FINAL 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

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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 definitions for the terms “manufacturer”, “authorised representative”, “distributor” and “importer”. Regulatory Authorities developing such definitions or amending existing ones are encouraged to consider the adoption of those in this document, as this will help reduce the diversity of terminology worldwide and facilitate the process of harmonization.

Where another GHTF guidance document is referenced within this text, its title is italicised for clarity.

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 harmonized definitions of the terms "manufacturer", "authorised representative", "distributor" and "importer". These terms appear in guidance documents published by the Global Harmonization Task Force. Adopting the definitions from this document will allow a Regulatory Authority to identify the various persons making a medical device available for use and their different roles.

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 also improve understanding of existing GHTF guidance documents.

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"*.

3.0 Reference

GHTF/SG1/N29:2005 *Information Document Concerning the Definition of the Term "Medical Device"* (under revision).

4.0 Definitions

None other than those in Section 5.0.

5.0 Definitions of the terms "manufacturer", "authorised representative", "distributor" and "importer"

A single party may fulfil 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.

5.1 Manufacturer

"Manufacturer" means any natural or legal person[2] with responsibility for design and/or manufacture of a medical device with the intention of making the 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 another person(s).

[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 legal 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, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

2. The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

3. 'Design and/or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

4. Any person who assembles or adapts a medical device 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 medical device.

5. Any person who changes the intended use of, or modifies, a medical device 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. An authorised representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

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

5.2 Authorised Representative

"Authorised representative" means any natural or legal person established within a country or jurisdiction who has received a written 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.

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

5.3 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.

NOTES:

1. More than one distributor may be involved in the supply chain.

2. Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

5.4 Importer

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