

Final

**GLOBAL COOPERATION GROUP MEETING REPORT
TUESDAY NOVEMBER 8, 2005**

*Chicago, Illinois, United States of America
(Westin Michigan Hotel)*

PARTICIPANTS:

Dr. Yves Juillet (<i>Co-Chair</i>)	EFPIA
Mr. Mike Ward (<i>Co-Chair</i>)	Health Canada
Dr. Ibrahim A. Al-Showaier	GCC
Dr. Peter Arlett	EU
Mr. Kazuhiko Chikazawa	MHLW
Ms. Rosario D'Alessio	PANDRH
Dr. Petra Doerr	EFTA
Mr. Kazutaka Ichikawa	JPMA
Ms. Sheesha Jankee	SADC
Dr. Yuppadee Javroongrit	ASEAN
Dr. Sabine Kopp	WHO
Dr. Caroline Loew	PhRMA
Dr. Justina Molzon	FDA
Dr. Odette Morin	IFPMA
Prof. Dr. Pakdee Pothisiri	APEC

Also present:

Ms. Joan Blair	FDA
Dr. Spiros Vamvakas	EU
Mr. Stéphane Callewaert	EFPIA
Ms. Sema Hashemi	FDA
Dr. Michelle Limoli	FDA
Ms. Sonia Myers	HC
Invitee Dr. Susanne Keitel	EU

REPORT

1. Welcoming remarks and adoption of the agenda

The Co-chairs welcomed all participants to the meeting of the Global Cooperation Group (GCG). Special mention was made that the current ICH meetings represented the first at which Regional Harmonisation Initiatives (RHI) GCG members could attend SC and EWG discussions.

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 his term as the permanent representative to the GCG for the LSIF/APEC would end this year and that the LSIF was currently identifying his replacement, with the final decision expected after the meeting of Ministers at the end of the month.

Dr. Yuppadee Javroongrit reported that as Co-chair of the Pharmaceutical Product Working Group (PPWG)/ASEAN, she would be serving as the permanent representative to the GCG through the end of 2006.

Ms. Rosario D'Alessio reported that she would be serving as the representative to the GCG on behalf of the PANDRH Steering Committee through 2006.

Ms. Sheesha Jankee reported that the Chair of SADC was now held by Botswana so it could be expected that at the next meeting of the GCG, the representative to the GCG would be from Botswana.

Dr. Ibrahim Al-Showaier reported that he would be the GCC representative to the GCG through the end of 2006.

Dr. Yves Juillet reported that he would be leaving the ICH SC after the current meeting, but his role vis-à-vis the GCG was yet to be determined. It was expected that it would be determined by the time of the next SC telecom.

3. ICH Secretariat Report

Ms. Joan Blair updated the GCG on the main discussions and activities taking place this week under the auspices of ICH:

- MedDRA Management Board (held on November 5th and 6th)
- Several Informal discussions are taking place on possible new subjects and/or areas:
 - Biotechnology Brainstorming Session
 - Efficacy Informal Working Group (Q&A on E5)
 - Pharmacogenomics Informal Working Group
 - Quality Systems for Continuous Improvement
 - Risk Communications
- An ICH Workshop organized by the Gene Therapy Discussion Group (GTDG) on Oncolytic Viruses is to take place November 7. The GTDG is to meet during the week subsequent to the workshop to continue its on-going work.
- Other Expert discussions are also taking place on the on-going topics, e.g.:
 - Data Elements and Standards for Drug Dictionaries (M5 Expert Working Group[EWG])
 - Regulatory Acceptance of Pharmacopeial Interchangeability (Q4B EWG)
 - Maintenance of Controlled Terminology Lists
 - Electronic Submission of Individual Case Safety Reports revision (E2B(R2))
 - Electronic Standards for Transfer of Information (M2)

4. Summary of discussions and outcomes from the pre-GCG RHIs meeting

Ms. D'Alessio reported on the pre-GCG RHI meeting. The pre-meeting was essentially a brainstorming session and, as such, did not generate any common positions for reporting to the larger GCG. The RHIs did agree that the pre-meeting was useful for sharing information, and comparing areas of common interest and areas of need. The GCG draft training document was discussed and it was felt that each RHI would like to more fully share and discuss the document with their respective initiatives before addressing specifics to the GCG. Prof. Pakdee also noted that the RHI would welcome requests for input or views on specific issues from the GCG. In conclusion, the RHIs supported continuing the practice of a pre-meeting of the RHIs.

