Definition of the Terms “Manufacturer”, “Authorised Representative”, “Distributor”, and “Importer”

4th APEC-Funded Seminar on
Harmonization of Medical Device Regulation

The Role of Regulators, Industry, and Distributors in Harmonization of Medical Device Regulation in the Asia/Pacific Region

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Introduction

- Basic document in GHTF “global regulatory model”
- Who is deemed a “manufacturer”, “authorised representative”, “distributor”, or “importer” and why?
- Foundation for regulation
  - “What” is regulated?
  - “Who” is regulated?
  - “How” are they regulated?
- Determines jurisdiction, roles and responsibilities

Draft GHTF guidance document

- Early stage drafting in Study Group 1
  - Consultation with SG-3 and SG-4
- Not yet available on GHTF website
- This preview presentation based on current Study Group draft
  - ***Note:*** Document subject to change, perhaps significantly
- Comments to Study Group 1 welcome

Rationale

- Term “manufacturer” appears in many GHTF documents – but is undefined
- Term is associated with various obligations and responsibilities
- Consistent, harmonised definition would support convergence of regulatory systems
- Benefits to regulatory authorities and parties responsible for making and/or placing medical devices onto market

Purpose

- To provide harmonised definitions of terms “manufacturer”, “authorised representative”, “distributor” and “importer”
- To allow regulatory authority to establish identity of person who takes responsibility for ensuring the finished medical device meets relevant regulatory requirement within its jurisdiction
- Guidance for regulatory authorities, conformity assessment bodies, and industry
- Improve clarity of existing GHTF guidance

Scope

- Applies to products that fall within GHTF definition of “medical device”, including IVDs

Definitions – Manufacturer

- Any natural or legal person …
  - “Person” includes legal entities such as a corporation, a partnership, or an association

Definitions – Manufacturer

- Any natural or legal person who designs and/or manufactures …

Definitions – Manufacturer

- Any natural or legal person who designs and/or manufactures a medical device …
  - GHTF definition of “medical device”

Definitions – Manufacturer

- Any natural or legal person who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, …
  - Intention – need not yet have made device available for use
  - “Finished device” intended to exclude subcontractors, contract sterilisers, etc.

Definitions – Manufacturer

- Any natural or legal person who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, under his name; …
  - Importance of labelling in determining who is “manufacturer”

Definitions – Manufacturer

- Any natural or legal person 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)

Definitions – Manufacturer

- This natural or legal person has the 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

- Manufacturer’s responsibilities described in other GHTF guidance documents – include pre- and post-marketing requirements (e.g., vigilance reporting and notification of field safety corrective actions)

Definitions – Manufacturer

- Design and/or manufacture may include
  - Specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilisation, installation, or remanufacturing; and/or
  - Assembly, packaging, processing and/or labelling of one or more finished products

Definitions – Manufacturer

- 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)

Definitions – Manufacturer

- 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

Definitions – Manufacturer

- To the extent an accessory is subject to regulatory requirements (see definition of “medical device”), the person responsible for the design and/or manufacture of that accessory is deemed to be a manufacturer

Definitions – Authorised Representative

- 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

Definitions – Distributor

- 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
  - In some circumstances, more than one distributor may be involved in this process
  - A distributor who indicates his 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 many affect safety, performance, or intended use, is not considered a manufacturer

Definitions – Importer

- 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
  - 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

Guidance

- A single party may fulfil one or more of these roles
  - e.g., a manufacturer may not only distribute the products it manufacturers but it may also act as a distributor or importer of devices from a different manufacturer

Questions?