

Record of Discussions
20th GHTF STEERING COMMITTEE MEETING
11-13 May 2011
Brisbane, Australia

Participants: AUSTRALIA	Organization
Larry Kelly - Chair	TGA
Anne Trimmer – Vice Chair	MTAA
Andrea Kunca	TGA
Johan Brinch	MTAA (Cochlear Limited)
Linda Martin – Secretariat	TGA
Karen Bedford – Secretariat	TGA
Participants: CANADA	Organization
Supriya Sharma	Health Canada
Stephen Dibert	MEDEC
Participants: UNITED STATES	Organization
Lillian Gill	FDA
Michelle Limoli	FDA
Gail Costello	FDA
Janet Trunzo	AdvaMed
Michael Gropp	AdvaMed (Medtronic Inc)
Terrence Sweeney	MITA (Philips Medical Systems)
Participants: JAPAN	Organization
Toshiyoshi Tominaga	PMDA
Kentaro Azuma	MHLW
Hiroshi Ishikawa	JFMDA (Toshiba Medical Systems)
Shigetaka Miura	JFMDA (Sakura Seiki)
Participants: EUROPE	Organization
Laurent Sellès	European Commission
Matthias Neumann	Federal Ministry of Health - Germany
Joanna Kilkowska	–The Office for Registration of Medicinal Product Medical Devices and Biocidal Products (Poland)
Benny Ons	EDMA (BD Bioscience)
Nicole Denjoy (by telecom for Item 13)	COCIR
John Brennan	Eucomed
Participants: STUDY GROUP CHAIRS	Organization
Isabelle Demade (SG2) (by telecom)	European Commission
Egan Cobbold (SG3) (by telecom)	Health Canada
Other participants: LIAISON BODIES AND OTHERS	Organization
Joanna Koh	Singapore HSA and AHWP
Takako Nakayama (observer)	PMDA

Apologies	Organization
Jean Yves Carentz	Eucomed (Stryker)
Francois Simondet	EUROM VI (Medical Technology)(Air Liquide Sante' International)
Rohan Hammett	TGA

1. Welcome

L Kelly welcomed all members to the Steering Committee (SC) meeting. J Brennan, A Kunca and T Nakayama were welcomed to their first SC meeting. J Koh, from Health Sciences Singapore representing the Asian Harmonization Working Group and the ASEAN MDPWG was welcomed as an observer.

2. Approval of the Agenda

The proposed Agenda was approved. An update from M Limoli on the UN secretariat's proposed treaty on the banning of mercury and its impact on the medical device sector was added to the agenda under 'other business' (Item 17).

3. Update Steering Committee Membership List and Contact Details

SC members were asked to update the contact list and return the document with any changes to the Secretariat.

Action Item:

- *GHTF Secretariat will post the revised and updated list to the website.*

4. Approval of Record of Proceedings from March 2011 Steering Committee Teleconference

The draft minutes from the March teleconference had been circulated to members. The following changes were suggested:

- T Sweeney to represent MITA rather than AdvaMed.
- M Neumann asked to note that technical problems had prevented the European regulators from participating in the teleconference

The minutes were accepted.

Action Item:

- *GHTF Secretariat will post the minutes on the secure website.*

5. GMDN Update

J Trunzo updated the Steering Committee on activities since the last meeting. One of the goals of the new governance structure for GMDN was to make the system more internationally accepted. In line with this the Board of Trustees has commenced communications with IHTSDO about pursuing opportunities to integrate GMDN into SNOMED-CT. Several meetings have already occurred, with a proposed 6 to 9 months timeframe for completion of this project. The Board of Trustees of the GMDN Agency unanimously approved this approach, which is seen to be very positive collaboration. It is hoped that a final decision will be made quickly.

An update was also provided on the WHO informal consultation on nomenclature held in Geneva. Participants included representatives from the GMDN agency, AHWP, IHTSDO, GHTF and industry. It was a good discussion and was an opportunity for WHO to hear the support for use of the GMDN system. Presentations from government agencies were very helpful.

L Kelly noted that he had recently received an update from the GMDN Agency, which advised of an increased uptake of the GMDN system, including across Europe.

On behalf of the SC, the Chair thanked Janet for her considerable work in relation to GMDN.

6. Revision of GMDN website statement

An agreed statement in support of the GMDN system had previously been posted on the website. Some suggested amendments were subsequently put forward. It was agreed that the current statement adequately addresses concerns previously raised, and will not be amended at this time.

7. GHTF Glossary revised version

A revised version of the Glossary had been presented to the March teleconference. It had been agreed to further discuss duplicate definitions. There was a discussion on the need for a glossary and the best way to ensure it is maintained as future documents are developed.

