

Final

**GLOBAL COOPERATION GROUP MEETING REPORT
TUESDAY JUNE 6, 2006**

*Yokohama, Japan
(Yokohama Royal Park Hotel)*

PARTICIPANTS:

GCG Members:

Mr. Kazutaka Ichikawa	JPMA
Dr. Justina Molzon	FDA
Dr. Alice Till	PhRMA (<i>replacing Dr. Caroline Loew</i>)
Dr. Peter Arlett	EU
Dr. Yves Juillet (<i>Co-Chair</i>)	EFPIA
Mr. Mike Ward (<i>Co-Chair</i>)	Health Canada
Dr. Petra Doerr	EFTA
Dr. Lembit Rägo	WHO
Dr. Odette Morin	IFPMA

Regional Harmonisation Initiatives

Prof. Dr. Pakdee Pothisiri	APEC
Dr. Yuppadee Javroongrit	ASEAN
Prof. Dr. Saleh Abdullah Bawazir	GCC
Ms. Rosario D'Alessio	PANDRH

Also present:

Mr. Kazuhiko Chikazawa	MHLW
Dr. Minoru Kubota	JPMA
Ms. Joan Blair	FDA
Ms. Sema Hashemi	FDA
Dr. Michael Garvin	PhRMA
Dr. Eric Abadie (partly)	EU
Dr. Spiros Vamvakas	EU
Dr. Christine-Lise Julou	EFPIA
Dr. James Ritchie (partly)	EFPIA
Dr. Dawn Ronan	IFPMA

REPORT

1. Welcoming remarks and adoption of the agenda

The Co-chairs welcomed all participants to the meeting of the Global Cooperation Group (GCG). The draft agenda was adopted as proposed.

2. Review of current membership

On behalf of the Secretariat for the Life Sciences Innovation Forum (LSIF)/APEC, Prof. Pakdee Pothisiri reported that this would be his last meeting serving as the permanent representative to the GCG. His replacement from the State Food and Drug Administration of the People's Republic of China, Dr. Ding Jianhua, had been identified too late for him to join the current meeting, but would participate in the next GCG meeting in Chicago, US. The LSIF/APEC has established the policy that a new representative would be selected for a one year rotation with staggered representation. Therefore, for each meeting beginning with the Yokohama meeting, the plan was to have two individuals attend: the current official representative and the upcoming representative. This approach is intended to assure continuity and aid with the transition between changes in representation.

Prof. Saleh Abdullah Bawazir introduced himself as the new GCC representative to the GCG.

Dr. Minoru Kubota introduced himself as the new JPMA representative to the GCG.

The Chair reported that SADC was unable to send a representative due to a major scheduling conflict and noted that Dr. Alice Till was participating as replacement for Dr. Caroline Loew, the PhRMA GCG representative.

Dr. Yves Juillet reported that he has left the ICH SC after the Chicago meeting. The new official SC EFPIA representative to the GCG will be Dr. James Ritchie but Dr Juillet will still be involved in the GCG as EFPIA participant .

A proposal to have a staggered two year rotation of the GCG chairs was discussed. The JPMA expressed a strong interest for Dr. Kubota to replace Dr. Juillet as the industry co-chair. Under this proposal, Mr. Mike Ward would continue to serve as regulatory co-chair until the end of 2007. Proposals were supported and would be put to the ICH SC for decision.

3. RHI pre-Meeting report

Ms. D'Alessio reported on the pre-GCG RHI meeting. In that meeting, the RHIs agreed on a rotation for presenting the pre-meeting report to the larger GCG. The ASEAN representative would be making the presentation at the next GCG meeting. Discussion took place regarding a potential common format for reporting RHI updates and it was agreed that each RHI would identify a standard set of reporting elements that would be routinely used. It is hoped that this will facilitate the comparison between successive reports and thus assist in noting any progress made. Also, the RHIs agreed to the inclusion of "capacity building" as one of the standing agenda items for the RHI pre-meeting. In terms of issues to be brought before the GCG, the RHIs agreed that they would like to request more substantial updates on the ICH work products in advance of each meeting. After some discussion of this point, it was agreed that the usual ICH Secretariat status report included in each GCG meeting could be disseminated in advance of the meeting to maximize the RHIs preparation. Finally, the RHIs formally acknowledged the change in the representation to the group.

