

Record of Discussions
21st GHTF STEERING COMMITTEE MEETING
17-19 April 2012
Kyoto, Japan

| Participants: JAPAN | Organization |
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| Kazunari Asanuma – Chair | MHLW |
| Kazuo Ogino – Vice Chair | JFMDA (Nihon Kohden Corporation) |
| Kentaro Azuma | MHLW |
| Atsushi Tamura | PMDA |
| Tomomichi Nakazaki | JFMDA (Allergan Japan K.K.) |
| Shigetaka Miura | JFMDA (Sakura Seiki) |
| Madoka Murakami - Secretariat | PMDA |
| Participants: AUSTRALIA | Organization |
| Larry Kelly | TGA |
| Participants: CANADA | Organization |
| Nancy Shadeed (for Don Boyer) | Health Canada |
| Participants: UNITED STATES | Organization |
| Kimberly Trautman | FDA |
| Michelle Limoli | FDA |
| Michael Gropp | AdvaMed (Medtronic Inc) |
| Janet Trunzo (by telecom for Item 5) | AdvaMed |
| Terrence Sweeney (by telecom) | MITA (Philips Medical Systems) |
| 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) |
| Francois Simondet (by telecom) | EUROM VI (Medical Technology)(Air Liquide Sante' International) |
| Nicole Denjoy (by telecom for Item 8) | COCIR |
| 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 | AHWP (Singapore HSA) |

| Apologies | Organization |
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| Andrea Kunca | TGA |
| Anne Trimmer | MTAA |
| Don Boyer | Health Canada |
| Brian Lewis | MEDEC |
| Jean-Claude Ghislain | AFSSAPS |
| Jean Yves Carentz | Eucomed (Stryker) |

1. Welcome

K Asanuma welcomed all members to the Steering Committee (SC) meeting and thanked the previous members of the SC, Ms. Gail Costello and Mr. Stephen Dibert, for their hard work and contributions.

2. Approval of the Agenda

The proposed Agenda was approved without any changes.

3. Review of GHTF Steering Committee Membership List and Contact List

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

Action Item:

The secretariat to post the updated list on the GHTF website.

4. Approval of Record of Proceedings from January 2012 Steering Committee Teleconference

The draft minutes from the January teleconference had been circulated to members. The minutes were accepted without any changes.

Action Item:

GHTF Secretariat to post the minutes on the secure website.

5. GMDN Update

J Trunzo updated the Steering Committee on activities since the last meeting. The numbers of GMDN users are rapidly increasing and the GMDN Agency plans to hire additional term developers. A Phase 1 cooperation agreement with International Health Technology Standards Development Organization (IHTSDO), which will place GMDN terms into the IHTSDO Systematized Nomenclature of Medicine--Clinical Terms (SNOMED CT), is nearly completed.

Discussion on a possible phase 2 cooperation agreement, including financial matters will start on after the phase 1 agreement is completed.

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

6. GHTF Glossary revised version

A revised version of the Glossary including definitions from GHTF/AHWP-GRM/N1R13, SG1/N63, SG1/N071 and GHTF/AHWG-UDI/N2R3 was provided.

There was a proposal that approval of the revised Glossary should be postponed because changes arising from final documents newly approved in this meeting are necessary. It was agreed to finalize the Glossary at the SC meeting in Tokyo in October 2012.

It was also suggested to remove references to national regulations, national standards and international standards.

The SC agreed that references to national regulations and standards, and international standards, should be removed from the each definition and a note to refer to the original GHTF documents should be added.

Action Item:

- *Secretariat to prepare the revised glossary for publication based on the finalized documents and the proposed documents to be finalised, removing the national regulations and national standards and adding an explanatory note.*

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

7.1 Australia

L Kelly provided an update from the Australian regulator perspective, which includes:

- Review of current regulatory system for medical devices
- Up-classification of orthopaedic joint replacement implants
- Expansion of scope of conformity assessment reviews by TGA
- Discussion on joint regulatory authority with New Zealand

7.2 Canada

N Shadeed provided an update from the Canadian regulator perspective on behalf of D Boyer, which includes:

- Revision of the Food and Drugs Regulations including the Medical Device Regulation
- Increase in user fees and decrease in number of applications
- Guidance on the content of quality management system audit reports
- Analysis of the regulatory authorities regarding reprocessing of single-use devices and refurbished devices.
- Metal-on-Metal Hip Implants Notice
- Implementation of the STED

7.3 Europe

L Selles provided an update from the European regulator perspective, which includes:

- Review of premarket process and postmarket surveillance following the PIP breast implant scandal
- Implementation of UDI system
- Revision of the Medical Device Directive

