REPORT OF THE JOINT MEETING OF STUDY GROUPS 1/3/4 ON FEBRUARY 5th, 2008 IN BONN, GERMANY

Attendees

SG1 Chair - Ginette Michaud
SG1 Vice-Chair - Benny Ons
SG1 Secretary - Alan Kent
SG3 Chair – Egan Cobbald
SG3 Vice Chair – Gunter Frey
SG4 Chair – Markus Zobrist

North America

Mark Melkerson – FDA, SG1
Nancy Shadeed - Health Canada, SG1
Brenda Murphy – MEDEC, SG1
Michael Gropp – AdvaMed, SG1
Marlene Valenti – AdvaMed, SG1
Kimberly Trautman – FDA, SG3

Europe

John Brennan – European Commission, SG1
Ekkehard Stösslein – German regulator, SG2
Elke Lehmann – BfArM, SG1
Peter Linders – COCIR/EMIG, SG1
Carl Wallroth – EUROM VI/EMIG, SG1
Dirk Wetzel – BfArM, SG3
Reiner Krumme – European CAB, SG4
Rainer Edelhauser – ZLG Germany, SG4
Carlos Anglebe – Industry representative, SG3
Victor Dorman-Smith – Industry representative, SG3

Asia/Australasia

Mike Flood – TGA, Australia, SG1
Hiroshi Yaginuma – MHLW, Japan, SG1
Naoki Morooka – JFMDA, Japan, SG1
Tomomichi Nakazaki JFMDA, SG1
Shintaro Tobiishi – MHLW, Japan, SG3
Munehiro Nakamura – JFMDA, Japan, SG3
Hideki Asai – JFMDA, SG3

Asian Harmonization Working Party

Daphne Yeh – AHWP, industry representative, SG1

Apologies

Cliff Spong - MIAA, Australia, SG1
Alfred Kwek – Health Sciences Authority, Singapore, SG1
Kiyoshi Ikeda – PMDA, Japan, SG1

1 Welcome to the meeting and introduction of delegates

Dirk Wetzel, Head of the Medical Devices Division of the Federal Institute for Drugs and Medical Devices (BfArM) in Bonn, welcomed attendees to BfAfM.

Ginette Michaud described the arrangements for the day and thanked Dirk Wetzel and Elke Lehmann for the invitation to hold the meeting in Bonn

2 Adoption of Agenda and discussion of procedures for this meeting

The Agenda was agreed.

3 SG1(WD)/N055R5 Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer.

Alan Kent acted as Chair during the discussion of this document.

Prior to the meeting, the latest Working Draft (dated 1 October 2007) had been circulated for comment. A consolidated list of the comments received had been circulated to attendees on 31 January, 2008. It was agreed that editorial comments would be incorporated into the document after this meeting, allowing attendees to concentrate on those of a technical nature.

The technical comments were discussed and, where agreed, incorporated into the guidance document. The list of comments, including an indication of the outcome decision, is attached to this Meeting Report.

The guidance document will be revised and circulated to attendees.

Action: Alan Kent

Provided there are no significant adverse comments, it will be sent to the Steering Committee for endorsement as a Proposed Document and published on the GHTF website for public comment.

Action: Alan Kent/Ginette Michaud

4 SG1(WD)/N065R3 Registration of Manufacturers and Listing of Medical Devices

Ginette Michaud acted as Chair during the discussion of this document.

Michael Gropp described the background to the document. It was noted that the Steering Committee has set a high priority for the document.

The meeting began to discuss the document, starting at Section 5.0. Some progress was made although much more work is required. It was agreed that SG1 will continue to work on the document during its meeting later in the week and circulate a revised copy to all SGs by mid-May.

Action: Alan Kent/Ginette Michaud

5 Date and place of next meetings

- Buenos Aires, Argentina, from July 8 to 11th , 2008. Nancy Shadeed agreed to contact Tim Missios of Boston Scientific.