It was agreed that a systematic review should not be undertaken at this stage but rather the individual definitions should be addressed as each document comes up for review. It was agreed that the Secretariat would prepare the document for publishing on the website, with an introductory note explaining why there may be variances in definitions, streamlining references, and referring the reader to the originating document for context.

Action Item:

- *Secretariat to prepare the revised glossary for publication, with explanatory note.*
- *Study Group Chairs to be advised to use existing glossary definitions in any papers currently in preparation.*

8. Update of Main Developments in Founding Members' Regulatory Systems

Canada

S Sharma provided an update from the Canadian regulator perspective. She noted there had recently been a national election, with a majority government now in place. This change may have an impact on the modernization agenda. She was hopeful that the modernisation of the Food and Drugs Act will continue to move forward, but stated that non legislative options were also being pursued.

As of 1 April 2011 new user fees came into effect, which was the first update in 14 years. This was the result of a 5 year project, with extensive consultation and parliamentary submissions. This new user fee regime also signals a change in how performance is measured and reported, with penalties through fee reductions if targets are not met. It also provides built-in incentives for submission planning as average performance time is reported. Increased revenue has provided for increased scientific staff. It was noted that there has also been some renewed interest in the reprocessing and refurbishing of devices.

Europe

L Selles provided an update from the European regulator perspective. He noted that a Formal Objection has been launched in relation to 11 ISO Standards. The major focus of the objection is that the EN versions of these standards claim a broader coverage of legal requirements than what is assured in reality. It is likely that a simple modification of the EN version of the standard is sufficient to rectify the issue. There are also some content inconsistencies to be noted, for example in ISO 14971 (risk management) and ISO 13485 (quality management). Again in the case of any inconsistencies, Europe will strive for a solution primarily for the EN version, however, in some instances it may result in Europe suggesting modification of the ISO versions. Overall, the major purpose of the Formal Objection is to invite the European standardization bodies to work more precisely in terms of European legal requirements in order to strengthen the standardization system.

A high level conference dealing with "The role of medical technology innovation and regulation" took place in Brussels on 22 March 2011. The conclusions were endorsed by a Council session in May.

Some of the main conclusions were that:

- Innovation should be increasingly patient- and user-centred and demand-driven *e.g.* through increased involvement of patients, their families and users in the research, innovation and development processes in order to improve individual health and quality of life;
- Innovation should be a more integrated process, building on experience and knowledge acquired in other sectors, such as IT and the development of new materials;
- Innovation should be based on a holistic approach (*i.e.* it should take into account the whole healthcare process and all patients' needs - physical, social, psychological, etc);
- Innovation should focus on public health priorities and healthcare needs *inter alia* in order to improve cost-effectiveness;

- There is a need to increase research in order to identify public health needs and priorities still to be addressed and to better define patients' medical needs;
- Future legislative actions in this area must, when adapting the European regulatory framework, specifically aim to increase patients' safety while at the same time creating a sustainable legislative framework favourable to medical device innovation that can contribute to a healthy, active and independent life.
- As the medical device sector is a global one, a stronger coordination with international partners is desirable in order to ensure that medical devices are manufactured according to high safety requirements worldwide; and
- It should be considered how to address regulatory gaps in the system, for instance in relation to medical devices manufactured utilising non-viable human cells and tissues.

The preparation of the recast proposal of the EU directives is underway. Proposals are expected in the spring of 2012.

Japan

K Azuma provided an update from the Japanese regulator perspective. He advised that an ad hoc Advisory Council review commenced in March 2011 which will consider medical product safety measures, with the main focus on drug safety. This ad hoc Advisory Council includes industry representatives, regulators, patient groups, academia and others. Discussions are still ongoing to assist in determining the contents of the review. Consequential draft amendments are expected in spring next year. He indicated he would provide a future update, particularly on the medical devices aspects.

United States

L Gill provided an update from the US regulator perspective. She noted that the Institute of Medicine report on the 510k process is expected in June/July. She also noted that a series of discussions had been held with manufacturers and developers of products around innovation. This is a new initiative where regulators are becoming involved in accelerating the development of new medical devices. One direct guidance has been issued, which is guidance for industry and FDA staff in relation to processing and reprocessing of medical devices in the healthcare setting. It is an update and clarification on the content and review procedures concerning the labelling instructions and more detail on the validation process. This updated guidance does not apply to the reprocessing of single use devices.

It was also noted that the FDA have announced some internal changes and reorganisations within the medical device centre for improved consistency and efficiency. For example, the Centre is proposing to consolidate the radiation/radiology programs that are currently located in a number of offices.

