

Document number: SG1(PD)/N055R6 of Feb26 2008

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

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Comment Number	Affiliation (e.g. TGA)	Page / Section / Line	Editorial or Technical	Comment and rationale	Proposed revised text	SG1 Decision (Sydney, 21 January 2009)
1.	Lithuanian Accreditation Agency	General	Tech	The terms “manufacturer” and “authorized representative” are defined in the EU Medical Devices Directives but definitions of the terms “distributor” and “importer” have not been introduced there. The subjects associated have separate authorizations for placing the medical device on the market, e.g. a manufacturer has ultimate responsibility for ensuring compliance with all applicable regulatory requirements. The real roles played by these subjects are multifunctional and this factor could create the	<p>We do not propose to delete the terms “distributor” and “importer”.</p> <p>We like only to note that the national Regulatory Authorities should apply the Medical Device Directives where the mentioned terms are not introduced.</p> <p>At the same time the real problems exist - the real roles played by economic operators are multifunctional and this factor often creates the complicated situations with regard to their obligations.</p> <p>An interpretation of the actual terms and related definitions presented in the document GHTF/SG1/(PD)/N055R6 will help (insofar it will be inside MDD) more</p>	SG1 thanks the Lithuanian Accreditation Agency for its comment but sees no reason to modify the text.

				<p>complicated situations with regard to their obligations.</p> <p>The interpretation of the terms and related definitions presented in the document proposed will help apply explicitly the procedures that are used whether a medical device conforms to the regulations.</p>	explicitly to apply the regulatory procedures.	
2.	EU (Commission)	Throughout text	Tech.	There is no definition of "finished" medical device.	Delete "finished".	Accepted. Document modified in various places including Section 2.2 Purpose
3.	MTAA	Page 5 Section 2.2 Purpose	Ed	Should "guidelines" be replaced by "guidance" or at least in the singular?		Accepted.
4.	EU (Commission)	Page 5 Section 2.2 Purpose	Ed	Delete "documents" and "finished" in para 1 and "harmonized" in para 2	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	Accepted with modification. Use guidance documents as the preferred term.

					<p>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.</p> <p>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.</p>	
5.	EU (Commission)	Page 5 Section 2.3 Scope	Ed		Delete: including those used for the in vitro diagnostic examination of specimens derived from the human body.	Accepted.
6.	MTAA	Page 5 Section 2.3 Scope	Ed	I am not sure what agreement, if any, has been reached about italicising the words “in vitro”.		Preferred term ‘IVD medical device’ without italics

7.	EU (Commission)	p. 5, section 4.0 TITLE	Ed.	Delete "Harmonized" from title.	Definitions of the terms "manufacturer", "authorised representative", "distributor" and "importer"	Accepted.
8.	Health Sciences Authority Singapore	Page 5 / Section 4.1 Manufacturer	Technical	<p>"...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)..."</p> <p>Comment: Whilst the definition of manufacturer (as it appears in the draft) mentions manufacturing by a third party(ies), it will be worthwhile defining what a third party manufacturer normally does, and what it does not do. This clarifies that section 4.1 of this draft document does not aim to define such "third party manufacturers" as manufacturers.</p> <p>This adds clarity when implementing the guidance and reflects the realities of outsourcing of medical device manufacturing.</p>		Not accepted but changed 'third party' to 'another person'.

9.	MTAA	Page 5 / Section 4.1 Manufactur er	Tech		Add:- In some jurisdictions the term “legal manufacturer” may also be used in place of the term “manufacturer”.	Note 1 changed to add the word ‘legal’.
10.	ZLG	P. 5 / Sec. 4.1 Definition Manufactur er	Technic al	<p>Why does the definition of manufacturer contain « finished » medical device? This term is neither used within the definition of medical device (see GHTF/SG1/N29R16:2005) nor necessary. If kept, user would also ask for such a definition.</p> <p>The current wording and construction of the definition is not really “user friendly”. Why not simply a construction as suggested in the right column. With this approach, all of the previous intentions would also be covered.</p> <p>The definition should be drafted in a way of just</p>	<p>Delete “finished”</p> <p>“Manufacturer” means any natural or legal person¹ who intends to make a medical device available for use under his (own) name, whether or not such a medical device is designed or manufactured by that person himself or on his behalf.</p>	<p>Accepted.</p> <p>Not accepted after considerable discussion and some changes to the definition to introduce the words ‘responsibility for’.</p>

¹ 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.

