

Final

**GLOBAL COOPERATION GROUP MEETING REPORT
TUESDAY JUNE 14, 2011**

*Cincinnati, OH, USA
(Hilton - The Netherlands Plaza Hotel)*

PARTICIPANTS:

Mr. Shinobu Uzu	MHLW(GCG Co-Chair)
Dr. Peter Honig	PhRMA (GCG Co-Chair)
Dr. Justina Molzon	FDA
Ms. Irène Sacristan Sanchez	EU
Dr. André W. Broekmans	EFPIA
Mr. Kohei Wada	JPMA
Dr. Lembit Rägo	WHO
Mr. Mike Ward	Health Canada
Dr. Petra Dörr	EFTA
Dr. Odette Morin	IFPMA
Mrs. Patricia Pineda	APEC
Mr. Mauricio Gómez	APEC
Dr. Christina Lim	ASEAN / DRA of Singapore
Prof. Dr. Saleh Bawazir	GCC
Mr. Joseph Mthetwa	SADC
Ms. Fortunate Fakudze	SADC
Dr. Harry Rothenfluh	DRA of Australia
Dr. Zhang Wei	DRA of China
Dr. Chen Zhen	DRA of China
Dr. Meir Chyun Tzou	DoH of Chinese Taipei
Dr. Churn Shiouh Gau	DoH of Chinese Taipei
Dr. Sun Hee Lee	DRA of Korea
Dr. Huei-Xin Lou	DRA of Singapore

Also Present:

Ms. Joan Blair	FDA
Dr. Michelle Limoli	FDA
Dr. Michael Garvin	PhRMA
Dr. Thomas Salmonson	EU
Dr. Matus Ferech	EU
Dr. Sabine Haubenreisser	EU (EMA)
Dr. Emer Cooke	EU (EMA)
Dr. Toshiyoshi Tominaga	MHLW (PMDA)
Ms. Yasuko Inokuma	MHLW
Mr. Masaaki Tsukano	MHLW (PMDA)
Dr. Kurajiro Kishi	JPMA
Dr. Samvel Azatyan	WHO
Dr. Louise Déry	Health Canada
Dr. Sarah Adam	ICH Secretariat
Dr. Dawn Ronan	ICH Secretariat

1. Welcoming Remarks and Adoption of the Agenda

Mr. Shinobu Uzu (GCG Co-chair, MHLW) and Dr. Peter Honig (GCG Co-chair, PhRMA) welcomed all participants to the meeting of the ICH Global Cooperation Group (GCG).

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.

Mrs. Patricia Pineda (APEC) was introduced to the GCG as the new APEC representative replacing Dr. Sumol Pavittranon. *Mr. Mauricio Gómez* was also introduced as the second representative from APEC who was nominated by the APEC Secretariat to attend the Cincinnati meeting in replacement of the current representative from APEC, Mrs. Barbara Norton.

Dr. Christina Lim (DRA of Singapore) informed the GCG that she had been nominated as the acting second representative from ASEAN, in replacement of the current representative from ASEAN, Dr. Yuppadee Javroongrit who unfortunately was also unable to attend the meeting.

Dr. Harry Rothenfluh (DRA of Australia) was introduced to the GCG as the new representative from the DRA of Australia replacing Dr. Ruth Lopert.

A welcome was also extended to **Dr. Chen Zhen** from the DRA of China, **Dr. Churn-Shiouh Gau** from the DoH of Chinese Taipei and **Mr. Nam Soo Kim** from the DRA of Korea who were nominated as the new representatives replacing Dr. Jianhua Ding, Dr. Jaw-Jou Kang and Ms. Eun Hye Park, respectively.

Apologies were received from Dr. James Fitzgerald (PANDRH), Dr. Yuppadee Javroongrit (ASEAN), Dr. John Donohoe (DRA of Australia), Dr. Raposo de Mello and Mrs. Soares Jucá da Silveira e Silva (DRA of Brazil), Mr. Debasish Panda and Dr. Surinder Singh (DRA of India), Mr. Nam Soo Kim (DRA of Korea), and Dr. Elena Barmanova and Mr. Alex 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 May 19, 2011 (Ref: GCG 138R)

The GCG noted that the draft report of the GCG teleconference (Ref # GCG138) which was held on May 19, 2011, was circulated for comments to the ICH GCG, RHIs/DRAs/DoH on May 26, 2011 with a deadline for comments by June 2, 2011. Minor editorial comments were received from FDA, EFPIA, JPMA, the DRA of Singapore and the DoH of Chinese Taipei accepted the draft report without comments.

