ADMINISTRATIVE ORDER
No. _____

SUBJECT: Guidelines on the Labeling Requirements for Medical Devices in the Philippines

I. RATIONALE

The Food and Drug Administration (FDA) through the Center for Device Regulation, Radiation Health and Research (CDRRHR) is the primary agency authorized to enforce regulatory requirements on manufacture, importation, distribution, sale, and offering for sale of medical devices in accordance with the provisions of Republic Act 9711 also known as FDA Act of 2009, and its Implementing Rules and Regulations (IRR). As stipulated in the IRR, the CDRRHR is mandated to establish an effective regulatory system and mechanism to ensure the safety, quality and performance of medical devices in the Philippines.

The Philippines as a signatory to the ASEAN Agreement on Medical Device Directive (AMDD), adheres to continuously harmonize the technical procedures and requirements to reduce diversity in the regulations of medical devices.

The issuance of the guidelines on labeling requirements for medical devices, serves to communicate safety instructions related to information to users and/ or patients, as well as to standardize the required policy, and to assure the highest quality of medical devices used in the country.

II. OBJECTIVE

This Administrative Order aims to provide guidelines on the labeling requirements for medical devices aligned with the provisions of the ASEAN Medical Device Directive.

III. SCOPE

This guideline shall apply to all medical devices including In-vitro diagnostic (IVD) medical devices that are marketed and or sale in the Philippines.

IV. DEFINITION OF TERMS

For the purpose of this Administrative Order, the term below shall be defined as follows:

1. **Contraindications** - means a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under

which the medical device should not be used because the risk of use clearly outweighs any possible benefit.

2. **Custom-Made Medical Device** - means a medical device that:

    a. is made at the request of qualified practitioner (QP) and in accordance with the specifications of QP regarding the design characteristics or construction of the medical device;
    b. is intended to be used only in relation to a particular individual; and
    c. is not adapted from a mass-produced medical device.

3. **Healthcare Professional -** a person with proficient skill and experience with the use of medical device so that they can aid or train care patients and caregivers to use and maintain the quality and performance of the health product.

4. **Instruction For Use (IFU) / Patient Information Leaflet (PIL)** - Information provided by the product owner to inform the medical device user/ and or patients of the product's proper use and of any precautions to be taken.

5. **Intended Purpose/ Intended Use** - means the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device.

6. **In-Vitro Diagnostic (IVD) Medical Device** - refers to any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the product owner to be used for the examination of specimens, including blood or tissue donation, derived from the human body solely or principally for the purpose of

    a. providing information concerning a physiological or pathological state or;
    b. providing information concerning a congenital abnormality; or
    c. determining the safety and compatibility with potential recipients; or
    d. monitoring therapeutic measures.

7. **Label** - Written, printed or graphic information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple medical devices.

8. **Labeling -** The label, instructions for use, and/or any other information that is related to identification, technical description, intended purpose and proper use of the medical devices but excluding shipping documents.

9. **Lay person** - An individual who does not have formal training in a relevant field or discipline.

10. **Medical Device -** means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

- intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose/s of

  - diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
  - investigation, replacement, modification, or support of the anatomy or of a physiological process;
  - supporting or sustaining life;
  - control of conception;
  - disinfection of medical devices;
  - providing information for medical device or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

- which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended functions by such means.

11. **Near patient -** beside the patient, or immediately the patient bedside.

12. **Primary Level of Packaging -** the first level of packaging in direct contact/ attached to the medical device.

13. **Product Name -** refers to the name of the medical devices registered in the FDA.

14. **Precautions** - It alerts the user to exercise special care necessary for the safe and effective use of the medical device. It may include actions to be taken to avoid effects on patients/users that may not be potentially life- threatening or result in serious injury, but about which the user should be aware.

15. **Product Owner -** in relation to a medical device, means any person who:

    a. supplies the medical device under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

    b. is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the medical device, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

16. **Qualified Practitioner** (QP) - A physician or a health care professional who is qualified by education, training licensure/ regulation (when applicable) and facility privileging (when applicable) who performs a professional service within his/ her scope of practice and independently reports that professional service. (AMA)

17. **Reagent** - Any chemical, biological or immunological components, solutions or preparations intended by the product owner to be used as IVD medical devices.

18. **Refurbished Medical Device -** refers to a medical device that was previously owned and reconditioned for re-sale and meets the safety and performance parameters set by the manufacturers.

19. **Research Use Only -** is where the medical device is made available to institutions/laboratories subject to studies intended for collation of data only. The product is not intended for any medical purpose or objective.

20. **Single Use Device -** means the medical device is intended to be used in an individual patient during a single procedure and then disposed of. It is not intended to be reprocessed and re-used.

21. **Secondary Level of Packaging** - means the second layer of packaging of the medical device.