4. Regional harmonisation update, including ICH-related issues

- ***APEC LSIF Update Highlights***

Prof. Pakdee Pothishiri (Vice-Chairman of the APEC-LSIF & Chairman of Expert Groups; Secretary-General, Thai FDA, Ministry of Public Health, Thailand) presented a summary of activities of the APEC LSIF Planning Group which held two meetings since the last ICH meeting: February 20, 2006 in Ha Noi, Vietnam, which was attended by approximately 40 participants from 11 economies; and May 22, 2006 in Ho Chi Minh City, Vietnam which was attended by approximately 35 participants from 11 economies. A proposal for a new Terms of Reference (TOR) for the APEC-LSIF initiative emerged from these meetings and will be considered for endorsement by the APEC-LSIF leadership. The proposed TOR includes a proposal for a major revision in the leadership structure of the initiative.

The Planning Group also considered nomination criteria for identifying a representative to the ICH Q10 EWG which was accepted. A representative will be selected from the applications with a goal of participation by the Chicago (October 2006) meeting.

Agreement was reached on forming a Steering Committee on Harmonization which would oversee two work groups: biomedical products and medical devices. The scope and structure of this Steering Committee were elaborated, with one Chair to serve as the Committee lead, and two co-Chairs. Mr. Mike Ward has been nominated by Thailand to serve as the first Chair of this Steering Committee.

The APEC-LSIF IV meeting is anticipated to be held September 6-7, 2006 in Nha Trang, Vietnam, with confirmation shortly.

During the discussion that followed Prof. Pothishiri's presentation it was noted that several of the RHIs have overlapping membership and that coordination is desirable. Specific to the APEC-LSIF, Prof. Pothishiri responded that it is hope that the establishment of the Steering Committee will help with such coordination.

- ***ASEAN Update***

by Dr. Yuppadee Javroongrit (Co-chair ACCSQ/PPWG; Drug Control Division, Thai FDA) presented outcomes of the 11th meeting of the Pharmaceutical Products Working Group (PPWG) held March 2006 in Vietnam, including:

- the activities within the Bioavailability/Bioequivalence including the formation of an ASEAN MRA Taskforce on BA/BE Studies
- progress on implementation issues on ASEAN harmonized products including the ASEAN Stability Guideline and the ASEAN CTD (ACTD)
- discussion of the "Dialogue with Industries" which was initiated and will continue
- activities related to the ASEAN Healthcare Integration Roadmap, foremost of which was the continued efforts of the ASEAN MRA Task Force on GMP Inspection which is moving forward with a Sectoral MRA with a signing goal of late 2007
- agreement to include a Vaccine Chapter in PPWG's activities

In the discussion that followed the presentation, Dr. Yuppadee Javroongrit informed the GCG that the ACTD is still limited to a paper version, although Malaysia accepts the paper format

on-line and Thailand intends to be able to also accept this format on-line in the coming year. In terms of real experience with the ACTD, it was noted that experience is limited, but that by the end of 2008, use of the ACTD will be mandated.

- ***PANDRH Update***

by Ms. Rosario D'Alessio, Regional Advisor in Medicines and Pharmaceutical Services, PAHO/WHO, presented on behalf of PANDRH with:

- updates on the PANDRH Working Groups (GMP, Good Clinical Practice, Vaccines, Bioequivalence, Pharmacovigilance, Medicinal Plants, Good Laboratory Practices, Drug Counterfeiting, Drug Approval Registration, Pharmacopoeia and Drug Promotion)
- a description of the four phases that constitute the process for developing PANDRH proposals;
- a summary of the documents and guidelines that have reached each phase;
- a review of the regular activities of the working groups: 1) follow-up and direct support to countries for the implementation of approved guidelines; 2) external quality control program; 3) the conduct of national seminars (GCP, BE); and 4) educational programs
- a reminder that all PANDRH products must receive official acceptance through the biennial Conferences

Ms. D'Alessio also reported that at the current ICH meeting, PANDRH did send an official representative to participate in the Q10 Expert Working Group.

- ***GCC Update***

Prof. Dr. Saleh Abdullah Bawazir provided a verbal update. He reported that Yemen has been added as a new member to the group of six countries that are members of the GCC. He reminded the GCG that the GCC was formed as a health initiative that has evolved into one with a goal of establishing a regional bulk purchasing program and drug registration system with a centralized procedure. The initiative is promoting regional harmonization in areas such as GMP inspections and pharmacovigilance. A major effort has been launched to review, and revise as needed, all the technical guidelines associated with drug registration. When an ICH document exists on a topic, it is intended that the ICH document will serve as the backbone for the GCC document.