			<p>saying what a manufacturer is. All other responsibilities and requirements should be written in requirement documents like those on conformity assessment, quality management requirements etc.</p> <p>When the most relevant aspect is the “making available under the manufacturer’s own name” there is no need to “limit” the definition to “design and/or manufacturing” in one definition twice. Also “and/or” is not necessary.</p> <p>In addition, the use of the term “Third parties” for suppliers should be avoided because normally this term is to be seen for bodies being independent from the manufacturer (like conformity assessment bodies/Notified Bodies; see use in ISO/IEC 17000) and its products, i.e. not to have a supplier relation.</p>		
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11.	EU (Commission)	p. 5, section 4.1	Tech.	Makes the text more easily readable.	Modify to read:- “Manufacturer” means any natural or legal person who makes [or intends to make] a medical device available for use under his name; whether or not such a medical device is designed or manufactured by that person himself or on his behalf.	Not accepted after considerable discussion and some changes to the definition to introduce the words ‘with responsibility for’.
12.	EU (Commission)	p. 5, section 4.1 Manufacturer Note 2	Tech.		Delete: This includes adverse event reporting and notification of corrective actions.	Not accepted. Other SGs asked for these examples to be provided.
13.	MTAA	P. 6 / Sec. 4.1 Note 1. Manufacturer	Edit		Add to Note 1:- While the manufacturer has the ultimate responsibility, in some jurisdictions responsibility for ensuring compliance with regulatory requirements can be also borne by a local authority or an authorised representative.	Not accepted. The role of the authorized representative is described in 4.2 (now 5.2). More detail will appear in the Registration and Listing document.

14.	ZLG & EU Commission	P. 6 / Sec. 4.1 Notes : 3. Manufacturer	edit	“and/or” is not necessary	Delete “and” (consequence from comment above)	Not accepted – ‘and/or’ still part of the definition.
15.	ZLG	P. 6 / Sec. 4.1 Notes : 3. Manufacturer	tech	<p>The listing and especially the multiple use of “assembly” in a) and b) is more confusing than helpful.</p> <p>Taking note of the intention to also address “sets / procedure packs” as medical devices the question is if this note is the right place. We suggest to delete b) and – if really necessary – to introduce a separate note explaining the applicability of the definition of medical device (and therefore of manufacturer) also for “sets, systems, and procedure packs”.</p>	To be discussed	Accepted. Paragraph rewritten.
16.	EU (Commission)	p. 6, section 4.1, note 3	Ed.	The difference between paragraphs a) and b) may need to be clarified		Accepted. Paragraph rewritten.
17.	Health Sciences	Page 6 / Notes 3:	Technical	Typically these days, with globalization and	Suggest creating a separate section to reflect the activities of 3PL and	Added Note in Section 5.3

	Authority Singapore	Design and/or 4.1 manufacturer Page 6 / Section 4.3 distributor Page 7 / Section 4.4 importer		outsourcing of non-core activities, medical device companies do not deal with the warehousing or transportation of medical devices themselves. These functions are normally outsourced to specialized supply chain providers known as 3 rd party logistics (3PL) companies. Medical device companies may outsource their international or domestic <u>courier services</u> to 3 rd party logistics companies. In this respect, it should be clarified that the 3 rd party logistics companies is not an importer or distributor, but merely a service provider. Also see comment below that relates to “distributor” and “importer”	clearly differentiate them from the manufacturers, importers and distributors. Please see attached slide for an illustration of the supply chain for a medical device that is imported into a country.	to cover storage and transport.
18.	ZLG	P. 6 / Sec. 4.1 Notes : 4. Manufactur	edit	The note could be clarified because it contains two different aspects. First, that adaptation of	Depending on the intention.	

		er		<p>(medical) devices does not fall under the definition of “manufacturer” as long as this adaptation is in line with the instructions for use.</p> <p>Second: Is the intention to make clear that persons who manufacture “custom-made” medical devices for individual persons are also “manufactures” according to the definition?</p> <p>Depending on the intention, the note should be shortened or split into one for the adaptation and one for custom-made devices.</p> <p>At least, there is no need for the plural “device(s)” and “medical” should be added.</p>	... or adapts a <u>medical</u> device(s) that has ...	Accepted this change to the text.
19.	EU Commission	P. 6 / Sec. 4.1 Notes : 4. Manufacturer	edit	Delete “ (s) “ in two places		Accepted this change to the text.
20.	ZLG	P. 6 / Sec. 4.1 Notes :	edit	As consequence of the comment above, please	...intended use of, or modifies, a finished medical device ...	Accepted.

		5. Manufactur er		delete « finished »		
21.	MTAA	P. 6 / Sec. 4.1 Notes : 5. Manufactur er		Regarding the phrase “... that may affect safety or performance” While the connection between modifying the intended use and the ultimate safety of a device is accepted, there can be instances where a change to the intended purpose does not adversely affect the safety or performance and yet the action should still mean that the person doing this should be referred to as the manufacturer or else increase the manufacturer’s liability without them being aware.		Accepted. Deleted “... that may affect safety or performance”
22.	Belgian CA	p.6/ NOTE 5 4.1 manufactur er	Tech	No restriction on the possible modification should be given, in order to avoid exclusion from this note.	Any person who changes the intended use of, or modifies a finished medical device in any way that may affect safety or performance , without acting on behalf of the original manufacturer, is considered the manufacturer of the modified medical device, and	Deleted “... that may affect safety or performance” But not the

					should make it available for use under his own name.	other suggested changes. The basic definition of 'manufacturer' requires that the manufacturer makes the device available under its own name.
23.	Belgian CA	Page 6 4.1 manufacturer NOTE 6	Tech	Replace 'deemed' by 'considered' Change 'a' manufacturer in 'the' manufacturer	To the extent that an accessory is subject to regulatory requirements of a medical device ² , the person responsible for the design and/or manufacture of that accessory is considered the manufacturer.	Accepted change to 'considered' but not 'the'.
24.	EU (Commission)	p. 6, section 4.2 authorized representative	Tech	Add "written"; this may increase legal certainty.	Modify to read:- received a <u>written</u> mandate from the manufacturer	Accepted.
25.	EU (Commission)	Section 4.3 (distributor	Tech	Replace "furthers the availability" since this may	Modify to read:- "Distributor" means any natural or legal person in the supply chain,	No support for excluding