Australia

L Kelly provided an update from the Australian regulator perspective. He briefly updated members on the TGA21 reforms outlined at previous meetings. He also noted that the new TGA website was launched on 4 May, which provides for enhanced navigation. In addition, a transparency review is underway reviewing how the TGA's business can become more transparent. This report is due in June 2011. New business processes within the prescription medicine stream have now been implemented. Other reviews throughout TGA include advertising, recalls procedures, complementary medicines and medical devices. An outline of

the medical devices reforms was provided, which includes reclassification of joint implants from Class IIa to III; arrangements involving third party CABs; amending the way device information is held in the ARTG; and the provision of device-related information on the TGA website.

Dr Kelly also provided a statistical update from the NCAR secretariat.

Action Item:

Secretariat to circulate a copy of Dr Kelly's presentation to SC.

STUDY GROUP ITEMS

9. SG1/N70:2011 Label and Instructions for Use for Medical Devices – consideration for progression as a Final Document

This paper was presented to the SC for their consideration. This update results from a periodic review of the 2005 Final Document. One concern was raised about the removal from the revised text of the statement about the provision of paper versions of instructions for use. This was a late comment and had not been considered through the usual document development process.

It was agreed that a statement of the concern should be forwarded to Study Group 1, with a request that they come back to the Steering Committee with a proposed way forward.

Action item:

Secretariat to forward a summary of the concerns to Study Group 1 for their consideration and proposal of a solution.

10. SG2&5 N5R9 Reportable Events During Pre-Market Clinical Investigations - consideration for progression as Proposed Document

Comment was invited on this paper. It was noted that some comments had been received late and hence had not been incorporated. It was proposed that editorial changes would be made to the document prior to it being posted, with the more significant comments considered during the official comment period.

Some concern was expressed that not all Study Group 2 and 5 members had been included in the clearance process. L Kelly undertook to ask that both groups be fully included in the future clearance process.

Action item:

Minor editorial changes to be included prior to posting on the website for a 6 month comment period. Study Group 2 and 5 to be fully involved. It was agreed to post the document on the website with a 6 month comment period.

11. Training for Post Market Surveillance including the National Competent Authority Report Exchange Programme – reconsideration of proposed internal document

The document had been included in the meeting papers. It was discussed and confirmed that this was an internal training document for Study Group 2, but should not be a public document. It was noted that if a broader paper is needed in the future, it can be further developed at that time. A vote of thanks to be sent to the Chair of Study Group 2.

Action Item:

Secretariat to pass on to Study Group 2 Chair the thanks of the SC.

AD HOC WORKING GROUPS AND OTHER UPDATES

12.1 Regulatory Change Management AHWG Update

The delay in the development of the document was noted. There was a discussion on the status of the document, with differing views as to how much further work would be required to finalise it, and its value.

The Steering Committee agreed to review the document during this meeting and then decide whether to continue with the work. Discussion on this item was continued as part of Item 16.

12.2 Unique Device Identifiers AHWG Update

L Selles provided an update on the work of the UDI AHWG. He noted that the comment period of the document had closed, with 21 submissions received. A two day meeting had been held to review the comments and amend the document as appropriate. He noted that it had been an effective AHWG.

The purpose of UDI is to facilitate and enhance post market safety and surveillance as well as contributing to reducing critical errors. He noted that it was a complex paper to produce which may not be apparent to the reader. A hard copy of the revised document was distributed at the meeting.

A suggested work plan was outlined. This included the next steps of implementation and database decisions, and development of a roadmap for delivery for a final guidance document by the end of 2012, noting that it would require a larger group to progress it.

The Chair summarised that the process for the SC is that the document will be electronically distributed to them for consideration at a future meeting (as the end of phase 1 of the work). A New Work Item would then be required to progress what would become phase 2.

The Chair expressed the SC's thanks to the members of the AHWG for their significant work.

Action Item:

- *Secretariat to circulate an electronic copy of the revised paper for consideration at the next teleconference.*
- *L Selles to prepare a New Work Item proposal with timeline in relation to phase 2 of the work.*

12.3 GHTF Regulatory Model AHWG

The Final Document was posted on the website, following consideration at the previous teleconference, the incorporation of some editorial changes and an additional two week comment period for members. There had been comments about the structure of the document, which will be considered as part of a future review. It was suggested all other comments are also to be considered at that time.

13. Standards Rapporteur Update

N Denjoy, in her role as the Standards Rapporteur, provided a detailed update by teleconference. Having liaised with Study Groups, it was noted that the list of ISO technical committees which relate to the work of GHTF was complete and accurate. It was noted that there is a proposal for ISO TC62 to expand its scope to include software and communication. It was noted that the Chair of TC210 has written to the Chair of GHTF in relation to a review of ISO 13485.

