

Final

**GLOBAL COOPERATION GROUP MEETING REPORT
TUESDAY NOVEMBER 9, 2010**

*Fukuoka, Japan
(Hilton Fukuoka Sea Hawk Hotel)*

PARTICIPANTS:

Ref: GCG 132F

Ms. Lenita Lindström	EU (GCG Co-Chair)
Dr. Alice Till	PhRMA (Acting GCG Co-Chair)
Dr. Hideo Utsumi	MHLW (PMDA)
Mr. Shinobu Uzu	MHLW
Mr. Tadaharu Goto	JPMA
Mr. Kohei Wada	JPMA
Dr. Justina Molzon	FDA
Dr. André W. Broekmans	EFPIA
Dr. Lembit Rägo	WHO
Mr. Mike Ward	Health Canada
Dr. Petra Dörr	EFTA
Dr. Odette Morin	IFPMA
Dr. Sumol Pavittranon	APEC
Dr. Yuppadee Javroongrit	ASEAN
Prof. Saleh Bawazir	GCC
Dr. Alphonse Mulumba	SADC
Dr. Ding Jianhua	DRA of China
Dr. Zhang Wei	DRA of China
Ms. Chien-Wen Hsu	DoH of Chinese Taipei
Dr. Surinder Singh	DRA of India
Dr. Sun Hee Lee	DRA of Korea
Dr. Chong Hui Hong	DRA of Korea
Dr. Christina Lim	DRA of Singapore
Dr. Huei-Xin Lou	DRA of Singapore

Also Present:

Dr. Toshiyoshi Tominaga	MHLW (PMDA)
Ms. Michiko Suzuki-Aida	MHLW
Dr. Masaaki Tsukano	MHLW (PMDA)
Dr. Kurajiro Kishi	JPMA
Ms. Joan Blair	FDA
Dr. Michelle Limoli	FDA
Ms. Mary Morrison	FDA
Dr. Michael Garvin	PhRMA
Dr. Thomas Salmonson	EU
Dr. Sabine Haubenreisser	EU (EMA)
Dr. Elisa Siviglia	EFPIA
Dr. Dawn Ronan	ICH Secretariat

1. Welcoming Remarks and Adoption of the Agenda

Ms. Lindström (GCG Co-chair, EU) welcomed all participants to the meeting of the ICH Global Cooperation Group (GCG) on behalf of herself and Dr. Till (acting GCG Co-chair, PhRMA).

The agenda was adopted without modification.

2. Review of Current Membership

The GCG noted that there were no changes to the current GCG membership, however a warm welcome was extended to several representatives who were attending the GCG meeting for the first time.

Dr. Alphonse Mulumba was introduced to the GCG as the SADC representative replacing Mr. Mthetwa who was unfortunately unable to attend the Fukuoka meeting. Dr. Mulumba also informed the GCG that Ms. Germina Mphoso from the Republic of Lesotho had been nominated as the second representative from SADC, but unfortunately she was also unable to make the meeting.

Ms. Chien Wen Hsu was welcomed as the representative from the DoH of Chinese Taipei, in replacement of GCG members Dr. Kang and Dr. Tzou who were unable to attend the Fukuoka meeting.

A welcome was also extended to Dr. Chong Hui Hong from the DRA of Korea, who was replacing her colleague Ms. Park who was unable to attend the meeting.

Apologies were received from Dr. Honig (GCG Co-chair, PhRMA), Dr. Fitzgerald (PANDRH), Mr. Mthetwa and Ms. Mphoso (SADC), Dr. Donohoe and Dr. Lopert (DRA of Australia), Dr. Raposo de Mello and Mrs. Soares Jucá da Silveira e Silva (DRA of Brazil), Dr. Kang and Dr. Tzou (DoH of Chinese Taipei), Mr. Panda (DRA of India), and Dr. Barmanova and Mr. Terekhov (DRA of Russia).

The GCG was invited to communicate to the ICH Secretariat any forthcoming changes in GCG membership.

3. Final Approval of the Report of the GCG Teleconference held on October 8, 2010 (Ref: GCG 130)

The GCG noted the comments submitted by Korea on the GCG teleconference report (GCG 130) and approved the revised report as final.

Action/Decision:

- *The GCG approved as final the report of the GCG teleconference held on October 8, 2010.*

4. RHI pre-meeting Report

Dr. Pavitranon (APEC) reported to the GCG on the outcome of the RHI pre-meeting held prior to the GCG meeting. The main issues discussed included the importance of collaborating efforts on Good Manufacturing Practice (GMP) for Active Pharmaceutical Ingredients (APIs), Good Clinical Practice, and Good Review Practice (GRP). The need for more training, both in the form of face-to-face training and remote training, via web conferences and recorded downloadable training modules, was also discussed. A suggestion was also made to develop an ICH certificate which participants could use to confirm that they had attended a training event or followed an online training module.

