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

DRUG AND DRUG PRODUCTS ADVERTISEMENT REGULATIONS 2018

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS (ending 29th August, 2018).

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ARRANGEMENT OF REGULATIONS

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug product Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drug products and Related Products (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 PRODUCT ADMINISTRATION AND CONTROL with the approval of the Honourable Minister of Health hereby makes the following Regulations:-

1. **Scope**

   These Regulations apply to all advertisements or promotion of drug products both single and compound entity, manufactured, imported, exported, sold, distributed or used in Nigeria.

2. **Prohibition**

   (1) No person shall advertise any drug or drug product unless it has been registered by the Agency.

   (2) No person shall advertise any drug product unless the advertisement has the pre-clearance and approval of the Agency.

   (3) No person shall engage in consumer promotions of any kind, including but not limited to gifts or free samples of drug or drug products to the consuming public.

   (4) No person shall carry out product launch for drug or drug products unless approval/clearance has been obtained from the Agency.

      (a) Where the product launch is for Prescription Only Medicines claims made for the drug or drug product shall be published in Medical or Scientific Journals only.

      (b) All press releases stating the product name and indications shall be submitted for vetting and approval by the Agency before release to the public.

3. **Nature of advertisement**

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

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

4. **Non-referential advertisement**

   (1) No advertisement of a drug or drug product shall;

(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.

5. **Application for the approval of advertisement**

All advertisement materials including scripts, story-boards, art work, radio scripts and any other advertisement material as may be required by the Agency shall be submitted along with an application, to the Agency.

6. **Particulars of application**

(1) An application submitted by an advertisement agent, distributor, manufacturer or the sponsor of the advert 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 where applicable;

(d) the place of importation or local manufacturer;

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

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

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

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

(i) any 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.

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

7. **Validity of approval**

The approval of an advert shall be valid for a period of one year beginning from the date of the approval.

8. **Alteration in approved script**

Any alteration in the format of the approved script or recording without the approval of the Agency shall render the approval null and void.

9. **Withdrawal of an approval**

(1) The Agency may withdraw the approval for an advertisement if-

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

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

(c) in the light of new scientific evidence against claims contained in the advertisement.

10. **Appeal in case of withdrawal of approval within the one year specified**

(1) If the approval of an advertisement of drug or drug product is withdrawn within the validity period of approval, the applicant may, within 30 days of the receipt of the withdrawal notice, lodge an appeal to the Governing Council of the Agency in writing and accompanied by supportive information; if no appeal is made after thirty days, the withdrawal stands as issued

(2) Where no appeal is made after thirty days, the withdrawal stands as issued.

11. **Advertisement to effect caution in drug product usage**

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

12. **Boxed warning**

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

13. **Drug Product Advertisement Claims**

(1) No advertisement for Over-The-Counter drug products shall state or imply in absolute terms or by quotations taken out of context, that any 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 such claims can be supported by the pharmacokinetic attributes of such 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.

14. **Restriction**

(1) No advertisement of any drug or drug product shall contain;

(a) any false or misleading information;

(b) half-truths, inadequate qualification and limitations regarding safety or effectiveness of the drug product;

(c) vague, unsubstantiated statements, or suggestions 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 via Out-Of-Home, Television, Radio, SMS, online media or any such media.

Prescription drug products

15. **Labelling advertisement for Prescription drug products and particulars of prescription**

(1) Notwithstanding Regulation 13(5), prescription drug products shall be advertised in accordance with the provisions of these regulations via scientific and medical journals, "Leave Behinds", pamphlets or scientific literature on health newsletters which shall be used for distribution to healthcare professionals only provided that such materials have been satisfactorily vetted and approved by the Agency.

(2) Prescription drug products for advertisement shall be properly labelled in accordance with NAFDAC Drug Labelling Regulations, 2018.

16. **Data comparison misrepresentation**

(1) All comparison on drug or drug product package shall be supported by current scientific data and shall not be misleading, directly or by implication

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

(3) All data illustrations presented in the advertisement including charts, graphs, tables, etc., 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.

17. **Side effect and contra-indications**

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

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

18. **Contents of advertisements with specific therapeutic claims**

(1) Advertisement of drug products containing specific therapeutic claims shall contain within the advertisement –

(a) the brand name and non-proprietary or generic names 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 Certificate of Registration Holder.

19. **Accurate interpretation of research findings**

(1) All advertisement materials including scripts, story-boards, art work, radio scripts and any other advertisement material for drug or drug products shall be so written as to accurately interpret valid and representative research findings.

