GLOBAL COOPERATION GROUP MEETING REPORT
TUESDAY NOVEMBER 8, 2011

Seville, Spain
(Melia Sevilla Hotel)

PARTICIPANTS:
Ms. Lenita Lindström  EU
Dr. André W. Broekmans  EFPIA
Mr. Naoyuki Yasuda  MHLW (GCG Co-Chair)
Mr. Kohei Wada  JPMA
Dr. Justina Molzon  FDA
Dr. Peter Honig  PhRMA (GCG Co-Chair)
Dr. Lembit Rägo  WHO
Mr. Mike Ward  Health Canada
Dr. Petra Dörr  EFTA
Dr. Odette Morin  IFPMA
Mrs. Patricia Pineda  APEC
Mr. José Raul Ramírez  APEC
Mr. Gordon Sematiko  EAC
Mr. Hiiti Sillo  EAC/TFDA
Ms. Maria Luz Pombo  PANDRH
Ms. Fortunate Fakudze  SADC
Ms. Gugu Mahlangu  SADC
Dr. Harry Rothenfluh  DRA of Australia
Dr. Churn Shiouh Gau  DoH of Chinese Taipei
Dr. Sun Hee Lee  DRA of Korea
Dr. Alexey Terekhov  DRA of Russia
Dr. Irina Krupnova  DRA of Russia
Dr. Christina Lim  DRA of Singapore
Dr. Huei-Xin Lou  DRA of Singapore

Also Present:
Dr. Thomas Salmonson  EU
Dr. Sébastien Goux  EU
Dr. Sabine Haubenreisser  EU/EMA
Dr. Toshiyoshi Tominaga  MHLW/PMDA
Ms. Yasuko Inokuma  MHLW
Mr. Masaaki Tsukano  MHLW/PMDA
Dr. Kurajiro Kishi  JPMA
Ms. Joan Blair  FDA
Dr. Michelle Limoli  FDA
Dr. Michael Garvin  PhRMA
Mr. Eduardo Pisani  IFPMA
Dr. Samvel Azatyan  WHO
Dr. Louise Déry  Health Canada
Dr. Sarah Adam  ICH Secretariat
Dr. Dawn Ronan  ICH Secretariat
Ms. Anastasia Nikitina  DRA of Russia (Translator)
1. **Welcoming Remarks and Adoption of the Agenda**

Mr. Naoyuki Yasuda (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 with a modification under agenda item 4 where Mr. Ward (Health Canada) would present to the GCG on a training strategy proposal.

2. **Review of Current Membership**

The GCG noted the recent nomination of two new RHI members from the East African Community (EAC) namely, **Ms. Jane H. Mashingia** (Senior Medicines and Food Safety Officer, EAC Secretariat) and **Mr. Hiiti B. Sillo** (Director General, Tanzania Food and Drugs Authority - TFDA) who have joined the Global Cooperation Group as EAC representatives in August 2011.

A warm welcome was also extended to several alternate representatives who were attending the GCG meeting for the first time.

**Mr. José Raul Ramirez** (APEC) was introduced as the second representative from APEC who was nominated by the APEC Secretariat to attend the Seville meeting in replacement of the current representative from APEC, Mrs. Barbara Norton.

The GCG welcomed **Mr. Gordon Sematiko** (EAC) who was nominated by the EAC Secretariat in replacement of Ms. Jane Mashingia who could not attend the Seville meeting.

**Ms. Maria Luz Pombo** (PANDRH) was introduced to the GCG as the representative from PANDRH who was nominated by the PANDRH Secretariat in replacement of Dr. James Fitzgerald who could not attend the Seville Meeting.

**Ms. Fortunate Fakudze** (SADC) was nominated by the SADC Secretariat in replacement of Mr. Joseph Mthetwa who could not attend the Seville meeting. **Ms. Gugu Mahlangu** from Zimbabwe was introduced as the second representative from SADC.

A welcome was also extended to **Dr. Irena Krupnova** (DRA of Russia) who was introduced as the representative from Russia in replacement of Dr. Elena Barmanova who could not attend the Seville meeting.

