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MEDICAL DEVICE GUIDANCE DOCUMENT

REQUIREMENTS FOR LABELLING OF MEDICAL DEVICES

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737);

b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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REQUIREMENTS FOR LABELLING OF MEDICAL DEVICES

1. Introduction

Labelling serves to 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 in a patient information leaflet.

Harmonized worldwide labelling requirements would offer significant benefits to the manufacturer, user and/or patient, and to Regulatory Authorities. Eliminating or reducing differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This document is intended to provide guidance to manufacturers and authorised representatives on the content of medical device labelling.

2. Scope and application

This document applies to all products that fall within the definition of medical device, as defined in MDA/GD/0006: Definition of Medical Device, including in vitro diagnostic (IVD) medical devices.

Promotional materials and product brochures are excluded from the scope of this document.

This document applies to all medical device except those that are exempted from registration as per Medical Device (Exemptions) Order 2016 and Circular Letter No. 4/2018 Exemption from Registration Requirement for Export Only Medical Device.

3 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

3.1 home use medical device

A medical device intended for users in any environment. This includes devices that are intended not only for use by healthcare professionals but also for use by lay persons.

a) A user is a patient (care recipient), caregiver, or family member that directly uses the device or provides assistance in using the device.

b) A qualified healthcare professional is a licensed or non-licensed healthcare professional with proficient skill and experience with the use of the device so that they can aid or train care recipients and caregivers to use and maintain the device.

3.2 instructions for use

Information provided by the manufacturer to inform the device user of the medical device proper use and of any precautions to be taken.

3.3 intended use/ purpose

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.

3.4 labelling or label

Written, printed or graphic matter presented by a manufacturer meant to provide information concerning a medical device to the users and others, which may be attached to the medical device itself, on its packaging or as a packaging insert or may be made available by other means, for example by electronic means, when appropriate for the purpose as an additional, or alternative way of transmitting certain information regarding the medical device.

3.5 lay person

Individual that does not have formal training in a specific field or discipline. (Source: ISO 18113-1).

3.6 manufacturer

As defined in Section 2 of Act 737.

3.7 performance evaluation

Review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

3.8 primary packaging

The first level of packaging in direct contact/attached to the medical device, and is the element of packaging system that maintains the sterility and/or integrity of a medical device.

3.9 refurbishment

A refurbishment of a medical device is to restore a used medical device or system to manufacturer defined safety and performance standards, which include actions such as repair, recondition, rework, software updates, replacement of worn parts with original parts. All actions are performed in a manner consistent with product specifications and service procedures defined by the manufacturer without changing its intended use.

3.10 research use only

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

3.11 secondary packaging

The process of repackaging of a medical device from its original packaging into another packaging, without breach of the primary package, before the medical device is supplied.

3.12 user

The person, either professional or lay, who uses a medical device.

4 Requirements for labelling

4.1 General requirements

The labelling for all medical devices shall adhere to these general requirements:

a) No person shall:

   i) place any medical device in the market unless it has been appropriately labelled;

   ii) use or operate any medical device to another person unless the appropriate label has been provided with the medical device when it is used on the other person;

   iii) use or operate any medical device to another person unless the appropriate label has been provided with the medical device when it is used to any other person in any investigational testing.

b) A registered medical device shall be labelled with Malaysian medical device registration number and this shall be carried out within 6 months from the date of registration of the medical device.

c) 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 Authority or the Ministry of Health or any of its organizational bodies.

d) The label of a medical device shall be legible, permanent and prominent.

e) The medium, format, content, readability and location of labelling should be appropriate to the particular 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 devices may require separate information for the healthcare professional and the lay user.

f) Paper versions of all labelling should accompany the product.

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

4.2 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 manufacturer without any such instructions.

4.3 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.

4.4 Labelling activities to meet the Medical Device Act and regulations, may be conducted post importation or manufacturing, but prior to placing in the market. Contents of labelling shall be as per submitted to the authority during medical device registration. There shall be no over labeling on the lot/batch or serial number, date of manufacturing and date of expiry.

