

Final

**GLOBAL COOPERATION GROUP MEETING REPORT
TUESDAY JUNE 8, 2010**

*Tallinn, Estonia
(Sokos Hotel Viru)*

Ref: GCG 124F

PARTICIPANTS:

Ms. Lenita Lindström	EU (GCG Co-Chair)
Dr. Alice Till	PhRMA (Acting GCG Co-Chair)
Dr. André W. Broekmans	EFPIA
Dr. Christine-Lise Julou	EFPIA
Mr. Shinobu Uzu	MHLW
Mr. Kohei Wada	JPMA
Dr. Justina Molzon	FDA
Dr. Lembit Rägo	WHO
Mr. Mike Ward	Health Canada
Dr. Petra Dörr	EFTA
Dr. Odette Morin	IFPMA
Dr. Sumol Pavittranon	APEC
Ms. Siripan Wongvanich	APEC
Dr. Yuppadee Javroongrit	ASEAN
Prof. Dr. Saleh Bawazir	GCC
Mr. Joseph Mthetwa	SADC
Dr. Mateus Fernandes	SADC
Dr. Dirceu Raposo de Mello	DRA of Brazil
Ms. Erica Mattos da Veiga	DRA of Brazil
Mr. Jinhua Ding	DRA of China
Dr. Sun Hee Lee	DRA of Korea
Ms. Eun Hye Park	DRA of Korea
Dr. Christina Lim	DRA of Singapore
Dr. Huei-Xin Lou	DRA of Singapore

Also Present:

Dr. Thomas Salmonson	EU
Dr. Matus Ferech	EU
Dr. Emer Cooke	EU
Dr. Spiros Vamvakas	EMA/EU
Dr. Sabine Haubenreisser	EMA/EU
Mr. Takayuki Okubo	MHLW
Dr. Masaaki Tsukano	MHLW/PMDA
Dr. Kurajiro Kishi	JPMA
Ms. Joan Blair	FDA
Ms. Mary Morrison	FDA
Dr. Michael Garvin	PhRMA
Dr. Sarah Adam	ICH Secretariat
Dr. Dawn Ronan	ICH Secretariat

1. Welcoming Remarks and Adoption of the Agenda

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

The agenda was adopted without any modification.

2. Review of Current Membership

A special welcome was extended to Ms. Siripan Wongvanich (APEC) and Dr. Mateus Fernandes (SADC, Republic of Angola) who were participating in the GCG meeting in Tallinn.

Ms. Erika Mattos was introduced to the GCG as the representative of the DRA of Brazil replacing Mrs. Ana Paula Soares Jucá da Silveira e Silva for the Tallinn meeting.

Mr. Ding (China) informed the GCG of the recent nomination of Mr. Zhang Wei (Director-General Department of Drug Pharmaceutical Registration at the Chinese SFDA) as new representative of the DRA of China.

Apologies were received from Dr. Honig (GCG Co-chair, PhRMA), Dr. Fitzgerald (PANDRH), Dr. Donohoe and Dr. Lopert (Australia), Dr. Kang and Dr. Tzou (DoH of Chinese Taipei), Dr. Singh and Mr. Panda (India), Dr. Barmanova and Mr. Terekhov (Russia).

Dr. Adam (ICH Secretariat) invited the GCG participants to communicate to the ICH Secretariat any current and future changes in GCG membership.

3. Final Approval of the Report of the GCG Teleconference held on May 6, 2010 (Ref: GCG122R)

Action/Decision:

- *The GCG approved as final the report of the GCG teleconference held on May 6, 2010.*

4. RHI pre-meeting Report

Dr. Javroongrit (ASEAN) reported on the Regional Harmonisation Initiative (RHI) pre-meeting. The RHIs discussed hot topics of the Regulators Forum which included *Good Manufacturing Practices (GMP) for APIs (ICH Q7)*, *Good Clinical Practices (GCPs) (ICH E6)* and *Good Review Practices (GRP)*. She highlighted the importance of sharing information on API inspection outcomes but also the value of developing training workshops for GCP and GRP.

Dr. Javroongrit also emphasized the importance of developing training programs and training modules for key ICH topics (Quality and GCP) to facilitate Guideline implementation.

Dr. Javroongrit mentioned the usefulness but also the challenges of currently used teleconferencing /webinar technologies for presentation on ICH topics and the importance to facilitate the participation of individual countries.