Actions/Decisions:

- *The GCG approved as final the report of the GCG teleconference held on May 19, 2011;*
- *The ICH Secretariat will post the final report of the GCG teleconference on the ICH website.*

4. RHI pre-meeting Report

Prof. Bawazir (GCC) reported to the GCG on the outcome of the RHI pre-meeting held prior to the GCG meeting where the main issues discussed included the importance of collaborating efforts on Good Manufacturing Practice (GMP) for APIs (ICH Q7), Good Clinical Practice (GCP), and Good Review Practice (GRP). The RHIs discussed also the need to understand the concept of the eCTD and to prepare the regions for its use. Requirements of the eCTD such as infrastructure (IT and Software) and training of the DRAs and Industry was discussed. Other issues included the integrity of supply chain, the organisation of webinars and the need for more training related to key ICH topics (e.g., Quality, GCP), both in the form of face-to-face training and remote training programs.

5. 7th Regulators Forum Report

Dr. Molzon (FDA) reported on several topics discussed during the 7th Regulators Forum such as quality, changing paradigm, supply chain integrity and cell therapy. Some participants also provided regulatory updates from their country/ region. The GCG noted that Dr. Zhang Wei (DRA of China) presented at the Regulators Forum the Chinese translation of the ICH booklet published for the 20th anniversary of ICH on *The Value and Benefits of the International Conference on Harmonisation for Drug Regulatory Authorities – Advancing Harmonization for*

Public Health. Dr. Molzon also reported on the half day tour organised by FDA on June 13, 2011, at the FDA Forensic Chemistry Center located in Cincinnati.

Action/Decision:

- *The ICH Secretariat will post on the ICH website the Chinese version of the ICH booklet on the Value and Benefits of the International Conference on Harmonisation for Drug Regulatory Authorities.*

6. Participation of RHIs/DRAs/DoH in ICH Technical Working Groups / Orientation Session

The ICH technical working groups E2C(R2), M3(R2), M7, S10 and Q3D welcomed for the first time the participation of technical experts from the DRAs of China, Korea and Singapore in addition to experts from the DoH of Chinese Taipei.

In Cincinnati, most of the new technical experts in addition to other ICH members (experts, rapporteurs, SC and GCG) participated in the first orientation session on ICH which was organised by the ICH Secretariat. The short session welcomed 40 participants, provided background information on ICH and explained the role and responsibilities of ICH experts and Rapporteurs.

Mr. Ward (Health Canada) and Mr. Wada (JPMA) both commented on the usefulness of this orientation session. Mr. Ward also proposed that the materials could be used as a first introductory module for training on ICH Guidelines. Ms. Blair (FDA) also suggested posting the session materials on the ICH website for a broader outreach. Dr. Lou (DRA of Singapore) commented that once posted, the slides could also be used internally for briefing on ICH.

Actions/Decisions:

- *The ICH Secretariat will post on the ICH website the package of information used for the orientation session;*
- *The orientation session will be organised bi-annually during the ICH week and will welcome the participation of any formal or new ICH member.*

7. Presentation on New ICH Guidelines

E2C(R2) Guideline: Dr. Luik (E2C(R2) Rapporteur, EFPIA) presented to the GCG on the revision of the ICH E2C(R1) Guideline on *Periodic Safety Update Reports (PSURs)* for Marketed Drugs which is expected to reach *Step 2* in November 2011 and for which technical experts from the DRAs of China, Korea, Singapore and the DoH of Chinese Taipei have been nominated to participate. Dr. Luik presented to the GCG the main objectives of the PSUR (including its modular approach) and the challenges encountered since the Guideline was first developed. She described the proposed steps and timelines for the guidance revision. Feedback was received from the DRAs/DoH who had experts nominated to this group.

