REPORT OF THE SG1 MEETING HELD FROM 14th TO 17th OCTOBER, 2008 IN OTTAWA, CANADA

Attendees

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

North America

Mark Melkerson – FDA, USA
Nancy Shadeed - Health Canada
Brenda Murphy – MEDEC, Canada
Marlene Valenti – AdvaMed, USA

Europe

Elke Lehmann – European Regulatory Authority
Peter Bischoff-Everding – European Commission
Peter Linders – COCIR/EMIG

Asia/Australasia

Mike Flood – TGA, Australia
Atsuchi Tamura – PMDA, Japan
Naoki Morooka – JFMDA, Japan
Tomomichi Nakazaki - JFMDA, Japan

Apologies

Cliff Spong - MIAA, Australia
Alfred Kwek – AHWP, Health Sciences Authority, Singapore
Daphne Yeh – AHWP, Industry representative, Chinese Taipei
Carl Wallroth – EUROM VI/EMIG
Hiroshi Yaginuma – MHLW, Japan

1 Welcome to the meeting and introduction of delegates

Ginette Michaud, Chair of SG1, welcomed SG1 members to the SG1 meeting and thanked Nancy Shadeed for inviting SG1 to Ottawa for the meeting.

The Chair welcomed Peter Bischoff-Everding of the European Commission to his first meeting where he is replacing John Brennan who recently joined EUCOMED, an industry federation.

The Chair provided apologies from five absent members of SG1 and described arrangements for the meeting.

Elke Lehmann reported that she is attending her last SG1 meeting because she has recently taken up a new position in the German MoH. The Chair thanked Elke for her significant contribution to the work of SG1 over many years and wished her well in her new role.

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

The Agenda was agreed after adding an item on the recent Steering Committee meeting and an update on both Latin America and the proposed recast of the European Directives for medical devices.

3 **Review of the report of the SG1 meeting held on the 8th to 11th July in Buenos Aires (*Document GHTF. SG1. N72*)**

The following actions have been completed:-

- SG1 members voted overwhelmingly to insert additional text into *SG1-N46:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices* and the document on the GHTF website was changed to suit.

- A note has been added to the GHTF website to explain the discrepancy between guidance given in the STED and in *Principles of Conformity Assessment for Medical Devices*.

- To consider applying to the Steering Committee for undertaking a New Work Item on the subject of Change Control and Technical Documentation and discuss in Ottawa if appropriate.

- Discuss with the other SGs whether there is a need to prepare a justification for a new Work Item on what should be understood by "technical documentation" (i.e. the entirety of technical documentation and not only its summary as described in the STED).

- The Chair has provided feedback from the meeting to Antonio Hernandez of PAHO.

- Modified text for the description of SG1's purpose has been provided to the GHTF website co-ordinator and the other Study Group Chairs.

- The presentations made during the meeting in Buenos Aires were circulated to SG1.

The following actions are carried over:

- AHWP delegates did not produce a report of activities for circulation to SG1.

- Circulate an updated list of SG1 members to the GHTF website co-ordinator.

Action: Chair

- The EU Commission will prepare a paper on topics related to *Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices* (i.e. batch release verification and the so-called Common Technical Specifications). When this has been completed and submitted to SG1, it will be discussed at a future meeting of the IVD Medical Devices sub-group of Study Group 1.

Action: Peter Bischoff-Everding

4 **Review of SG 1 accomplishments.**

Prior to the meeting, the Secretary had circulated the most recent version of the *Status of Active GHTF Study Group Work Programme* (SG1/N034R31) dated 2nd October 2008.

The Secretary reported progress as follows:-

a) GHTF/SG1/N046:2008 of February 26th, 2008: *Principles of Conformity Assessment of In Vitro Diagnostic (IVD) Medical Devices* has been updated to include new wording, as reported above.

b) SG1/N055R6 of 26th February, 2008 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer* has been endorsed by the Steering Committee as a Proposed Document and is on the GHTF website for public comment. Comments will be accepted until mid- December.

c) SG1/N065R06 of 8th July, 2008: *Registration of Manufacturers and other Parties and Listing of Medical Devices* was discussed with other Study Groups on the 14th October. The outcome of the discussion is included in the report of the joint meeting.

d) SG1/N068R01 *Essential Principles of Safety and Performance of Medical Devices* has been circulated to SG1 together with an updated list of comments. These will be discussed later in this meeting.

e) Comments received for consideration when SG1 revises its guidance entitled *Labelling for Medical Devices,* have been consolidated and circulated. These will be discussed later in the meeting.

f) Comments received for consideration when SG1 revises its guidance entitled *Information Document Concerning the Definition of the Term "Medical Device"*, have been consolidated and circulated to SG1. These will be discussed at a future meeting.

