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

Medical Devices, In vitro Diagnostics and Related Products Labelling 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)

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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 labelling of medical devices, in vitro diagnostics (IVDs) and related products manufactured, imported, exported, advertised, sold, distributed, or used in Nigeria.

2. **Prohibition**
   A person shall not manufacture, import, export, distribute, advertise, display for sale, or use a medical device, in vitro diagnostic (IVD) and related product, except it is labelled in accordance with the provisions of these Regulations.

3. **Labelling Information**
   (1) Information required to be indicated on the label shall be informative, accurate, prominent, legible and distinct.
   (2) The statement shall appear in font size and style type, which is adequate for clarity and on sufficient contrasting background without obscuring designs or vignettes or crowding within written, printed, or graphic matter.
   (3) Information shall be in English Language and may include any other languages.
   (4) The letters of the name of the medical device, in vitro diagnostic (IVD) and related product and the net content or net weight shall be of a size reasonably related to the predominant character on the label.
   (5) Labelling shall not be false or misleading, deceptive or likely to create an erroneous impression regarding its character, quality, quantity and origin.
   (6) Information and statements as required by these Regulations shall appear on the part or panel of the label which is presented or displayed under customary conditions of purchase.
   (7) The label space shall not be used to present information, statement or graphics not required by these Regulations in such a manner that will make the label space insufficient for the prominent placing of such information or statements required under these Regulations.
   (8) Medical device, in vitro diagnostic (IVD) and related product label shall state the following:-
      (a) the brand name (where applicable).
      (b) the product's statement of identity;

(c) batch or lot number;
(d) net content or net weight;
(e) manufacture, expiry date;
(f) manufacturer's name and location address including country of origin;
(g) NAFDAC registration number assigned to it in a manner as prescribed by the Agency
(h) Warnings and cautions
(i) instruction for use
(j) storage conditions; and
(k) any other information as may be prescribed by the Agency.

(9) Notwithstanding the provisions of regulation 8 of this regulation, a medical device, in vitro diagnostic (IVD) and related product in a container having inadequate space shall indicate the following-
(a) the brand name (where applicable);
(b) the product statement of identity;
(c) lot or batch number;
(d) net content, net weight;
(e) expiry date (where applicable);
(f) manufacturer's name and address; and
(g) registration number assigned to it in a manner prescribed by the Agency.

(10) Where a medical device, in vitro diagnostic (IVD) and related product container is covered with a packaging material, the label shall be readily legible through the outer packaging material and shall not be obscured by it.

(11) Labels of medical device, in vitro diagnostic (IVD) and related product shall be affixed in a manner that is not removable from the medical device or related product container.

(12) No label shall bear words, pictorial or other means which refers to any other product or falsely suggests either directly or indirectly, that the medical device, in vitro diagnostic (IVD) and related product is connected with such other product.

(13) Information and statements as required by these Regulations shall appear on the part or panel of the label which is presented or displayed under customary conditions of purchase.

(14) Any claims on the medical device, in vitro diagnostic (IVD) and related product shall be substantiated.

(15) Special labelling requirements and product safety information shall be clearly stated.

(16) Any other information as may be required by the Agency.

4. **Expiry Date**

(1) Medical device, and in vitro diagnostic (IVD) and related product label shall indicate the expiry date of the product as indicated in regulation 3 (8) and (9).

(2) Notwithstanding Regulations 4 (1), for Medical device, in vitro diagnostic (IVD) and related product for continuous use, the expiry date will suffice.

5. **Name and address of Manufacturer, Holder of Certificate of Registration, Packer on label**

(1) The label of a medical device, in vitro diagnostic (IVD) and related product shall be conspicuous, indicating the name and manufacturing address of the manufacturer.

(2) Where a medical device, in vitro diagnostic (IVD) and related product is manufactured under a contract manufacturing arrangement, the name and manufacturing address shall be indicated

by a phrase that reveals the connection with the entity such as "Manufactured by ....., for.....", 'Manufactured for ..... by .....", or any other wording that expresses the facts.

(3) The name and address of the manufacturer and packer of a medical device, in vitro diagnostic (IVD) and related product shall be specified on the packaging component label (where present) in such a manner that is easily readable.

