

Final

**GLOBAL COOPERATION GROUP MEETING REPORT
8 May 2007**

Ref: GCG 65F

Participants List

Mr. Kohei Wada	JPMA	Co-chair
Mr. Mike Ward	Canada	Co-chair
Dr. Peter Arlett	EU	
Dr. James Ritchie	EFPIA	
Dr. Yves Juillet	EFPIA	
Dr. Toshiyoshi Tominaga	MHLW	
Dr. Justina Molzon	FDA	
Dr. Alice Till	PhRMA	
Dr. Lembit Rāgo	WHO	
Dr. Petra Doerr	EFTA	
Dr. Odette Morin	IFPMA	
Dr. Jianhua Ding	APEC	
Dr. Dong-Sup Kim	APEC (2nd representative)	
Dr. Yuppadee Javroongrit	ASEAN	
Dr. Saleh Bawazir	GCC	
Dr. Jose Luis Di Fabio	PANDRH	
Mr. Joseph Mthetwa	SADC	part of the meeting by teleconference
Mr. Frank Hlangwane	SADC (2nd representative)	

Also attending

Dr. Martin Terberger	EU
Mr. Thomas Lönngrén	EMEA
Dr. Patrick Le Courtois	EMEA
Dr. Hans-Georg Eichler	EMEA
Dr. Spiros Vamvakas	EMEA
Dr. Christine-Lise Julou	EFPIA
Dr. Michael Garvin	PhRMA
Dr. Minoru Kubota	JPMA
Dr. Kurajiro Kishi	JPMA
Dr. Dawn Ronan	IFPMA
Ms. Daniela Renggli	IFPMA

FINAL MINUTES

1. Welcoming remarks and adoption of agenda

Mr. Mike Ward (Health Canada, GCG co-chair) introduced Mr. Kohei Wada (JPMA) as the new GCG co-chair for JPMA, replacing Dr. Minoru Kubota (JPMA) as of the Brussels meeting. Dr. Kubota seconded Mr. Wada to ensure a smooth transition.

Mr. Wada welcomed all.

The agenda was adopted without any modification. Mr. Ward asked to follow-up on the invitation sent to the Indian Drugs Controller on 22 January 2007 under agenda item #13 Any Other Business.

2. Review of current membership

Mr. Wada welcomed the new members to the Global Cooperation Group.

- ▶ Dr. José Luis Di Fabio: interim representative for PANDRH, replacing Ms. Rosario D'Alessio .

Dr. Di Fabio confirmed that PANDRH/PAHO was looking for a replacement for Ms. D'Alessio as permanent representation to the GCG.

- ▶ Dr. Dong-Sup Kim: second representative for APEC.

Dr. Jianhua Ding was confirmed as the primary APEC representative to the GCG and also the Q10 expert.

APEC will confirm the rotation (two-year vs. one-year rotation) of representatives to the GCG at their next Senior Officials' Meeting and will inform the GCG of their decision.

- ▶ Mr. Falaza Frank Hlangwane: second representative for SADC from the Republic of South Africa.

At the GCG teleconference held on 12 March 2007, Mr. Joseph Mthetwa (SADC) informed the GCG that SADC would send a representative (a technical expert) from one of SADC's member states as second representative to GCG meetings. The position of SADC second representative to the GCG will rotate between the different SADC member states at each GCG meeting.

Mr. Wada informed the GCG that Mr. Mthetwa had been unable to travel to Brussels. A conference call was set up for him to participate in agenda items 8 to 13.

3. Final approval of the revised report of the GCG teleconference held on 12 March 2007 (Ref: GCG62R)

The draft report was sent on 12 April to all for comments by 2 May 2007. No comments were received and the revised report was submitted at the GCG meeting for final approval.

Dr. Saleh Bawazir (GCC) mentioned that he still wished to add comments to the revised report.

Action:

- *The Secretariat will circulate the revised report with GCC comments to the GCG and RHIs for final approval.*

4. RHI pre-meeting report

Dr. Bawazir reported on the outcome of the discussion held by RHIs during their pre-meeting.

The RHIs were asked by the GCG co-chairs to reflect on the following:

- How to best solicit comments to Step 2 guidelines?
- Questions to be discussed during the brainstorming session relating to the goals of the GCG and how to best achieve them (agenda item 10)

The RHIs discussed ways that communication between ICH and other regions could be improved and were in agreement that ICH can reach non-ICH countries more easily through the RHIs.

Over the past four years, since their admission in the GCG the RHIs not only spread the message for harmonization, but also contributed to a better implementation of ICH guidelines owing to a better understanding of the guidelines and what might be required for their implementation. Furthermore, it was acknowledged that the RHIs could help their respective region to invite ICH experts for training.