5 **Report from the In Vitro Diagnostic Medical Devices Subgroup**

The last meeting was in May 2008. The sub-group's major work item is drafting an IVD STED and the objective is to present it to the SG1 meeting in January 2009.

The next meeting of the sub-group will be held in November 2008.

The sub-group is also working on drafting a document in collaboration with SG5 on clinical studies for IVD medical devices.

If time allows the sub-group will consider the changes made to the revised document on *Labelling* as they relate to IVD medical devices.

If time allows the sub-group will consider the changes made to the revised document on *Essential Principles* as they relate to IVD medical devices.

Action: Nancy Shadeed

6 Report from the Asian Harmonization Working Party

The AHWP has not submitted a written report to update SG1 on progress within their region.

It was agreed that the Chair would set up a teleconference with the AHWP representatives to discuss the situation in their region and the AHWP Work Plan.

Action: Chair

7 Report from the Latin America

During discussion of the situation in Latin America, the Chair proposed that each of the Study Groups should offer 2 places (one regulator and one from industry) to the Latin American countries. The only stipulation was that each representative should liaise with the region he/she represented and not act in isolation. This suggestion was agreed by SG1.

Action: Chair to discuss with other SG Chairs

8 Status of Recast EU Medical Device Directives

Peter Bischoff-Everding provided a progress report on the EU Commission's project to "recast" the medical device directives. The presentation led to discussion of various points made during his presentation.

The "principle "drivers" for the project are:

- simplification;
- the separate action to revise some common elements of all EU New Approach Directives (the 3 current medical device directives are members of this "family");
- fill some gaps in the regulations;
- take account of GHTF guidance.

The primary objectives are to:

- maintain a high level of patient safety;
- ensure that there is a level playing field within the EU's internal market with no new national obstacles that hinder the marketing of medical devices within a Member State;
- maintain the competitiveness of the industry;
- encourage innovation/new technologies;
- increase the transparency of regulatory decisions made by a particular Member State e.g. providing access to reports generated in other countries;
- provide a robust regulatory framework suitable for the next 10 to 20 years.

Important elements of the work are to:

- consider merging some of the different legal texts (e.g., should IVD Directive be integrated with the MDD?)
- consider the pros and cons of the legal instrument being a 'regulation' rather than a 'directive';
- align the classification of IVDs to the GHTF model;
- determine whether invasive/implantable devices for aesthetic purposes should be treated as if they are medical devices;
- improve the designation and oversight of Notified Bodies and reduce different practices between Member States;
- Public authorities' involvement in assessment of certain MDs – when new technology is involved – when no standards are developed for certain devices – perhaps RAs should look at these devices and decide if this fits under their risk management; idea is not to replace the NB, but to look more broadly at a device grouping – horizon scanning purpose also;
- pool expertise;
- consider centralisation of decisions in certain areas rather than leaving this to the different Member States (e.g., vigilance, the classification of borderline devices).

The current timeline is:

- public consultation in May-July 2008;
- publication of summary of responses in Nov 2008;
- impact assessment (i.e. the social, economic and environmental impact of different policy options that may be employed, such as 'do nothing' / 'take a strict approach' / 'take a more limited approach') in early 2009;
- preparation of legal draft and adoption by the Commission in 1st semester 2009;
- legislative procedure in Council and the European Parliament during the period 2010 to 2011;
- adoption by Member States with a long transition period and final implementation in 2015.

During discussion it was noted that:

a) the use of the European databank (EUDAMED) by Member States will soon become mandatory. The databank will contain information regarding medical devices placed on the market and include vigilance reports. It will not immediately replace Member States notification or registration requirements since these are allowed under existing statutes.