Action: Nancy Shadeed

- Ottawa from 14th to 17th October for a joint Study Group meeting – to be confirmed.

Action: Nancy Shadeed

Document number: **SG1(WD)/N055R5** **Title:** **The Definition of the Term Manufacturer, Authorised Representative, Distributor and Importer and Related Entities of October 1st, 2007**

Submitted by (name): **Consolidated** **Circulated:** **31 January 2008**

Comment Number	Affiliation (e.g. TGA)	Page / Section / Line	Editorial or Technical	Comment and rationale	Proposed revised text	Decision (Discussed on 5 February, 2008 in Bonn)
1.	Gropp	Page 4, section 1.0, 3rd paragraph, 2nd line	Editorial	Inconsistent plural/singular; delete "a" and add "s" at end of "definition" as more than one definition is offered in the document.	"…. Regulatory systems through offering ~~a~~ harmonised definitions for the terms …"	Accepted
2.	AdvaMed	Page 4 Sec.1.0 Introduction Par. 5	Technical	Delete this sentence as it does not add value to the document and just over emphasize what has been stated in the previous paragraph regarding the need for and encouragement of harmonization of regulatory definitions across jurisdictions	Delete the sentence: "~~The regulatory requirements of some countries do not, at this time, align fully with this guidance~~."	Accepted
3.	Health Canada Inspectorate	Page 4 1.0 Introduction 3rd paragraph second sentence	T	The sentence, "A single party may fulfill one or more of these roles, e.g. a manufacturer may also distribute its own products or a distributor may act as the importer." has been shown to be	Any person may be one or more of the following: manufacturer, importer, distributor, authorised representative, with respect to all devices. With respect to a single device, a person may only be one of the above, that is the manufacturer, the	Not agreed – but text modified to improve understanding.

				confusing, with respect t to defining activities, in Health Canada's experience. An activity of a "person" could be an overall activity (i.e.: they are a manufacturer), or a device-specific activity. While a manufacturer is also a distributor of its own devices (logically) the higher level of regulatory requirements on a manufacturer would apply for those specific devices. For manufacturers who **also** distribute another manufacturer's devices, for those devices only the regulatory requirements of a distributor would apply. The same would be true of a manufacturer who imports another manufacturer's devices; for those devices, only the requirements of an importer would apply. Further, while an importer is also a distributor of its own devices (logically) the higher level of regulatory requirements on an importer would apply for those specific devices. For importers who also distribute devices which they did not import, for those devices only the regulatory requirements of a distributor would apply (ie: they would merely be a	importer, the distributor, the authorised representative.	

				distributor for those devices). In other words, on a device specific basis, taking into account the regulatory requirements on manufacturers, importers and distributors, the definitions are mutually exclusive. They are not, however, mutually exclusive on the basis of the sum total of the activities of the natural or legal person		
4.	Gropp	Page 4, section 2.1 Rationale, 1st line	Editorial	Suggest noting that defined party has various obligations and responsibilities.	"The term "manufacturer" appears in many GHTF documents and is associated with various obligations and responsibilities."	Accepted
5.	FDA	Page 4, Section 2.1, Rationale	Ed	Consider: • editorial changes to improve flow of first paragraph • insertion of sentence from "Purpose" (see second paragraph) to describe rationale.	2.1 Rationale The term "manufacturer" appears in many GHTF documents. The development of a consistent, harmonized definition for a "manufacturer" ~~that could be used within a global regulatory model~~ would support global convergence of regulatory systems and would offer significant benefits to Regulatory Authorities and the organisations responsible for making and/or placing medical devices onto the market ~~and to Regulatory Authorities, and support global convergence of regulatory systems~~. . Harmonization of the terms "authorised representative", "distributor" and "importer" would be ~~is~~ of benefit, too.	Accepted