The RHIs suggested ways of improving productivity: each region should hold special sessions to communicate the outcome of the ICH GCG meeting, organize more training on guidelines and mini symposiums to get more technical input on *Step 2* guidelines, identify better technical ICH experts, and invite ICH representatives to regional forums.

The GCG co-chairs and members complimented the RHIs for their productive brainstorming that would constitute a solid basis for the brainstorming session on GCG discussion topics.

5. RHI update on ICH-related matters

▶ APEC

Dr. Dong-Sup Kim reported on the 5th annual APEC LSIF (Life Sciences Innovation Forum) meeting held in Adelaide, Australia, on 19-20 April 2007. The theme was "Developing an Integrated and Innovative Approach to Emerging Health Challenges".

One of the outcomes of the meeting identified a need for developing an integrated approach to health system resource allocations with a better coordination between the public and private sector involving scientific, health policy, and financial expertise. Key challenges are communicable diseases and the rapid ageing of populations, with the consequence that health issues are becoming central to economic and social viability.

It was also noted that a higher priority should be given to prevention, early detection and intervention in economies.

The key messages and recommendations from the 5th LSIF meeting will be transmitted to senior finance officials during the Finance Ministers meeting to be held on 31 July – 3 August 2007.

▶ ASEAN

Dr. Yuppadee Javroongrit reported on the outcome of the 12th ASEAN ACCSQ PPWG (Consultative Committee on Standards and Quality, Pharmaceutical Product Working Group) meeting held on 1-3 November 2006 in Jakarta, Indonesia.

The meeting focused on implementation issues of the ASEAN harmonized product. Amongst other things, progress was achieved on:

- ▶ ASEAN Mutual Recognition Agreements (MRA) for Pharmaceuticals
 - ASEAN MRA – BA/BE Studies
 - ASEAN MRA – GMP Inspection

- ▶ ACTD Quality and ASEAN technical guidelines
- ▶ “ACTD implementation”

It was noted that member countries are committed to the ACTD format for submission of product registration, but are allowed to exercise flexibility in accepting the ICH-CTD format for New Chemical Entities (NCEs) and biologics product.

The PPWG discussed also the following ICH-related matters:

Training and Capacity-building: The PPWG agreed that participation of RHI members in capacity-building can be considered on a case-by-case basis and that each member country can decide for itself whether to invite other RHIs to participate in their national activities.

Stability guideline: The PPWG agreed to a common position for the ASEAN stability storage condition (30C/75%RH).

Draft questionnaire: The PPWG agreed that member countries should submit their comments on the ASEAN “Draft Questionnaire” (RHI Profile) to Dr. Javroongrit by 30 January 2007. It was noted that Dr. Javroongrit had not received any response to date.

The next meeting of the ASEAN PPWG will take place in August 2007 in Malaysia.

▶ **GCC**

Prof. Dr. Saleh Bawazir reported on the three meetings held since the GCG October 2006 meeting.

The 31 GCC_Drug Regulatory Policy meeting held on 28-30 November 2006 in Riyadh, Saudi Arabia.

The meeting focused on policies, adapting guidelines and regulatory issues, and amongst other things, the Stability guideline. It was agreed to update the Stability guideline taking into account:

1. Stability testing of Active Drug Substances
2. Annex for Testing Parameters
3. In use stability (Multi-dose Products)
4. Post registration variations

It was agreed further to use the standard form for stability assessment and that the dossier should include a summary sheet.

The Stability guideline was revised and approved.

The GCC countries reached agreement on their categorization as climatic zones III & IV (30C/65%RH).

The Arab Union for Pharmaceuticals Manufacturers (AUPAM) meeting on 19-20 February 2007 in Jeddah, Saudi Arabia.

The meeting addressed issues regarding harmonisation between industry and regulatory authorities.

It was agreed to work towards a unified CTD for drug registration in the Arab world. The ICH CTD was recommended as the format to be adopted.

The GCC Committee of Regulators will consider this recommendation rather than develop a GCC-type CTD, in view of the global nature of the industry.

The GCC Drug Quality Symposium on 26-27 February 2007 in Riyadh, Saudi Arabia

WHO and EMRO representatives, among others, were present at the meeting. The main issues raised at this meeting related to counterfeit products. All points raised regarding counterfeit were addressed in the Declaration of Riyadh.