The current work by the GHTF on registration and listing is not influencing the development of the EUDAMED database.

b) E-labelling is not part of the recasting exercise.

c) The European Union has no jurisdiction over reimbursement issues since it is a Member State responsibility. There is no harmonization within Europe.

d) It was suggested that the GHTF should consider the regulation of invasive/implantable devices for aesthetic purposes being a suitable subject for a new work item.

The Chair thanked Peter for his interesting presentation.

9 **Update on the Recent Steering Committee Meeting**

The Chair reported on aspects of the Steering Committee meeting held in Ottawa in early October.

- Global Regulatory Model - the plan is to submit a revised draft document to the Steering Group in December.
- Michelle Limoli of the FDA has joined the Steering Committee and has extensive knowledge of the ICH.
- GMDN – the Maintenance Agency has been approached suggesting a new governance structure and business model.
- Retrospective Report – it was decided the document should be posted on the GHTF website together with a response to it on behalf of the Steering committee.
- Co-operation with AHWP – status of the role of the AHWP continues to be discussed.
- Training Partnership ad-hoc WG – looking for volunteers to join it. Peter Linders and Mike Flood put their names forward as potential members.

Action: Chair to submit names to the Steering Committee

- SG working procedures – there had been discussion of different ways of working that would reduce the number of meetings and/or improve efficiency but no decision had been taken. An ad-hoc Group has been asked to make recommendations for process improvement.
- Glossary – will be posted on the GHTF website.
- Presentation by Matthias Neumann on the standard operating procedures for placing and maintaining a SG is in Maintenance mode – discussion continues.

10 **Update on Combination Products**

The Chair described the presentation she made to the Steering Committee and the e-mail she had sent to Michael Gropp of the Steering Committee on the subject. Other SGs had provided similar inputs from their own perspective.

Discussion:

- Need to define what is and, what is not, a "combination product".
- Need to describe a high level mechanism to allocate the different responsibilities of the regulatory participants.
- It was suggested that the major difficulty was not in deciding how the regulatory responsibilities are partitioned but in deciding the appropriate regulatory requirements for the non-medical device part of the combination (the medicine or biologic) for a particular device. This can not be accomplished without input from the other regulatory stakeholders.
- Many individual regulatory agencies have yet to clarify their individual procedures.
- Should we do more work on this before the 'Heads of Agencies' meet to discuss the topic?
- If new work items go forward, the subsequent work programme will be resource intensive.
- It is the task of the ad-hoc working group to establish the manner in which each Founding Member regulator handles different combination products.
- It was agreed that the first step was for the GHTF Steering Committee to give clear direction to the ad-hoc WG (and subsequently to SGs) in relation to the scope and priorities of its analysis.

The Chair will circulate the Steering Committee's ad-hoc group's document on the subject.

Action: Chair

Individual SG1 members may respond to Michael Gropp directly on any further issues that document raises and copy such information to the Chair, Vice-Chair and Secretary.

Action: SG1

11 **Revision of GHTF/SG1/N41:2005 *Essential Principles of Safety & Performance of Medical Devices***

The list of consolidated comments and the document revised at the last meeting have been circulated and provided the basis for the discussion that followed. The comments were discussed in turn and the document revised as agreed.

The revised document and updated list of comments will be circulated to SG1 by mid-November in order that they may consider the changes made.

Action: Secretary

After taking account of any feedback from SG1, the document will be forwarded to the Nancy Shadeed for discussion by the IVD sub-group during its November meeting.

Action: Secretary

Subject to the outcome of this meeting the document will be forwarded to the Steering Committee as a Proposed Document for public comment.

Action: Chair

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

The list of consolidated comments on this document has been circulated and provided the basis for the discussion that followed. The comments were discussed in turn and the document revised as agreed but due to a lack of time some comments remain outstanding.

A major change to the layout of the document was made in order to separate requirements for the label affixed to the medical device / from those supplied by the manufacturer / from those for IVD medical devices / from those on the external packaging.

The revised document and updated list of comments will be circulated to the IVD sub-group by mid-November in order that they may consider the changes made. Discussion will continue in Sydney.

Action: Secretary

Feedback from the IVD sub-group will be provided to the Chair and Secretary.

