

GLOBAL HARMONISATION TASK FORCE

STUDY GROUP 5 – CLINICAL EVIDENCE

Minutes of Meeting Monday 1 October to Tuesday 2 October 2007

**Ronald Reagan Building and International Trade Center
1300 Pennsylvania Ave. NW, Washington, DC, USA**

A meeting of the Global Harmonisation Task Force (GHTF) Study Group 5 was held at the Ronald Reagan Building and International Trade Center, Washington, DC, USA on 1-2 October 2007.

Attendees at the meeting were:

Susanne Ludgate, MHRA, UK
Greg LeBlanc, MEDEC, CANADA
Barbara Westrum, AdvaMed, USA
Herbert Lerner, FDA, USA
Atsushi Tamura, PMDA, JAPAN
Johan Brinch, MIAA, AUSTRALIA
Isabel Scuntaro, Swissmedic, SWITZERLAND
Christophe Bailleul, Eucomed, BELGIUM
Kazuhiro Sase, Juntendo University Medical School, JAPAN
Gregory Campbell, FDA, USA

Observers representing Pan-American Health Organization jurisdictions were also present at the meeting.

Item 1 Welcome and Introductions

The meeting was convened by Greg LeBlanc, who, as vice-chair, agreed to chair the meeting due to Dr. Susanne Ludgate's absence for the morning of the first day, due to the need for her to attend the Steering Committee meeting taking place at the same time. All members were thanked for their attendance, and introductions were made.

Item 2 Adoption of Agenda

There were no changes to the draft agenda circulated in advance of the meeting, with the exception of the decision to switch the order of previously designated item 4 (Discussion of Clinical Investigations Document) with item 5 (Discussion of Post-Market Clinical Follow-Up Document) due to the need to await Dr. Ludgate's return from the Steering

Committee session prior to discussion of the Clinical Investigations Document. Thus, the following agenda was adopted:

1. Welcome, introductions and housekeeping information
2. Adoption of agenda
3. Discussion of Minutes from previous meeting and matters arising
4. Discussion of Post-Market Clinical Follow-Up Document
5. Discussion of Clinical Investigations Document – Feedback from Steering Committee
6. Other business
 - Update on recent ISO TC 194 WG4 Meeting
 - Discussion of 11th GHTF Conference
7. Next meetings

Item 3 Discussion of Minutes from Previous Meeting and Matters Arising

No significant issues or “matters arising” were brought forward or discussed. The minutes had been previously circulated and accepted via e-mail.

Item 4 Discussion of Post-Market Clinical Follow-Up Document

Dr. Ludgate joined the meeting and assumed the Chair early during the discussion of this item. The group continued the drafting and editing of the document. The group made a great deal of progress during the two days of work on the document, however, there was consensus that there is still a substantive amount of work remaining before the document is ready to be put forward in any form. Therefore, the conclusion was reached that the members should informally discuss the document with particular experts within their jurisdictions to get some preliminary feedback prior to the next SG5 meeting in order to help further guide the formation of the document and ensure that it is addressing appropriate issues. Members were requested to circulate this feedback by the middle of December to allow for the issues to be compiled for the next meeting.

Item 5 Discussion of Clinical Investigations Document – Feedback from Steering Committee

A discussion of the Clinical Investigations Document ensued. SG5 had been requested to provide an updated copy of the Clinical Investigations Document to the Steering Committee for their review. Feedback from the Steering Committee was that the document was progressing nicely and they believed that it was now appropriate for it to continue along the regular development pathway for GHTF documents. It was discussed within the group that the document should now be circulated for “jurisdictional comment”. Therefore, members were asked to distribute the document to experts within their various jurisdictions and solicit feedback to be discussed at the next meeting. It was

agreed that Greg LeBlanc would provide copies of the latest version of the document to each member to enable distribution within the jurisdictions. Comments were then to be provided to the group, and specifically to Greg LeBlanc for compilation, by the middle of December.

Item 6 Other Business

Communication with ISO TC 194 WG4

An update was provided by Barbara Westrum regarding the recent meeting of WG4, which she attended via teleconference, and the current status of their work. Susanne Ludgate also provided an update of her recent communications with Dr. Ziegler, the Convenor of WG4. The discussion included the fact that there still seemed to be some lack of clarity within WG4 regarding the nature of GHTF and the work of SG5, and it was agreed that Dr. Ludgate should communicate with Dr. Ziegler in this regard. It was also noted that the current draft of the ISO 14155 document includes information surrounding literature searches, as does the SG5 Clinical Evaluation document, and that this should be discussed with WG4.

Upcoming GHTF Conference

A brief discussion of the GHTF Conference being held during the remainder of the week was held, with logistical updates, etc. being presented.

Item 7 Next Meetings

The current schedule for upcoming meetings is as follows:

- Brussels, Belgium, 28-29 January 2008
- Tokyo, Japan, late May or early June (exact dates TBD) 2008

The Chair and group expressed thanks to Christophe Bailleul for making arrangements for the meeting in January to be held at the Eucomed offices in Brussels, and to the Japanese delegation for agreeing to make arrangements to host the subsequent meeting.

The meeting was then closed with thanks to all participants.