

Ref: GCG 50 Final

Final

**GLOBAL COOPERATION GROUP MEETING REPORT
TUESDAY OCTOBER 24, 2006**

*Chicago, United States
(The Westin Michigan Avenue Chicago)*

PARTICIPANTS:

Dr. Minoru Kubota (<i>Co-Chair</i>)	JPMA
Mr. Mike Ward (<i>Co-Chair</i>)	Health Canada
Dr. Jianhua Ding	APEC
Dr. Yuppadee Javroongrit	ASEAN
Prof. Dr. Saleh Abdullah Bawazir	GCC
Ms. Rosario D'Alessio	PANDRH
Mr. Joseph Mthetwa	SADC
Dr. Peter Arlett	EU
Dr. Toshiyoshi Tominaga	MHLW
Dr. Petra Doerr	EFTA
Dr. Justina Molzon	FDA
Dr. Alice Till	PhRMA
Dr. Odette Morin	IFPMA
Dr. Lembit Rägo	WHO
Dr. James Ritchie	EFPIA

Also present:

Dr. Martin Terberger	EU
Dr. Spiros Vamvakas	EMEA
Dr. Yves Juillet	EFPIA
Ms. Joan Blair	FDA
Dr. Michael Garvin	PhRMA
Dr. Peter Honig	PhRMA
Dr. Sabine Kopp	WHO
Dr. Dawn Ronan	IFPMA
Ms. Daniela Renggli	IFPMA

1. Welcoming remarks and adoption of the agenda

The Co-chairs welcomed all participants to the meeting of the Global Cooperation Group (GCG). It was noted that this was the first face-to-face GCG meeting for Dr. Tominaga, Dr. Ding and Mr. Mthetwa. The draft agenda was adopted with some minor revisions to time allotments.

2. Review of current membership and adoption of teleconference reports

Changes to the current membership of the GCG were noted: Dr. James Ritchie, Director Regulatory Policy at GlaxoSmithKline was confirmed as the GCG member for EFPIA, replacing Dr. Yves Juillet; Dr. Minoru Kubota, General Manager at Daiichi Pharmaceuticals Co., Ltd, became GCG Co-chair replacing Dr. Yves Juillet in that capacity; Dr. Alice Till, Vice President Science Policy and Technical Affairs, PhRMA, replaced Dr. Caroline Loew as the PhRMA member of the ICH GCG; and Dr. Ding Jianhua, Director of Division of Pharmaceuticals at the State Food and Drug Administration of the P.R. of China was serving as the current representative of the APEC Life Sciences Innovation Forum (LSIF) to the GCG.

The draft teleconference reports from 12 April 2006 and 11 September 2006 were put forward for adoption, but there were requests for additional review time. Therefore, adoption of the reports were deferred.

It was noted that Dr. Yves Juillet will also attend the GCG meetings for EFPIA.

3. RHI pre-Meeting report

In keeping with the RHI policy on a rotation for presenting the RHI pre-meeting report as agreed to at their last pre-meeting, the current presenter was Dr. Yuppadee Javroongrit (ASEAN). Dr. Javroongrit opened the report by noting that PANDRH had reported at the last GCG meeting and that the upcoming rotation for presenting would be in the following order: GCC, APEC, then SADC.

In accordance with the RHI pre-meeting standing agenda, it was reported that the RHIs discussed special requests to be made to the larger GCG; inter-regional collaboration; capacity building; and involvement/support to ICH. Under the item of special requests, the RHIs agreed that the request be made for ICH experts to be identified for each ICH topic as a training resource for the RHIs. Under inter-regional collaboration, it was agreed that the RHIs should invite each other to their own regional conferences as opportunities to learn from each other; that at each future RHI pre-meeting, thirty minutes should be dedicated to intensive information sharing; and that the RHIs should encourage their memberships to attend important global meetings such as the WHO International Conference of Drug Regulatory Authorities, Drug Information Association meetings in the ICH regions, etc. Under capacity building, it was agreed that the RHIs should be encouraged to share more information inter-regionally and should engage in networking among themselves. With respect to ICH guidelines, it was agreed that the RHIs need more extensive training and considered how this could be accomplished in a sustainable way, noting that they needed to identify a strategy to achieve this. Under the 'support to ICH' agenda item, the RHIs observed that they had each received very few comments to the Step 2 guideline that each had

circulated for comment (Q4B guideline and annex). The RHIs concluded they needed to find ways to encourage comments. It was noted that sufficient time for comment (at least 8 weeks) was necessary to allow for circulation of Step 2 guidelines within the RHIs. A range of ideas for improving the solicitation of comments were then discussed with the GCG.

4. Regional harmonisation update, including ICH-related issues

Each of the RHIs made formal presentations to the GCG which provided overviews of their respective initiatives, informed the GCG of progress made and challenges being faced, and communicated the public health context and relevance to the harmonisation activities. The APEC presentation included a request for a speaker at the LSIF V meeting (April 2007) and for trainers for four LSIF projects.