					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.	
6.	Gropp	Page 5, section 2.2 Purpose 1st paragraph, 3rd line	Editorial	Clarity	"… allow a Regulatory Authority to establish the identity of the person who …"	Accepted
7.	AdvaMed	Page 5 Sec. 2.2 Purpose Par. 2	Editorial	Editorial improvement	Replace the existing sentence with the following sentence – "Harmonization ~~should~~ of these terms improves the consistency and the transparency of regulatory requirements and related controls."	Accepted
8.	AdvaMed	Page 5 Sec. 2.2 Par. 3 1st Sentence	Editorial	Revise sentence to incorporate editorial improvements and eliminate redundant information.	Replace existing sentence with the following sentence – "This document ~~will have as its audience~~ is intended to serve as guidance for Regulatory Authorities, Conformity Assessment bodies, and the regulated Industry."	Accepted
9.	FDA	Page 5, Section 2.2, Purpose	Ed	Consider: • editorial change in first paragraph • striking second paragraph as it belongs in "Rationale"	**2.2 Purpose** To provide a harmonized definition of the terms "manufacturer", "authorised representative", "distributor" and "importer". Recommendations within this guidance ~~and~~ will thereby allow a Regulatory Authority to establish the	Accepted

					person who takes responsibility for ensuring the finished product meets relevant regulatory requirements for a medical device that is made available within its jurisdiction. ~~Harmonization should improve consistency and the transparency of regulatory controls.~~ This document will have as its audience 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.	
10.	AdvaMed	Page 5 Sec. 2.3 Scope 2nd Sentence	Editorial	Grammatical correction. Replace "of" with "for."	"It provides definitions ~~of~~ for the terms...."	Accepted
11.	FDA	Page 5, Section 2.3, Scope	Ed	Consider: • adding text that identifies relevant SG1 document • striking text that does not describe the Scope of the document.	**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*. ~~It provides definitions of the terms "manufacturer", "authorised~~	Accepted.

					~~representative", "distributor" and "importer" that appear in guidance documents published by the Global Harmonization Task Force.~~	
12.	Gropp	Page 5, Section 3.0 References	Editorial	Flag for future revision of referenced document N29; no action appropriate in this document (N55)	Clean up referenced document title by deleting "Information Document Concerning the"	Bookmark
13.	JFMDA PMS	P5 Section 3	T	According to the Public Comment from FDA No 3. Specified document number has been deleted.	Delete SG1 document number Or add SG2N54R8,SG4N28	Not Accepted.
14.	Gropp	Page 5, section 4.1 Definition Manufacturer	Technical	What is meant by "regulatory responsibility"? The manufacturer is not the Regulatory Authority who, in fact, has "regulatory responsibility". Do we mean to say "… has ultimate responsibility for ensuring compliance with regulatory requirements …"?	Clarify meaning of "regulatory responsibility"	A revised definition of "manufacturer" was agreed at the meeting.
15.	AdvaMed	Page 5, section 4.1 3rd line	Technical	The phrase "regulatory responsibility" is very vague. For the purposes of GHTF, the responsibilities should only include responsibility for quality, safety and effectiveness of the device	"Manufacturer" means any natural or legal person who designs and/or manufactures a finished medical device, or who has such a medical device designed or manufactured, under his name or mark and has ultimate ~~regulatory~~ responsibility for the quality, safety and effectiveness of the medical device in the countries or jurisdictions where it is intended to be made available or sold.	A revised definition of "manufacturer" was agreed at the meeting.
16.	Zimmer (Canada)	Page 5, Section 4,1	Technical	Definition of "manufacturer" not acceptable. Inclusion of "…,	"Manufacturer" means any natural or legal person who designs and/or manufactures a finished medical device, or who has such a	A revised definition of

				under his name or mark…" in the definition will prevent trade-marking of a third-party manufactured product (design control held by third-party). In Canada, the Health Canada Medical Device Regulations states "a person who sells a medical device under their own name, or under a trade-mark, design, trade name, or other name or mark owned or controlled by the person,…". This definition has prevented our Canadian subsidiary from bringing into Canada the above mentioned product. Branding or trade-marking a medical device is a common practice in US, EU, and around the world. The manufacturer is clearly identified on the label. The presence of the "TM" statement on the label should not be the reason why the owner of the trademark should now be considered the manufacturer of these third-party manufactured product. Should this definition be adopted by GHTF, FDA, and other GHTF member countries, this will shut down this practice of branding or trade-marking medical device products manufactured by third-parties (who hold design control).	medical device designed or manufactured, and has ultimate regulatory responsibility for the medical device in the countries or jurisdictions where it is intended to be made available or sold.	"manufacturer" was agreed at the meeting.