Action/Decision:

- *The ICH Secretariat will explore affordable IT tools (such as "Elluminate") for the organisation of teleconferences/webinars.*

5. 5th Regulators Forum Report

Ms. Lindström reported on the fifth ICH Regulators Forum held on June 7, 2010 in Tallinn where participants provided regulatory updates from their regions. The EU informed the participants of recent legislative changes. The US presented the outcome of the CDER Forum, and Japan updated the Regulators on a tripartite research study between Japan, China and Korea on *Ethical Aspects of Clinical Trials*. Regulators continue to discuss and exchange views on three major project initiatives on GMP, GCP and GRP. The GCG noted the establishment of contact points for inspection.

6. Finalization of RHI Profiles

Mr. Mthetwa (SADC) informed the GCG on the progress made in Tallinn towards finalization of the SADC profile.

Dr. Pavitranon (APEC) informed the GCG that the APEC profile was under development in collaboration with the LSIF Regulatory Harmonisation Steering Committee. The profile will be submitted to the GCG in Fukuoka in November 2010.

Actions/Decisions:

- *The ICH Secretariat will follow-up with APEC and SADC regarding the finalization of their regional profiles;*

- *The RHIs will inform the ICH Secretariat of any changes in their regional profiles in order to maintain the GCG public website up-to-date.*

7. Celebration of ICH 20th Anniversary

In Commemoration of the 20th anniversary of ICH, Dr. Molzon (FDA) distributed to the GCG a printer's proof version of the article *the Value and Benefits of the ICH to Drug Regulatory Authorities – Advancing Harmonisation for Better Public Health*. Dr. Molzon provided an overview of the article which is complementary to a report written ten years ago by Dr. Nutley Loew (PhRMA) on the *Value and Benefits of ICH to Industry*. In the overview of the document, Dr. Molzon explains where ICH stands ten years later and the impact of the incorporation of the Common Technical Document into regulatory processes in ICH and non-ICH countries. The article which is dedicated to ICH experts in recognition of their work will be distributed at the next ICH meeting in Fukuoka and at the public pre-meeting on Harmonisation at the 14th International Conference of Drug Regulatory Authorities (ICDRA) in Singapore in November 2010.

Actions/Decisions:

- *The RHIs and DRAs/DoH were invited to provide their comments on the printer's proof version of the document by the end of June 2010;*
- *FDA will publish booklets to be distributed at the time of the ICH meeting in Fukuoka and at the ICDRA meeting to be held in November 2010.*

8. Step 2 Guidelines for Consultation

The GCG, RHIs and DRAs/DoH noted that several comments were submitted to the ICH Secretariat on the following *Step 2 Guidelines*: Addendum to ICH S6 on *Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals*; and the Q4B Annexes 11 and 12 on *Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Capillary Electrophoresis General Chapter* and on *Analytical Sieving General Chapter*.

The GCG noted that China, Korea and Singapore commented on the Addendum to ICH S6 Guideline. Singapore also commented on the Q4B Annexes 11 and 12.

9. Webinars on Step 2 / Step 4 Guidelines

The GCG, RHIs and DRAs/DoH discussed the organization of future webinars on *Step 2 / Step 4 Guidelines*. ICH topics proposed for consideration were: ICH S6 Guideline on *Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals* and ICH E2F Guideline on *Development Safety Update Report*, once *Step 4* is reached and ICH Q11 Guideline on *Development and Manufacture of Drug Substances* once *Step 2* is achieved. Additional topics close to finalization (*Step 4*) such as ICH E16 on *Genomic Biomarkers* and ICH E7 Q&As were also suggested to the RHIs and DRAs/DoH.

Action/Decision:

- *The RHIs and DRAs/DoH will be invited to confirm/suggest ICH topics on which they would like a webinar.*

10. Presentation on ICH Topics

The GCG, RHIs and DRAs/DoH received a brief presentation on ICH topic Q11 on *Development and Manufacture of Drug Substances*; and on *ICH work with Standard Development Organizations (SDOs)* which aims to make ICH electronic standards international.

Mr. Withers (Q11 Rapporteur, EFPIA) provided an overview on the current structure, objectives and status of the ICH Q11 Guideline. The GCG noted that the draft Guideline contains 5 sections (Process development, Manufacturing Process, Control Strategy, Process Validation / Evaluation and Product Lifecycle). Each section provides guidance on what information to file for small and large molecules. Mr. Withers informed the GCG that the group is working towards reaching *Step 2* in Fukuoka, Japan in November 2010.

