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PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Labelling for Medical Devices (revised)

Authoring Group: Study Group 1 of the Global Harmonization Task Force

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Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development

1.0 Introduction

The primary way in which the Global Harmonization Task Force (GHTF) achieves its goals is through the production of harmonized guidance documents suitable for implementation or adoption by member Regulatory Authorities, as appropriate taking into account their existing le gal framework, or by nations with developing regulatory programmes.

This guidance document is one of a series that together describe a global regulatory model for medical devices. Regulatory Authorities require and specify information that manufacturers are expected to incorporate on the labels attached to their product, and within the documents that accompanies it, when it is placed onto the market. The GHTF identified as a priority the need to harmonize requirements for labelling and has published guidance on the subject entitled *Labelling for Medical Devices* (SG1/N009 of February 24, 2000) that applied to the majority of medical devices but not to *in vitro* diagnostic devices. This document is now revised to include specifically the labelling of medical devices for the *in vitro* examination of specimens derived from the human body **and supersedes the previous version**.

Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This guidance document has been prepared by Study Group 1 of the Global Harmonization Task Force (GHTF). Comments or questions about it should be directed to either the Chairman or Secretary of GHTF Study Group 1 whose c ontact details may be found on the GHTF web site.

2.0 Rationale, Purpose and Scope

2.1 Rationale

Labelling serves to communicate safety and performance related information to users of medical devices and/or patients as well as to identify individual devices. Suc h information may appear on the device itself, on packaging (or as a packaging insert), or as information for use. Consistent world-wide labelling requirements would offer significant benefits to the manufacturer, patient or consumer, and to Regulatory Authorities.

2.2 Purpose

To encourage manufacturers to manufacture medical devices with labelling that complies with this guidance and for Regulatory Authorities to avoid, or keep to a minimum, prescriptive, country-specific requirements for labelling text, content, or the format of labels or labelling.

2.3 Scope

This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Information Concerning the Definition of the Term "Medical Device"*, including those used for the *in vitro* examination of specimens derived from the human body. Its purpose is to describe harmonized requirements for the labelling of medical devices.

In some regulatory schemes promotional documentation/materials may be considered labelling. Such materials are outside the scope of this document.

3.0 References

GHTF final documents

GHTF/SG1/N009R6:2000 *Labelling for Medical Devices*

GHTF/SG1/N012R10:2000 *Role of Standards in the Assessment of Medical Devices.*

GHTF/SG1/N020R5:2000 *Essential Principles of Safety and Performance of Medical Devices*

GHTF documents available for public comment

SG1(PD)/N011R17 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices.*

SG1(PD)/N015R22 *Medical Devices Classification.*

SG1(PD)/N029R13 *Information Document Concerning the Definition of the Term 'Medical Device'.*

SG1(PD)/N041R6 *Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices).*

GHTF working draft document not yet available for public comment

SG1/N040 *Principles of Conformity Assessment for Medical Devices.*

4.0 Definitions

Clinical evaluation: The review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation.

Clinical investigation: Any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device. (Source – ISO/DIS 14155-1)

Label: 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 devices.

Labelling: Written, printed or graphic matter

- affixed to a medical device or any of its containers or wrappers, or,
- accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. (Source – ISO 13485)

Instructions for use: Information provided by the manufacturer to inform the device user of the products proper use and of any precautions to be taken.

Intended use / purpose: Use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer. (Source – ISO 14971)

Medical device: Refer to GHTF guidance document: *Information Concerning the Definition of the Term "Medical Device"* (SG1/N029).

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.