5. Regional harmonisation update, including ICH-related issues

• *APEC LSIF Update*

by Prof. Pakdee Pothishiri (Vice-Chairman of the APEC-LSIF & Chairman of Expert Groups; Secretary-General, Thai FDA, Ministry of Public Health, Thailand)

Prof. Pothishiri presented outcomes of the APEC LSIF III meeting held September 8-9, 2005 in Gyeongju, Korea:

- the objective of the meeting was to identify and recommend priority implementation projects to give effect to the endorsed APEC Strategic Plan for LSIF
- priority areas in LSIF are research, regulatory harmonisation, access to capital and health services
- key challenges identified:
 - risk of infectious disease pandemic
 - rise in chronic diseases
 - aging demographic
- among the final recommendations on harmonization were:
 - identify all relevant harmonization initiatives in the region; develop and implement harmonization projects; implement existing harmonized guidelines with a focus on one or two areas for training and building infrastructure (GCP and/or GMP)
 - develop training guidelines and a funding strategy; promote region-wide APEC regulatory harmonization activities
 - form a Steering Committee to oversee two work groups: biomedical products and medical devices

• *ASEAN Update*

by Dr. Yuppadee Javroongrit (Co-chair ACCSQ/PPWG; Drug Control Division, Thai FDA)

Dr. Javroongrit presented outcomes of the 10th meeting of the Pharmaceutical Products Working Group (PPWG) held August 2005 in Singapore, including:

- the activities within the Bioavailability/Bioequivalence and Stability discussion groups
- implementation issues in relation to the ASEAN CTD
- consideration of the formation of an ASEAN Pharmaceuticals Advisory Group of Experts
- interest in pursuing an ASEAN effort with respect to the regulation of vaccines

Dr. Javroongrit shared the position of the PPWG that ICH should engage directly with individual countries within the initiative for input and feedback on ICH guidelines/issues. The GCG co-chairs responded that one premise of the GCG is that the RHI representatives to the GCG are to serve as conduits for information sharing with their respective regional initiatives. Dr. Javroongrit agreed to report this information back to the PPWG.

• *PANDRH Update*

by Ms. Rosario D'Alessio, Regional Advisor in Medicines and Pharmaceutical Services, PAHO/WHO

Ms. D'Alessio's presentation provided:

- updates on the PANDRH Working Groups (Drug Registration, Good Manufacturing Practices, Good Clinical Practice, Vaccines, Bioequivalence, Pharmacovigilance, Medicinal Plants, Good Laboratory Practices)
- update on the PANDRH Secretariat: following up on Working Group meetings; engaging in implementation planning with NRAs; drafting project proposal for

PANDRH Steering Committee on a glossary of terms

- update on the PANDRH web page: a dedicated page with easier navigation from PAHO site is now operational

- **SADC Update**

by Ms. Sheesha Jankee – Past Chair of the SADC MRA Forum

Ms. Jankee's presentation provided updates on SADC progress:

- the SADC Medicines Regulatory Authorities (MRAs) Forum is intended to meet on a twice-yearly basis but in 2005 was only able to meet once due to funding issues
- regarding status of guidelines being harmonized, a review was undertaken and members who had not been able to attend the MRA Forum for some time were reassigned some of the guidelines
- the Forum discussed issues and a proposed protocol for implementation of guidelines by Member States
- the SADC Secretariat organized a first meeting of a Core Task Force on SADC Pharmaceutical Programme to discuss implementation issues with respect to this Programme
 - meeting was held in Gaborone in September 2005
 - goal was to develop a Business Plan for future action
 - the Task Force identified activities to undertake in the short, medium and long term
 - agreed a Project Manager was needed to coordinate the development of the Business Plan

- **GCC Update**

by Dr. Ibrahim Al-Showaier – Vice President of the Saudi Food and Drug Administration

Dr. Al-Showaier's reported that Yemen has now joined the GCC. His presentation focused on a National Drug Policy Workshop to be held in November 2005:

- led by Saudi FDA
- focused on regulations for biologicals, vaccines, blood and blood products, and biosimilar products
 - Final drafts to go to GCC Executives meeting in December 2005, followed by GCC Ministers meeting in January 2006 for final approval and adoption
- Addressed other issues: GMPs, mechanism of inspections, raw materials and certificates of suitability

Dr. Al-Showaier also reported that at the December 2005 GCC Executives meeting, a review would take place of all actions over the past five years.