Action/Decision:

- *The ICH Secretariat to develop a standard ICH certificate of completion based on examples to be provided by GCG members. This standard form will then be made available to the host organisers of training events for signature by either the host or trainers.*

5. 6th Regulators Forum Report

Mr. Uzu reported on the outcome of the 6th Regulators Forum. The GCG noted that the meeting was well received by participants who included the representatives of the RHIs, DRAs and DoH, in addition to the ICH regulators and ICH Observers. Mr. Uzu commented that the forum provides a good opportunity to share views and experiences regarding the implementation of ICH Guidelines.

Topics discussed at the 6th Regulators Forum included GRP, the ICH E6 Guideline on GCP, and the ICH Q7 Guideline on GMP for APIs. Several of the participants also provided regulatory updates, and WHO and Singapore reported on the organisation of the upcoming ICDRA (International Conference of Drug Regulatory Authorities) meeting to be held in Singapore in November 2010.

6. Finalisation of RHI Profiles

SADC Profile

The GCG noted that Mr. Mthetwa (SADC) had provided the ICH Secretariat with an updated draft profile for SADC and that the ICH Secretariat was in the process of finalising the profile for publication on the ICH website.

APEC Profile

Dr. Pavitranon (APEC) reported that the APEC profile was in the process of being developed and a draft would be submitted ahead of the next ICH meeting in Cincinnati in June 2011.

Actions/Decisions:

- *The ICH Secretariat to finalise the SADC profile for publication on the ICH website;*
- *The RHIs were invited to inform the ICH Secretariat of any changes in their regional profiles in order to keep the GCG public website up-to-date.*

7. Celebration of ICH 20th Anniversary

Dr. Molzon (FDA) presented the GCG with copies of the publication on “*The Value and Benefits of the International Conference on Harmonisation for Drug Regulatory Authorities – Advancing Harmonization for Public Health*”. The GCG noted that following the last GCG meeting in Tallinn, in June 2010, Dr. Molzon had worked to incorporate the colours and logo of the new ICH website into the document. Dr. Molzon also informed the GCG that prior to the publication of the document the authorisation of all authors had been sought. The GCG also noted that the document had been made available on the ICH website. Dr. Molzon commented that 3,000 copies of the document had been printed, 400 of which would be sent for distribution at the forthcoming ICDRA meeting in Singapore, in November 2010.

8. Step 2 Guidelines for Consultation

The GCG noted that the ICH Secretariat had sent letters to the RHIs and DRAs/DoH on July 23, 2010 inviting them to comment on the following ICH Guidelines which reached *Step 2* in / prior to the Tallinn meeting in June 2010:

- Q3C(R4): *Impurities - Guideline for Residual Solvents PDE for Cumene;*
- Q4B Annex 13: *Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Bulk Density and Tapped Density of Powders General Chapter;*
- Q4B Annex 14: *Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Bacterial Endotoxins Test General Chapter.*

Comments were invited by the end of September 2010 for the Q3C(R4) Guideline and October 22, 2010 for Q4B Annex 13 and 14.

The GCG noted that no comments had been received from RHIs/DRAs/DoH on these documents.

9. Webinars on Step 2 / Step 4 Guidelines

Dr. Ronan (ICH Secretariat) reported to the GCG on the webinar held on October 19, 2010 on the ICH E16 Guideline which reached *Step 4* in August 2010. The GCG noted that the webinar, presented by Dr. Goodsaid (E16 Rapporteur, FDA), had been attended by almost 20 participants from APEC, ASEAN, and the DRAs of Korea and Singapore.

RHIs/DRAs/DoH were invited to propose to the ICH Secretariat other topics in which there would be interest to have a presentation. The GCG agreed that consideration could also be given to the organisation of webinars on older ICH Guidelines if there was interest.

Dr. Ronan also updated the GCG on the ICH Secretariat’s investigation of affordable IT tools for the organisation of webinars/teleconferences which take advantage of Voice Over Internet Protocol (VoIP) technology. The GCG noted that the ICH Secretariat planned to pilot the use of one of these tools and hoped to have it available for the next GCG teleconference in spring 2011.

Action/Decision:

- *The RHIs, DRAs and DoH were invited to propose to the ICH Secretariat any ICH topics on which they would be interested to have a webinar.*

10. Presentation on ICH E2F Guideline

Dr. Barry Arnold (E2F Topic Leader, EFPIA) presented to the GCG on the E2F Development Safety Update Report (DSUR) Guideline which reached *Step 4* in August 2010. Dr. Arnold informed the GCG of the general principles of the DSUR, and of the challenges anticipated with the implementation of the Guideline. The GCG noted the benefits of the DSUR in harmonising the format, content and scheduling of annual reports, with the development of a single DSUR for each Investigational Drug. Dr. Arnold also informed the GCG that two example reports would shortly be made available on the ICH website which he hoped would be helpful for the RHIs/DRAs/DoH.

