ETHIOPIAN FOOD AND DRUG AUTHORITY

GUIDELINES FOR MEDICAL DEVICE LABELING

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ACRONYMS AND ABBREVIATIONS

EFDA	Ethiopian Food and Drug Authority
IFU	Instruction for Use
IU	International Unit
IVD	In Vitro Device
MRI	Magnetic Resonance Imaging
RFID	Radio-Frequency Identification
U.S. FDA	U.S. Food and Drug Administration
WHO	World Health Organization

1. Introduction

The Ethiopian Food and Drug Authority (EFDA) is mandated to safeguard the health and safety of patients and users by ensuring that manufacturers of medical devices follow specified procedures during the design, manufacture, and marketing as described in Food and Medicine Administration Proclamation 1112/2019. Particularly, by this proclamation, the Authority is given power to evaluate the quality, safety and effectiveness of medical device made available in the country. Accordingly, medical device labelling is one of the essential requirements that are to be evaluated by the Authority to ensure that the provided information are adequate, appropriate, not misleading and correctly representing the device under question.

Article 53 of Food and Medicine Administration Proclamation 1112/2019 requires the medical devices to be marketed in the Country to be appropriately packed and contain labeling that is not misleading, does not contain information that is inaccurate and should include barcode. This guideline is developed pursuant to sub-article 4 of the same article that states that the Authority prepares supplementary document for the labelling requirements

Labelling serves to identify a device and its manufacturer, as well as communicate safety and performance related information to users of medical devices and/or patients as well as to identify individual devices. Such information may appear on the device itself, on packaging, as instructions for use or package insert.

Therefore, this guideline is intended to provide guidance to manufacturers and authorized representatives or agents on the content of medical device labelling.

2. Definitions

For the purposes of this Guideline, the following have the meanings hereby assigned to them. They may have different meanings in other contexts.

Accessory

A finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices. Accessories are designed specifically for a device, and may include consumables, parts, add-ons, and other components for use in conjunction with, or for upgrade, replacement and repair of parts of a medical device.

Authority

The Ethiopian Food and Drug Authority

Intended use

The objective intent of the manufacturer regarding the use of a device, process or service as reflected in the specifications, instructions, and information provided by the manufacturer of the medical device

Labeling

The label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

Label

All labels and other written, printed, or graphic material that is affixed to a medical device or any of its container or wrapper and includes insert;

Lay person

An individual who does not have formal training in a specific field or discipline

Instructions for use

General and technical information provided by the manufacturer to inform the user of the medical device or IVD medical device's intended purpose and proper use and of any contraindications, warnings, or precautions to be taken. It is provided by the manufacturer to support and assist the device users in its safe and appropriate use. Instructions for use can also be referred to as "package insert."

Refurbishment

To recondition medical devices for safety and effectiveness with no significant change in their performance, safety specifications or service procedures as defined by the manufacturer and their original intended use.

Research use only

A medical device that has been made available to institutions/laboratories solely for their use in studies involving the collection of data. The device is not intended for any medical purpose or objective.

Primary packing

The covering, wrapper, or container that has direct contact with the medical device.

Secondary packing

The packing that cover the original (primary) packing of a medical device. It doesn't come into direct contact with a medical device and would include a carton.

User

The person, either professional or lay, who uses a medical device. It also include patients.

3. Scope

The guideline is applicable to all medical devices including in vitro diagnostic (IVD) medical devices as well as separately packaged accessories and spare parts of the devices. However, promotional materials of medical device are excluded from the scope of this guideline.

4. Objective

The objective of this guideline is to provide guidance on the content of the label, instructions for use, and information intended for the patient in order to support the safe and effective use of medical devices and IVD medical devices by their intended users.

5. Medical device labelling requirements

5.1. General

All medical device labeling should be in English and/or Amharic language. Furthermore, such labels should be legible, indelible and not easily detachable. Any information appearing on the labelling about the product information should be based on scientific justification.

The labelling should not contain any information or language regarding the manufacturer's liability in the case of damage or injury resulting from any use or malfunction of the medical device or IVD medical device that contradicts the laws or regulations in the jurisdiction of use.

The labelling should not contain any disclaimers related to the safety and performance of the medical device or IVD medical device for its intended purpose that are incompatible with the existing and new regulatory requirements., or the obligations of the manufacturer to design and manufacture a product that is safe and performs as intended throughout its expected lifetime.

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

Any residual risk identified in the risk analysis should be reflected as contraindications or warnings within the medical device labelling.

Instructions for 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 manufacturer without any such instructions.

Labelling may be provided to the user in various media and by several means such as printed documents, through a display screen incorporated into the device, the manufacturer's website

and magnetic or optical media. Whatever the media or the means, information should be targeted to the anticipated user population.