6. Topics of interest to the Regional Harmonisation Initiatives

6.1 Comments on Step 2 guidelines (Q8, Q9, M5) - No comments were provided. Dr. Juillet noted that this is an important opportunity for the RHIs to provide input on the technical topics.

6.2 Views on EWG discussions - The RHI representatives noted they encountered certain difficulties with respect to attending EWG discussions. It appeared that a series of communication failures occurred that needed to be corrected in the future to assure the success of this activity. Additionally, it was clear that meeting materials (current draft of document under development, EWG workplan, etc.) needed to be circulated to the RHI representatives in advance of the EWG meetings to allow for adequate preparation. Mr.

Ward commented that it was also important for the RHI representatives to hear the SC presentations by the EWGs as they typically provide background, history of the topic, and summary of the issues.

6.3 Zone 4 Stability update

Dr. Kopp and Dr. Susanne Keitel (Q1F Rapporteur) updated the GCG on the various efforts and discussions aiming at solving the differences in stability testing requirements between the ICH Guideline, the WHO Guideline, and other guidelines recently developed in some regions and/or countries (e.g. ASEAN). The issue was discussed at the October 2005 WHO Expert Committee on Pharmaceutical Preparations. The Committee endorsed a compromise position which provides choice in selecting Zone IV storage conditions (Zone IVa - 30°/65% and Zone IVb - 30°/75%). Countries in the CZ IV area should declare themselves whether they belong to Zone IVa or Zone IVb. The compromise was informally discussed among the ICH experts at the current meeting and it was suggested that the ICH Q1F guideline should therefore be withdrawn, leaving the original Q1 recommendations (for the “ICH zones” Zones I and II) in place. A formal recommendation would need to be confirmed via email with the full Q1F working group for submittal to the SC prior to its next meeting. Following approval by the SC, an explanation will be published on the ICH website to inform the public about the withdrawal of Q1F and the reasons.

6.4 Proposals from RHIs - There were no proposals from the RHIs.

7. Training and Capacity Building

7.1 Review of training strategy – Mike Ward reviewed the draft “Strategy on Training and Capacity-building Related to the Use of ICH Guidelines” which was circulated to the GCG a short time in advance of the meeting. Several RHI members noted that the issue of training and capacity building is a highly significant one and they would therefore want additional time to fully review the draft with the memberships of their initiatives. Observations were made by several members on current training opportunities in place. Some RHI representatives commented on the need for national-level training and for training on non-ICH topics. Sabine Kopp commented that from WHO’s experience training needs to be tailored to a given region/country. The GCG Co-chairs noted that training activities undertaken through the GCG were meant to make best use of existing resources and served to complement regional and country-level efforts. Dr. Molzon commented that training programs which combine ICH and non-ICH related topics could be provided by the regulators (e.g., CDER forum for International Drug Regulatory Authorities, held twice a year). Dr. Vamvakas advised of the EMEA’s proposal for 2006 to allow for experts from RHIs to attend training sessions and Working party meetings organised by the Agency.

Regarding industry versus regulatory trainers, several RHI members noted that for technical/scientific topics, industry training is acceptable, but for implementation issues, regulator trainer was preferred.

Following discussion on the resource implications of establishing and maintaining a comprehensive inventory of training events, Mr. Ward proposed as an alternative the concept of a clearinghouse of training requests and opportunities, as per recent LSIF III recommendations.

7.2 Development of strategic plan – The proposal to undertake developing a strategic plan for training and capacity building was postponed for a future discussion to allow the RHIs to

circulate and receive substantive feedback from their members on the draft document per above. Written comments were to be provided to Mike Ward.

8. Survey of RHIs Communications

Mike Ward reported on 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 a report or article was discussed. The paper could potentially discuss the work of the GCG, the attributes and processes of the RHIs and Good Harmonisation Practices/Principles. It was suggested that perhaps two separate papers would be more helpful – one, a descriptor or RHI profile document; a second, principles based on experience. Justina Molzon and Mike Ward volunteered to generate a draft document to be circulated before the next GCG telecom as a basis for further discussion.

9. Communications

Only a limited discussion was possible due to time constraints. Discussion focussed on the value in improving weblinks and consideration of establishing webpages devoted to pharmaceutical harmonisation activities. Mike Ward reported that links to the RHI websites were now included on the GCG webpage.

10. Any Other Business

None.

11. Summary of recommendations and next steps

Points for presentation to the Steering Committee were reviewed and the meeting was closed.