M7 Guideline: Dr. Ku (M7 Rapporteur, PhRMA) presented to the GCG on the ICH M7 Guideline on *Assessment and Control of DNA Reactive (Mutagenic) Impurities in*

Pharmaceuticals to Limit Potential Carcinogenic Risk and for which technical experts from the DRAs of China and Singapore have been nominated to participate. Dr. Ku introduced to the GCG the concept of the M7 Guideline, presented the issues faced by the Expert Working Group (EWG) while drafting this new guidance and the recent progress made towards reaching *Step 2* of the ICH process. Dr. Ku commented also on the benefits to have new experts from non-ICH regions participating in the group's discussions. He reported to the GCG on the group's experience with *Elluminate Live!* as it's new web-conferencing system. The GCG noted that this tool which is provided by the ICH Secretariat will be available for future GCG teleconferences and webinars and that this system was already used in PANDRH and APEC and that it also features very sophisticated tools to perform training remotely.

Action/Decision:

- *The ICH Secretariat will circulate information on Elluminate Live! and provide this new web-conferencing system for future GCG teleconferences and webinars.*

8. 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 June 12, 2011. The GCG noted that several topics were discussed such as *the Use of MedDRA in Clinical Trials, Japanese Experience with MedDRA; the Roles of the MSSO and JMO; and MedDRA Funding*. The GCG also noted that the DRA of Singapore presented on *Singapore Experience with MedDRA* which included the outcome of a 2½-day training course held on May 3-5, 2011 in Singapore.

The presentations of the MedDRA Management Board Special Session were well received by the RHIs and DRAs/DoH and provided the opportunity for the participants to raise questions on specific issues such as how to inform academics on MedDRA particularly its use in Clinical Trials.

9. Presentation on eCTD – Focus on Implementation and Experiences / Challenges

Mr. Watanabe (M8 Rapporteur, MHLW/PMDA) presented to the GCG a general overview of the electronic Common Technical Document (eCTD) including its history, its organisation, and facts on how eCTD is currently used in the three ICH regions. The GCG noted several advantages of using eCTD over CTD such as; easy navigation, efficient search function and less paper used which contribute overall to the improvement of the data quality, reusability and life cycle management. Mr. Watanabe presented some figures on how eCTD usage has progressed within the three ICH regions and highlighted the challenges faced with the use of eCTD. Lastly, Dr. Watanabe presented new challenges with the development of eCTD v4.0 in collaboration of the Standard Developing Organisations and its future benefits.

Mr. Ward (Heath Canada) and Dr. Molzon (FDA) commented on the importance of training on the eCTD in order to facilitate its implementation in a country /region.

10. Training and Capacity Building

❖ GCG-Endorsed Training

ASEAN – Dr. Lou (ASEAN / DRA of Singapore) reported to the GCG on the outcome of the training on the Q5C Guideline on *Stability testing for Biotechnological /Biological Products*, held in Kuala Lumpur on May 30-31, 2011 and for which the EU was nominated as the lead ICH

Party. Dr. Lou commented that the training was successful and welcomed 117 participants from ASEAN member states, as well as Korea. The focus of the training was to provide better understanding of several key elements of stability testing/profile and relevant elements of ICH Q5E and ICH Q6B Guidelines. The training included discussions on studies required to establish product storage conditions and shelf life and updates on the ICH and EU regulatory Guidelines. The GCG noted ASEAN future training needs on Q8/Q9/Q10 and Quality by Design.

GCC – Prof. Bawazir (GCC) reported on the outcome of the training on the ICH Q5A-Q5E Guidelines, for which the EU was nominated as the lead ICH Party. The GCG noted that the two-day workshop which took place in Riyadh, Saudi Arabia on April 19-20, 2011 was successful and welcomed over 60 participants. Prof. Bawazir commented that the training was an excellent opportunity to discuss valuable information with specialists from the European agency during this two day workshop.

SADC – Mr. Mthetwa (SADC) reported to the GCG on the organisation of training on the ICH Q7 Guideline on *Good Manufacturing Practice for APIs* to be held in Arusha, Tanzania on June 27-30, 2011 and for which the EU was nominated as the lead ICH Party. The GCG noted that all aspects of the ICH Q7 Guideline would be covered (e.g., the CTD format, API, stability studies, drug products and regulatory aspects ...). Mr. Mthetwa informed the GCG of the organisation for the SADC region of a Flagship Course on *Pharmaceutical Reform* to be held in Cape Town, South Africa on July 10-16, 2011 and a FDA-SADC *Good Clinical Practices (GCP) Phase 2* training to be held in Pretoria, South Africa on August 29 – September 2, 2011.