5.0 Labelling Requirements

5.1 General Principles

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 (or as a packaging insert), or as instructions for use. Consistent world-wide labelling requirements would offer significant benefits to the manufacturer, patient or consumer, and to Regulatory Authorities. To achieve this purpose, the following principles are recommended:

- 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, and / or on the packaging of multiple devices. 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 manufacturer 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 format, content and location of labelling should be appropriate to the particular device and its intended purpose.
- Instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

- Instructions 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 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, downloaded from the manufacturer's Web Site using the Internet, magnetic or optical media. Whatever the media or the means, information should be targeted to the anticipated user population.
- Country-specific requirements for labelling text, content, or the format of labels or labelling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.
- Taking into consideration the type of user anticipated for the device, national language requirements should be kept to a minimum.
- The use of internationally recognised (i.e. standardised) symbols should be 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.

Regulatory Authorities and industry should encourage the development and use of international labelling guidelines for medical devices.

Regulatory Authorities that are developing regulatory requirements to address device labelling, or modifying existing requirements, are encouraged to consider the adoption of these recommendations. This will help minimise the diversity of labelling requirements world-wide and facilitate the process of harmonization.

5.2 Content of Labelling

The labelling should bear the following particulars.

In general:

a) The name or trade name and address of the manufacturer and, if appropriate, a phone number and/or fax number and/or website address to obtain technical assistance.

   For imported devices, information may be required to contain in addition, the name and address of either the importer established within the importing country/region or of an authorized representative of the manufacturer established within the importing country/region.

b) 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.

c) 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, and to allow appropriate actions to trace and recall the devices and any detachable components,

d) An indication of the date until which the device may safely be used (i.e. put into service), expressed at least as the year and month (e.g. on single-use disposable devices or reagents) where this is relevant.

e) For devices other than those covered by (d) 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 or serial number.

f) Any special storage and /or handling conditions at the appropriate packaging level.

g) Any warnings, precautions, limitations or contra-indications.

h) The performance intended by the manufacturer and, where relevant, any undesirable side effects.

i) The information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature, and frequency of preventative and regular maintenance, replacement of consumable components, and calibration needed to ensure that the device operates properly and safely during its intended life.

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

Where applicable:

k) An indication that the device is sterile and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization.

l) An indication that the device has been specified by the manufacturer for single-use only.

m) An indication that 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).

n) An indication that the device is intended for premarket clinical investigation or, for *in vitro* diagnostic medical devices, performance evaluation only.

o) An indication that the device is intended only for presentation or demonstration purposes.

p) 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.

q) If the device is implantable, information regarding any particular risks in connection with its implantation.

r) 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).

s) If the device is reusable, 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. Where a device is supplied with the intention that it is sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still comply with the *Essential Principles of Safety and Performance of Medical Devices.*

t) If the device emits radiation for medical purposes, details of the nature, type and where appropriate, the intensity and distribution of this radiation.

The instructions for use should also include, where appropriate, details allowing the medical staff to brief the patient on any contra-indications, warnings and any precautions to be taken. These details should cover in particular:

u) Precautions to be taken in the event of changes in the performance, or malfunction, of the device including a contact telephone number, if appropriate.

v) Precautions 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.

w) Adequate information regarding any medicinal product or products, which the device in question is, designed to administer, including any limitations in the choice of substances to be delivered.

x) Precautions to be taken against any special, unusual risks related to the disposal of the device.

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

z) Degree of accuracy claimed for devices with a measuring function.

aa) Any requirement for special facilities, or special training, or particular qualifications of the device user.

For in vitro diagnostic medical devices:

ab) Additional directions/instructions for the proper use of *in vitro* diagnostic medical devices which may include:

- Intended use / purpose (e.g. monitoring, screening or diagnostic) including an indication that it is for *in vitro* diagnostic use.
- Test principle.
- Specimen type, collection, handling and preparation.
- Reagent description and any limitation (e.g. use with a dedicated instrument only).
- Assay procedure including calculations and interpretation of results.
- Information on interfering substances that may affect the performance of the assay.

- Analytical performance characteristics, such as sensitivity, specificity, accuracy (trueness and precision).
- Diagnostic performance characteristics, such as sensitivity and specificity.
- Reference intervals.
- The use of drawings and diagrams is highly recommended.