7.4 Japan

K Azuma provided an update from the Japanese regulator perspective, which includes:

- Expansion of PMDA
- MHLW/PMDA's new program, such as pharmaceutical affairs consultation on R&D and human resource exchanges between PMDA and research institutions
- Revision of the Pharmaceutical Affairs Law
- Transition to third party certification for all class II medical devices

7.5 United States

K Trautman provided an update from the US regulator perspective, which includes:

- FDA's discussion on Metal-on-Metal hip replacement
- Public meeting regarding strengthening the national medical device postmarket surveillance system
- Publication of the guidance document "Factors to Consider When Making Benefit-Risk Determination in Medical Device Premarket Approval and De Novo Classifications."
- Launch of the Innovation Pathway 2.0.
- Agreement in principle on medical device user fees
- Draft guidance regarding in vitro companion diagnostic devices

8. Standards Rapporteur Update

N Denjoy, in her role as the Standards Rapporteur, provided a detailed update by teleconference. The written report was provided after the meeting.

N Denjoy indicated that there were some updates on ISO/TC 210, TC 62, TC 173, and TC 84. Especially, TC 62 has approved a new scope of the TC 62 to include software used in healthcare. TC 62 will have a meeting in September 2012 in Nuremberg.

In relation to standards implementation in the regulatory framework, it was reported that CEN-CENELEC agreed on a draft common format for Annex ZA/ZZ and the standard IEC 60601-1; Ed 3 will be applied from June 2012.

N Denjoy also reported on recent trade issues in BRIC countries. The Chinese International Medical Device Forum (CIMDR) will be held in Beijing on September 4-7, 2012. A Customs Union between Russia, Belarus and Kazakhstan is planning a draft regulation that a registration in one country will be valid in the other two countries.

N Denjoy advised that the standards rapporteur activity should be transferred to the IMDRF.

Action Item:

STUDY GROUP ITEMS

9. Study Group work – Progress reports and remaining items/revisions to be considered by the IMDRF

9.1 Study Group 1

N Shadeed provided an update based on the written report of the work of SG1. She reported that public comments on PD/N078R3 – Principles of Conformity Assessment for Medical Devices (for Final Document) and PD/N077R4 – Principles of Medical Device Classification (for Final Document) were reviewed. These documents will be circulated for finalization in July. The report was noted by the SC.

9.2 Study Group 2

I Demade provided the update on the work of SG2 by telephone. SG 2 had not received any comments on the proposed document regarding the NCAR exchange program and now is preparing the final document to be published.

I Demade reported that PD/N87R7 - Post Market Surveillance: An XML Schema for the electronic transfer of adverse event data between manufacturers, authorised representatives and National Competent Authorities (for Final Document) and PD/N111R9 - Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions (for Final Document) would be circulated before early-June to the SC after the SG2 meeting in May 2012 in Chicago. The SC agreed that these documents should be considered for finalization in July.

9.3 Study Group 3

E Cobbold provided an update based on the written report of the work of SG3 by telephone. He reported that internal comments on WD/N19 – Medical Devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange (for Proposed Document) were reviewed and the document was circulated to the SC for discussion in the SC meeting in Kyoto. The report was noted by the SC.

9.4 Study Group 4

No update due to no activity.

9.5 Study Group 5

B Ons provided an update on SG5 activities on behalf of S Ludgate. He reported that PD/N6R3 - Clinical Evidence for IVD Medical Devices - Key Definitions and Concepts (for Final Document) and PD/N7R4 - Clinical Evidence for IVD Medical Devices - Scientific Validity Determination and Performance Evaluation (for Final Document) were to be discussed at the IVD subgroup meeting on May 2012 in Dublin. He also noted that PD/N8R3 - Clinical Performance Studies for In Vitro Diagnostic Medical Devices (for Final Document), which was in the public comment period until June, was to be discussed at the meeting scheduled for July in Singapore. These documents will be circulated to the SC in August.

10. SG1/N71:2012 Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’ – consideration for progression as a Final Document

N Shadeed spoke to the document.

The document was approved as a Final Document.

Action item:

The secretariat to post the Final Document on the GHTF website.

11. SG3(WD)/N19 Medical Devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange – consideration for posting as a Proposed Document

E Cobbold spoke to the document.

There was a discussion on the frequency of audits. The SG was asked to add a note which states that the frequency of audits in the document was based on the ISO guidance document and would have to be adjusted according to the regulatory authority’s requirements. The SC agreed to approve the document without any changes regarding the timeline. It was agreed that SG3 will discuss the SC’s comment regarding frequency of audits after the public comment period ends.