Declaration of Riyadh:

1. The office of the Executive Board of Health Ministers Council for Gulf Cooperation Council States should initiate action so as to actively engage themselves with worldwide activities like IMPACT (International Medicinal Products Anti-Counterfeit Task Force). The office of the Executive Board of Health Ministers Council for Gulf Cooperation Council States should take the lead to address this problem at the next meeting of Arab Health Ministers.
2. National pharmacovigilance infrastructure and implementation needs to be established and/or strengthened in the GCC member countries. The concept of pharmacovigilance is a broader concept than just ADR reporting and should be operationalized in this sense.
3. Develop network of Single Points of Contact (SPOC) per sector e.g. DRA, inspection, police, customs, industry to allow for communication and immediate action
4. Develop network of Official Medicines Control Laboratories (OMCL) and specific anti-counterfeit expertise.
5. Make an inventory of needs for Training and Education of officials e.g.; police, customs, prosecutors, as to the specifics of medicine counterfeiting.
6. Define Regional and National priorities based on risk analysis.
7. A multi-stakeholder national level committee should be formed involving at least MOH, customs department and law enforcement agencies to develop specific national strategies and operations to combat counterfeit problems.
8. A national level study should be launched to assess the situation with regard to counterfeit medicines
9. A three level approach should be adopted for collaborating with other countries in terms of joint action and information sharing:
 - a. At GCC level
 - b. At EMRO level
 - c. At global level

A number of recommendations regarding Drug Quality Reporting System, Quality of Pharmaceutical Ingredient (API), Good Manufacturing Practices (GMP) and Storage and Transportation also came out of the meeting.

► **PANDRH**

Dr. José Luis Di Fabio (PANDRH) reported on PANDRH activities since the last GCG meeting, also noting Dr. D'Alessio's recent absence due to illness.

Meetings had been held on: Bioequivalence, Combating Drug Counterfeiting, Good Laboratory Practices; as well as some educational seminars on GMP and GLP. Additional training seminars had also been planned.

Dr. Di Fabio noted that a strategic review of internal and external challenges facing PANDRH had been undertaken with a view to improving the operations of the network and the adoption and use of PANDRH guidelines at the country and regional levels. He also described the newly adopted process for developing PANDRH guidelines and the various categories of expert working group participants.

A proposal had also been developed that would require all working groups to review available technical guidelines, including those available from the WHO and ICH as well as within the subregions and countries, before contemplating the development of a PANDRH guideline.

Regarding the issue of adoption/adaptation of ICH guidelines, Dr. Justina Molzon (FDA) reported the PANDRH GCP guidance was based on the ICH E6 guideline with some small changes. She added that clinical trial data coming from the Americas were acceptable to the US FDA and Health Canada.

Dr. Peter Arlett asked whether there was a legal basis for Pharmacovigilance Practices as in Europe. Dr. Di Fabio replied that a WG was just being established and would base its proposal on what is available worldwide, as per PANDRH's usual process of establishing new proposals. The WG would therefore be very interested in learning more about the EU's activities and experience.

► **SADC**

Mr. Frank Hlangwane reported on behalf of SADC.

Mr. Hlangwane reminded the GCG about the objectives of the Program on pharmaceuticals, which is part of the Protocol Implementation Plan developed by SADC, which is covering the promotion of access to essential medicines that are safe, effective and of high quality through the development of appropriate technical standards, the establishment of a structure for harmonisation and of centres of excellence around control of medicines, training, etc.

The GCG noted the adoption of the ICH GCP guideline without any modification and the drafting of a project plan for pharmacovigilance activities.

Mr. Hlangwane also informed the GCG that a two-year plan of action (2007-2009) had been established (thanks to WHO funding) aimed, among others, at:

- Implementing adopted regulatory guidelines,
- Developing regional training programs (with commitment for funding and technical expertise from WHO)

Training programs focus on the evaluation of application dossiers for medicines regulation and authorization, qualification and accreditation of QA/QC laboratories, development and implementation of Quality Management Systems, Market surveillance and monitoring.

- Establishing SADC Shared Network (useful for communication between regions)

It was noted that the Shared Network should soon be accessible to ICH.

The regulatory challenges encountered will be the legislation for implementing guidelines different among the regions and the effective implementation of common guidelines that would allow recognition by all SADC members of a marketing authorization.

6. Comments on Step 2 Guidelines

The ICH *Step 2* guideline E15 was sent to the RHIs for comment on 29 November 2006. The deadline for sending comments to the Secretariat was extended from 28 February to 9 April 2007. No comments were received and in general up-to-now only few comments were received from RHIs on ICH draft guidelines.