17.	Gropp	Page 5, section 4.1	Technical	Definition appears circular, i.e., the manufacturer has certain obligations/responsibilities, therefore he is the manufacturer		A revised definition of "manufacturer" was agreed at the meeting.
18.	MEDEC	Page 5, 4.1 Manufacturer	Ed	The current definition of a manufacturer does not allow company A to design and manufacture a medical device and use the mark owned by company B, which would be the importer or distributor. In such scenario company A would have obtained the legal right to use the mark of company B for all markets where B is the importer and/or distributor of such product.	… or sold. The original manufacturer will retain his responsibility also in case he uses an Importer or Distributor for some jurisdictions where the mark is owned by the Importer/Distributor but legally contracted to the manufacturer.	A revised definition of "manufacturer" was agreed at the meeting.
19.	AdvaMed	Page 6 Sec. 4.1 Notes	Editorial	Remove the "Notes" designation under Manufacturer and make part of the definition- the "Notes" are a critical part of the Manufacturer definition that should be included in the main body instead of as a Note.		Not accepted. For regulatory purposes, "manufacturer" would be the defined term and the "Notes" would be incorporated into accompanying guidance.
20.	Gropp	Page 6, section 4.1, Note 1	Technical	What is the meaning of "public" in this context? Most manufacturer notifications of field corrective actions are not "public" in the	Delete "public"	Accepted.

				sense that they are not issued indiscriminately to the general public through newspapers, television, etc. Is "public" necessary here? The manufacturer's obligation is to notify the Regulatory Authority and purchasers/users of potentially affected devices.		
21.	Gropp	Page 6, section 4.1, Note 2	Editorial/ Technical	Is "redefining" the appropriate word here? Would it not be simpler to say "changing"?	Replace "redefining" with "changing"	Note 2 deleted
22.	Gropp	Page 6, section 4.1, Note 2	Editorial/ Technical	Where is the intended use/purpose of the device identified? What is the evidence that a person has established or changed the intended use/purpose?	Revise sentence to "Assigning or changing the intended use/purpose of the medical device, as shown in labelling, is considered part of the design process"	Note 2 deleted. Note 5 adapted but does not refer to "as shown on the labelling"
23.	JFMDA	Page6 /Section 4.1 Note 3	Te	We suggest to delete "accessory". [rational] We does not have enough consensus of 'Accessory'.	Note 3 ~~c)design and manufacture of an accessory.~~	Provided alternative text in new note 6.
24.	AdvaMed	Page 6 Sec. 4.1 Note 3	Technical	Revise note to clarify that when a party conducts these activities on behalf or for a manufacturer the party is not considered a manufacturer (e.g., contract sterilizer)	Parties that conduct these activities for the "manufacturer" are providing services and are not considered manufacturers.	Not accepted since modification to definition of "manufacturer" clarifies the situation
25.	AdvaMed	Page 6, Section 4.1., Note 3 (a)	Technical	Add reprocessing of single use devices to definition of remanufacturing activities	3.Design and manufacture may include: a) specification development, production, fabrication, assembly, processing,	Revised Note 5 addresses this issue.

					packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing; including reprocessing of single use devices, and/or	
26.	JFMDA	Page6 /Section 4.1 notes 2 and 3	Ed	We suggest the re-arrangement note 2 and 3 of section 4.1. [rational] For better understanding, functions of Design and Manufacturing are clearly identified .	2. Design may include: a) Assigning or redefining the intended use/purpose of the medical device is considered part of the design process. b) specification development, c) design of an accessory 3. ~~Design and~~ Manufacture 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; and/or, ~~design and~~ manufacture of an accessory.	Not Accepted the separation of design and manufacturing processes but text of Notes modified to improve clarity.
27.	Gropp	Page 6, section 4.1, Note 3	Editorial	This note, in conjunction with the proposed definition, could be construed to make contract sterilisers, etc. a "manufacturer"	Add sentence at end of note: "Parties who perform any of these functions at the direction of another are not considered to be a manufacturer"	Not Accepted since definition of "manufacturer" has been changed.
28.	FDA	Page 6, Section 4.1, Note 4	Editorial	For internal consistency ("intended use/purpose" appears at the beginning of the document but "intended use" appears throughout the remainder of the document)	. . . is not the manufacturer provided the assembly or adaptation does not change the intended use of the device/s.	Accepted
29.	Gropp	Page 6, section	Editorial	Clarity	Add comma after "… is not the	Accepted

		4.1, Note 4, 3rd line			manufacturer, provided the …."	
30.	AdvaMed	Page 6 Sec. 4.1 Note 4	Editorial	Correct typo device/s	device(s)	Accepted
31.	AdvaMed	Page 6 Sec. 4.1 Note 4	Editorial	Insert comma after "manufacturer"	"...instructions for use, is not the manufacturer, provided the assembly..."	Accepted
32.	MEDEC	Page 6, Note 5.	Tech	Any change to the design should make the person, who does it the manufacturer of this device. The effect of such change on safety, performance, or intended use may not be immediately identifiable or delayed.	Any person who transforms or modifies a finished medical device without acting on the behalf of the original manufacturer, should be considered the manufacturer of the modified medical device.	Text of Note 5 modified.
33.	AdvaMed	Page 6 Sec. 4.1 Note 5	Tech	Clarify intent to include reprocessors of single use devices by including as an example	"…without acting on the behalf of the original manufacturer, should be considered the manufacturer of the modified medical device, (e.g., reprocessor of single use device)."	Not Accepted but Note 5 modified.
34.	Gropp	Page 6, section 4.1, Note 5, 2nd line	Editorial	Clarity	Delete "the" before "behalf"	Accepted.
35.	JFMDA PMS	P6. Section 4.1 Note 5	T	Refurbisher How do we define the refurbisher? They have the obligation to make AE report if the event is related to their work.	Any person who refurbish or reprocess the finished medical device should be considered as the manufacturer of the medical device.	Not accepted here but bookmark for future revision.

				According to the public Comment No 17, reasons for deletion is due to they SUD and its is covered by Note 5, however in case they do not modify the original specification or safety issue then is not treated as manufacturer?		
36.	JFMDA PMS	P&. Section 4.1 Note 5	T	Reprocess According to the Public Comment No.16, the original comment has been withdraw by FDA, but in case of SUD and user may reprocess it and due to that reason, some AE occurred, the said user has the obligation to make AE report. So that we need to define some how reprocess issue.	Note 7 In case of reprocessing at user side is not the scope of this document, but some jurisdiction request AE report from user.	Comment refers to single-use devices. Not accepted.
37.	AdvaMed	Page 6 Sec. 4.1 Note 6	Editorial	Grammatical correction as this is intended to offer alternatives for the definition and is not intended as all inclusive. Replace “and” with “or.”	"The term "person" that appears in the definition includes legal entities such as a corporation, a partnership, ~~and~~ or an association."	Accepted.
38.	Health Canada Inspectorate	Additional Note #6 in Secn 4.1	T	The term, “person”, appears in numerous places in the document and the definitions, and is important to understanding the definitions.	Rather than including the definition of “person” in the notes to the definition of a manufacturer, the definition of “person” (as written) should stand on its own.	Addressed through adding modified text as a ‘footnote’.
39.	JFMDA	Page6 /Section 4.1 additional note 7	Te	We suggest to add the additional paragraph as 7 into note of section 4.1. [rationale]	7. Manufacturer is consist of above functions (e.g. Design and Manufacture), and their described in Design information and Manufacturing process of STED. However, Manufacturer has, in whole or in part, outsourced the supply of parts,	Not accepted for this document but may be relevant to guidance on ‘Registration &