Action/Decision:

- *The ICH Secretariat to follow-up regarding the development of a recording of Dr. Arnold's presentation for publication on the ICH website.*

11. Training and Capacity Building

❖ GCG-Endorsed Training

SADC

Dr. Mulumba (SADC) presented 12 topics for the programme for the SADC training on the ICH Q7 Guideline which should take place in March 2011 in Tanzania. Dr. Mulumba confirmed that SADC was in the process of finalising the programme and the number of days for the training event. The EU confirmed that it would be pleased to be the lead ICH Party for the SADC training.

ASEAN

Dr. Javroongrit (ASEAN) reported to the GCG on the organisation of the training on the Q5C Guideline, for which the EU was nominated as the lead ICH Party. Dr. Javroongrit commented that the training would take place in either March 2011 or in Q2 2011. The GCG also noted the successful organisation in July 2010 of the training on Q8/Q9/Q10 which took place in Kuala Lumpur, Malaysia.

GCC

Prof. Bawazir (GCC) reported on the organisation of training on the ICH Q5A-Q5E Guidelines, for which the EU was nominated as the lead ICH Party. The GCG noted that the training would take place in spring 2011, either in March or April.

Action/Decision:

- *The EU was nominated as the lead ICH Party for the SADC training on the ICH Q7 Guideline.*

12. APEC Harmonisation Center (AHC)

Dr. Lee (DRA of Korea) reported on the recent activities of the AHC. The report included feedback from the 2010 Multi-Regional Clinical Trials Workshop - highlighting Korea-China-Japan Tripartite Symposium which was held in Seoul, in September 2010. Korea-China-Japan Tripartite activities were also presented, which included a report on the 2010 Director General-level meeting.

13. RHI, DRA and DoH Update on ICH-related Matters

RHIs, DRAs and DoH were invited to provide presentations to the GCG on their respective initiatives and current activities.

ASEAN - Dr. Javroongrit reported to the GCG on the outcome of the 17th PPWG meeting held in Indonesia in July 2010. Some important outcomes included a proposal to study the safety and efficacy guidelines of ICH as well as other international guidelines, and a proposal to establish a Technical Working Group for Biologics. The draft ASEAN Variation Guideline was also discussed.

APEC - Dr. Pavittranon reported to the GCG on the work of the LSIF (Life Sciences Innovation Forum), including its achievements, one of which included the establishment of the AHC. She informed the GCG that the LSIF IX would take place in the US in 2011.

Mr. Ward (Health Canada) reported to the SC on progress made at the recent APEC Regulatory Harmonization Steering Committee (RHSC) meeting which took place in Sendai, Japan in September 2010. Issues discussed included how to improve the funding for RHSC-endorsed projects and how to prioritise project proposals. The RHSC also approved a number of project proposals, including a proposal to repeat the training on the ICH Q8/Q9/Q10 Guidelines which was recently carried out in the ICH regions. The GCG noted that a request for a Q8/Q9/Q10 workshop to be held in 2011 would be submitted shortly.

Mr. Ward also reported on the outcome of the APEC Good Review Practices Workshop on Pharmaceuticals held in Taipei City on November 3-6, 2010, and informed the GCG of future plans to submit a proposal to the ICH Steering Committee on the need for an ICH Guideline on Multi-Regional Clinical Trials which would move beyond the ICH E5 Guideline on *Ethnic Factors in the Acceptability of Foreign Clinical Data*.

GCC – Prof. Bawazir reported to the GCG on recent GCC activities, which included the organisation of the 14th annual AUPAM meeting in Amman, Jordan on September 22-23, 2010. The GCG noted that the meeting was organised by the Arab Union for Pharmaceutical Association of Manufacturers, and was attended by both industry and regulators. He confirmed that all parties had agreed to use the ICH CTD. Prof. Bawazir also reported to the GCG on the GCC-DR (Gulf Central Committee for Drug Registration) 50th meeting which took place in Dubai on October 18-22, 2010.

14. African Initiative

Dr. Rågo (WHO) reported to the GCG on the harmonisation of medicines registration in Africa. He informed the GCG that since 2009 a continental project had been adopted using a sub-regional approach on harmonising medicines regulation in Africa. He presented the different African Regional Economic Communities which included SADC, EAC (East African Community), CEMAC (Economic & Monetary Community of Central Africa States), and UEMOA (Economic & Monetary Union of West Africa). Dr. Rågo updated the GCG on the African Medicines Registration Harmonisation (AMRH) initiative in which WHO participates. The GCG noted that the first project to be rolled out would be the EAC project in 2011 and that future AMRH activities would be based on how this project progresses.