The document was approved as a Proposed Document for a 2 month public comment period.

Action item:

The secretariat to post the Proposed Document on the GHTF website with a 2 month public comment period.

AD HOC WORKING GROUPS AND OTHER UPDATES

12. Update on the GHTF Conference

T Nakazaki updated the SC members on the draft program for the GHTF Conference 2012 in Japan. The Conference will be held on Wednesday, October 31st and Thursday, November 1st. The SC meeting and GHTF Conference will be held at the Tokyo Midtown Conference in Tokyo, Japan. It was also informed that registration for the conference will be opened in June or July. Following discussion, the SC agreed the revised program of the conference.

Action item:

The secretariat to circulate the revised program to the SC and post it on the GHTF website.

13. Update of the “History of GHTF”

S Miura stated that he would update the short history of the GHTF on the GHTF website and also he would make a presentation on the history of GHTF at the GHTF Conference. It was suggested to collect photos of the SC and SGs and to project them during breaks in the conference.

Action item:

The secretariat to ask the SG Chairs to provide photos for the conference.

14. Update on AHWP activities

J Koh delivered a presentation which provided SC members with feedback from the November 2011 AHWP TC meeting in Bali, and provided an update on AHWP activities. She also provided the proposed issues for the AHWP Strategic Framework such as expansion of the AHWP membership, harmonizing in key areas based on the GHTF principles, supporting WHO efforts, etc.

The 15th AHWP TC meeting will be held on 5-7, June 2012 in The Philippines and the 17th AHWP meeting will be held on 2-6, November 2012 in Chinese Taipei.

OTHER BUSINESS

15. Update on the International Medical Device Regulator Forum (IMDRF)

15.1 Formation and operation of IMDRF and outcome of the February 2012 IMDRF meeting in Singapore

L Kelly reported that Management Committee (MC) members of the IMDRF agreed to five items for initial work by the IMDRF: 1) a Review of the NCAR System, 2) Roadmap for Implementation of UDI Systems, 3) Medical Device Single Audit Program, 4) Recognized Standards, 5) Regulated Product Submission. The IMDRF secretariat is preparing the operating procedures for the IMDRF. The next IMDRF meeting will be held in Sydney in September.

15.2 Update on Unique Device Identification (UDI) Working Group

L Selles updated the SC members on UDI Working Group activity. The UDI WG will make a roadmap for UDI implementation and will present at the MC meeting in Sydney in September. The roadmap will have three sections, 1) Landscape, 2) Development of a Charter, 3) Identification of the Different Aspects of Implementation.

16. GHTF Transition planning (closed meeting)

16.1 Review of SG workplans and remaining items/revisions to be considered in the IMDRF

It was confirmed that the ongoing GHTF work items could not be transferred to the IMDRF in consideration of the differences in participation. The SC agreed the secretariat will urge the SGs to finalize their work items in time for consideration at the next SC meeting in October.

16.2 Transition of GHTF documents to IMDRF

It was suggested to put statement on both the GHTF website and the IMDRF website that the GHTF guidance documents will remain valid but will be transferred to the IMDRF website.

L Kelly noted that the IMDRF would discuss the maintenance system for GHTF guidance documents, including possible future revisions of documents by the IMDRF.

Action Item:

Secretariat to prepare the statement to post on the GHTF and the IMDRF website.

16.3 GHTF Website maintenance

It was agreed that the GHTF website will be transferred from FDA to TGA including the domain name of the website. It was pointed out that it will be necessary to consider which items on the GHTF website will be retained.

Action Item:

The Secretariat to make a draft list of the items in the GHTF website to be retained and transferred to the IMDRF website.

The Secretariat to ask SC members and SG chairs which items on the website to be retained after termination of the GHTF.

16.4 Transition of MOU arrangement with ISO

Following discussion on the transition of the current MOU between GHTF and ISO, the SC agreed to transfer the MOU agreement with ISO, including category A liaison status to the ISO/TC 210, to the IMDRF. It was agreed that the GHTF Chair will write a letter to the IMDRF Chair proposing that IMDRF take over the MOU between GHTF and ISO.

Action Item:

The chair to send a letter to the IMDRF chair, regarding transfer of the MOU between GHTF and ISO.

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| REMINDERS |
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- **19 July 2012** : GHTF SC 23rd Teleconference
- **29 -30 October 2012** : GHTF SC 22nd Meeting (Tokyo, Japan)
- **31 October-1 November 2012** : GHTF 13th Conference (Tokyo, Japan)