4.5 Location of labelling

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

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, and/or on the packaging for each unit (primary level of packaging), and/or the packaging of multiple medical devices (secondary level of packaging);

b) in the case of medical devices that are packaged together because individual packaging of the medical devices is not practical, the label shall be provided as leaflet, packaging insert, document or other media supplied with a single or multiple medical devices; and

c) 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 shall be supplied upon request.

4.6 Format

a) The format of labelling shall be in accordance with the international standard for medical device labelling where applicable.

b) The use of internationally recognised 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 home-used medical device or for a newly introduced symbol, an explanation shall be provided.

4.7 Language

a) The use of Bahasa Malaysia shall be required for home use medical devices.

b) English language shall be used on the labelling for other types of medical devices.

c) Other languages may be used as necessary.

4.8 General contents of labelling

The label of a medical device shall contain the following information:

a) details of medical device to enable user to identify it, which include name and model;

b) An indication of either the batch code/lot number (e.g. on single use disposable medical devices or reagents) or the serial number (e.g. on electrically-powered medical devices), where relevant, to allow appropriate actions to trace and recall the medical devices.

An unambiguous indication of the date until when the medical device may be used safely, expressed at least as the year and month (e.g. on medical devices supplied sterile, single-use disposable medical devices or reagents), where this is relevant. Where relevant, the storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions. For medical devices other than those covered by the above, and as appropriate to the type of medical device, an indication of the date of manufacture. This indication may be included in the batch code/lot number or serial number;

c) name and contact details (address and/ or phone number and/ or fax number and/ or website address to obtain technical assistance) of the manufacturer and AR on the labelling;

d) technical details concerning the medical device;

e) description and intended use of the medical device;

f) instructions for use of the medical device;

g) any undesirable side-effects, limitations, warnings and/or precautions on the safe use of the medical device;

h) any necessary post-market servicing needs for the medical device; and

i) any decommissioning or disposal information.

4.9 Specific contents of labelling

a) For some medical devices, the following specific contents shall be included in the labelling:

i) An indication on the external packaging of any special storage and/ or handling conditions that applies;

ii) verification that a medical device has been properly installed and can operate correctly and safely, 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 sterilisation, calibration, etc., that is needed before a medical device can be used;

iv) identification for a sterile medical device, its indication for sterility and precautions and instructions if the sterile packaging is damaged, and where appropriate, description of re-sterilisation methods;

v) the requirement for sterilisation of a medical device before it is used and instructions for cleaning and sterilisation processes;

vi) identification for a single-use medical devices;

vii) identification for a reusable medical device, information and instruction for cleaning, disinfecting, packaging and, where appropriate, the method of re-sterilisation, and any restriction on the number of reuse;

viii) If the device is intended for research use only, it must be labelled as “research use only”;

ix) 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;

x) particular risks in connection with implantation of an implantable medical device;

xi) the risks of reciprocal interference posed by a reasonably foreseeable presence of a medical device during specific investigation or treatment;

xii) the details of the nature, type, intensity and distribution of the radiation emitted by radiation emitting medical device;

xiii) indication that the medical device is refurbished medical device. The refurbishment date shall also be indicated.

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

4.10 Instructions for use (IFU)

In addition to 4.8, an IFU shall contain the following details on any contra-indications, warnings and precautions to be taken:

a) precautions to be taken if there are changes in the performance or malfunction of the medical device;

b) precautions with respect to exposure to environmental conditions like magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, temperature, humidity, acceleration, thermal ignition sources, proximity to other devices, etc.;

c) where drugs or medicinal products are incorporated into the device as an integral part this should be indicated in the label;

d) adequate information regarding the drug or medicinal products which a device is designed to administer, including any limitations in the choice of substances to be delivered;

e) precautions to be taken against any special, unusual risks related to the disposal of the device;

f) for medical device with measuring function, the degree of accuracy claimed by the manufacturer;

g) requirements for special facilities, special training or particular qualifications for the medical device user.

The IFU 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.

4.11 Additional information for in vitro diagnostic medical devices

4.11.1 For in vitro diagnostic medical devices, the following additional information shall be included in its label:

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. selftesting 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.

4.11.2 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.).

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