(4) When a medical device, in vitro diagnostic (IVD) and related product undergoes any processing which affects its contents in another country, such a country shall be considered as the country of manufacture for the purpose of labeling.

(5) When a medical device, in vitro diagnostic (IVD) and related product undergoes any processing which does not affect its contents in another country, such a country shall be considered as the country of packaging for the purpose of labeling.

(6) The address of the manufacturer of a medical device, in vitro diagnostic (IVD) and related product shall be complete on labels of all packaging components (i.e., Primary, Secondary and Tertiary), unless the immediate container of the medical device, in vitro diagnostic (IVD) and related product is inadequate, in which case the address needs not be shown on the Primary label.

6. **Product identification**

(a) Trademark and Brand name

(1) The brand name or trademark shall be displayed on the label and shall not give a wrong impression of the nature or quality of the medical device, IVD and related product.

(2) Where the brand name or trademark registration is in conflict with any Regulations or requirements of the Agency, the latter shall supersede and prevail.

(3) The brand name or trademark of a medical device, IVD and related product shall not be a sound or look alike to an already registered medical device or related product.

(b) Statement of identity

(1) The label of a medical device, in vitro diagnostic (IVD) and related product shall be bear the name of the medical device or related product which shall indicate the accurate nature of the medical device or related product.

(2) Where a common name or statement of identity has been established for the medical device, in vitro diagnostic (IVD) and related product it shall be used in conjunction with the brand name of the medical device, in vitro diagnostic (IVD) and related product.

(3) Where no common name or statement of identity exists for a medical device, in vitro diagnostic (IVD) and related product, an appropriate descriptive name shall be affixed to it.

(4) Where a coined or fanciful name is used for the medical device, in vitro diagnostic (IVD) and related product, the name shall not be misleading and shall be accompanied by an appropriate descriptive term.

(c) Product specific identifier

1. Medical device, IVD and related product shall have product specific identifier such as batch number, lot number, batch code, lot code, serial number, control number or version number where applicable.

2. The product specific identifier shall be indicated on all packaging components of medical device, IVD and related product and where it is impossible, for reasons of size, for details of the product identifier to appear on all packaging components, the details shall be given on the primary packaging.
3. The Use of internationally recognized Symbols, Unique Device Identification (UDI), QR Code, Electronic labelling may apply.

7. **Composition/components**

(1) A complete list of composition or components of the medical device, in vitro diagnostic (IVD) and related product shall be declared on the primary and secondary label where applicable in decreasing order of predominance.
(2) Where there is no secondary packaging, the list of composition or components shall appear on the primary label.
(3) Composition or components in concentrations of less than 1% may be listed in any order after those concentrations of 1% or more.
(4) Where the composition or components of a medical device, in vitro diagnostic (IVD) and related product have more than one composition or component, the name of the composition or components shall be included in the list of composition or components.
(5) The declaration of composition or components shall be prominent, readable, and understood under normal conditions of purchase.
(6) Where a medical device, IVD and related product contains a pharmaceutically active composition or components, the declaration of composition or components shall declare the active drug composition or components in accordance with the Agency's extant Drug Labelling Regulations.
(7) Where an composition or components of a medical device, in vitro diagnostic (IVD) and related product is known to cause hypersensitivity, such shall be declared on the label.
(8) Where multi-packs are involved, the following shall apply -
    (a) where the composition or components labeling is on the secondary packaging, the composition or components for each product may be separately listed or combined into one list;
    (b) where labeling on the secondary packaging is impossible for practical reasons or impracticable for reasons of size or shape, the list shall be given on a leaflet, label, tag, tape or card enclosed with the product and the consumer shall be referred to the text either by abbreviated information or by a special symbol on the outer pack;
    (c) if the products within the multi-pack have containers which are individually labeled or printed with an composition or components list, there is no need for a separate leaflet, label, tape, tag or card; and
    (d) in the case of transparent packaging, where the composition or components labeling of the products is clearly visible, separate labeling is not required.