Action: Nancy Shadeed

Discussion of this document and outstanding comments will continue in Sydney.

Action: Chair

13 **Study Group 1 Communications Database**

The Secretary reported on the status of the Communications Database. The Latin American attendees have been added and a new version circulated to SG1.

14 Document Priorities and Timetable

Work in progress is as follows:

DOCUMENT TITLE	REFERENCE	STATUS	PRIORITY	TARGET FOR COMPLETION
Study Group 1 – New Documents				
Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer.	**SG1/N055**	**Proposed document available for public comment.**	**1**	**Final Document 2009/Q4**
Registration of Manufacturers and other Parties and Listing of Medical Devices	**SG1/N065**	**Comments on Working Draft discussed in Buenos Aires and revised document circulated.**	**1**	**Proposed Document 2009/Q1**
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/N063**	**Working Draft in preparation.**	**1**	**Proposed Document 2009/Q2**
Revision of SG1 Final Documents				
Essential Principles of Safety and Performance of Medical Devices (revised)	**SG1/N069**	**Comments received on GHTF/SG1/N041:2005 discussed in Buenos Aires and revised document circulated.**	**2**	**Proposed Document 2009/Q4**
Information Document Concerning the Definition of the Term "Medical Device" (revised)	**SG1/N071**	**Comments received on GHTF/SG1/N029:2005 to be considered in Ottawa.**	**3**	**Proposed Document 2010/Q2**
Labelling for Medical Devices (revised)	**SG1/N070**	**Comments received on GHTF/SG1/N043:2005 to be considered in Ottawa.**	**3**	**Proposed Document 2009/Q4**

15 Any Other Business

None.

16 **Date and place of next meeting**

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- Sydney, Australia from 20th to 23rd January, 2009, at the invitation of J&J. Further information on hotels and other matters will be circulated before the event.

Action: Chair

- SG1 will meet in Toronto in May from Sunday 10th to mid-day on Tuesday the 12th, as will the Steering Committee. The GHTF Conference will be held from Noon on Tuesday 12th May until 3:00 pm on Thursday the 14th. The date for the joint meeting of the SGs has yet to be agreed. A training session will be held after the Conference.

- Brussels in 13 – 16th October, 2009, possibly at the invitation of an Industry Association – to be confirmed.

SUMMARY OF ACTIONS

For the Chair

- Circulate an updated list of SG1 members to the GHTF website co-ordinator.
- It was agreed that the Chair would set up a teleconference with the AHWP representatives to discuss the situation in their region and the AHWP Work Plan.
- To discuss with other SG Chairs the proposal that each of the Study Groups offer 2 places (one regulator and one from industry) to the Latin American countries.
- To circulate the Steering Committee's ad-hoc group's document on combination products.
- To submit the names of Peter Linders and Mike Flood as available to join the Training Partnership ad-hoc WG.
- The revised document *onRegistration Registration of Manufacturers and other Parties and Listing of Medical Devices* will be forwarded to the Steering Committee as a Proposed Document for public comment.
- The revised guidance document on *Essential Principles* will be forwarded to the Steering Committee as a Proposed Document for public comment.
- To provide further information on the meeting to be held in Sydney.

For the Secretary

- To update *Status of Active GHTF Study Group Work Programme* (SG1/NO34) and SG1 Work Plan before the next meeting and reissue to members.
- The revised document on *Essential Principles* and the updated list of comments will be circulated to SG1 by mid-November in order that they may consider the changes made.
- The revised document on *Labelling* and updated list of comments will be circulated to the IVD sub-group by mid-November in order that it may consider the changes made.

For Nancy Shadeed

- To submit the revised document on *Labelling* for consideration by the IVD Medical Devices Subgroup.
- To submit the revised document on *Essential Principles* for consideration by the IVD Medical Devices Subgroup.

All Members of SG1

- Individual SG1 members may respond to Michael Gropp directly regarding any further issues raised by his paper on combination products (providing the Chair, Vice-Chair and Secretary with a copy of any communication).

EU Commission

- The EU Commission will prepare a paper on topics related to *Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices* (i.e. batch release verification and the so-called Common Technical Specifications). When this has been completed and submitted to SG1, it will be discussed at a future meeting of the IVD Subgroup of Study Group 1.