				Some different styles of manufacturer exist (e.g. Virtual Manufacturer or Multisite Manufacturer). And the definition of manufacturer is linking with Registration of Manufacturer (SG1(WD)/N65R1) and the Manufacturing Process in the STED.	material, services or finished medical devices into the other natural/legal person . In the other case, Manufacturers are considered to be a multi-site organization if they typically have an identified central (or corporate) office or location at which certain activities are planned, controlled or managed and a network of local offices or branches at which such activities are fully or partially carried out. For Conformity assessment, QMS of the finished medical device should be established on such outsource or location at which certain activities are planned, controlled or managed. And such outsource or location may be required to register as manufacturer based on SG1(WD)/N065R1 " Registration of Manufacturers and Listing of their Medical Devices".	Listing'.
40.	Gropp	Page 6, section 4.2 Authorised Representative, 2nd line	Editorial	Is it necessary to specify that the "mandate" be "written"?	Delete "written"	Accepted.
41.	AdvaMed	Page 6 Sec. 4.2 Note 1	Technical	There are additional terms for the local authorized representative. Allowance should be made for such variations.	"In some jurisdictions this person may be called the "~~O~~official ~~C~~correspondent",~~or~~ the "~~S~~sponsor", the "local agent", "the local responsible person" (LRP), etc."	Note deleted.
42.	Gropp	Page 7, section 4.3 Distributor, 2nd line	Technical/ editorial	Clarity	Suggest adding "obtained from another party, e.g., the manufacturer" after "… availability of a medical device"	Comment withdrawn.
43.	AdvaMed	Page 7	Technical	**Modify the definition to**	"Distributor" means any natural or legal	Not accepted as

		Sec. 4.3 Definition of Distributor		**clarify the distributor is not engaged in manufacturing.**	person in the supply chain who, on his own behalf and without performing any of the tasks associated with the definition of manufacturer, furthers the availability of a medical device to the end user.	subject was addressed in the third paragraph of the 'Introduction'.
44.	Health Canada Inspectorate	Definition of distributor	T	This is a question: What is the definition of the term "end-user", as used in the definition of Distributor? Is it the patient or could it be the physician or other healthcare professional (ie: the end-user of an orthopaedic drill is not the patient, but is the physician)? We have had problems with this term and thus created the term "ultimate consumer', in its place.	Our definition of "ultimate consumer" could be used for the definition of end-user (although we chose to use a different term): "The individual who purchases or receives a device for their own personal use (including use within their household) or receives treatment or diagnosis with a device from a third party such as a healthcare facility or health care provider. Note 1: Businesses which purchase devices solely for the use by their employees during work activities (e.g. first aid kits, disposable gloves) are also considered ultimate consumers as long as they are not in the business of offering health services to employees or other individuals."	Not accepted.
45.	Gropp	Page 7, section 4.3	Technical	Could this definition be construed to mean that the hospital who makes a device (purchased by the hospital) available to a patient (e.g., for home use) a "distributor"? Is that correct? What is meant by "on his own behalf"?		Discussed but no change to the text. Further discussed while writing guidance for 'Registration & Listing'. "On his own behalf" excludes DHL, Post

