

GLOBAL HARMONISATION TASK FORCE

STUDY GROUP 5 – CLINICAL EVIDENCE

Minutes of Meeting Tuesday 25 April and Wednesday 26 April 2006

**Edwards Lifesciences
One Edwards Way, IRVINE, CALIFORNIA, USA**

A meeting of the Global Harmonisation Task Force (GHTF) Study Group 5 was held at the Edwards Lifesciences facility in Irvine, California, USA on 25 and 26 April 2006.

Apologies were received from the Chair of the group, Dr. Graeme Harris, as well as Klaus-Dieter Willamowski, Mitchell Krucoff, Christophe Bailleul, Mary Anne Hinkson, Kazuhiro Sase and Wolfgang Ecker. Attendees at the meeting were:

Greg LeBlanc, MEDEC, CANADA (acting chair)
Patricia Garvey, AdvaMed, USA
Yoshihiro Noda, JFMDA, JAPAN
Guy Hibbins, TGA, AUSTRALIA (for Graeme Harris)
Herbert Lerner, FDA, USA
Atsushi Tamura, PMDA, JAPAN
Kimber Richter, FDA, USA
Johan Brinch, MIAA, AUSTRALIA
Peter Rattke, COCIR, AUSTRIA
Keith Butler, Health Canada, CANADA
Susanne Ludgate, Medicines and Healthcare products Regulatory Agency, UK

Item 1 Welcome and Introductions

The Acting Chair welcomed everyone to the meeting, and expressed thanks on behalf of the group to Patricia Garvey for her role in arranging the meeting and the facilities. The new participants were officially welcomed, and everyone introduced themselves. The group expressed regrets that Dr. Harris was unable to attend the meeting and collective best wishes for a quick return.

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. Key Definitions and Concepts Document – SG5(WD)/N1R6

5. Clinical Evaluation Document – SG5(WD)/N2R6
6. Other Business
7. Next Meeting

Item 3 Discussion of Minutes from Previous Meeting and Matters Arising

It was noted by the group that draft minutes from the previous meeting had not yet been circulated nor had final minutes been posted on the GHTF website. Greg LeBlanc agreed to investigate the matter and determine whether minutes from the Sydney meeting could be prepared and circulated appropriately.

No significant “matters arising” were discussed beyond the work to be undertaken in regards to the Key Definitions and Concepts (N1) and Clinical Evaluation (N2) documents.

Item 4 Key Definitions and Concepts Document – SG5(WD)/N1R6

Following the Sydney meeting, a revised draft of the document was circulated to the members of the group. The document was then circulated by the various representatives to experts within the groups they represent in order to facilitate a final revision of the working draft document. Some of the comments received were incorporated into the document, and the group came to a consensus that the document was ready to proceed to the Steering Committee with a view to having the document posted for public comment. Greg LeBlanc was to forward the document to the Steering Committee following the meeting.

Item 5 Clinical Evaluation Document – SG5(WD)/N2R6

As agreed at the Sydney meeting, Graeme Harris and Johan Brinch took the key points discussed at the meeting and incorporated them into a revised draft of the document, which was then circulated to the members. These drafts were then circulated as described above for the Definitions document.

The group expressed its sincere appreciation for the work undertaken by Graeme Harris and Johan Brinch in the preparation of the latest version of the document for the quality of the results.

The group reviewed the comments that were received as a result of the circulation of the documents, and proceeded to incorporate some of them into the document. In the interest of moving forward with the document, it was decided not to incorporate some of the comments at this time with a view to seeing how the document evolved during the review of the full spectrum of public comments received at the next stage.

During the discussion of this document, the group came to the conclusion that ultimately, the issue of In-Vitro Diagnostic Devices should be addressed in a separate document and

references to devices of this type should be removed from this document for future consideration.

Following incorporation of comments and discussion of the document, consensus was reached that the document was ready to be forwarded to the Steering Committee for consideration for release for public comment. Greg LeBlanc was to forward the document to the Steering Committee following the meeting.

Item 6 Other Business

No significant other business was raised. Plans for the next meeting were discussed, with some questions arising as to the agenda given that the documents that currently filled the meeting agenda would be with the Steering Committee. Greg LeBlanc agreed to ask for guidance from the Steering Committee in that regard, specifically whether the N1 and N2 documents would remain on the agenda or whether it was time to consider other Terms of Reference. Also, it was discussed that the timing of subsequent meetings beyond the Lübeck meeting would depend on the feedback received from the Steering Committee and the availability of group members.

In closing the meeting, the Acting Chair thanked everyone for their attendance and participation in a productive meeting, and once again thanked Patricia Garvey and Edwards Lifesciences for hosting the meeting.

Item 7 Next Meeting

- Lübeck, Germany, 26 and 27 June 2006 (prior to GHTF Conference 28-30 June)
- (tentative) Toronto, Ontario, Canada, 3 and 4 October 2006 - TBD