Dr. Marr (M2 Rapporteur, EFPIA) presented on ICH's work with SDOs to develop international standards for ICH E2B (ICSR - Individual Case Safety Report) and M5 (IDMP - Identification of Medical Products) messages. Dr. Marr highlighted the importance of the ICSR and IDMP for drug safety monitoring and evaluation. The GCG noted the value of Dr. Marr's presentation as an overview on ICH's work with SDOs and expressed its interest to have a training module on this topic (video recording and transcript) to facilitate understanding of this complex topic.

Action/Decision:

- *The GCG requested that the ICH Secretariat follow up with Dr. Marr regarding the preparation of a training module.*

11. Quality IWG Training Workshop for Q8/Q9/Q10 Guidelines

Dr. Robert (Quality IWG Rapporteur, EU) reported on the outcome of the first regional Quality IWG Training Workshop on *Implementation of ICH Guidelines Q8, Q9 and Q10* held in Tallinn on June 2-4, 2010. The event was well received and welcomed over 240 participants including 7 from outside the ICH regions. The GCG noted that several case studies were presented at the workshop which provided comprehensive information about technical development, manufacturing details, and pharmaceutical quality systems in addition to regulatory aspects including regulatory expectations, dossier preparation /assessment and GMP inspections. Dr. Molzon (FDA) highlighted also the value of videotaping the US Workshop as a training resource.

The GCG noted that the second and third regional workshops will be held in Washington DC, USA on October 6-8, 2010 and October 25-27, 2010 in Tokyo Japan, respectively.

12. Training and Capacity Building

❖ GCG-Endorsed Training

ASEAN Training

Dr. Javroongrit (ASEAN) briefly reported on the outcome of the MedDRA workshop hosted by the National Pharmaceutical Control Bureau (NPCB) of the Malaysian Ministry of Health and held in Kuala Lumpur, Malaysia on March 17-19, 2010. This event was attended by 22 ASEAN Regulators from Brunei, Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore and Vietnam in addition to 28 representatives of local pharmaceutical and multinational companies.

Dr. Javroongrit also updated the GCG on the organisation of two additional GCG-endorsed regional training events to be held in Malaysia. A workshop on ICH Q8-Q10 Guidelines will be held on July 26-28, 2010 and will be open to both Regulators and industries. A workshop on ICH Q5C Guidelines is aimed to be held in the last quarter of 2010. The EU which has been nominated ICH lead for this event provided new contact points to facilitate the coordination of this event.

GCC Training

Prof. Bawazir (GCC) updated the GCG on the organisation of training on ICH Q5A-Q5E Guidelines to be held either in November or December 2010. He informed the GCG that due to the H1N1 flu pandemic the organisation of this workshop had been delayed. The GCG noted that the training programme was currently being reviewed by the EU (ICH party nominated as the ICH lead for this event).

LSIF Regulatory Harmonisation Updates

Mr. Ward (Health Canada and chair of the LSIF Regulatory Harmonisation Steering Committee, RHSC) provided an overview of the APEC LSIF including, challenges and strategies for regulatory harmonisation.

Mr. Ward presented the outcome of the 2nd RHSC meeting held in Hiroshima, Japan on March 2-4, 2010, where Japan (MHLW / PMDA) joined the RHSC as a Steering committee member and Singapore (HSA) as an official observer, and where a RHSC Secretariat was established. The GCG noted the progress made in the development of RHSC infrastructure and a strategic action plan.

Mr. Ward informed the GCG that training topics endorsed by the RHSC in Hiroshima for 2010-2011 included *Multi-Regional Clinical Trials*, *Good Review Practices*, *Pharmaceutical Quality*, *Pharmacovigilance* and *Stem Cells*.

Mr. Ward also discussed the RHSC's strategic approach for building a better Harmonization model.

AHC Activities

Dr. Lee (DRA, Korea) provided a brief overview on AHC goals including the support of best practices and guidelines, the support of information sharing and the promotion of conduct of clinical trials to meet international standards.

She also reported on the outcome of the second and third AHC workshops conducted in 2009 on *Biosimilars* and *GMP Pharmaceutical Validation* held on September 17-18, 2009 and December 3, 2009 respectively. The GCG noted that the *GMP Validation* workshop was a domestic workshop due to the flu pandemic, and was attended by over 450 participants from Government, Industry and Academia. The event provided practical and informative training to Korean stakeholders in addition to a forum for discussion. Dr. Lee also reported on the outcome of the workshop on *Globalisation in the Pharmaceutical Supply Chain* which was held in May 12-14, 2010 and welcomed over 280 participants from Government, Industry and Academia. The workshop presented the challenges in the globalisation of drug development, approvals, and distribution, and discussed special topics and related regulatory concerns.