22. **User -** the person, either professional or lay, who uses a medical device. The patient can be a user.

23. **Warnings** - This is the specific hazard alert information that a user needs to know before using the medical device.

V. GENERAL GUIDELINES

1. The label shall be appropriately located depending on a particular medical device and its intended use, in accordance with the following forms:

    a. As far as it is practical and appropriate, the information needed to identify and use the medical device safely shall be provided on the medical device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit (primary level of packaging), and / or on the outer packaging of multiple medical devices that are packaged together (secondary level of packaging);

    b. if individual packaging of each unit is not practicable or appropriate, the information shall be set out in the instructions for use (IFU) see Annex A (e.g. leaflet, packaging insert, manual or other supplied media); and

    c. where the product owner supplies multiple medical devices to a single user and/or location, it may be sufficient and appropriate to provide with them only a single copy of the instructions for use. In these circumstances the medical device user shall have access to further copies upon request.

2. The medium, format, content, readability and location of labeling shall be appropriate to the particular medical device, its intended purpose and the technical knowledge, experience, education or training of the intended user/s. In particular, instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some medical devices may require separate information for the healthcare professional and the lay person.

3. Instructions for Use (IFU) may not be needed or may be abbreviated for medical devices of low or moderate risk if they can be used safely and as intended by the product owner without any such instructions.

4. Paper versions/ hard copies of all labeling shall accompany the medical device.

5. Any residual risk identified in the risk analysis shall be reflected as contraindications, precautions or warnings within the labeling.

6. The use of internationally recognized symbols is encouraged provided that medical device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the symbol is not obvious to the medical device user e.g. for a lay-user or for a newly introduced symbol, an explanation should be provided.

7. All characters on labeling shall be of adequate of size and legibly printed.

8. The product labeling shall be written in English and/ or Filipino.

9. The color contrast between labeling and package background, designs shall not obscure information.

10. For medical device software, user instructions shall be supplied in electronic data storage device like compact disc, digital video disc or USB flash drive/ or other media.

11. For information downloadable from the internet, the internet web address shall be clearly printed on the physical label of the device and displayed in such a manner that highlights its purpose to the user. The product owner shall ensure that the electronic label is identical in content to the paper format (where applicable) that is submitted with the product registration application. Users and/or other relevant parties shall also have access to a paper version of the IFU upon request.

12. The label shall not contain any statement to the effect, whether directly or indirectly, that the placement in the market, or usage or operation of the medical device is being promoted or endorsed by the Department of Health – Food and Drug Administration, or any of its organizational bodies.

VI. SPECIFIC GUIDELINES

A. Medical Devices

The following specific content of labeling that shall appear in the packaging for medical devices:

1. Product name, trade name or brand name to permit the user to identify the medical device.

2. Name, address and contact details (e.g. phone number, and website address to obtain technical assistance) of the product owner.

3. Certificate of Medical Device Notification Number or Certificate of Medical Device Registration number issued by the FDA-CDRRHR on all levels of packaging.

4. Name and address of the importer and/or distributor. It is mandatory to all levels of packaging unless the sterility and self-life will be compromised.

5. Sufficient details for the user to identify the medical device and, where these are not obvious, its intended purpose, user and patient population of the medical device; also, where relevant, the contents of any packaging.

6. Batch code, lot number or the serial number, if applicable.

7. Expiration date expressed at least as year and month (e.g. 2020-NOV), if applicable.

8. Special storage/container, handling conditions and/or storage conditions.

9. Manufacturing date expressed at least as year and month.

10. The information needed to verify whether the medical device is properly installed and can operate correctly and safely, including details of the nature, and frequency of preventive and regular maintenance, where relevant any quality control, replacement of consumable components, and calibration needed to ensure that the medical device operates properly and safely during its intended life, if applicable

11. The performance intended by the product owner and, where relevant, any undesirable side effects.

12. Details of any further treatment or handling needed before the medical device can be used (e.g. sterilization, final assembly, calibration, preparation of reagents and/ or control materials, etc.) where relevant.

13. Identification for “sterile medical device” and where appropriate, the sterilization method (e.g. sterilized using aseptic processing techniques; sterilized using ethylene oxide; sterilized using irradiation and/or sterilized using steam or dry heat); the information about what to do if the sterile packaging is damaged; and instructions for re-sterilization, if applicable.

14. Identification for “single-use only” medical device as specified by the product owner.

15. Identification for “reusable medical device”, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses.

16. The requirements for sterilization of a medical device before it used and instructions for cleaning and sterilization process.

17. Indication for “refurbished” medical device and the date of refurbishment shall be indicated.

18. Identification for a "custom-made" medical device and a statement that it shall be used by a qualified practitioner.

19. If the medical device is intended for "clinical investigation" or, for IVD medical devices, "performance evaluation only", an indication of that situation.