8. **Date marking instructions**

(1) The date marking shall be stated for medical device, IVD and related product and shall be stated on the packaging components (where present).
(2) The batch number and date markings shall not be pre-printed on the label.

9. **Storage condition**

The required storage condition shall be specified on the packaging components (where present).

10. **Trademark and Brand name**

(4) The brand name or trademark shall be displayed on the label and shall not give a wrong impression of the nature or quality of the medical device, IVD and related product.

(5) Where the brand name or trademark registration is in conflict with any Regulations or requirements of the Agency, the latter shall supersede and prevail.

(6) The brand name or trademark of a medical device, IVD and related product shall not be a sound or look alike to an already registered medical device or related product.

11. **Registration number assigned by the Agency**

(1) The packaging component of a medical device, IVD and related product shall clearly show the registration number (NAFDAC REG. NO.) of the product assigned to it by the Agency as indicated on the Certificate of Registration in a manner prescribed by the Agency.

(2) Where a medical device has tertiary, secondary and primary packaging materials and the content of a 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.

(3) Where primary package is a Trade Item, NAFDAC REG. NO shall be assigned to the primary package.

12. **Instruction for use**

Directions for use shall be included on the label to ensure correct utilization of the medical device or related product.

13. **Warnings and cautions**

The label of medical device, IVD and related product shall carry clear and adequate warning to prevent any danger in the use of the product.

14. **Displayed information, etc.**

(1) Any information displayed on a label which misleads or deceives a consumer in anyway shall constitute an offence under these Regulations.

(2) No person shall remove, add to, alter, deface or render illegible any statement upon a label printed on or attached to the packaging or container in pursuance of these Regulations.

15. **Net content**

(1) The accurate average net content or net weight of medical device, IVD and related product shall be declared on the inner and outer label in the metric system.

(2) Medical device, IVD and related product that have only inner label shall meet the same requirements as those for the outer labels of products having both an outer and inner label.

16. **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.

17. **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.

18. **Enforcement of the Regulations**

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

19. **Interpretation.**

In these regulations—

"Address" means a place where the business of manufacture, sale, distribution, storage and display of medical devices is carried out which includes the house number, plot number, street name, town or city, state, country.

'**Agency**" means the National Agency for Food and Drug Administration and Control.

Expiry date" means any date after which a medical device or related product is not recommended for use.

'Intended use' means the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

"Label" means any tag, brand, mark, pictorial, or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to a package or container of medical device or related product.

"Labelling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

'Manufacturer' means any natural or legal person with responsibility for the design and/or manufacture of a medical device with the intention of making the medical device available for use, under its name; whether or not such a medical device is designed and/or manufactured by that person, or on that person's behalf, by another person(s).

"**Medical device**" means any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or in animal.

Medical device' also means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings or animals, for one or more of the specific medical purpose(s) of:

a. diagnosis, prevention, monitoring, treatment, or alleviation of disease,
b. diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
c. investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life,
d. control of conception,
e. disinfection of medical devices,
f. providing information by means of in vitro examination of specimens derived from the human body;
   and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such **means.**

"Medical device family" means a group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use;

"Medical device group" means medical devices comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name;

"Medical device group family" means a collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that differ only in the number and combination of products that comprise each group;

"Package" means any suitable container in which any medical device or related is wholly or partly placed or packed.

"Primary packaging material" means packaging material that come in direct contact with the product e.g. bottle, blister, aluminum foils, etc.;

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

'Reagent' means any chemical, biological or immunological component, solution or preparation intended by the manufacturer to be used as IVD.

"Secondary packaging material" means packaging material in which primary packaging material is enclosed;

"Service Medical Device" means medical device including In vitro diagnostic (IVD) that are not registered by the Agency and is required for certain or critical medical purpose but which cannot be found in-country.

"Test kit" means an in vitro diagnostic medical device that consists of reagents or articles, or any combination of these Regulations, and that is intended to be used to conduct a specific test;

"Tertiary packaging material" means outer carton in which multiples of saleable units are packed i.e. shipper carton;

20. **Citation.**
These Regulations shall be cited as the Medical Devices, In vitro Diagnostics and Related Products Labelling 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)