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

Medical Devices, In vitro Diagnostics and Related Products Advertisement Regulations 2024

CLOSED FOR COMMENTS; UNDERGOING GAZETTING

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Arrangement of Regulations

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

Medical Devices, In vitro Diagnostics and Related Products Advertisement Regulations 2024

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 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 ADMINISTRATION AND CONTROL with the approval of the Minister of Health hereby makes the following Regulations: -

1. **Application**

These Regulations shall apply to the advertisement or promotion of medical devices, in vitro diagnostics (IVDs) and related products manufactured, imported, exported, sold, distributed or used in Nigeria.

2. **Application for the Approval of Advertisement**

(1) Advertisement materials including scripts, story-boards, artwork, radio scripts and any other advertisement material shall be submitted along with an application and accompanying documents in a manner as may be prescribed by the Agency.

(2) Advertisement materials submitted under these Regulations shall be authenticated by the Chief Executive or the appropriate technical person of the medical device and related product company sponsoring the advertisement.

(3) Application submitted by an advertising agent, distributor, manufacturer or the sponsor of the advert shall contain the following -

(a) the brand name of the medical device and related product, if any;
(b) place of importation or local manufacturer;
(c) the name and address of the manufacturer;
(d) the name and address of the local distributor;
(e) the name and address of the advertising company;
(f) the date of first introduction of the medical devices, IVDs and related products to the Nigerian market, for new products;
(g) information about any previous advertisement of the medical devices, IVDs and related products in Nigeria, where necessary;
(h) the proposed media of the advertisement;
(i) evidence of current product registration;
(j) a justification for any special claims on the medical devices, IVDs and related products;
(k) scripts and recordings; and
(l) such other materials as may be required by the Agency from time to time.

3. **Labelling Information**

Medical devices, IVDs and related products for advertisement shall be labelled in accordance with the Agency's extant Medical Devices In Vitro Diagnostics and Related Products Labelling Regulations.

4. **Nature of advertisement**
   (1) Advertisements of medical devices, IVDs and related products shall be accurate, complete, clear and designed to promote credibility and trust by the general public.
   (2) Statements or illustrations contained on the packaging or advertisement material shall not mislead directly, indirectly or by implication.

5. **Non-referential advertisement**
   Advertisement of medical devices, IVDs and related products shall not: -
   (a) imitate the general layout, text, slogan or visual presentation of another medical device, IVD and related product in a manner likely to mislead or confuse the consumer; or
   (b) be stated in such a manner to induce fear among users leading to the purchase of medical device.

6. **Validity of approval**
   (1) An approval for advertisement of medical device, IVD and related product shall be valid for a period of one year at first instance from the date of the approval.
   (2) Subsequent advertisement applications shall be valid for two years provided no alteration is made and conditions of renewal approval remain the same.
   (3) Notwithstanding regulation 1 of this regulation, consumer promotions shall have validity period of 15 weeks.

7. **Alteration in approved Advertisement material**
   Any alteration in the format of the approved script or recording without the approval of the Agency shall render the approval invalid.

8. **Withdrawal of approval within the validity period**
   The Agency may withdraw the approval for an advertisement: -
   (a) if the grounds on which the approval is granted is found to be false or incomplete;
   (b) if any of the conditions under which the approval is granted has been contravened; or
   (c) for reasons of new scientific evidence

9. **Reference to professional bodies or associations etc.**
   Advertisement of medical device, IVD and related product shall not make reference directly or indirectly to any individual member of professional body or association, as approved by the Agency.

10. **Advertisement not to prejudice public confidence**
   A person shall not advertise medical device, IVD and related product in a manner that brings the industry to disrepute or prejudice public confidence in the medical devices, IVDs and related products.

11. **Accurate interpretation of research findings**
   (1) Any copy of advertisement shall be written as to accurately interpret valid and representative research findings.
   (2) Statistics in an advertisement shall be written to reflect only their true validity and significance.

12. **Scientific articles and literature**
   (1) A claim or quotation shall contain both the negative and positive findings and shall be readily

verifiable by the Agency.

(2) A claim based on, or quotation that has been selected from a scientific article or series of articles which emphasize only the positive features while ignoring negative findings, shall not be acceptable.

13. **Contravention of ethical standards**

Advertisement of medical devices, IVDs and related products shall not contravene the ethical standard of the health care profession.

14. **Unfairly disparage competition**

Advertisement shall not unfairly disparage any company of its competitive products either directly, indirectly or by implication.