The GCG noted AHC future activities for 2010, which includes the assessment of training needs, the development of the AHC website and the strengthening of international cooperation with APEC and non-APEC Government, Industry and Academia.

To conclude, Dr. Lee invited other interested governments, cooperations and foundations to work cooperatively with AHC and invited the GCG to provide any suggestions for future AHC training and capacity building activities.

❖ *Anticipating Future Training Needs*

SADC Request, Mr. Mthetwa presented to the GCG a request for a regional training on *Good Manufacturing Practices (GMP) for Active Pharmaceutical Ingredients (ICH Q7)* to be held in Arusha Tanzania in March 2011. The GCG endorsed the training request. The lead ICH Party will be confirmed once the training program will be finalised.

APEC, Dr. Pavittranon informed the GCG that 3 training programs on *Good Review Practices for Medical Devices, Best Regulatory Practices for Pharmaceuticals and Medical Devices* and *Quality Insurance/Quality Control for Stem Cells* were submitted to the APEC LSIF for funding consideration before submission to the GCG.

China, Mr. Ding informed the GCG on China's training strategy to respond to the increased number of training requests in the country. The strategy consists firstly of studying ICH Guidelines and then requesting additional clarification, if needed, by submitting training requests to the GCG. The GCG noted the importance of the "train the trainers" approach to facilitate the sharing of knowledge.

Actions/Decisions:

- *The GCG endorsed the SADC training request on ICH Q7;*
- *Once the SADC training program is finalised, it will be submitted to the ICH secretariat in order for the GCG to confirm the lead ICH party for the organisation of this event.*

13. Evolution of the EU System for the Authorisation of medicinal Products

Dr. Cooke (EMA) provided an overview on the evolution of the EU Regulatory System for approval of pharmaceutical products. She explained the role of the European Medicines Agency (EMA) as the secretariat co-ordinating the scientific resources put at the disposal by the Member States for the Evaluation of Medicinal Products in the European Union.

Dr. Cooke presented to the GCG the organisation of the EU regulatory framework and its objectives which include the completion of the single EU market for pharmaceuticals, and the protection and promotion of public and animal health. The GCG noted that 3 different procedures exist at EU level (in addition to the national procedure) for the authorisation of medicinal products, namely: Centralised Procedure, Mutual Recognition Procedure and Decentralised Procedure. Apart from certain specific medicinal products, for which the Centralised Procedure is mandatory under EU legislation, the individual pharmaceutical companies will decide which procedure to opt for depending on their respective needs.

Dr. Cooke presented EU worksharing principles between Member States underlying the EU assessment including examples on inspections, Periodic Safety Update Reports and Post-authorisation changes.

Last, she summarized EU regulatory system achievements based on mutual cooperation and efficiencies which can be used also by other non EU-countries.

Dr. Broekmans (EFPIA) presented an Industry view and perspectives on the European Regulatory System explaining its main characteristics and attractiveness for the innovative industry.

14. RHI and DRA Update on ICH-related Matters

RHIs and DRAs/DoH provided formal presentations to the GCG on their respective initiatives and current activities. The presentations will be made available on the ICH website.

APEC, Dr. Pavittranon provided background information on the APEC Life Sciences Innovation Forum (LSIF) including its mission and regulatory performance. She highlighted the efforts of Regulators, Industry and Academia in promoting greater synergies and coordination, to optimise benefits derived from interactions with international harmonization initiatives; and to develop mechanisms to sustain training and capacity-building work.

Dr. Pavittranon reported on the LSIF VII meeting held in Singapore on August 3-4, 2009. The two-day meeting, which welcomed over 200 participants, raised the importance of detection and prevention for health care, financing for R&D in an economic downturn, and the value of Health innovation.

The GCG noted the recommendations made to the ministers which included supporting the review of the *enablers of investment checklist*, reaffirming the central role of Regulators in harmonisation among APEC economies, and endorsing the RHSC Terms of Reference and workplan. Dr. Pavittranon reported on the LSIF Planning Group Meetings held in Japan in February and May 2010 where the use of the *enablers of investment checklist* was encouraged and funding for training was discussed.

Lastly, the GCG noted the organisation of the LSIF VIII forum on *Enhancing Health and Driving Innovation in APEC Economics Growth* to be held in Sendai, Japan in September 2010.

