



FINAL DOCUMENT

Title: Labelling For Medical Devices

Authoring Group: SG1

Endorsed by: The Global Harmonization Task Force

Date: February 24, 2000

A handwritten signature in black ink that reads 'Beth Pierson'.

Beth Pierson, GHTF Chair

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

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

*GHTF.SG1.N009R6
FINAL DOCUMENT*

**GLOBAL HARMONIZATION TASK FORCE
STUDY GROUP 1**

LABELLING FOR MEDICAL DEVICES

This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement. It is intended for use by medical devices regulators, Conformity Assessment Bodies and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. The document will be of value to countries developing or amending regulations. The regulatory requirements of some countries may not, at present, reflect the contents of this document.

LABELLING FOR MEDICAL DEVICES

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 information 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 means supplied with one or multiple devices.
- The format, content and location of labelling should be appropriate to the particular device and its intended purpose.
- 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 (who, with some products, could be a member of the public), it should be described in words associated with the symbol.
- Information on device use and instructions 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, trans-telephonically, magnetic or optical media, etc. Whatever the media or the means, information should be targeted to the anticipated user population.
- Instructions for use should be written in terms readily understood by the intended user.
- 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 without any such instructions.

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.

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

CONTENT OF LABELLING OF LABELLING

The labelling should bear the following particulars.

In general:

- a) The name or trade name and address of the manufacturer; and the intended purpose, user and patient population of the device where these are not obvious.
For imported devices, the label, or the outer packaging, or instructions for use, may be required to contain in addition, the name and address of either the importer established within the importing country or of an authorized representative of the manufacturer established within the importing country.
- b) Sufficient details for the user to identify the device or, 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 the serial number (e.g. on electrically-powered medical devices), where relevant, and to allow appropriate actions to trace and recall the devices and detachable components,
- d) An indication of the date until which the device may safely be used (i.e. put into service), expressed as the year and month (e.g. on single-use disposable devices) 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 on the external packaging.
- g) Any warnings and /or precautions.
- h) The performance intended by the manufacturer and 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 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 clinical and /or performance investigations prior to placing it on the market.
- 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 in order to operate as required for its intended purpose, 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 or treatment; (e.g. electrical interference from electro-surgical devices or magnetic field interference from Magnetic Resonance Imagers).
- 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 devices are supplied with the intention that they be 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”¹.

- t) If the device emits radiation for medical purposes, details of the nature, type, 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:

- i) Precautions to be taken in the event of changes in the performance of the device.
- ii) 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, acceleration, thermal ignition sources, proximity to other devices, etc.
- iii) 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.
- iv) Precautions to be taken against any special, unusual risks related to the disposal of the device.
- v) Any medicinal substances incorporated into the device as an integral part of the device.
- vi) Degree of accuracy claimed for devices with a measuring function.
- vii) Any requirement for special facilities, or special training, or particular qualifications of the device user.

¹ Approved by the Global Harmonization Task Force; reference GHTF.SG1.N020R4.