Apologies were received from Dr. Yuppadee Javroongrit (ASEAN), Prof. Dr. Saleh Bawazir (GCC), Dr. Dirceu Brás Barbano and Mrs. Soares Jucá da Silveira e Silva (DRA of Brazil), Dr. Chen Zhen and Mr. Zhang Wei (DRA of China), Dr. Meir-Chyun Tzou (DoH of Chinese Taipei), Mr. Debasish Panda and Dr. Surinder Singh (DRA of India), and Mr. Nam Soo Kim (DRA of Korea).

Dr. Adam (ICH Secretariat) invited the GCG, RHIs, DRAs/DoH to communicate to the ICH Secretariat any forthcoming changes in GCG membership.

3. **African Medicines Regulatory Harmonisation**

**East African Community (EAC)** – Mr. Sematiko (EAC) presented to the GCG background information on the EAC, including the priority of the EAC Treaty and challenges faced on access to essential medicines in the region. The presentation also included an overview on the African Medicines Regulatory Harmonisation (AMRH) initiative, in which WHO participates, and its current and future vision on regulatory capacity. Mr. Sillo (EAC) presented to the GCG the EAC Medicine Regulation Harmonisation (EAC MRH) project as a collaborating effort with WHO and the African Union-New Partnership for Africa’s Development (NEPAD). The GCG noted that the goal of the project is to have harmonised and functioning medicines registration system within
the EAC, in accordance with national and internationally recognised policies and standards (e.g., ICH, WHO). Mr. Sillo presented also the main EAC MRH project objectives which consist of the implementation in all EAC Partner States of (i) an agreed common technical document for registration of medicines, (ii) a common information system and (iii) a quality management system for medicines registration. The GCG welcomed this important project and offered its support to assist EAC if needed to achieve its objectives and milestones (e.g., training).

**African Medicines Registration Harmonisation (AMRH)** – Dr. Rägo (WHO) updated the GCG on the AMRH initiative. The GCG noted the recent progress made within several African Regional Economic Communities on how the medicines registration process could be improved and which included SADC, WAHO (West African Health Organisation), UEMOA (Economic & Monetary Union of West Africa), EAC (East African Community), and Northern Africa. The GCG noted that the Trust Fund under the umbrella of the World Bank to finance the first two years of the EAC project had been established and that the official launch of the EAC project is planned in February 2012.

4. **Training and Capacity - Building**

- **APEC Life Sciences Innovation Forum (LSIF)**

**Regulatory Harmonisation Steering Committee (RHSC) Activities** – Mrs. Pineda (APEC) reported to the GCG on the outcome of the APEC LSIF RHSC meeting held in San Francisco on September 14 – 15, 2011 where roadmaps and priority work areas were reviewed and where the strategic framework on Regulatory Convergence of Medicinal Products was reviewed and endorsed. The GCG noted other key outcomes of this meeting such as the endorsement and the use of a roadmap template, the development of concept notes and projects (e.g., supply chain integrity, biosimilars); the agreement on a global mapping plan and the implementation of a strategic approach, and synergic cooperation with key international partners (e.g., WHO, EMA).

The GCG noted that the next APEC LSIF RHSC meeting will be held in Moscow, Russia in early 2012.

**APEC Harmonisation Center (AHC) Activities** – Dr. Lee (DRA of Korea) presented to the GCG the 2011/2012 AHC Training Programme which included the outcome of the *Quality by Design* (ICH Q8/Q9/Q10) workshop held in Seoul on October 4 – 5, 2011 and proposed recommendations. Dr. Lee also reported to the GCG on the outcome of the *Multi Regional Clinical Trial (MRCT)* workshop held in Tokyo on November 1 – 2, 2011, highlighting the Korea, China and Japan Tripartite Symposium. The GCG noted that this event was co-hosted by MHLW, PMDA, the Society for Regulatory Science of Medical Products (SRSM) and the AHC, and supported by JPMA, and was attended by over 400 participants from nine countries. The GCG noted the major achievements of the workshop such as, the building of a network for future cooperation with MRCT experts, the posting on the AHC website of training materials and facilitating future training in other regions.