Contents of labelling should be as per terms and conditions submitted to the authority during medical device registration. There should be no over labeling on the lot/batch or serial number, date of manufacturing and date of expiry.

If the labels includes symbols and safety related identification colors, the marking should be explained, where necessary.

If a packer, distributor, or seller intends a device for uses other than those intended by the person from whom he received the device, these parties must furnish adequate labeling in accordance with the new intended use.

If a manufacturer knows or has information indicating that his device is to be used for conditions or purposes other than which it was intended, he is required to provide adequate labeling in accordance with such other uses.

The Authority may require any other additional information to be included as medical device labelling.

5.2. Location of labelling

The label should be appropriately located depending on a particular medical device and its intended use, in accordance with these following manners:

- As far as it is practical and appropriate, the information needed to identify and use the medical device safely should be provided on the medical device itself, and/or on primary packing when it is difficult to place a the label on the device itself. If primary packaging has no sufficient space, the secondary packing and instruction for use should have all the required labeling information.
- In the case of medical devices that are packaged together because individual packaging of the medical devices is not practical, the label should be provided as packaging insert, document or other media supplied with a single or multiple medical devices. In addition, the combined packaged of devices should have common label containing the adequate information of the manufacturer and products in the package.

- If multiple medical devices are supplied to a single user and/or location or packaged together as one package, it may be appropriate to provide only a single copy of the label but more copies should be supplied upon request.

5.3. Label format and symbols

- The label should be provided in a human-readable format may be supplemented with machine-readable forms such as radio-frequency identification (RFID) or bar codes.
- The format of labelling should be in accordance with the international standard for medical device labelling, where applicable.
- The use of internationally recognized symbols such as those found in ISO 15223 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 home-used medical device or for a newly introduced symbol, an explanation should be provided.

5.4. Content of Labelling

5.4.1. Label on medical device itself

For devices which the labels are affixed on medical device itself (e.g. X-ray, ultrasound, MRI, machines, chemistry analyzer, etc..), It should contain the following information:

a. Device name: Product's generic name, and brand name (if exist),
b. Batch/lot number (e.g. on single use disposable medical devices or reagents) or model and the serial number (e.g. on electrically-powered medical devices), version number, where relevant, to allow appropriate actions to trace and recall the medical devices.
c. Manufacturing date and/or expiry date.
d. Name and address of manufacturer/license holder
e. Country of origin (i.e.- "made in [the country's name]").
f. Technical details concerning the medical device (e.g. power rating, operating altitude);
g. warnings and/or precautions on the safe use of the medical device;

5.4.2. Device package label

Medical devices should be appropriately packaged with primary and sometimes secondary packaging. The package label of the devices should contain at least the following information.

a. Device name: Product's generic name and brand/trade name (if exists),
b. Batch/lot number or model and the serial number, version number, where relevant, to allow appropriate actions to trace and recall the medical devices.
c. Manufacturing date and/or expiry date, as appropriate: The month and year of manufacture cannot be coded or abbreviated. The month and year of manufactured and expired or use-by-date as follows:-
    - Manufactured "MM/YYYY"
    - Expiry date "Expired MM/YYYY". And it should follow the format "DD/MM/YYYY" where it is mandatory to specify the date for products having short life span.

    Where DD is date, MM is month and YYYY is year.
d. Name and address of the Manufacturer and the License holder (where the license holder is different from the original device manufacturer). This information should include the name and place of business of manufacturer, packer, or distributor including the street address, city, state, and zip code.
e. Intended use or Intended purpose of the medical device;
f. Warnings and/or precautions on the potential misuse or mishandling of the medical device;
g. Storage conditions of the product. The meaning of some words of storage condition on the label are described in Annex I of this guidelines.
h. Where relevant, the net quantity of contents, expressed in terms of weight or volume (including volume after reconstitution), pieces or numerical count, or any combination of these or other terms which accurately reflects the contents of the package.

If the secondary package is used and contains multiple products such as kits or sets, the name of the kit/set should exist on the secondary package and the packing list should be affixed or available as an insert.