ASEAN, Dr. Javroongrit provided background information on ASEAN, principles and structure. She also presented the ASEAN Economic Community highlighting its role in economic cooperation and its objectives to be a single market and single production unit by 2015. Dr. Javroongrit also explained to the GCG the structure and work of the Pharmaceutical Product Working Group (PPWG) including harmonisation objectives.

Lastly, the GCG noted also the organisation of the 17th ACCSQ/PPWG and the 18th ACCSQ/PPWG meeting to be held in Indonesia in July 2010 and in Thailand in 2011, respectively. Dr. Javroongrit outlined possible topics for a one-day seminar to be held prior to the 18th ACCSQ/PPWG meeting such as ICH Regulators Forum projects (GCP, GRP, ICH Q7), WHO prequalification programme (Pharmaceuticals), WHO GMP new Guidelines, eCTD, Q4 series and MedDRA.

GCC, Prof. Bawazir provided background information on the structure of the Gulf Central Committee for Drug Registration (GCC-DR) including the outcome of GCC 2010 activities. The GCG noted the organisation of the First Arab Meeting - *Towards Advancing Pharmaceutical Industry* held in Sharm Alshakh on February 21-23, 2010 where Regulators and Industry representatives discussed the proposal to establish an Arab Forum for Harmonising Drug Registration.

Prof. Bawazir presented the outcome of the 48th GCC-DR meeting held in Kuwait on February 21-25, 2010. He informed also the GCG that during the 49th GCC-DR meeting held in Riyadh on May 30 - June 2, 2010, the ICH CTD format was approved to become effective as of January 2011.

Lastly, Prof. Bawazir reported on the organisation of the GCG-endorsed workshop on *Biosimilars* (ICH Q5A-Q5E) to be held in 2011.

SADC, Mr. Mthetwa presented an update on SADC 2010 activities. The GCG noted the outcome of two workshops organised back-to-back to the SADC Medicines Regulatory Forum on the *Development of Regional Guidelines for Disposal of Unwanted Medicines* and on the *Development of Regional Strategy for the Control of Counterfeit Medicines* held on March 4-5, 2010 and on March 6-8, 2010, respectively.

Mr. Mthetwa also reported on ongoing Expert Working Group discussions on the *Development of a Regional Strategy for Pooled Procurement of Essential Medicines and commodities for HIV and AIDS, Tuberculosis and Malaria* and on a *Strategic Framework for Regional Manufacturing for Essential Medicines and commodities for HIV and AIDS, Tuberculosis and Malaria*.

Last, Mr. Mthetwa noted that the outcome of discussions on *Feasibility Study for Procurement and Local Production of Essential Medicine* for Malaria, HIV/AIDS and Tuberculosis will be discussed during a Dissemination workshop to be held in July 2010 in Lilongwe, Malawi.

China, Mr. Ding provided background information on the organisation and structure of the ICH China Research Working Group for which the Department of Drug Registration of the State Food and Drug Administration (SFDA) is lead.

He presented an overview of the China Research Working Group 2010 main objectives and a detailed schedule plan for the Sub-Groups' work and tasks from July 2009 to September 2010. The GCG noted that one of the objectives of the Working Group was to translate into Chinese and publish all ICH Guidelines to facilitate training. Additionally, China would like to increase contact with ICH and with the ICH parties.

Finally, Mr. Ding noted that China would like involvement in ICH beyond GCG (e.g., in Q11).

15. African Initiative

Time did not allow Dr. Rågo (WHO) to provide a report on harmonisation of medicines registration in Africa, therefore Dr. Rågo will be invited to provide to the GCG an update on this matter at the next GCG meeting in Fukuoka, Japan to be held on November 9, 2010.

16. MedDRA Management Board Special Session

Time did not allow the RHIs and DRAs/DoH to provide to the GCG any feedback on the one hour special session of the MedDRA Management Board held on June 6, 2010.

Action/Decision:

- *The Secretariat will invite the RHIs and DRAs/DoH were invited to provide by email any feedback on the one hour special session of the MedDRA Management Board held on June 6, 2010.*

17. Any Other Business

Date of the Next GCG Meeting

November 9, 2010

Fukuoka, Japan

June 14, 2011

Cincinnati, OH, USA

GCG Co-Chairmanship

Following the Fukuoka meeting in November 2010 the Regulator Co-Chairmanship will rotate from EU to MHLW.