20. It shall be labeled if the medical device is intended for "research use only" and for "presentation or demonstration purposes only": not use on humans.

21. If the medical device is intended for research use only, it must be labelled as "research use only".

22. Particular risks in connection with implantation of an "implantable" medical device.

23. If the medical device "emits radiation" for medical purposes, where the details of the nature, type and where appropriate, the intensity and distribution of this radiation shall be indicated. A radiation symbol on the specific part of the medical device where the radiation source will be originated (e.g. x-ray tube) shall be also labeled.

24. Information regarding the "risks of reciprocal interference" posed by the reasonably foreseeable presence of the medical device during specific investigations, evaluations, treatment or use (e.g. electromagnetic interference from other equipment).

25. If the medical device is to be installed with or connected to other medical devices or equipment, or with dedicated software, in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct medical devices or equipment to use in order to obtain a safe combination.

26. IVD medical device shall be labeled as "In-vitro diagnostic" or "IVD"

B. In- vitro Diagnostic Medical Devices

In addition to the information required in *Specific Guidelines- A. Medical Devices*, directions/ instructions for the proper use of IVD medical device shall contain the following:

a. For HIV test kit, a stick-on label indicating "For DOH accredited laboratory use only" as per Republic Act No: 5804.

b. Intended purpose, with the following information:

   i. Type of analyte or measurand of the assay.
   ii. Whether the test is quantitative or qualitative.
   iii. Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring.
   iv. Disease or condition that the test is intended for.
   v. Type of specimen to be used e.g. serum, plasma etc.

vi. The intended users (e.g. self-testing by lay person, near patient by trained personnel or professionals).
vii. Assay type e.g. immunoassay, chemistry, cytochemistry, image analysis, immunohistochemistry.
viii. The specific name of the instrument required for the assay, if any.
ix. For instruments, the intended purpose should also include the modes of operation for instruments e.g., random access, batch, stat, open tube, closed tube, automatic, manual.

c. Test principle.

d. Specimen type.

e. Conditions for collection, handling, storage and preparation of the specimen.

f. Reagent description and any limitation (e.g. use with a dedicated instrument only).

g. The metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order.

h. Assay procedure including calculations and interpretation of results.

i. Information on interfering substances that may affect the performance of the assay.

j. Performance characteristics (summarized analytical and diagnostic sensitivity, specificity, reproducibility, etc.)

k. Reference intervals.

l. Study design (population studies, N, type of sample, matrix, dilution, target concentrations, etc.).

VII. TRANSITORY

All medical devices upon the effectivity of this A.O. prior to introduction for sale, distribution, and marketing shall comply with this A.O. All those already in the market shall not be affected by this A.O.

VIII. PENALTY

Any violation of this Administrative Order consistent with Republic Act No. 3720 and Republic Act No. 9711 and its implementing rules and regulations shall be a ground for filing appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation or revocation of any license, permit or registration issued by FDA.

IX. REPEALING AND SEPARABILITY CLAUSE

All administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provision of this order are hereby repealed or modified accordingly.

If any provision in this Administrative Order, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Administrative Order shall not be affected.

X. EFFECTIVITY

This Administrative order shall take effect after fifteen (15) days following its publication in two (2) newspapers of national circulation and upon filing to the University of the Philippines Law Center-Office of the National Administrative.

Signed
Secretary of Health

Annex A

For medical devices where an instruction for use (IFU)/ patient information leaflet (PIL) is applicable, the following additional information shall be contained therein:

a. Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

b. Precautions and/or measures to be taken in the event of changes in the performance, or malfunction, of the medical device including a contact telephone number, if appropriate.

c. Precautions and/or measures to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, temperature, humidity, acceleration, thermal ignition sources, proximity to other medical devices, etc.

d. If the medical device administers medicinal products, adequate information regarding any medicinal product(s) which the medical device in question is designed to administer, including any limitations in the choice of substances to be delivered.

e. Any medicinal substances or biological material incorporated into the medical device as an integral part of the medical device.

f. If the medical device has a measuring function, the degree of accuracy claimed for it.

g. Any requirement for special facilities, or special training, or particular qualifications of the medical device user and/or third parties.

h. Any precautions to be taken related to the disposal of the medical device and/or its accessories (e.g. lancets), to any consumables used with it (e.g. batteries or reagents) or to any potentially infectious substances of human or animal origin.

i. Where relevant, for medical devices intended for lay persons a statement clearly directing the user not to make any decision of medical relevance without first consulting his or her health care provider.

j. For further information, an electronic copy of IFU / PIL or the Quick Response (QR) code shall be available online through manufacturer's website written on the packaging.

k. Where relevant, for devices intended for home users, the IFU should contain a statement clearly directing the user not to make any decision of medical relevance without first consulting his or her health care provider.