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HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-23: Guidance on Labelling for Medical Devices

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PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors.

1. INTRODUCTION

1.1. Purpose

This document is meant to provide general guidance on labelling for medical devices.

1.2. Background

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 the packaging, as instructions for use or in a patient information leaflet.

1.3. Scope

This document applies to all medical devices, including in vitro diagnostic medical devices.

1.4. Definitions

Definitions that do not indicate they are set out in the Health Products Act 2007 (*Act*) or Health Products (Medical Devices) Regulations (*Regulations*) are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

CLINICAL INVESTIGATION: Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device.

Explanation: This term is synonymous with ‘clinical trial’ and ‘clinical study’. Clinical investigations include feasibility studies and those conducted for the purpose of gaining market approval, as well as investigations conducted following marketing approval.

Routine post market surveillance may not constitute a clinical investigation (e.g. investigation of complaints, individual vigilance reports, literature reviews).

LABEL (as set out in the Act): in relation to a health product or an active ingredient, means any written, printed or graphic representation that appears on or is attached to the health product or active ingredient or any part of its packaging, and includes any informational sheet or leaflet that accompanies the health product or active ingredient when it is being supplied.

LAY PERSON: An individual who does not have formal training in a relevant field or discipline.

INSTRUCTIONS FOR USE: Information provided by the product owner to inform the device user of the product's proper use and of any precautions to be taken.

INTENDED PURPOSE: The use for which the medical device is intended according to the specifications of its product owner as stated on any or all of the following:

- the label of the medical device;
- the instructions for use of the medical device;
- the promotional materials in relation to the medical device.

MEDICAL DEVICE: means a medical device as described in the First Schedule of the Act.

PERFORMANCE EVALUATION: A review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

PRODUCT OWNER: for the purposes of this guidance document, means a person who sells a medical device under his own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the

person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

REFURBISHMENT: A refurbishment of a medical device is taken to have occurred if the medical device, or a part of the device, is substantially rebuilt from one or more used medical devices of that kind so as to create a medical device that is able to be used for the purpose originally intended by the product owner of the original device.

A refurbishment of a medical device may involve the following actions:

- stripping the device into component parts or sub-assemblies;
- checking parts of the device for suitability for reuse;
- replacing component parts or sub-assemblies of the device that are not suitable for reuse;
- assembling reclaimed or replacement component parts or sub-assemblies of the device or another used device;
- testing a reassembled device against the specifications of the original device or, if the product owner has revised those specifications, the revised specifications;
- identifying an assembled device as a refurbished device.

“RESEARCH USE ONLY” MEDICAL DEVICE: 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.

2. LABELLING REQUIREMENTS

2.1. General Guidelines

The labelling for all medical devices should adhere to these general guidelines:-

- As far as it is practical and appropriate, the information needed to identify and use the device safely should be provided on the device itself, and /or on the packaging for each unit (primary level of packaging), and / or on the packaging of multiple devices (secondary level of packaging). If individual packaging of each unit is not practicable, the information should be set out in the leaflet, packaging insert or other media supplied with, or applicable to, one or multiple devices.
- Where the product owner supplies multiple 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 device user should have access to further copies upon request.
- 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.
- Instructions For Use (IFU) may not be needed or may be abbreviated for devices of low or moderate risk if they can be used safely and as intended by the product owner without any such instructions.
- Paper versions of all labelling must accompany the product.
- Any residual risk identified in the risk analysis should be reflected as contraindications or warnings within the labelling.
- The use of internationally recognised symbols is encouraged provided that 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 device user, e.g. for a lay-user or for a newly introduced symbol, an

explanation should be provided.

- All characters on labelling must be of adequate size and legibly printed.
- The product labelling must be in English.

2.2. Content of Labelling

2.2.1. Primary and Secondary Levels of Packaging

Contact Information

It is mandatory to include the name and contact details (address and/or phone number and/or fax number and/or website address to obtain technical assistance) of the Product Owner on the labelling.

General

The labelling for all medical devices should bear the following:-

- Sufficient details for the user to identify the device and, where these are not obvious, its intended purpose, user and patient population of the device; also, where relevant, the contents of any packaging.
- An indication of either the batch code/lot number (e.g. on single-use disposable 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 devices.
- An unambiguous indication of the date until when the device may be used safely, expressed at least as the year and month (e.g. on devices supplied sterile, single-use disposable 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 devices other than those covered by the above, and as appropriate to the type of device, an indication of the date of manufacture. This indication may be included in the batch code/lot number or serial number.
- The information needed to verify whether the device is properly installed and can operate correctly and safely, including details of the nature, and frequency of preventative and regular maintenance, where relevant any

quality control, replacement of consumable components, and calibration needed to ensure that the device operates properly and safely during its intended life.