RHIs were asked to discuss on ways to improve the solicitation of regional comments on ICH draft guidelines within their region, based on slides prepared by Mr. Wada, which identified possible challenges faced by the RHIs. RHIs reported that the lack of response was not due to communication/dissemination difficulties within the region or the countries, but rather due to the difficulty identifying appropriate experts within countries or the region for a particular topic, consultation periods that are too short, competing workloads, language issues and lack of appreciation of the importance in commenting on *Step 2* guidelines.

As ways to improve the solicitation of comments, the GCG and RHIs identified the importance of promoting better understanding of topics through interactions with ICH experts and the potential value in establishing a regional “pool of experts”.

7. Stability Guideline developments

Dr. Sabine Kopp (WHO) updated the GCG on the outcome of the WHO Expert Committee meeting on Specifications for Pharmaceutical Products held in October 2006. The Expert Committee recommended that WHO would review the guideline for stability testing based on the EMRO document and on confirmed long-term stability conditions in regions and countries. Dr. Kopp reported that requests for information had gone out to major regional harmonization groups and the WHO regional offices in an effort to confirm stability conditions in all WHO member states.

Comments on the EMRO guideline (now to become a WHO guideline) have been addressed and the revised document circulated for comments.

Next steps will be to analyze all comments received and to review the guideline at a meeting to take place end of May 2007. The revised document would be circulated for comments in June 2007 for discussion at the next WHO Expert Committee meeting to be held in October 2007.

8. RHI Survey update

Review of RHI profiles and comparative table

The Secretariat provided an update on the status of the draft RHI profiles and comparative table. The profiles were circulated first in September 2005. They have undergone different steps of revisions and are about to be finalized: the documents need to be reviewed for consistency and the comparative table has to be completed.

Discussions took place on the usefulness of knowing which RHI guidelines are based on the ICH guidelines, in full or in part. Dr. Yves Juillet (EFPIA) recommended applying a consistent format of presentation for each region in order to clarify whether ICH guidelines are implemented or not and which other guidelines are used in developing a regional guideline. He also suggested adding a column to describe the nature of the adaptation, where this occurs. This should contribute to a better understanding of the extent ICH guidelines are used and factors leading to their adaptation. While

acknowledging the limitations of this exercise, i.e. simple tables cannot confirm realities at the country level, the publication of tabulated data was nonetheless seen as a useful first step in promoting transparency regarding the use of ICH guidelines.

It was noted that once all profiles are completed, a comparative table would be completed by the Secretariat for posting on the public section of the ICH website. Publication would also imply maintenance of the information it contains. It was felt therefore necessary to add caveats if made public.

Action:

- *The Secretariat to add a column to allow for a description of the adaption of ICH guidelines.*

9. GCG Principles and Procedures

Mr. Ward reported on the status of the GCG Principles and Procedures document.

It was agreed at the Chicago meeting held in October 2006 that this document would undergo a two-step revision. The first step revision (i.e. to solve ambiguities and to change the name of the document from GCG Principles to GCG Principles and Procedures) has been completed and the revised document has been approved on 26 March 2007.

The GCG and RHIs pursued their dialogue on the issue of roles and expectations, which constitutes the second step of the revision process of the GCG procedures document. It was noted that the document would be put on hold until consensus is reached on the role of RHIs and on the future of the GCG. The document would then be modified according to decisions made during these discussions.

The GCG Procedures and Principles document will be annexed to the general ICH procedures document. The ICH procedures document is a living document and is revised annually:

Revisions or additions to any part of the general document agreed upon by the SC at their fall meeting are incorporated as part of the annual revision. Matters not resolved at the time of the fall meeting are considered for the revision of the document at the subsequent fall meeting.

Action:

- *The Secretariat to revise the GCG Principles and Procedures document once discussions on the role of the RHIs and the future of the GCG are final.*

10. Brainstorming Session on GCG discussion topics

Mr. Ward asked the RHIs to share their views on what they see as the goals of the GCG and how they can best be achieved. Related to this, he also solicited views on

- training and implementation of ICH guidelines, and
- the adoption and adaption of ICH guidelines.

Since its evolution from information dissemination body to establishing partnerships with other harmonisation initiatives, Mr. Ward noted that the time has come for the GCG to consider its achievements and to reflect on what has yet to be achieved and how to best do so. Dr. Juillet added that reference to the Mission statement was necessary as basis for framing the discussion.