Action/Decision:

- *The ICH Secretariat will update the ICH Public website with the training presentations from the ASEAN; GCC and upcoming SADC training.*

11. RHIs and DRAs/DoH Update on ICH-related Matters

APEC / LSIF RHSC – Mrs. Pineda (APEC) reported to the GCG on the outcome of the APEC Life Science Innovation Forum Regulatory Harmonisation Steering Committee (LSIF RHSC) meeting held in Washington, D.C. on March 3-4, 2011. Mrs. Pineda updated the GCG about changes in RHSC membership and informed the GCG of the expression of interest in joining the RHSC which was received from the Philippines and Indonesia. The GCG noted the progress made in defining the RHSC strategic framework which consists of a coordinated approach to promote regulatory convergence for medical products by 2020. Mrs. Pineda explained the different elements of the strategic approach such as the establishment of roadmaps and the definition of priority work areas. She reported on additional achievements including the adoption of overall work plan for 2011 and 2012, the endorsement of several project proposals and the first roadmap on Multi-Regional Clinical Trials (MRCTs). Lastly, the GCG noted the organisation of an ICH workshop on ICH Q8/Q9/Q10 Quality Guidelines in collaboration with the Quality Implementation Working Group and the APEC Harmonisation Center (AHC) to be held in Seoul, Korea on October 4-5, 2011.

APEC / AHC – Dr. Lee (DRA of Korea) provided a brief overview on the AHC including its vision and activities, and reported on its recent AHC training programs in 2009 and 2010. The report included feedback from the *2010 Medical Devices Workshop* held in Seoul, Korea on November 15-16, 2010 and future plans for workshops scheduled in 2011 and 2012 which were in principle endorsed at the RHSC meeting in Washington, D.C. Dr. Lee also reported to the GCG on the outcome of the first AHC/DIA/IFPMA co-sponsored workshop on *ASIA's Role in*

Global Drug Development held in Seoul, Korea on April 26-28, 2011 which was fruitful and welcomed 730 participants from 24 economies. The GCG noted the topics discussed included an update on ICH activities with focus on new activities, Asia's regulatory harmonisation initiatives, regulatory trends in clinical trials in Asia and practical cooperation between regulators and industry.

ASEAN – Dr. Lou (ASEAN, DRA of Singapore) reported to the GCG on the outcome of the 18th PPWG meeting held in Singapore on June 7-10, 2011 which welcomed over 260 participants from ASEAN regulatory agencies and industry. At the meeting the Technical Working Groups and Implementation Working Groups discussed the ASEAN quality, safety and efficacy guidelines, the variations guidelines and the implementation of the ASEAN Common Technical Dossier (ACTD). Dr. Lou informed the GCG that the Terms of Reference of a new Technical Working Group for Biologics was discussed.

GCC – Prof. Bawazir (GCC) provided background information on the GCC including its organisation and structure. The GCG noted also the recent GCC activities which included the organisation of the past three GCC-DR (Gulf Central Committee for Drug Registration) meetings and the outcome of a workshop on CTD held in Abu Dhabi on June 1-2, 2011.

SADC – Ms. Fakudze (SADC, Swaziland) presented to the GCG the objectives of the SADC Pharmaceutical Programme and the priority Strategic Actions of the 2007-2013 Pharmaceutical Business Plan. The GCG noted the priority in medicine regulation in the SADC region. The GCG also noted that SADC was currently supported by funds from the African Development Bank which supports African countries in improving access to quality essential medicines and African traditional medicines, and from UK-DFID which supports the Southern African Regional Programme for Access to Medicines and diagnostics project (SARPAM). Ms. Fakudze reported also on the regulation of medicines in Swaziland including its objectives and challenges.

12. PIC/S, a Way for Improving Confidence between Regulators

Dr. Morenas (Quality IWG Topic Leader, EU) presented to the GCG on the Pharmaceutical Inspection Co-operation Scheme (PIC/S) which is leading the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and which celebrated its 40th anniversary this year. Dr. Morenas presented the PIC/S structure and highlighted its main objectives which included the assessment of GMP inspectorates and the development and promotion of harmonised GMP standards and guidance documents. The GCG noted that the PIC/S membership currently includes 39 members and that several other agencies had expressed interest to join PIC/S (e.g., Japan, China, Hong Kong, South Korea, Russia and Turkey). Dr. Morenas explained the application process and also highlighted the benefits of PIC/S membership such as cost savings, facilitation of export of medicines, access to tools, training/seminars and to a network of contact persons / organisations. Dr. Morenas presented to the GCG the new challenges of PIC/S such as globalisation of the supply chain and increasing the efficiency of the market surveillance. The GCG noted also the new opportunities for PIC/S in developing activities in the field of API and potentially in other fields such as GDP; GCP; GPvP.