² See GHTF/SG1/N29 *Information Document Concerning the Definition of the Term "Medical Device"*

	sion))		be too general (advertising or transport is also "furthers" the availability of a product.)	<u>other than the manufacturer or importer, who makes a medical device available on the market.</u>	the manufacturer and importer from the definition.
26.	EU (Commission)	P. 7 / Sec. 4.3 Distributor Notes : 1	Ed	Simplification	Modify to read:- More than one distributor may be involved in the supply chain.	Accepted.
27.	ZLG	P. 7 / Sec. 4.3 Distributor Notes : 2.	edit	« In addition » should be added for clarification to make clear that this applies only as long as the name of the manufacturer is still on the labelling.	A distributor who indicates its own address and contact details <u>in addition</u> on the medical device or its packaging but	Accepted.
28.	Belgian CA	p.7 4.3 distributor Note 2	Tech	No restriction on the possible modification should be given, in order to avoid modifications applied by the distributor.	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 any way that may affect safety, performance or intended use, is not considered a manufacturer.	Accepted with modification.
29.	EU (Commission)	P. 7 / Sec. 4.3 Distributor Notes : 2	Ed	Clarification	Modify to read:- A distributor who in addition to the manufacturer indicates its own "", etc	Not accepted. Additional Note 3 to cover logistics organizations.

30.	Belgian CA	p.7/ 4.3 distributor NOTE 3	Tech	Additional note advisable	If the address and contact details of the distributor is indicated on the medical device or its packaging, a clear identification of this information and of the manufacturers' address, contact details and trade name shall be made.	Not accepted for this document but will be discussed when SG1 revises its guidance on labelling.
31.	Health Sciences Authority Singapore	Page 6 / Section 4.3 distributor Page 7 / Section 4.4 importer	Technical	See comment 17 This comment is provided as a literal interpretation of Section 4.3 and 4.4 may be taken out of context and be misinterpreted to cover 3 rd party logistics companies , either as importer or distributors. Furthermore, there may also be instances whereby 3 rd party logistics companies engage in some form of secondary repackaging for and on behalf of the medical device manufacturer. , As part of their value added services to the device manufacturers, this may take the form of bulk secondary	I suggest adding a note to Section 4.3 and Section 4.4 to clarify SG1's intent and also to capture the "real world" dynamics of the supply chain of medical devices. Please see attached slide for an illustration of the supply chain for a medical device that is imported into a country.	Added Note in Section 5.3 to cover storage and transport.

				repackaging, whereby imported bulk quantities are broken up at the regional distribution centers into smaller quantities for distribution, either domestically or to overseas markets. Do they then fall within the definition of a manufacturer, as per “page 6 / notes 3: Design and/or manufacture”?		
32.	MTAA	Page 7 / Section 4.4 importer	Edit	Modify text.	“Importer” means any natural or legal person who is the first in a supply chain in a country or jurisdiction who makes a medical device, manufactured in another country or jurisdiction, available in a country or jurisdiction where it is to be marketed.	Accepted in part.
33.	MTAA	Page 7 / Section 4.4 importer	Tech		Add to the text:- It is possible that a number of importers could be making the same medical device available in a country or jurisdiction.	Withdrawn.
34.	EU (Commission)	Section 4.4 (importer)	Tech	Add "established in a country or jurisdiction" since with the current definition also foreign manufacturers could be covered.	Modify to read:- “Importer” means any natural or legal person <u>established within a country or jurisdiction</u> who first makes a medical device, manufactured in another jurisdiction,	Not accepted. Does not work for Canada where the importer

					available in a country or jurisdiction where it is to be marketed.	could be in the USA.
35.	Belgian CA	p.7 NOTE 1 4.4 importer	Tech	No restriction on the possible modification should be given, in order to avoid modifications applied by the importer.	An importer does not repackage or relabel the device or device package, and does not transform or modify a medical device in any way that may affect safety, performance or intended use.	Deleted Note entirely.
36.	MTAA	p.7 NOTE 1 4.4 importer	Tech	An importer may need to repackage or relabel a product as part of an arrangement with a manufacturer without affecting or hindering the manufacturer's labelling responsibilities. This could be due to a legal requirement in the jurisdiction. The connection between modification of a medical device and subsequent effects on the safety or performance is accepted but the simple act of modifying the device can increase the manufacturer's liability without them being possibly aware of it.		Deleted Note entirely.

37.	EU (Commis sion)	p.6/7, sections 4.3 and 4.4	Ed.	Reverse order of sections: first importer than distributor		Withdrawn.
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