N Denjoy made some observations for the Steering Committee to note. Firstly she noted that the ISO definition of labelling is different to that in the GHTF's N70 document and flagged that this could usefully be reviewed at the next revision. It was also noted that given the change in Essential Principles (N68) it may be appropriate to bring this to the attention of ISO (in relation to their TR16142).

The importance of maintaining consistency with ISO standards was acknowledged.

Action Item:

Secretariat to circulate the Rapporteur's presentation and report to the SC.

14. ISO

14.1 ISO liaison, update on SG3 and ISO TC210 liaison and Study Group 3 update

E Cobbold joined discussion on this item by teleconference. He reported that there had been a joint Study Group 3/TC210 meeting, which had agreed to collaborate on a review of ISO 13485. A new work item proposal has been drafted for consideration by ISO members, with a user survey seeking input as to what updates would be required. Once finalised it will be posted on the ISO website with a 3-4 month comment period.

A letter had been received by the GHTF Chair from Dr E Hoxey, Chair of TC210, advising of the review. It was noted that the revision of ISO 9001 may impact on the review of ISO 13485.

E Cobbold also provided an update on the work program of Study Group 3, in particular the timeline for document N19, which is scheduled to be considered by the SC around October 2012 at the earliest. Study Group 3 was asked to continue work on their work program, including their liaison with TC210, but to note the desire of the SC to have work items finalised by the end of 2012.

14.2 Update on liaison relationship between GHTF and ISO

Covered under Item 14.1.

15. Update on AHWP activities

J Koh presented an update on the work of AHWP, in particular on AHWP membership and its Technical Committees. It was noted that a permanent secretariat was set up in December 2010. An update was also provided on the collaboration status of GHTF Study Groups and AHWP Working Groups. The next AHWP meeting is scheduled for November 2011 in Bali. At this meeting the next AHWP Chair will be elected, for a three year period.

On behalf of AHWP, Ms Koh sought clarification on the future maintenance of GHTF guidance documents and the current collaborative work, given recent announcements about the future directions of GHTF. In response, the Chair provided an outline of the current thinking which was that GHTF documents would continue to be supported and that collaboration with AHWP would be maintained.

OTHER BUSINESS

16. GHTF strategic directions (closed session)

As part of a discussion on the future directions of GHTF, there was a closed session discussion. This included a review of the current Study Group and Ad Hoc Working Group work plans. It was agreed that:

- B Ons will come back to the SC, providing a history/background on the clinical performance document under preparation by the IVD subgroup and timelines for its completion.
- E Cobbold will be asked to provide the SC with an indication of whether the N19 can be progressed to Proposed Document stage by mid 2012
- UDI Ad Hoc Working Group Phase 1 work and proposed Phase 2 plan to be considered at the next Steering Committee meeting
- The work of the Change Management Ad Hoc Working Group will not be continued. The document is to be archived in its current internal draft form for possible progression at a future time.

Action items:

- *B Ons to provide background/history and timeline to SC in relation to the IVD document*

- *Secretariat to request a response from Study Group 3 Chair regarding timeline for N19*
- *Secretariat to pass on Steering Committee's decision to those who have contributed to the work to date on the Change Management document.*
- *Secretariat to check the website is updated to reflect SC decisions.*

There was also a discussion on the announced new directions for GHTF and the possible structure for the new forum based on some very preliminary discussions by regulator members. Industry representatives also made a presentation to SC members, including details of their concerns about ensuring appropriate industry input to the harmonization goal.

It was noted that the structure and name for the new forum have not yet been decided, nor the operating procedures determined.

A meeting outcome statement was agreed for publication on the GHTF website.

17. Other items

17.1 Update on UN Secretariat Treaty on banning of mercury and impact on medical devices

M Limoli updated members on a UN endeavour to create an international treaty to ban the use of mercury, as used in pharmaceutical, medical devices and cosmetic products. She noted that the US had been involved since the commencement of negotiations. It was also noted that to this stage in negotiations participants had primarily been environmental experts, rather than health regulators or industry. She encouraged all members to become involved in negotiations due to the significant implications in terms of potential bans or phasing-down of use. A wide range of products could be affected. The next meeting is scheduled for 30 October, with attendance applications available on the UN website.

In closing the meeting the Chair offered a vote of thanks to the Secretariat for their hard work during the last 18 months. Thanks were also offer to MTAA, and in particular Anne Trimmer and Joanne Franks , for hosting the meetings under the Australian Chair.

It was agreed the proposed October 2011 meeting would not proceed. A teleconference will be organised with details to be provided by Japan. It was proposed that the next face to face meeting be held in April or May 2012 in Japan.

Meeting close.