Dr. Limoli (FDA) informed the GCG that a meeting of the PIC/S expert circle on *Active Pharmaceutical Ingredients* will be held in Singapore on October 12-14, 2011.

13. Challenges and Activities to Promote Multi-Regional Clinical Trials

Mr. Uzu (GCG Co-chair, MHLW) presented to the GCG background information on guidance on global clinical trials in the three ICH regions. The GCG noted the challenges to promote Multi-

Regional Clinical Trials (MRCTs) related to study design, GCP implementation and operational aspects. The GCG noted also that several workshops/symposiums related to MRCT had already been organised since 2008. Mr. Uzu presented a MHLW proposed a roadmap including a step by step approach for 2011-2020, to facilitate the acceptance of MRCT results for drug review by regulatory authorities in APEC regions. The GCG noted that the approach consists of the assessment of current practices and the establishment of a common understanding within the APEC region regarding key issues and enablers to promote MRCTs (step 1, in 2011/ 2012), which will be followed by the organisation of a series of training/workshops (step 2, in 2013/2015), the assessment of the training conducted (step 3, in 2016) and subsequent recommendations for regulatory harmonisation (step 4, in 2017/2020). Mr. Uzu informed the GCG that the outcome of each training/workshop will be shared with the GCG and also the Regulators Forum.

The China-Korea-Japan tripartite activities were also presented including research on ethnic factors, exchange of information on clinical trials and development of consideration to conduct MRCT among East Asia countries/regions. Mr. Uzu discussed the Japanese experience with MRCT which included a discussion on acceptance of foreign clinical data and highlighted the importance of bridging studies in simultaneous global drug development.

The GCG noted that a second APEC MRCT workshop will be conducted in Tokyo, Japan in November 1-2, 2011. The workshop co-hosted by MHLW, JPMA and AHC will include a report of the last Korea/China/Japan Director Generals meeting and discussions on Study Design, the importance of Asia in Global Development Strategy and Case Studies on Oncology.

14. African Medicines Registration Harmonisation Initiative

Dr. Răgo (WHO) presented to the GCG background information on the African Medicines Registration Harmonisation (AMRH) Initiative in which WHO participates. The GCG noted the progress made within several African Regional Economic Communities which included SADC, WAHO (West African Health Organisation) and UEMOA (Economic & Monetary Union of West Africa), EAC (East African Community), and Northern Africa. Dr. Răgo informed the GCG of the outcome of a workshop held in Lilongwe, Malawi in May 2011 to determine the scope of support needed for SADC Medicines Registration Harmonisation (MRH) project and to finalize the MRH project proposal in collaboration with the SARPAM. The GCG noted that organisation by WHO of four implementation workshops on ICH CTD in different regions of Africa. Dr. Răgo informed the GCG that EAC would have the first project to be funded by the Trust Fund established under the World Bank. The GCG noted EAC project objectives were focussing on medicines registration and quality management systems and on the development of a framework for mutual recognition based on the EAC treaty.

Dr. Morin (IFPMA) informed the GCG that a letter was received from the EAC Secretariat regarding its expression of interest to join the GCG. The GCG noted that the EAC expression of interest would be submitted to the SC for its consideration at its meeting, in June 15, 2011¹.

15. Any Other Business

PANDRH Update

¹ At the Steering Committee meeting held in Cincinnati on June 15, 2011, the SC endorsed the EAC proposal and welcomed the participation of EAC as a new RHI in the next GCG meeting and Regulators Forum to be held in Seville, Spain.

Dr. Molzon (FDA) informed the GCG that the VI Pan American Conference on Drug Regulatory Harmonization will be held in Brasilia, Brazil, on July 6-8, 2011. The theme of the conference will be *Strengthening National Health Regulatory Authorities Within the Context of Health Systems*. The GCG noted that the program for this Conference offers an opportunity for sharing views on matters with a significant public health impact, in search of strategies to advance drug regulatory harmonization processes in the region of the Americas.

Dates of the Next GCG Meetings

November 8, 2011

Seville, Spain

June 4, 2012

Fukuoka, Japan