(2) Statistics in an advertisement of cosmetic products shall be so 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 cosmetic products shall be provided to the Agency for verification.

20. **Claims and quotations from scientific literature to be mentioned**

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

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

21. **Scientific articles and literature to contain both positive features and negative findings**

(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) Accordingly all claims and quotations shall contain both negative and positive findings and shall be verifiable by the Agency.

22. **Restriction or selection of quotation**

No selected quotation shall refer to another brand of the same active ingredient, or to a different formulation of the same active ingredients.

23. **Prohibition of advertisement for certain diseases**

No person shall advertise a drug product as a treatment, prevention or cure for any disease, disorder or abnormal physical state specified in the Schedule to these Regulations.

24. **Exemption**

Notwithstanding the provisions in Regulations 22 above, 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.

Over-the-counter drug products

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

(1) The package and advertisement of an Over-The-Counter drug product in Nigeria shall be properly labelled in accordance with the provision of the NAFDAC Labelling Regulations, 2018.

(2) Over-the-counter drug products 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 or exaggerated as to amount to a misrepresentation.

(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.

(4) 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 or exaggerated as to amount to a misinterpretation.

(5) All labelling information shall be in English language.

26. **Advertisement to contain certain information**

(1) The advertisement of a drug product shall contain the following information;

(a) the name of the drug product;

(b) the pack size(s) being promoted;

(c) the different forms in which the drug product is available (if necessary); and

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

27. **Restriction on use of advertisement**

(1) No over-the-counter drug products advertisement shall-

(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 dramatize any symptoms by way of drawing a picture of a pregnant woman, patient with backache, or use throbbing sounds like heartbeats, coughing or agonising cries; and

(d) denigrate or attack unfairly any competitive products.

28. **Advertisement of Over-The-Counter drug products in mass media**

No person shall advertise any drug product unless such advertisement states clearly both the generic and brand names (if applicable) of the drug product.

29. **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 50,000 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.

30. **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.

31. **Interpretation**

In these Regulations, unless the context otherwise requires:

"**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.

"**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**" or "**Drug product**" 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**" in respect of any claim means shall be in the light of current knowledge acceptable to the Agency;

"**Label**" means a display of written, printed or graphic matter upon the immediate containers to the drug product;

"Labelling" "Package labelling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or (2) accompanying such article"

"L**ocation address**" means a place where the activity of manufacture, sale, distribution, storage and display of drug products is carried out which includes the house number, plot number, street name, town or city, state, country, etc.;

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

"P**rescription 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(s);

"**Prescribing information**": It is 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. The prescribing information 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

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

"**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 (e.g. anxiolytic, diuretic, analgesic, antibiotic, etc.) or the identity of the purpose(s) for which the drug product is intended (migraine, hypertension, etc.,) or both.

"**Top Parity**": 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.

32. **Repeal of Drug Products Advertisement Regulations 1995**

(1) The Drug Products Advertisement Regulations 1995 is hereby repealed.

(2) The repeal of these Regulations specified in Regulations 29(1) shall not affect anything done or purported to be done under the repealed Regulations

33. **Citation**

This Regulation may be cited as the Drug Products Advertisement Regulations, 2018.

MADE at Abuja this …….day of ……..2018

……..

Inuwa Abdulkadir Esq

Chairman Governing Council

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

Schedule

Alcoholism

Appendicitis

Arteriosclerosis

Asthma

Blood disorders

Cancer

Cataract

Cholera

Diabetes

Diphtheria

Disorders of menstrual flow

Disorders of prostate gland

Dysentery

Ebola infection and other haemorrhagic fevers

Encephalitis

Enteric fever

Epilepsy

Erysipelas

Filariasias

Gallstones, kidney stones and bladder stones

Gangrene

Any genital or urinary diseases not mentioned elsewhere in the Schedule Glaucoma

Goitre

Hay fever

Heart disease

Hernia

High blood pressure

Infective hepatitis

Influenza and flu

Jaundice

Kidney disease

Leprosy

Locomotor ataxis

Loss of youth

Measles
Meningitis
Mental conditions
Mumps
Nervousness
Nutritional disorders
Obesity
Onchocerciasis
Paralysis
Plague
Pleurisy
Pneumonia
Poliomyelitis
Rabies
Rheumatic fever
Schistosomiasis
Sexual impotence, loss of virility or sterility
Sleeping sickness
Small pox
Snake bite
Syphilis
Tetanus
Trachoma
Tuberculosis
Tumours
Typhoid fever
Undulant fever
Ulcers of the gastro-intestinal tract
Venereal diseases
Yaws
Yellow fever