5. General update and report on stability guideline developments

Dr. Kopp (WHO) reviewed the history of the divergent recommendations for storage condition limits specific to Zone IV contained in WHO and ICH stability guidelines and the efforts to resolve them. She reported on the recent recommendation of the WHO Expert Committee on Specifications for Pharmaceutical Products to use a recently finalized WHO Eastern Mediterranean Regional Office (EMRO) document as a basis for revising the current WHO stability guideline. A key element of the updated EMRO guideline is a comprehensive list of countries within the region and their corresponding limits for storage conditions. This feature aligns with WHO's intent to include in its revised stability guideline a comprehensive list of WHO Member States with their recognized storage condition limits. Dr. Kopp reported that a draft revised WHO stability guideline would be circulated for comment as soon as certain terminology was confirmed and information was collected from other regions on their respective recognized storage condition limits.

6. ICH Secretariat Report

Ms. Blair updated the GCG on the main discussions and activities taking place in the current ICH meetings. Ms. Renggli followed with a progress report on the Secretariat's efforts to improve preparation of RHIs for the ICH meeting in general and for selected EWG and topic sessions. Ms. Renggli reported that improvements were on-going in the package of information provided to the RHIs, including a schedule of meetings open to RHIs and listing of RHI-selected meetings to be participated in. Additionally, pre-meetings between RHIs and rapporteurs had been arranged whenever possible. These improvements have allowed for better planning and preparation on the part of both RHIs and rapporteurs.

7. Comments on Step 2 Guidelines

The only active ICH draft guideline out for comment prior to the current meeting was Q4B and its annex. Comments were provided by PANDRH. Discussion followed on the difficulties the RHIs were experiencing in soliciting comments and potential mechanisms to address those difficulties, including establishing points of contacts in each country, creating a 'regional expert pool' and developing an active communication tool or channel within the region.

It has been considered useful that at the next GCG meeting an information is given by RHIs on progress made.

8. Training and Capacity Building implementation

As a reminder, it was noted that this item is a standing GCG agenda item. Substantial discussion took place regarding the merits of the just launched calendar of training activities reported above and its functioning as a web-based clearinghouse of training opportunities. Clarification was sought on the scope of the document and suggestions were offered on improving the current configuration such as the inclusion of short descriptors of event items and links to associated websites containing more detailed information. It was recognized that the training calendar/clearinghouse was only one tool to pursue capacity building and that training should take place within a larger training strategy that reflected the needs of a given region.

9. Feedback on confidential GCG section of ICH website

Ms. Renggli reported on the newly established confidential section of the ICH website for the GCG, noting that it included a calendar of training activities and a listing of GCG membership with full contact details which are not provided on the public website listing. It was proposed for the future to add a section where documents being developed could be posted.

In discussion of this item, it was noted that some RHIs had experienced difficulties in accessing the site. It was agreed that the site was useful for preparing for the GCG meetings and was of value in being a single repository of all GCG-related documents. Further, it was agreed that a more appropriate descriptor for the site would be “GCG Working area” and that it should include RHI-related information. The issue of access to the site was discussed, but members felt further reflection was needed before concluding this discussion point.

10. GCG procedures

An action item from the 2006 Yokohama meeting was to update the ICH Procedures document to reflect recent SC decisions as well as document current practices. The GCG therefore undertook to document its procedures. A draft procedures document was written and circulated for comment by the GCG, which then also was the focus of this agenda item. The draft document prompted discussion on the role of the RHIs, ICH expectations and the need to clarify terms, including ‘observers’. It was agreed that as a way forward, a two step approach should be followed. First, ambiguities in the draft document would be corrected, and the title of the document would be changed to “Principles and Procedures.” Secondly, further dialogue would take place on the issue roles and expectations at the next meeting in Brussels, 2007.

11. Update on Survey of RHIs

Dr. Ronan reported on her efforts to more fully populate RHI profiles that were based on a model using the PANDRH initiative that was previously considered by the GCG. The profiles were shared and suggestions for improvements were offered. The GCG expressed its appreciation to Dr. Ronan for her hard work in developing the profiles which were seen as useful documents. Discussion followed regarding the comparative table of the RHIs which was originally intended to serve as a potential tool to identify good harmonization principles. It was recognized that while there are many different reasons for and ways to accomplish harmonisation, there may well exist common keys to success that are worth the effort to identify, taking advantage of the collective experience embodied in the GCG. It was agreed

that next steps would be the completion of the draft profiles and table by the Brussels 2007 meeting.

12. Any Other Business

PhRMA brought to the attention of the GCG the expression of interest on the part of the Drug Controller of India to pursue the formation of a South Asian regional harmonisation initiative as a prelude to joining the GCG. Discussion followed on the timing and nature of an interaction of the GCG with India, and the potential implications of a future engagement from a public health perspective. The GCG agreed to put to the ICH Steering Committee for endorsement the proposal to contact the Indian DCI to explain the criteria for involvement of RHIs in the GCG that was developed previously by the GCG and to suggest a possible one time opportunity to “observe” the GCG once sufficient progress with the formation of a RHI was made.

No additional business was raised and the meeting was closed.