5.4.3. Instruction for use (IFU) or packaging Insert

Instruction for use should contain the following information:

1. Device name: Product name, brand name (if exist),
2. Name and address of the manufacturer/license holder: The label of a device should contain the name and place of business of manufacturer, packer, or distributor including the street address, city, state, and zip code.
3. Description of the medical devices, it's intended use and intended purpose
4. The device's working principles and any preparation necessary for use.
5. Stepwise description of how different components of the device are used in combination to carry out the intended purpose.
6. The instruction of how to interpret the result (e.g. if the device is RDT).
7. Where medicinal products are incorporated into the device as an integral part, this should be indicated in the label;
8. Adequate information regarding the medicinal product which a device is designed to administer, including any limitations in the choice of the substance to be delivered.
9. Precaution to be taken against any special, unusual risks related to the disposal of the device
10. Degree of accuracy claimed for medical devices with a measuring function
11. Any requirements for special facilities, or special training/ personnel qualification, or particular qualifications of the device use
12. Any warnings, precautions, measures to be taken and limitations of use regarding the medical device. This information should cover, where appropriate:
    a. warnings, precautions and/or measures to be taken in the event of malfunction of the medical device or changes in its functionality that may affect safety or performance;
    b. warnings, precautions and/or measures to be taken in regard to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;

c. warnings, precautions and/or measures to be taken in regard to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);
d. precautions related to materials incorporated into the device that are potentially carcinogenic, mutagenic or toxic, or could result in sensitization or allergic reaction for the patient or user; and
e. precautions related to potentially infectious material that is included in a medical device.

The instruction for use should include the date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

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.

5.4.4. Device manuals

Where applicable, medical devices should be accompanied with device manual. Device manual may be presented as a soft copy and/or a hard copy.

In addition to the information mentioned in section 5.4.3, device manual should have:

- ✓ Use or function;
- ✓ Installation procedures and requirements;
- ✓ Principles of operation;
- ✓ Performance characteristics and specifications;
- ✓ Operating instructions;
- ✓ Qualification or calibration procedures, including equipment and/or materials;
- ✓ Trouble shooting;
- ✓ Operational precautions and limitations;
- ✓ Hazards, symbols
- ✓ Care, cleaning, disinfecting and sterilization information
- ✓ Service and maintenance information
- ✓ Accessories and spare parts
- ✓ Storage conditions

- ✓ Safety, transportation and disposal method

6. Additional Labelling requirements for Specific medical Devices

a. For some medical devices, the following specific contents should be included in the labelling:
    i. An indication on the external packaging of any special storage and/ or handling conditions that applies (e.g. flammable medical devices);
    ii. Method for verification of proper installation and operation, the nature and frequency of preventative and regular maintenance, replacement of consumable components, and calibration needed to ensure optimal and safe operation of a medical device;
    iii. further treatment or handling, such as sterilization, calibration, etc., that is needed before a medical device can be used;
    iv. identification for a single-use medical devices;
    v. identification for a reusable medical device, information and instruction for cleaning, disinfecting, packaging and, where appropriate, the method of re-sterilization, and any restriction on the number of reuse;
    vi. If the device is intended for research use only, it must be labelled as “research use only”;
    vii. sufficient details to obtain a safe combination for a medical device that 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;
    viii. particular risks in connection with implantation of an implantable medical device;
    ix. the risks of reciprocal interference posed by a reasonably foreseeable presence of a medical device during specific investigation or treatment;
    x. the details of the nature, type, intensity and distribution of the radiation emitted by radiation emitting medical device;
b. indication that the medical device is refurbished medical device.

6.1. Specific labelling requirements for IVD medical device

For in vitro diagnostic medical devices, the following additional information should be included in its labeling:

6.1.1. Labels

The label should state that the IVD medical device is for in vitro diagnostic use.

6.1.2. Instruction for use for IVD medical device

a. Intended use/ purpose (e.g. monitoring, screening or diagnostic) including an indication that it is for in vitro diagnostic use and these following information:
   i. type of analyte or measurement of the assay;
   ii. whether the test is qualitative or quantitative;
   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, etc.); and
   viii. the specific name of the instrument required for the assay, if any. For instruments, the intended use should also include the modes of operation for instruments e.g., random access, batch, stat, open tube, closed tube, automatic, manual.
b. test principle;
c. specimen type, collection, handling and preparation;
d. reagent description and any limitation (e.g. use with a dedicated instrument only);
e. assay procedure including calculations and interpretation of results;
f. information on interfering substances that may affect the performance of the assay;
g. analytical performance characteristics, such as sensitivity, specificity, accuracy (trueness and precision);
h. reference intervals; and
i. use of drawings and diagrams.
j. For reagent, a means to assure that the product meets appropriate standards of purity, quality, etc., at the time of use, including one or more of the following:
   i. The common name, if any, and quantity, proportion, or concentration or each reactive ingredient; and for biological material, the source and measure of its activity;

ii. Net content
iii. Adequate directions for reconstitution, mixing, dilution, etc.
iv. Physical, biological, or chemical indications of instability or deterioration
v. Statement of any visual indication of alteration;
vi. Instructions for a simple check to assure product usefulness

The additional information for IVD should also include the following:

a. 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.
b. study design (population studies, N, type of sample, matrix, dilution, target, concentrations, etc.).