						Office etc.
46.	MEDEC	Page 7, 4.3 Distributor	Ed	The terms 'distributor' and 'importer' are still overlapping, e.g. a 'global distributor' is actually an importer for all jurisdictions other than the 'country of origin' of the device.	Notes: 3. If distribution of a medical device brings such device from one jurisdiction to others e.g. through global distribution, the person who performs such activity is considered an importer.	Comment withdrawn.
47.	AdvaMed	Page 7 Sec. 4.3 Distributor Note 2	Editorial	Provide an example to note to further understanding.	"… is not a manufacturer, (e.g., a distributor who uses a sticker to add its contact information without obscuring original labeling)."	Not accepted but text modified as suggested in Comment 48.
48.	FDA	Page 7, Section 4.3 Distributor, Notes, (2)	Tech	Adds clarity and precision -- and is now more consistent with "Importer" Note (1) (which separates out repackaging & relabelling from the "transform or modify" language)	A person who additionally 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 transform or modify the medical device in a way that affects safety, performance or intended use, is not considered a manufacturer.	Accepted
49.	AdvaMed	Page 7 Sec. 4.3 Note 2	Technical	Remove Note 2 from definition of Distributor- the inclusion of multiple names and addresses on device labeling causes confusion among customers and governments and is not a regulatory requirement	~~2. A person who additionally indicates its own address and contact details on the medical device or its packaging but does not transform or modify a medical device in a way that affects safety, performance or intended use, is not a manufacturer.~~	Not Accepted as it is a regulatory requirement in some jurisdictions
50.	AdvaMed	Page 7 Sec. 4.3 Distributor	Technical	Include information about private label distributors		Not Accepted.
51.	Health Canada	Page 7,	T	Under the definition of importer, there is the term "marketed". This	Importer means any natural or legal person in the supply chain who first makes a	Comment withdrawn.

	Inspectorate	Section 4.4 Definition of Importer		would seem to imply that a hospital would not be an importer (since they do not "market"), but in Canada, they can be considered so. For example, a foreign company sells a device directly to a hospital or healthcare provider in Canada. The hospital is considered the importer of the device, but is exempt from Canada's establishment licensing provisions, because they are not marketing the device; they are using it on the end-user/ultimate consumer. If they do market devices also, they would be considered importers or distributors (as appropriate), and would no longer be exempt from Canada's establishment licensing provisions	medical device, manufactured in another jurisdiction, available in a country or jurisdiction where it is to be marketed or, in the case of a healthcare facility or provider, where it is to be used.	
52.	AdvaMed	Page 7 Sec. 4.4 Importer	Technical	Add note to clarify end user is not included within definition of importer	**NOTE:** 2. The end user of the product is not an importer.	Not Accepted. The word 'first' is important within the definition.
53.	FDA	Page 7, Section 4.4 Importer Note (1)	Ed &Tech	Suggested an additional Note (2) to conform with FDA regulations. Also deleted hyphen in "relabel" for internal consistency.	1. An importer does not repackage or relabel the device or device package, and nor does it transform or modify a medical device in a way that affects safety, performance or intended use. 2. A person who initially imports a device manufactured in a foreign establishment is considered a manufacturer, even if that	Accepted removal of hyphen. Technical – Addition is not accepted since we are writing harmonized

					person would otherwise be considered an importer under Note (1).	guidance.
54.	FDA	Pages 6-7: Section 4.1, Notes, (5) & Section 4.3, Notes, (2) & Section 4.4, Notes, (1)	Ed	This phrase appears throughout the document. The concern is that actual effect would have to be proven. The modifier "potentially" would ease the evidentiary burden.	in a way that potentially affects safety, performance or intended use.	Accepted but used 'may' instead of 'potentially'.
55.	Health Canada Inspectorate	Additional Definitions	T	There may also be a need to define what a retailer is (we found it so, in our jurisdiction)	Retailer: Any person who sells a device solely to the end-user (as defined above). Note 1: With respect to sale to a healthcare facility or a healthcare provider, the patient is considered to be the end-user whether or not the facility or provider sells the device to them or sells services involving the use of the device. Therefore, persons selling any devices (regardless of the amount) to healthcare facilities or providers are not retailers, but are distributors. A central purchasing and distribution facility that supplies devices to a chain of retail outlets which are individually owned and operated (either independently or under a franchise agreement) is also considered to be a distributor and not a retailer.	Not Accepted