The GCG noted the success of the MRCT workshop held in Japan which was made possible by the joint efforts of the regulatory authorities, the industry and the academia, and for which participation in future workshops was encouraged by Dr. Tominaga (MHLW/PMDA). Mr. Ward (Health Canada) commented on the progress and achievements of the RHSC towards regulatory convergence since its establishment in June 2009, and which would have an impact beyond the APEC region.

Lastly, Dr. Lee also presented to the GCG the future AHC training programme on *Biosimilars, Pharmacovigilance and Combination Products* to be held in the region in 2012.
GCG-endorsed Training

**SADC** – Ms. Fakudze (SADC) reported to the GCG on the outcome of the training on the ICH Q7 Guideline on *Good Manufacturing Practice for APIs* held in Arusha, Tanzania on June 27 – 30, 2011 and for which the EU was nominated as the lead ICH party. The GCG noted the outcome of the SADC Flagship Course on *Pharmaceutical Reform* held in Cape Town, South Africa on July 10 – 16, 2011 and the FDA–SADC *Good Clinical Practices (GCP)* training for Clinical Trial Sites - Part II held in Pretoria, South Africa on August 29 – September 2, 2011. Ms. Fakudze also presented the regional activities planned for 2012 in the SADC region including training on ICH Q8/Q9/Q10 Guidelines and the Part III of the FDA - SADC GCP training for Clinical Trial Sites to be held in Pretoria, South Africa in autumn 2012.

Future GCG Training

**Health Canada Training Strategy Proposal** – Mr. Ward (Health Canada) presented a Health Canada proposal to develop an internal training programme on all Quality (Q), Safety (S), Efficacy (E) and Multidisciplinary (M) ICH Guidelines and on ICH Organisation and Process to ensure an authoritative and consistent presentation of the ICH Guidelines and benefit not only Health Canada’s own purpose but all parties interested in understanding ICH. The GCG noted that although some stand alone training materials are already made available on the ICH website, important gaps are existing within ICH Guidelines and there are no integrated overviews of related ICH Guidelines available on the Q/S/E/M topics or presentations on specific topics (e.g., special populations, QT prolongation, how ICH works? or the role of ICH Guidelines in the regulatory framework). Mr. Ward suggested that the training programme could include audio–visual modules which could evolve in the future into e–learning modules, and that consideration could also be given to the use of a non-profit training organisation to assist the development and the delivery of training courses. Mr. Ward highlighted the importance of training to promoting a proper understanding and use of ICH Guidelines, and the strategic role that the GCG could also play in this regard.

The GCG acknowledged Health Canada’s training strategy proposal and discussed how to operationalise it, including how to develop the training modules, the need for translation, and the collaboration with a contractor to deliver and translate the courses.

**Action/Decision:**

- A small working group (FDA, Health Canada, PhRMA and SADC) was established to assess the materials available, to identify the gaps existing within ICH training materials and to draft a proposed approach.

**CDER World Modules** – In line with the above discussion to create a platform of information, Dr. Molzon (FDA) presented to the GCG the Center for Drug Evaluation and Research (CDER) *World Modules* that have recently been posted on the FDA website (Office of Compliance and Office of Generic Drugs) and which were created based on the ninth CDER Forum for International Drug Regulatory Authorities in response to the growing interest in these meetings from around the world. The GCG noted that *CDER World Modules*, would be an ever-growing compendium of information about how CDER carries out its mission, adapts to new legislative initiatives, and initiates directions in regulatory science to improve public health.
**Vietnam Training Request** – The GCG noted the national training request for a Quality workshop on ICH Q8/Q9/Q10 Guidelines which was submitted by the Drug Administration of Vietnam (DAV) to Dr. Javroongrit (ASEAN) on September 2, 2011 with a copy to the ICH Secretariat, and that unfortunately, ASEAN was not represented at the GCG meeting in Seville to present this proposal. The GCG discussed the importance of organising training at the regional level to benefit several countries within the region and also to maximize the resources available. The GCG suggested waiting for the Vietnam request to be discussed by ASEAN to see whether the training could be organised as a regional event.

