REPORT OF THE SG1 MEETING HELD FROM 13th TO 16th OCTOBER, 2009 IN BRUSSELS, BELGIUM

Attendees

Chair - Ginette Michaud
Vice-Chair - Benny Ons
Secretary - Alan Kent

North America
David Racine – FDA, USA
Brenda Murphy – MEDEC, Canada
Michael Morton - AdvaMed, USA

Europe
Lennart Philipson – European Regulatory Authority
Peter Bischoff-Everding – European Commission
Peter Linders – COCIR/EMIG

Asia/Australasia
Gary Burgess – TGA, Australia
Atsuchi Tamura – PMDA, Japan
Naoki Morooka – JFMDA, Japan
Tomomichi Nakazaki - JFMDA, Japan
Kentaro Azuma – MHLW, Japan

AHWP
Daphne Yeh – AHWP, Industry representative, Chinese Taipei

Apologies
Nancy Shadeed - Health Canada
Mark Melkerson – FDA, USA
Cliff Spong - MIAA, Australia
Carl Wallroth – EUROM VI/EMIG

1 Welcome to the meeting and introduction of delegates

Ginette Michaud, Chair of SG1, welcomed SG1 members to the SG1 meeting and thanked Peter Bischoff-Everding for inviting SG1 to Brussels for the meeting.

The Chair welcomed David Racine from the FDA who was replacing Mark Melkerson for this meeting and Kentarou Azuma from MHLW, Japan.

Sabine Lecrenier, Head of Unit, Enterprise and Industry Directorate-General, European Commission, joined the meeting and welcomed SG1 to Brussels. She emphasised the importance of the work of GHTF to the European Commission and wished SG1 a fruitful meeting.

2 Adoption of Agenda and discussion of procedures for this meeting.

The Agenda was approved.

3 **Review of the report of the SG1 meeting held on the 10th to 12th May in Toronto *(Document GHTF. SG1. N75*)**

The Meeting Report has been circulated and was approved. In respect of the actions, Peter Linders reported that he has discussed deviations of ISO 16142 from SG1 guidance with TC 210. In response, TC 210 has agreed to set up a Task Group to work on aligning the standard with SG1 guidance. The resolution reads:

> *"ISO/TC 210 agrees with the recommendation that a task group be established to align the revision of ISO/TR 16142:2006 with the GHTF/SG 1 document when it is published and directs the secretariat to establish a liaison with GHTF/SG 1."*

4 **Review of SG 1 accomplishments.**

Prior to the meeting, the Secretary had circulated the most recent version of the *Status of Study Group I Work Programme* (SG1/N034R33) dated 20th September 2009.

Individuals listed in the SG1 Communications Database will be asked to provide comments on the Final Documents GHTF/SG1/N015:2006 Principles of Medical Devices Classification and GHTF/SG1/N040:2006 Principles of Conformity Assessment for Medical Devices in anticipation of a planned revision of these guidelines by SG1 in 2010.

Action: Secretary

The SG1 Chairwoman, the SG1 Secretary, and the IVD Subgroup Chairwoman have submitted updated information to the GHTF Secretariat for inclusion on the GHTF website. This information and content includes current membership details, corrections to the Final and Archived Documents lists, meeting minutes for past meetings, and tables of consolidated comments (with resolution) from past discussions. This information now appears on the GHTF website.

Additional information to be provided to the GHTF website include an updated SG1 Work Plan, SG1 and IVD Subgroup Meeting Dates and recent Meeting Reports.

Action: Secretary

The GHTF Chairwoman has noted additional omissions from the SG1 membership information and will provide those details to the GHTF Secretariat..

Action: Chair

The *Status of GHTF Study Group 1 Work Programme* (SG1/NO34) and SG1 Work Plan will be updated before the next meeting.

Action: Secretary

5 **Report from the In Vitro Diagnostic Medical Devices Subgroup (IVD MD Subgroup)**

The Steering Committee endorsed SG1/N063 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD*

Medical Devices as a Proposed Document and it has been posted until 7th January, 2010 on the GHTF website for public comment**.**

Action: Secretary to inform those on the SG1 Communications Database

The IVD MD Subgroup last met in June 2009 at which time it drafted a document for SG5 regarding clinical evidence for IVD medical devices. This work continues.

The IVD Subgroup's next meeting will be held in November 2009 at which time it will continue with drafting guidance for SG5 and will review SG1 guidance on Labelling.

Action: Nancy Shadeed

6 **Update on the Work of the Steering Committee**

The Chair reported that:

- Benny Ons is joining the Steering Committee as an EDMA representative.
- A draft document GHTF/AHWG(PD1)/N1R5 *GHTF Medical Device Regulatory Model* has been posted on the GHTF website and is available for comment. The Secretary has prepared some personal comments and will add to them any other views expressed by SG1 members.

Action: Secretary

7 **Report from the Asian Harmonization Working Party**

Daphne Yeh reported:

- There are changes to the leadership of some AHWP Working Groups. She will send the Secretary details of the outcome.

Action: Daphne Yeh

- The Annual Meeting of the AHWP will be held in Hong Kong for 1 week from November 4th. The SG1 Chair will be presenting the work of SG1 to the meeting.

Action: Chair

- The Chair and Daphne Yeh will be conveying SG1's invitation to increase AHWP representation to four people with the AHWP leadership.

Action: Chair/Daphne Yeh

The Chair reported that in July she and the Vice-Chair participated in a teleconference with representatives of the AHWP. It was during this call that the AHWP was informed of a proposal, under consideration in Study Group 1, to increase the AHWP's membership in SG1. Also, the concept of inviting the AHWP to undertake a first review of SG1 documents on the Classification and Conformity Assessment of Medical Devices was raised. As a result, the Secretary has sent the AHWP the relevant documents, previously received comments on these documents, and two comments templates for the collection of new comments with (proposed resolution) by AHWP. There will be further such teleconference calls in the future.