15. MedDRA Management Board Special Session

RHI, DRA and DoH representatives were invited to provide feedback from the special session of the ICH MedDRA Management Board which was held on November 7, 2010. Dr. Javroongrit

(ASEAN) informed the GCG that she found the opportunity to participate in the special session of the Board very useful and that the Board had been very helpful to address the questions of the RHI, DRA and DoH representatives. Dr. Javroongrit also commented that she was pleased to hear that the Board could offer training on MedDRA. Prof. Bawazir (GCC) commented that he found the presentation on Health Canada's experience with the recent implementation of MedDRA to be very helpful, and suggested it could be interesting for other DRAs to share their experiences.

Dr. Ding (DRA of China) raised a question on the need for companies to pay a fee for access to MedDRA. Dr. Morin commented that while it was necessary to support the maintenance and development of MedDRA, as well as other services provided, the Board was flexible and could consider alternative options that would support MedDRA in the different regions/countries.

RHI, DRA and DoH representatives also confirmed their interest to maintain the current arrangement for discussions on MedDRA, whereby interested representatives can join a special session of the Board meeting to learn more about MedDRA and discuss with the Board. This was seen more favourably than including MedDRA discussions on the agenda of the GCG meeting since Board members would not be present for the GCG meeting.

16. Training Materials on ICH Website

In Tallinn, in June 2010, interest was expressed to record the Quality IWG training on the Q8/Q9/Q10 Guidelines to be held in the US in October 2010 so that the recordings could be made available on the ICH public website. Interest was also expressed in Tallinn in recording a presentation given to the GCG by Dr. Andrew Marr (M2 Rapporteur, EFPIA) on ICH's work with Standards Development Organisations (SDOs).

The GCG noted that the Secretariat had worked with a professional organisation to record the plenary sessions of the Quality IWG training event held in the US. Dr. Marr had also kindly recorded the presentation he gave to the GCG.

The GCG noted that the recordings would be made available on the ICH website.

In response to a request from Dr. Molzon (FDA), the ICH Secretariat also agreed to publish on the ICH website presentations from the 11th CDER Forum for International Drug Regulatory Authorities.

17. Any Other Business

Participation of RHIs, DRAs and DoH in ICH Working Groups

The GCG was updated by Mr. Ward (Health Canada) on the discussion of the SC regarding the interest of RHIs, DRAs and DoH to participate in ICH Working Groups (WGs). Mr. Ward presented the considerations and the criteria considered by the SC for participation of RHIs/DRAs/DoH.

Mr. Ward informed the GCG that the SC decision was complementary to the current situation, and RHI/DRA/DoH representatives on the GCG would continue to participate in the ICH meetings (GCG, Regulators Forum etc...), but each RHI/DRA/DoH would also be invited to nominate experts to participate in ICH WGs. He commented that RHIs/DRAs/DoH would have the same level of participation within the ICH WGs as ICH Observers. He informed the RHIs, DRAs and DoH that the SC would be pleased to have their input before it took a final decision.

Many of the RHI, DRA and DoH representatives expressed their appreciation for the decision of the SC, which some considered to be a sign of the openness and transparency of the ICH process.

Clarity was sought on several aspects of the considerations/criteria considered by the SC e.g., demonstrated support for the use of ICH Guidelines. The need for a clear procedure to be developed regarding the process for the nomination of experts to EWGs was also suggested.

In addition to providing feedback for the SC on the considerations/criteria for RHI/DRA/DoH participation in WGs, representatives also indicated specific interest to send experts to a number of WGs.

The GCG noted that the SC would try to accommodate the requests of the RHIs/DRAs/DoH to participate in the various WGs, however Mr. Ward commented that there was also a need to be pragmatic. The GCG noted the issues already faced regularly by ICH in trying to find appropriately sized meeting rooms to accommodate the various WG meetings.

Action/Decision:

- *RHI/DRA/DoH feedback to be provided to the SC regarding considerations and criteria for the participation of RHI/DRA/DoH experts in ICH WGs¹.*

GCG Co-Chairmanship

The GCG noted that following the Fukuoka meeting the Regulator Co-Chairmanship would rotate from EU to MHLW.

Dates of the Next GCG Meetings

June 14, 2011

Cincinnati, OH, USA

November 8, 2011

Europe – Location to be confirmed

¹Post-meeting note: RHI/DRA/DoH feedback was provided to the SC at its meeting in Fukuoka on November 10, 2010. Based on this feedback, the SC revised and finalised the considerations/criteria for RHI/DRA/DoH participation in WGs.