The ensuing discussion was found by all to be extremely valuable in understanding the views and realities of RHIs on the value of attending the GCG and ICH expert working group meetings. Discussions led to a number of important observations, including:

- “Everything needs time”
- Many factors come to bear on adopt/adapt issue: understanding and communication key to enabling intended use of ICH guidelines – both at regional and country level – from early on in process
- Regions/countries need to see value in ICH guidelines
- Misconceptions dispelled through participation
- EWG attendance at a minimum allows for better understanding of ‘theme’, its implications and what might be needed to implement
- Need for ICH to get out to regions

It was agreed that the brainstorming session was the highlight of the meeting and the meeting the most productive to date in underscoring the importance of the GCG and possible means of improving its effectiveness.

11. Training and Capacity-building implementation

Training procedure

The Secretariat reported on the development of a consistent process to handle training requests. The draft procedure and a standard template for training activities shall include information on scope, target audience, details on the training event and funding. These documents would facilitate the evaluation, organization and prioritization of training activities in a more efficient and transparent way.

Training activities and requests

Mr. Ward introduced the APEC LSIF sponsored training events to take place in 2007 and 2008, initially tabled at the Chicago meeting held in October 2006:

- 1) ICH 'Quality by Design' guidelines (Q8 & Q9)
- 2) Clinical trials: Assessment of Drug Development and GCP Inspections

1) ICH ‘Quality by Design’ guidelines (Q8 & Q9)

Dr. Dong-Sup Kim (APEC) provided a brief description of this training event.

The ICH Q8 & Q9 workshop is to take place on 13-14 September 2007 in Seoul Korea as part of BIO Korea 2007 symposium.

The program objectives are to provide a practical explanation of ICH guidelines and to engage in interactive discussions on anticipated challenges and opportunities associated with eventual implementation of Q8 and Q9 in the APEC region.

The agenda is structured after the ISPE (International Society for Pharmaceutical Engineering) sponsored workshop that took place in Brussels Belgium in February 2007. PhRMA, EFPIA, ISPE and Mr. Ward contributed to the development of the Korean workshop’s program.

Next steps are for ICH coordinators to provide comments and nominate speakers for this workshop.

Dr. Peter Arlett (EU) suggested that Q10 be added to the package, which would constitute an excellent opportunity to hold a regional workshop on a *Step 2* guideline, addressing one of the recommendations by RHIs during the brainstorming session.

2) Clinical trials: Assessment of Drug Development and GCP Inspections

Mr. Mike Ward provided a description of this training request.

The project will cover two main activities, which will be organized in two series of two training courses:

1. Review of drug development in clinical trials
2. GCP inspection

The training courses will take place in Bangkok Thailand in 2007 and 2008. The first training session should be held during the fall of 2007.

The expected outputs of these training courses are the demonstration of best practices in evaluation of clinical trials and in GCP inspection, networking and information sharing between drug regulatory authorities, and the development of standard templates.

The GCG noted that the US FDA had agreed to participate in the GCP inspection workshops and Health Canada in the clinical trial evaluation workshops. However, additional speakers from other ICH parties would be welcome.

It was agreed as a general principle that response to requests should be shared and that it was therefore not necessary for all ICH parties to participate in all training events. It was suggested that the Secretariat play a major role in assessing and coordinating training requests on behalf of the GCG. To date, the Secretariat's responsibilities have related to collecting information regarding the requests.

Actions:

- *The GCG members and ICH coordinators to provide comments and nominate speakers, in particular, for the Q8, Q9 & (Q10) workshop by beginning of June 2007.*
- *The Secretariat to reflect on playing a role in assessing and coordinating training requests.*

Clearinghouse: scope and use of the calendar

The discussion focused on the usefulness of the calendar and appropriateness of the scope.

It was suggested to add all training events open to ICH and RHIs and not to limit the calendar to ICH workshops. Furthermore, it was agreed that it would be useful to post all training materials on the calendar, since these will benefit all, even non-participants.

The Secretariat was tasked to collect training materials related to ICH guidelines. Thought was also given to the development of contextual GCG slides to relate the importance of ICH work.

Actions:

- *The Secretariat to add the APEC training requests on the calendar.*
- *The Secretariat to collect training materials related to ICH guidelines.*

Access to the GCG working area

This discussion was deferred to the Yokohama meeting to take place on 30 October 2007, due to lack of time.

12. ICH update report**Status of ICH topics and procedural matters, organization of the EWG/SC week**

This discussion was cancelled due to lack of time.

13. Any Other Business**Invitation to India Drugs Controller: Dr. Venkateswarlu**

Mr. Ward provided an update to the GCG and RHIs regarding the status of the invitation sent to the Drugs Controller General of India to attend a GCG meeting.

All were in favor of renewing the invitation to attend the next GCG meeting in Yokohama.

Action:

- *The Secretariat to send a new invitation letter to the India Drugs Controller.*