**Action/Decision:**

- The ICH Secretariat will inform the Drug Administration of Vietnam of the status of its training request and follow up with Dr. Javroongrit on the possible future step.

5. **Importance of ICH Regulatory Harmonisation from the IFPMA Perspective**

Mr. Pisani (Director General, IFPMA) presented to the GCG on the Globalisation of Health and Global Governance. Three main IFPMA policy priorities in line with current ICH objectives were described, which consist of improving access to medicines, promoting quality and safety, and fostering innovation of medicines.

6. **Good Review Practices**

Mr. Ward (Health Canada) presented to the GCG on the outcome of the first workshop on Good Review Practices (GRevPs) held in Taipei on October 12 – 14, 2011, and which was attended by more than fifty participants (Regulators and Industry) from seventeen economies. The report included some recommendations (e.g., development of a best practices document and a roadmap on GRevPs) and also presented good review guiding principles. Mr. Ward presented the advantages of sharing a GRevPs system between Industry and Regulators; and highlighted the belief that the implementation of GRevPs combined with the adoption of common science-based standards and guidelines that define regulatory expectations for establishing the safety, efficacy and quality of medicinal products are essential in building trust and confidence in regulatory systems. Dr. Broekmans (EFPIA) commented that further development of the GRevPs system was occurring in the European Medicines Agency and he proposed that the EU could provide an update on this matter at the next GCG meeting in Fukuoka and that all GCG members could also be invited to share information on activities in their respective regions.

7. **Overview of ICH S10 Guideline on Photosafety Evaluation**

Dr. Nakae (S10 Rapporteur, MHLW) presented to the GCG on the development of the draft ICH S10 Guideline on Photosafety Evaluation for which technical experts from the DRAs of China and Korea are participating. The report included some background information on Photosafety, and the tentative objectives. The scope and challenges of the ICH S10 Guideline were also presented. Dr. Nakae discussed a proposed tiered strategy consisting in assessing Active Pharmaceutical Ingredients (APIs) for photochemical properties (Tier 1) and if a positive result is obtained, to assess the APIs for photosafety (Tier 2). The GCG also noted the testing methods and the administrating route-specific selection used in the tiered strategy. Lastly, Dr. Nakae presented to the GCG the proposed milestones for this new guidance.

8. **RHI Pre-meeting Report**
Ms. Fakudze (SADC) reported on the outcome of the RHI pre-meeting where the need to encourage the registration of Clinical Trials (CTs), the establishment of CT registries/databases and best practices; and the need to share CT information with the region were discussed. The report also highlighted the importance of reporting on the outcome of ICH meetings within their respective regions, and the challenge faced to determine the implementation status of ICH Guidelines in all countries within their regions. With regards to training, the RHIs proposed to each conduct a regional survey to better address their region’s needs’ for training, and also suggested the development of online basic training modules to strengthen capacity building. The GCG welcome the proposal of the RHIs to develop meeting agenda and reports for future RHI pre-meetings to help ensure continuity of discussions.

**Actions/Decisions:**
- The RHIs will develop the agenda and minutes for future RHI pre-meetings;
- The RHIs agreed to develop the minutes of the RHI pre-meeting held in Seville, Spain.

### 9. 8th Regulators Forum

Ms. Lindström (EU) reported on the outcome of the 8th Regulators Forum where several participants provided regulatory updates. The GCG noted that Regulators discussed several topics such as regulation in Japan during a natural disaster, the new EU legislations on falsified medicines pharmacovigilance, the outcome of the Ottawa meeting on international collaboration in the Review of Generic Drugs, and Gene / Cell Therapy. Lastly, the GCG noted that regulators participants discussed ways to improve the GCG and the Regulators Forum (RF) based on the feedback received from the GCG Survey.

### 10. Quality IWG: Focus on Implementation and Experiences/Challenges

Dr. Robert (Quality IWG, Rapporteur, EU) presented to the GCG a general overview of the new Quality Paradigm which consists of developing a harmonised pharmaceutical quality system applicable across the life cycle of the product. Dr. Robert presented the Quality Risk Management Process (ICH Q9), the Pharmaceutical Quality System (ICH Q10) and the key steps for a product under Quality by Design. The report also included the tasks and achievements of the Quality IWG such as the conduct of integrated training in ICH and non-ICH regions, and development of Questions & Answers and Points to Consider documents. The GCG noted that all training materials and documents developed by the IWG are made available on the ICH website.