6.2. Labelling requirement for sterile medical device

Special attention should be given to the labeling of sterile devices, in addition to general device labeling requirements which is stated in section 5 of this guideline

1. An indication that the device is sterile and necessary instruction in the event of damaged to sterile packaging and, where appropriate, description of methods of re-sterilization.
2. Devices that are not sterile in their entirety (for example, sterility may be needed only for the lumen of certain devices) must be labeled to properly inform users what is actually intended to be "sterile" in the package. For example, a possible limiting statement might be **"Caution:** Only the fluid path of the set is sterile and non-pyrogenic. Do not use in a sterile or aseptic area without proper precautions. "
3. For devices that are intended to be sterilized by the user before use, the labeling should provide adequate information as to at least one suitable method of sterilization and any precautions or safeguards to be followed.
4. For single-use sterile devices, the labeling should include to advice against re-cleaning, disinfection, re-sterilization and reuse.
5. The label of multi-device kits or packages containing a combination of sterile and non-sterile products must not state or imply that all contents are sterile.
6. The need for users to have instructions on how to open a sterile device package to avoid contamination of the device also needs to be evaluated, and when necessary, such instructions should be included in the labeling.

6.3. Labelling requirements for active Medical device

In addition to general labeling provision indicated in section 5 of this guideline, manufacturers of electronic or active medical device should include the following:

1. For medical electrical equipment, the electrical needs of the equipment should be set to the standard voltage of 220V/50Hz for single phase and 380V/50Hz for three phase devices.

2. If the device is to be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient detail of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.
3. In addition to the section 5 of this guideline, if the device is radiation emitting medical device, the following points should be considered.
   a. If the device emits radiation for medical purposes, details on labeling should indicate the following information of the radiation to be emitted.
      - ✓ Nature
      - ✓ Type
      - ✓ intensity and
      - ✓ distribution of the radiation
   b. Detail, for X-ray emitting equipment that it should be calibrated and inspected by a qualified expert.
4. For light emitting medical device, in addition to the article discussed on section 5 of this guideline the following points should be included.
   a. laser devices require specific to their laser:-
      - ✓ type
      - ✓ class
      - ✓ wavelength and
      - ✓ power output
   b. For sunlamp products and ultraviolet lamps should have label(s) with the warning statement: "DANGER-Ultraviolet radiation, Avoid over exposure.”

6.4. Labelling requirements for implantable medical device

In addition to general labeling provision indicated in section 5 of this guideline, labelling of implantable medical device regarding any particular risks in connection with its implantation should include the following information on the product label and /or on instruction for use

a. An indication to its biocompatibility with human body
b. Duration of implantation
c. Any side effects or contraindications
d. Material property, origin of the material
e. Method of implantation

6.5. Labelling requirements for refurbished medical device

In addition to the labeling requirements in sections 5 of this guideline, label of refurbished medical device should contain:

- ✓ Bear “Refurbished”
- ✓ Refurbished by [company name, full address ,country]
- ✓ Refurbished date/month/year [DD/MM/YYYY]
- ✓ Validity date [the service or refurbishment and the period for the next service]
- ✓ Any upgrade, changed parameters, warnings/ precautions , limitations and methods from the original device should be indicated on instruction for use /user manual

1.1. Exemptions from labelling requirements for medical device

a. A product in the laboratory research phase not represented as a medical device that is prominently labeled: "For Research Use Only”. Not for use in diagnostic procedures;" and
b. A product that is being shipped or delivered for product testing prior to full commercial marketing that is prominently labeled: "For investigational Use Only”.

Reference

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6. Principles of Labelling for Medical Devices and IVD Medical Devices, IMDRF/GRRP WG/N52 FINAL:2019, International Medical Device Regulators Forum, 21 March, 2019.
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Annex I: Medical device temperature storage values and definition

Description on the Label	Interpretation and Guidance value
Freezer	The temperature is thermostatically controlled between 20°C and -10°C
Refrigerator	The temperature is thermostatically controlled between 20°C and -10°C
Cold place	The temperature does not exceed 8°C
Cool place	The temperature is between 8°C to 15°C
Room temperature	The temperature is between 15°C to 30°C
Warm	The temperature is between 30°C to 40°C
Excessive heat	The temperature is above 40°C
Do not store over 30°C	The temperature is between 2°C to 30°C
Do not store over 25°C	The temperature is between 2°C to 25°C
Do not store over 15°C	The temperature is between 2°C to 15°C
Do not store over 8°C	The temperature is between 2°C to 8°C
Do not store below 8°C	The temperature is between 8°C to 25°C