PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer.

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

Date: February 26, 2008

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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 objective of the Global Harmonization Task Force (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade whilst preserving the right of participating members to address the protection of public health by regulatory means considered to be most suitable.

The primary way in which the GHTF achieves its goals is through the production of a series of guidance documents that together describe a global regulatory model for medical devices. The purpose of such guidance is to harmonize the documentation and procedures that are used to assess whether a medical device conforms to the regulations that apply in each jurisdiction. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This document offers guidance to Regulatory Authorities, Conformity Assessment Bodies and industry. It has been developed to encourage and support global convergence of regulatory systems by offering harmonised definitions for the terms “manufacturer”, “authorised representative”, “distributor” and “importer”. Regulatory Authorities that are developing such definitions or amending existing ones are encouraged to consider the adoption of the definitions described in this document, as this will help to reduce the diversity of schemes worldwide and facilitate the process of harmonization.

This document was developed by GHTF Study Group 1 in collaboration with GHTF Study Groups 2, 3 and 4. Comments or questions about this document should be directed to either the Chairman or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF web page[1].

2.0 Rationale, Purpose and Scope

2.1 Rationale

The term “manufacturer” appears in many GHTF documents and is associated with various obligations and responsibilities. The development of a consistent, harmonized definition for a ”manufacturer” would support global convergence of regulatory systems and offer significant benefits to Regulatory Authorities and the organisations responsible for making and/or placing medical devices onto the market. Harmonization of the terms “authorised representative”, “distributor” and “importer” would be of benefit, too.

Harmonization should improve consistency and the transparency of regulatory controls. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

[1] www.ghtf.org

2.2 Purpose

This document is intended to provide a harmonized definition of the terms "manufacturer", "authorised representative", "distributor" and "importer". These terms appear in guidelines documents published by the Global Harmonization Task Force. Recommendations within this document will allow a Regulatory Authority to establish the identity of the person who takes responsibility for ensuring the finished medical device meets relevant regulatory requirements within its jurisdiction.

This document is intended to serve as guidance for Regulatory Authorities, Conformity Assessment Bodies and the regulated Industry. It should assist jurisdictions introducing medical device regulations for the first time and should improve the clarity of existing harmonized guidelines.

2.3 Scope

This document applies to those products which fall within the definition of a medical device that appears within the GHTF document *Information Document Concerning the Definition of the Term "Medical Device",* including those used for the in vitro diagnostic examination of specimens derived from the human body.

3.0 Reference

GHTF/SG1/N29:2005 *Information Document Concerning the Definition of the Term "Medical Device"*

4.0 Harmonized definitions of the terms "manufacturer", "authorised representative", "distributor" and "importer".

NOTE: A single party may fulfill one or more of these roles, e.g. a manufacturer may not only distribute the products it manufactures but it may also act as a distributor of devices from a different manufacturer.

4.1 Manufacturer

"Manufacturer" means any natural or legal person[2] who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by a third party(ies).

[2] The term "person" that appears here and in the other definitions of this document, includes legal entities such as a corporation, a partnership or an association.

NOTES:

1. This 'natural or legal person' has ultimate responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold.

2. The manufacturer's responsibilities are described in other GHTF guidance documents. They include a responsibility to ensure pre- and post-market regulatory requirements for a finished medical device are met. This includes adverse event reporting and notification of corrective actions.

3. "Design and/or manufacture", as referred to in the above definition, may include:

    a) specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing; and/or
    b) assembly, packaging, processing and/or labelling of one or more finished products.

4. Any person who assembles or adapts a device(s) that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the device(s).

5. Any person who changes the intended use of, or modifies, a finished medical device in a way that may affect safety or performance, without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

6. To the extent that an accessory is subject to regulatory requirements of a medical device[3], the person responsible for the design and/or manufacture of that accessory is deemed to be a manufacturer.

4.2 Authorised Representative

"Authorised representative" means any natural or legal person established within a country or jurisdiction who has received a mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

4.3 Distributor

"Distributor" means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

[3] See GHTF/SG1/N29 *Information Document Concerning the Definition of the Term "Medical Device"*

NOTES:

1. In some circumstances, more than one distributor may be involved in this process.

2. A distributor who indicates its own address and contact details on the medical device or its packaging but does not otherwise repackage or relabel the device or its packaging, and does not modify the medical device in a way that may affect safety, performance or intended use, is not considered a manufacturer.

4.4 Importer

"Importer" means any natural or legal person in the supply chain who first makes a medical device, manufactured in another jurisdiction, available in a country or jurisdiction where it is to be marketed.

NOTE:

1. An importer does not repackage or relabel the device or device package, and does not transform or modify a medical device in a way that may affect safety, performance or intended use.