Action: Chair

8 **Update on Latin America Membership of SG1**

Most members of SG1 have expressed their support of the Chair's proposal to expand membership of SG1 to include four members from Latin America.

The representative of Japanese industry asked for more information on the role of PAHO in representing the region. The Chair said PAHO is a facilitator for discussions between the regulators within the region but does not represent them. Neither has it a role regarding the region's industry.

After further discussion on the topic, the Japanese MHLW sought assurance that the Latin American delegates, if nominated for membership to SG1, would speak for the region rather than for individual organizations. The Chair restated that only delegates who have been designated by a regional Latin American organization to represent its membership will be admitted as members to Study Group 1.

The Chair noted agreement of the majority of SG1 with the proposed membership expansion, but agreed to pursue the concerns expressed when SG1 next meets in Brazil during January 2010.

Action: Chair

9 **Revision of GHTF/SG1/N43:2005 Labelling for Medical Devices**

Benny Ons reported on the progress made when SG1 last met in Toronto. He reported that different views are held regarding aspects of the document.

The most recent version of the document, incorporating changes made in Toronto, was circulated prior to this meeting (GHTF/SG1(WD)/N70R4 of 21 September 2009 *Labels & Instructions for Use*) and formed the basis of the continuing discussions held in Brussels.

During this meeting further changes were agreed and incorporated into the text. A clean version of the revised document together with an updated table of consolidated comments, with outcomes, will be circulated by the Secretary.

Action: Secretary

The clauses regarding labelling of IVD medical devices will be discussed when the IVD MD Subgroup next meets and a separate section for IVD medical devices will be created in the document. They will return the document with their suggested revisions to SG1 after that meeting.

Action: Nancy Shadeed

10 **Revision of SG1/N065: *Registration of Manufacturers and other Parties and Listing of Medical Devices***

SG1 reviewed the list of consolidated comments on the Proposed Document and modified the guidance as agreed. The document will continue to be developed at the next meeting of SG1.

A clean version of the revised document together with an updated table of consolidated comments, with outcomes, will be circulated by the Secretary.

Action: Secretary

11 **Study Group 1 Communications Database**

The Secretary reported on the status of the Communications Database. A further revision will be circulated before the next meeting.

Action: Secretary

12 Document Priorities and Timetable

Work in progress is as follows:

DOCUMENT TITLE	REFERENCE	STATUS	PRIORITY	TARGET FOR COMPLETION
Study Group 1 – New Documents				
Registration of Manufacturers and other Parties and Listing of Medical Devices	**SG1(PD)/ N065**	**Proposed Document – post-public consultation; comments under review by SG1**	**1**	**Final Document 2010/Q3**
SG1 IVD Medical Devices Subgroup – New Documents				
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices.	**SG1(PD)/ N063**	**Public Consultation ending Jan 7 2010**	**1**	**Final Document 2010/Q4**
Revision of SG1 Final Documents				
Information Document Concerning the Definition of the Term "Medical Device" (revised)	**SG1/N071**	**Revision in progress by SG1**	**2**	**Proposed Document 2010/Q4**
Essential Principles of Safety and Performance of Medical Devices (revised)	**SG1/N068**	**Document referred to IVD MD Subgroup for revision of IVD content**	**2**	**Proposed Document 2010/Q4**
Labelling for Medical Devices (revised)	**SG1/N070**	**Document referred to IVD MD Subgroup for revision of IVD content**	**2**	**Proposed Document 2010/Q2**
Principles of Medical Devices Classification	**SG1/N015: 2006**	**Revision pending – awaiting AHWP input**	**3**	
Principles of Conformity Assessment for Medical Devices	**SG1/N040: 2006**	**Revision pending – awaiting AHWP input**	**3**	

13 Any Other Business

None.

14 **Date and place of next meeting**

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- Brazil from 26th to 29th January, 2010. Further information will be provided as it becomes available.

Action: Chair

- Tokyo from 18th to 21st May, 2010 at the invitation of the MHLW. Further information will be provided as it becomes available.

Action: Chair

SUMMARY OF ACTIONS

For the Chair

- Correct information on AHWP membership as it appears on the GHTF website.
- Present the work of SG1 at the AHWP annual meeting and provide a letter of invitation to AHWP Chairman regarding membership expansion.
- To provide further information on the meeting to be held in Brazil (January, 2010) and Japan (May, 2010) when it becomes available.
- To communicate, with our Latin American counterparts, concerns expressed regarding procedures for membership expansion to Latin America when SG1 next meets in Brazil during January 2010.

For the Secretary

- To send the GHTF Secretariat an updated SG1 Work Plan, Meeting Dates and Meeting Reports for posting on the GHTF website.
- To update *Status of GHTF Study Group 1 Work Programme* (SG1/NO34) and SG1 Work Plan before the next meeting and reissue to members.
- The redrafted document on *Labelling*, together with an updated list of comments, will be circulated to the IVD MD Subgroup in order that it may consider the changes made. The document and comments will also be circulated to SG1 membership.
- The redrafted document on *Registration and Listing*, together with the updated list of comments, will be circulated to SG1.
- To update the *Communications Database* and reissue to SG1.
- To inform contacts listed in the Communications Database that SG1 is revising its two guidance documents on *Classification and Conformity Assessment of Medical Devices*, respectively and ask for comments.

For Nancy Shadeed

- To review the revised document on *Labelling* at the next meeting of the IVD Medical Devices Subgroup.

- To submit and discuss the redrafted document on *Essential Principles* at a meeting of the IVD Medical Devices Subgroup.