The GCG acknowledged the importance of training on ICH Guidelines and the need to meet the needs of each country/region. Dr. Molzon (FDA) suggested that the development of similar training materials for the ICH Q1 - Q7 Guidelines could be helpful.

### 11. Outcome of the GCG Survey

The outcome of the GCG survey which was conducted on an anonymous basis amongst 5 RHIs and 8 DRAs/DoH to solicit their opinions and get feedback on the GCG was discussed. Dr. Honig (Co-chair, PhRMA) welcomed the feedback of the 3 RHIs and 4 DRAs/DoH which participated in the GCG Survey and which indicated the added value of GCG and made several constructive comments on how to improve future meetings. The GCG agreed to re-circulate the Survey until
mid-February 2012 to collect further views and to obtain a more precise opinion on the GCG from countries/regions. The GCG recognised in particular the challenge faced by the RHIs to collect feedback from all member states, and encouraged the RHIs to try to circulate the Survey in their respective regions.

**Actions/Decisions:**

- The Secretariat will circulate the GCG Survey to the RHIs/DRAs/DoH to collect additional feedback by mid-February 2012;
- The Secretariat will consolidate all the comments received and provide the consolidated input to the GCG and the SC ahead of their respective teleconferences to be held in spring 2012.

12. Recent Developments/Challenges of RHIs and DRAs/DoH on ICH-related Matters

**PANDRH** – Mrs. Pombo (PANDRH) provided background information to the GCG on the Pan American Network on Drug Regulatory Harmonisation including its mission, structure and objectives. Mrs. Pombo also updated the GCG on current harmonisation activities in the Americas region such as the adoption of recent technical documents, PANDRH and National Regulatory Authorities (NRAs), strengthening in the Americas Region, and the adoption of the Resolution CD50.R9 related to the strengthening of the NRAs for Medicines and Biologicals.

The GCG noted the challenges and future perspectives inside the Americas Region including the promotion of Good Regulatory Practices and the use of modern technological platforms for regulatory exchange, knowledge transfer and capacity building.

**SADC** – Ms. Mahlangu (SADC) provided background information to the GCG on the Medicines Control Authority of Zimbabwe (MCAZ) including its legal framework and the role and responsibilities of the different units within the organisation. Challenges with the MCAZ and future objectives were also noted.

13. ICH Secretariat Report

Time did not allow the Secretariat to provide a report, therefore a written report is provided for GCG information.

**ICH Website Update** – The GCG confidential section of the GCG website is expected to be online in late 2011 / early 2012. The new members’ only website will include several features to enhance its functionality and user-friendliness.

**Use of the Elluminate Live! Web-conferencing System** – Elluminate Live! has been used since August 2011, as a pilot web conferencing system by the ICH SC, GCG, and several Working Groups (M7, E2C, E3, M2). One significant advantage of this system is to allow participants to join at no cost for the line or for the host. Additionally, the system has various interactive features to facilitate the meeting. A few audio problems were encountered at the outset that caused inconvenience. However, the Secretariat hopes that it has identified how these may be addressed. Detailed instructions on system requirements regarding internet connection and equipment (headset with microphone and headphone) will be circulated to participants to ensure proper implementation and optimal audio quality.
**Step 2/Step 4 Webinars** – A webinar on the ICH Q11 Step 2 Guideline\(^1\) on *Development and Manufacture of Drug Substances* was organised by the ICH Secretariat on September 9, 2011 to facilitate comments on the draft guidance. The presentation was given by Mr. McDonald (Q11 Rapporteur, EU) and the webinar welcomed more than 50 participants from the APEC, GCC, PANDRH, the DRAs of Australia and Singapore, the DoH of Chinese Taipei and the WHO.

