumps ;

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

MADE at Abuja this 7th day of July, 2021.

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