15. **Claims**

(1) Advertisement for medical device, IVD and related product shall not state, imply in absolute terms or by quotations taken out of context, that any medical device or related product is "safe", has "guaranteed effectiveness" 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 medical device, IVD and related product of choice", or any such statements, for a medical device, IVD and related product shall not be used unless it can be adequately substantiated and shall not imply superior effectiveness to other products in same category.

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

(4) Where an advertisement portrays a medical device as "fast", "immediate" "instant" or "rapid" in action, or any similar descriptions, such claims must be substantiated using studies based on the performance of the medical device and related products.

(5) "Duration of action" claims in medical device, IVD and related product advertisements shall be allowed provided the claims can be supported by performance studies.

(6) Where claims on performance are made in the advertisement of a medical device, IVD and related product, such claims shall be substantiated using performance studies carried out in actual patients.

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

16. **Restrictions**

(1) Advertisement for a medical device, IVD and related product shall not contain:-

(a) false or misleading information;

(b) incomplete truths, inadequate qualification and limitations regarding safety or effectiveness of the medical device, IVD and related product;

(c) vague, unsubstantiated statements, or suggestions of superiority over competing medical device or related product;

(d) false impression that the advertised medical device is for universal purpose or should be regarded as a more effective and safer alternative to other medical device or related product in the same category.

(2) Medical device, IVD or related product advertisement shall not:

(a) contain such word as **"magic" "miracle"**, **least harmful"**, "**best tolerated"** or description such as **"most effective"** or any other words as to induce the daily or continuous use of the medical device or related product outside of its intended use;

(b) contain a message that if the reader, viewer or listener does not use a particular medical device or related product, the user may not get the best result;

(c) disparage or attack unfairly any competitive brand of medical device or related product.

17. **Prohibition of misleading comparison**

(1) Comparison in an advertisement shall not mislead the public either directly, indirectly or by implication and where there is comparison it shall be supported by reliable current scientific data.

(2) A reference to a competitive manufacturer or its specialties in an advertisement shall be restricted to factual comparison without the use of identifiable regulated product or brand name.

(3) Data illustrations including charts and graphs, tables extracted from reference studies or other sources or reproduced by artwork, presented in an advertisement, shall -

(a) be accurate, complete and clear, with their source specifically identified;

(b) not be misleading or ambiguous or distort the original intended meaning or interpretation either directly or by implication.

18. **Labelling advertisement for medical devices or related product**

Medical devices, IVDs and related products not for lay users shall be advertised in accordance with the provisions of these Regulations via scientific and medical journals, "Leave Behinds", pamphlets or scientific literature or health newsletters which shall be used for distribution to healthcare professionals only, provided that such materials have been vetted and approved by the Agency.

19. **Accurate interpretation of research findings for Medical Devices, In vitro Diagnostics and related Products Registrations**

(1) Advertisement materials including scripts, story-boards, artwork, radio scripts and any other advertisement material for medical device, IVD and related product shall be written as to accurately interpret valid and representative research findings.

(2) Statistics in an advertisement of medical device, IVD and related product shall be written as to reflect only their true validity and significance.

(3) Copy of any reference cited by an applicant in the advertisement of medical device, IVD and related product shall be provided to the Agency for verification.

20. **Product launch and Press release for medical devices**

Product launch material or press release for medical devices, IVDs and related products shall be as approved by the Agency for the product advertisement materials.

21. **Prohibition**

(1) A person shall not advertise any medical devices, IVDs and related products except it has been registered and the advert material approved by the Agency.

(2) A person shall not display, screen or present an advertisement of a medical device or related product except in accordance with the provisions of these Regulations.

22. **Offences and Penalties**

(1) Any person who contravenes any of the provisions of these Regulations commits an offence and liable on conviction. In the case of: -

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N800,000:00 or both,

(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 any 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 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, commits an offence and liable to be proceeded against and punished 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.

23. **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; and

(b) any of the person's property or instruments 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.

24. **Enforcement of the Regulations**

The Agency is exclusively responsible for the enforcement of these Regulations

25. **Interpretation**

In these Regulations:-

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 Administration and Control;

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

Fast means the claimed effect of medical device 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 medical devices;

Labelling means any written, printed or graphic matter that is present on the label, accompanying the medical devices 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;

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

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.

26. **Citation**

This Regulations shall be cited as the Medical Devices, IVDs and related products Advertisement Regulations 2024.

MADE at Abuja this ……. day of …….2024.

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Chairman of the Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)