A webinar on the ICH S6(R1) Step 4 Guideline \(^2\) on *Preclinical Safety Evaluation of Biotechnology Derived Pharmaceuticals* was given by Dr. van der Laan (S6 Rapporteur, EU) on September 27, 2011. The webinar was well received and welcomed the participation of over 60 experts from APEC, GCC, PANDRH, the DRAs of Australia and Singapore, and the DoH of Chinese Taipei, in addition to experts from Health Canada and Swissmedic.

**Action/Decision:**
- The Secretariat will continue to organise webinars once an ICH Guideline would reach Step 2 or Step 4 of the ICH Process would be reached.

**Step 2 Guidelines for Consultation** – The ICH Secretariat sent letters to the RHIs and DRAs/DoH on July 8, 2011 inviting them to comment on the ICH Q11 Guideline which reached Step 2 in May 2011. Comments on the draft guidance were received from the DRA of Singapore.

**Participation of RHIs/DRAs/DoH in ICH Technical Working Groups** – To date, fifteen (15) technical experts have been nominated from China (on Q3D, Q11, S10, M3(R2), M7 and E2C), Chinese Taipei (on Q3D and E2C), Korea (on Q3D, S10, M7 and E2C), and Singapore (on Q11, M7 and E2C). In Seville, six (6) technical experts attended the Seville meeting while the other nominees were unable to attend.

**Special Session of the ICH MedDRA Management Board** – The fourth Special Session of the Board held for RHIs/DRAs/DoH took place on November 6 (14h30–17h00) and was attended by the majority of RHIs/DRAs/DoH in attendance of the Seville meeting. The agenda for the session was developed based on feedback from previous Special Sessions. Presentations were made on: Australian experience with MedDRA; electronic systems which facilitate adverse event reporting by companies, doctors and consumers (UK MHRA YellowCard Scheme & EudraVigilance); and analysis of adverse event data (FDA MAED Service). Input was also solicited for the organisation of future sessions.

**14. Final Approval of the Report of the GCG Teleconference held on October 11, 2011 (Ref: GCG 146R)**

The GCG noted that the draft report of the GCG teleconference (Ref # GCG146) which was held on October 11, 2011, was circulated for comments to the ICH GCG, RHIs/DRAs/DoH on 20 October, 2011 with a deadline for comments by October 28, 2011. Minor editorial comments were received from MHLW, SADC and the DRA of Korea. The DRA of Singapore accepted the draft report without comments.

---

\(^1\) The ICH Q11 Guideline reached Step 2 of the ICH process in May 2011.

\(^2\) The addendum of ICH S6 Guideline reached Step 4 of the ICH process in Cincinnati, in June 2011 and was integrated as Part II in the core Guideline which was subsequently renamed ICH S6(R1).
Actions/Decisions:
- The GCG approved as final the report of the GCG teleconference held on October 11, 2011;
- The ICH Secretariat will post the final report of the GCG teleconference on the members only section of the ICH website.

15. Any Other Business – Closing Remarks

Intergovernmental Negotiating Committee to Prepare a Global Legally Binding Instrument on Mercury
Dr. Limoli (FDA) presented on recent activities of the United Nations Environment Programme (UNEP) to prepare a global legally binding instrument on mercury. The GCG noted that this treaty is to address environmental releases of mercury, but may affect the regulation of the following product categories: thimerosal preservatives in human and veterinary pharmaceuticals, Over The Counter (OTC) and cosmetic products, measurement devices (thermometers and sphygmomanometers), dental amalgam, and traditional medicines.
Dr. Limoli reported that the negotiations by environmental and foreign affairs ministries began in June 2010 and are planned to be completed by 2013. WHO and a small group of health regulators have been helpful to provide input, but more involvement by medical product regulators, industry and stakeholders is needed. The GCG noted that the next negotiating session would be held in June 25 – 29, 2012 in Uruguay.

GCG Co-Chairmanship
The GCG noted that following the Seville meeting the Industry Co-Chairmanship would rotate from PhRMA to EFPIA.

Dates of the Next GCG Meetings
June 5, 2012 Fukuoka, Japan
November 13, 2012 San Diego, CA, USA