- Any warnings, precautions, limitations or contra-indications.
- The performance intended by the product owner and, where relevant, any undesirable side effects.
- An indication on the external packaging of any special storage and /or handling conditions that applies.
- Details of any further treatment or handling needed before the device can be used (e.g. sterilisation, final assembly, calibration, preparation of reagents and/or control materials, etc.) where relevant.

The inclusion of the manufacturing site of the medical device and contact information of the importer is optional.

*NOTE Please note that "manufactured/made in Singapore" or other similar wordings can only be printed on the labels if there is significant processing of the products in Singapore. The following are **excluded**: simple operations consisting of removal of dust, sifting or screening, sorting, classifying, matching (including the making up of sets of articles), washing, painting, cutting up; changes of packing and breaking up and assembly of consignments; simple placing in bottles, flasks, bags, cases, boxes, fixing on cards or boards, and all other simple packing operations; the affixing of marks, labels or other like distinguishing signs on products or their packaging; etc.*

Additional Requirements

The labelling for some medical devices should contain the following additional information:

- If the device is **sterile**, an indication of that condition and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilisation.
- If the device has been specified by the product owner as intended for **single-use only**, an indication of that state.
- If the device is **reusable**, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where

appropriate, the method of re-sterilisation and any restriction on the number of reuses. Where a device is supplied with the intention that it is sterilised before use, the instructions for cleaning and sterilisation should be such that, if correctly followed, the device will still perform as intended by the product owner and comply with the *Essential Principles of Safety and Performance of Medical Devices*.

- If the device is a **refurbished** device, identification of the device as a refurbished device.
- If the device is for use by a single individual and has been manufactured according to a written prescription or pattern (i.e. it is **custom-made**), an indication of that state.
- If the device is intended for **clinical investigation** or, for in vitro diagnostic medical devices, **performance evaluation** only, an indication of that situation.
- If the device is intended for **research use** only, it must be labelled as “research use only”.
- If the device is intended for **presentation or demonstration purposes** only, it must be labelled as “for presentation or demonstration purposes only: not for use on humans”.
- If the device is **implantable**, information regarding any particular risks in connection with its implantation.
- If the device **emits radiation** for medical purposes, details of the nature, type and where appropriate, the intensity and distribution of this radiation.
- Information regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations, evaluations, treatment or use (e.g. electromagnetic interference from other equipment).
- If the 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 use, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.
- If the device is an **in vitro diagnostic** medical device, it must be labelled as “in vitro diagnostic” or “IVD”.

2.2.2. Instructions For Use (IFU)/ Patient Information Leaflet

For medical devices where an IFU or a patient information leaflet is applicable, additional information on the date of issue or latest revision of the instructions for use and, where appropriate, an identification number should be provided.

The instructions for use should also include, where appropriate, details informing the users and/or patient and allowing the medical staff to brief the patient on any contra-indications, warnings and any precautions to be taken.

These details should, in particular, cover:-

- Precautions and/or measures to be taken in the event of changes in the performance, or malfunction, of the device including a contact telephone number, if appropriate.
- 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 devices, etc.
- If the device administers medicinal products, adequate information regarding any medicinal product(s) that the device in question is designed to administer, including any limitations in the choice of substances to be delivered.
- Any medicinal substances or biological material incorporated into the device as an integral part of the device.
- If the device has a measuring function, the degree of accuracy claimed for it.
- Any requirement for special facilities, or special training, or particular qualifications of the device user and/or third parties.
- Any precautions to be taken related to the disposal of the 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.

- Where relevant, for 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.

In Vitro Diagnostic Medical Devices

For in vitro diagnostic medical devices, in addition to the information required above, directions/instructions for the proper use of in vitro diagnostic medical devices that should be contained in the labelling include:

- Intended purpose, including the following information:-
 - (a) Type of analyte or measurand of the assay.
 - (b) Whether the test is quantitative or qualitative.
 - (c) Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring.
 - (d) Disease or condition that the test is intended for.
 - (e) Type of specimen to be used e.g. serum, plasma, etc.
 - (f) The intended users (e.g. self-testing by lay person, near-patient by trained personnel or professionals).
 - (g) Assay type (e.g. immunoassay, chemistry, cytochemistry, image analysis, immunohistochemistry, etc).
 - (h) The specific name of the instrument required for the assay, if any.
 - (i) 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.
- Test principle.
- Specimen type.
- Conditions for collection, handling, storage and preparation of the specimen.
- Reagent description and any limitation (e.g. use with a dedicated instrument only).
- 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.
- Assay procedure including calculations and interpretation of results.

- Information on interfering substances that may affect the performance of the assay.
- Performance characteristics (summarised analytical and diagnostic sensitivity, specificity, reproducibility, etc).
- Reference intervals.
- Study design (population studies, N, type of sample, matrix, dilution, target concentrations, etc).

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