5. Stability studies in Zone IV countries

Dr. Suzanne Keitel (Q1F Rapporteur) updated the GCG on the status of efforts to resolve the divergence of the Q1F temperature limits for storage conditions specific to Zone IV with other existing recommendations. Per prior direction of the ICH SC, the Q1F EWG representatives reconvened at the current ICH meetings and following discussion, agreed that the Q1F guideline should be withdrawn. The EWG would be recommending to the ICH SC that an explanatory note should be posted on the ICH website pursuant to this withdrawal. With respect to the still remaining issue of intermediate storage conditions, the ICH regulators agreed that they would be willing to accept storage conditions that are more stringent than those specified in the Q1F guideline. Dr. Keitel acknowledged the contribution of the RHIs

input in drafting the explanatory note. WHO reported that following the position endorsed at the last WHO Expert Committee for Pharmaceutical Preparations which provided for the self-selection for Zone IVa and Zone IVb, no one to date had self-selected the IVa option. As a consequence, it is anticipated that the IVa option would be deleted.

6. ICH Secretariat Report

Ms. Blair updated the GCG on the main discussions and activities taking place in the current ICH meetings. Dr. Morin followed with an update on the Secretariat's efforts to improve transparency as requested by the ICH SC; specifically, to improve the ICH website to be more user friendly. To that end, a Frequently Asked Questions (FAQ) section had been added; links to more information was added; a glossary is being developed; and a summary of the ICH week is now being posted subsequent to meetings. She also introduced Dr. Dawn Ronan who was recently hired to fill the post vacated by Dr. Krause.

Specific to GCG-related matters, Mr. Ward observed that with the opening of some meetings of expert groups and corresponding portions of the SC deliberations to the RHIs, that current procedures were in need of updating. He proposed that at the next GCG meeting, the group should review the GCG procedures. The GCG agreed to the proposal.

7. RHI participation in EWG and topic sessions

A table compiling the current work efforts at the current ICH meetings that was distributed to the RHIs as an information tool was reviewed. The review served as a starting point for a more substantive discussion on the nature and extent of RHI participation in ICH activities. The RHI representatives shared their perspective on the process to-date. The Chair expressed his appreciation for the feedback and observed that it would only contribute to an improvement to the evolving process of RHI participation in ICH activities. There was agreement on the need to further clarify roles and procedures as part of this process.

8. Strategy on Training and Capacity Building final discussion

The draft "Strategy on Training and Capacity-building Related to the Use of ICH Guidelines" that had been initially circulated at the previous GCG meeting and subsequently commented on by GCG members was revised and considered for final adoption by the GCG for presentation to the ICH SC. Some final revisions were considered and a final draft was adopted. Towards implementation of the strategy, a clearinghouse of training activities and harmonisation events would be prepared for use on a pilot basis by the ICH Secretariat with the proactive input of members and RHIs. Training materials are also to be posted on the GCG webpage.

9. Update on Survey of RHIs

At the last GCG meeting, members discussed the preliminary results of a RHI global questionnaire intended to obtain basic information on the structure, organization and processes of the RHIs, and to obtain information on good harmonization practices. The goals of conducting the survey were to promote transparency, identify opportunities for greater cooperation, better understand challenges and potential solutions to harmonization issues, leverage collective experience and knowledge, document Good Harmonisation Practices, and

provide a more strategic approach to GCG activities. The possibility of capturing the findings of the survey in two companion pieces (either as a report and/or article) was discussed at that time. The GCG revisited the potential for generating such documents. After a range of possible approaches were discussed, Ms. Ronan volunteered to undertake an initial effort to further capture baseline information from the RHIs that would build a comparative body of information on existing regional harmonization initiatives. This would follow RHI response to a gap analysis of survey information to be prepared by Health Canada. A model profile using PANDRH would serve as the template for organizing the information.

10. Review of the GCG

The Chair introduced for consideration by the group the desirability of undertaking a self-assessment/review of the GCG and its activities to-date. Discussion followed with the conclusion that the earlier agreement to review/revise the current GCG procedures could provide the platform from which a review could be considered.

11. Any Other Business

Mr. Ward closed the meeting with words of praise for the efforts of Dr. Juillet on behalf of the GCG, as the current meeting would be his last as co-chair of the GCG. It was noted that the progress of the GCG has been in large part due to the efforts of Dr. Juillet.