GLOBAL HARMONISATION TASK FORCE

STUDY GROUP 5 – CLINICAL EVIDENCE

Minutes of Meeting Monday 5 February to Wednesday 7 February 2007

Doubletree Alana Hotel
1956 Ala Moana Boulevard, Honolulu, Hawaii, USA

A meeting of the Global Harmonisation Task Force (GHTF) Study Group 5 was held at the Doubletree Alana Hotel, Honolulu, Hawaii, USA on 5-7 February 2007.

Attendees at the meeting were:

Susanne Ludgate, MHRA, UNITED KINGDOM (Chair)
Greg LeBlanc, MEDEC, CANADA
Barbara Westrum, AdvaMed, USA
Guy Hibbins, TGA, AUSTRALIA
Herbert Lerner, FDA, USA
Atsushi Tamura, PMDA, JAPAN
Johan Brinch, MIAA, AUSTRALIA
Peter Rattke, COCIR, AUSTRIA
Mitchell Krucoff, Duke University Medical Center/FDA, USA
Yoshihiro Noda, JFMDA, JAPAN
Kazuhiro Sase, Juntendo University Medical School/MHLW, JAPAN
Maria Carballo, Health Canada, CANADA
Wolfgang Ecker, Ministry of Health, Family and Youth, AUSTRIA
Mary Anne Hinkson, NEMA, USA
Isabel Scuntaro, Swissmedic, SWITZERLAND
Christophe Bailleul, Eucomed, BELGIUM

Item 1 Welcome and Introductions

The group welcomed Dr. Susanne Ludgate as the new Chair of the committee. Dr. Ludgate, a pre-existing member of the group, was thanked for her willingness to step into the role of Chair given Dr. Graeme Harris's resignation from the position. Hearty thanks were offered to Dr. Harris for his past leadership and the supreme effort he put forth to get the group successfully underway.

Several new members of the group were introduced, including: Barbara Westrum (AdvaMed), replacing Dr. Patricia Garvey who has retired; Maria Carballo (Health Canada), replacing Dr. Keith Butler who has retired; and Isabel Scuntaro (Swissmedic), filling the vacancy left when Maria Teresa de Martin resigned from the group. It was also mentioned that Benny Ons will be replacing Klaus-Dieter Willamowski, who has

retired, as the EDMA representative at the next meeting. Benny was unable to attend this meeting due to a pre-existing scheduling conflict.

Item 2 Adoption of Agenda

There were no changes to the draft agenda circulated in advance of the meeting. Thus, the following agenda was adopted:

1. Welcome and Introductions
2. Adoption of Agenda
3. Discussion of Minutes from Previous Meeting and Matters Arising
4. Discussion of Public Comments for Key Terms and Definitions Document
5. Discussion of Public Comments for Clinical Evaluation Document
6. Development of Draft of Clinical Investigations Document
7. Update on formation of Subcommittee for Work on Clinical Evaluation for IVDs
8. Other Business
9. Next Meetings

Item 3 Discussion of Minutes from Previous Meeting and Matters Arising

No significant issues or "matters arising" were discussed. The comment period for the Key Definitions and Concepts (N1) and Clinical Evaluation (N2) document has closed and a discussion of the comments and finalization of these documents are an agenda item for this meeting.

Item 4 Discussion of Public Comments for Key Terms and Definitions Document

The comments received in response to the posting of the Proposed Document were circulated to the group and reviewed. Those that were considered appropriate were incorporated into the document. Once all comments had been addressed, the group was satisfied that the document was ready for submission to the Steering Committee for promulgation as a Final Document.

Item 5 Discussion of Public Comments for Clinical Evaluation Document

The comments received in response to the posting of the Proposed Document were circulated to the group and reviewed. Those that were considered appropriate were incorporated into the document. Once all comments had been addressed, the group was satisfied that the document was ready for submission to the Steering Committee for promulgation as a Final Document.

Item 6 Development of Draft of Clinical Investigations Document

The group continued development of the Clinical Investigations Document. Following the group's deliberations, it was agreed that the draft was ready to be circulated for jurisdictional consultation, with the resulting comments to be discussed at the next meeting.

Item 7 Updated on the Formation of Subcommittee for Work on Clinical Evaluation for IVDs

There was some initial discussion surrounding the definitions of IVDs and similarities/differences amongst the various jurisdictions. This was followed by a conversation regarding what Clinical Evaluation really encompassed when discussing IVDs, and the expertise of SG5 to address the issue. There was also discussing around the concepts of performance evaluation, clinical utility and clinical validity. It was determined that in order to stay within the mandate of SG5 and provide useful guidance, that the document to be developed should focus on diagnostics for which a clinical claim is being made – that is, where the manufacturer is indicating that the data provided by the diagnostic device provide direct clinical information (for example, that a test indicates whether or not the individual being tested is pregnant versus only providing an hCG level which must then be interpreted).

Several volunteers were solicited to work with members of the IVD Subgroup of SG1 at the upcoming joint meeting in May to work, in detail, on adapting the current SG5 Clinical Evaluation document to address IVDs.

Item 8 Other Business

Discussion of "other business" included:

- Nomination of Secretariat Position for SG5
- Letter from Dr. Ziegler of ISO TC194 WG4
- Potential New Work Items

The first item involved discussion of the administrative functions of the group and providing some administrative support to Dr. Ludgate as she steps in as Chair. It was agreed that Greg LeBlanc would assist in this regard in his capacity as Vice-Chair, until such time as another volunteer stepped forward.

The second item involved the letter to Kimber Richter by Dr. Ziegler, the Convenor of ISO TC194 Working Group 4 seeming to indicate that ISO TC194 is hoping to work with the ICH with a view to a revision of the ICH GCP (E6) Guideline. At the last meeting, it was agreed that Greg LeBlanc would draft a letter to Dr. Ziegler on behalf of the group asking for clarification of the matter in order to help determine its impact on SG5,

however this was put on hold during the nomination of a new Chair for the group and given revelations that the individuals who were acting as liaison between SG5 and ISO TC194 were no longer participating in one or the other group. The issue was discussed and it was decided to carry over the discussion to the next meeting pending further updates.

The third item involved group discussion of potential New Work Items to be put forward to the Steering Committee and addressed at future SG5 meetings. One subject that was proposed was post-market clinical follow-up, and there was agreement within the group that this subject was indeed ripe to be addressed, with there being a lack of appropriate guidance and a need expressed from both manufacturers and regulators. It was noted that liaison with Study Group 2 would be both appropriate and necessary. It was determined that a New Work Item would be put forward to the Steering Committee to address this topic. No other items were proposed at this time.

Item 9 Next Meetings

The current schedule for upcoming meetings is as follows:

- Los Angeles, California, USA, 8-10[1] May 2007
- Washington, DC, USA, 1-2 October 2007

The meeting was closed by the Chair with thanks to all for their participation in what was a very productive meeting.

[1] Note: Full SG5 Meeting 8-9 May, IVD Joint Subcommittee Meeting only 10 May