GLOBAL COOPERATION GROUP MEETING REPORT
TUESDAY JUNE 5, 2012

Fukuoka, Japan
(Hilton Sea Hawk Hotel)

PARTICIPANTS:
Mr. Naoyuki Yasuda MHLW (GCG Co-Chair)
Mr. Kohei Wada JPMA
Dr. Justina Molzon FDA
Ms. Lenita Lindström EU
Dr. Sabine Luik EFPIA (GCG Co-Chair)
Dr. Lembit Rägo WHO
Mr. Mike Ward Health Canada
Dr. Petra Dörr EFTA
Dr. Odette Morin IFPMA
Dr. Kui-Lea Park APEC
Dr. Yuppadee Javroongrit ASEAN
Ms. Jane Mashingia EAC
Mr. Ndintonda Benno Chukilizo EAC
Prof. Saleh Bawazir GCC
Mr. Joseph Mhetwa SADC
Dr. Harry Rothenfluh DRA of Australia
Mr. Zhang Wei DRA of China (Skype)
Mr. Xu Xiaojing DRA of China (Skype)
Ms. Zhou Fang DRA of China (Skype)
Dr. Jinbo Yang DRA of China - CDE (Skype)
Dr. Churn Shiouh Gau DoH of Chinese Taipei
Dr. Meir-Chyun Tzou DoH of Chinese Taipei
Dr. In-Sook Park DRA of Korea
Dr. Yoon Joo Park DRA of Korea
Dr. Christina Lim DRA of Singapore
Dr. Huei-Xin Lou DRA of Singapore

Also Present:
Dr. Thomas Salmonson EU
Dr. Sébastien Goux EU
Dr. Stéphanie Lane EFPIA
Dr. Toshiyoshi Tominaga MHLW/PMDA
Ms. Yasuko Inokuma MHLW
Dr. Jun Kitahara MHLW/PMDA
Dr. Kurajiro Kishi JPMA
Dr. Theresa Mullin FDA
Ms. Joan Blair FDA
Dr. Michelle Limoli FDA
Dr. Michael Garvin PhRMA
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. Naoyuki Yasuda (GCG Co-chair, MHLW) and Dr. Sabine Luik (GCG Co-chair, EFPIA) welcomed all participants to the meeting of the ICH Global Cooperation Group (GCG).

2. **Review of Current Membership**

The GCG noted the recent nominations of **Dr. Kui-Lea Park** (Director, National Institute of Food and Drug Safety Evaluation Center for Drug Development Assistance, Korea Food & Drug Administration (KFDA) as the new representative for the APEC Secretariat in replacement of Mrs. Ana Patricia Pineda; and **Dr. Gyanendra Nath Singh** (Drugs Controller General, Directorate General of Health Services, Central Drugs Standard Control Organization) as the new representative for the DRA of India in replacement of Dr. Surinder Singh and Mr. Debasish Panda. The GCG noted also that **Ms. Eun Hye Park** (Reviewer & Scientific Officer, Drug Evaluation Department, KFDA) replaced Mr. Nam Soo Kim as the alternate representative for the DRA of Korea.

**Dr. Ndionda Benno Chukilizo** (Manager, Medicines and Cosmetics Evaluation and Registration Tanzania Food and Drugs Authority) was nominated by the EAC Secretariat to replace Mr. Hiiti B. Sillo who could not attend the Fukuoka meeting.

**Dr. In-Sook Park** (Director, Pharmaceutical Standardization Division, Drug Evaluation Department, KFDA) and **Dr. Yoon Joo Park** (Director, Cell and Gene Therapy Products Division, KFDA) were nominated by the KFDA in replacement of Dr. Sun Hee Lee and Ms. Eun Hye Park respectively, who could not attend the Fukuoka meeting.

Apologies were received from Mr. Hiiti Sillo (EAC), Dr. James Fitzgerald (PANDRH), Dr. John Donohoe (DRA of Australia), 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), Mr. Gyanendra Nath Panda (DRA of India), Dr. Elena Barmanova and Dr. Alex Terekhov (DRA of Russia).

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

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

3. **Final Approval of the Report of the GCG webconference held on May 10, 2012 (Ref: GCG 157)**

The GCG noted that the draft report of the GCG webconference (Ref # GCG157) which was held on May 10, 2012, was circulated for comments to the ICH GCG, RHIs/DRAs/DoH on May 18, 2012 with a deadline for comments by May 25, 2012. EFPIA, SADC, and the DRAs of China and Singapore accepted the draft report without comments.

**Actions/Decisions:**

- The GCG approved as final the report of the GCG webconference held on May 10, 2012;
- The ICH Secretariat will post the final report of the GCG teleconference on the members’ only section of the ICH website.
4. **African Medicines Regulatory Harmonisation**

**EAC** – Ms. Mashingia (East African Community) presented to the GCG background information on the East African Community, including the regional inter-governmental organisation of the five partner states. The GCG noted also the objectives and critical milestones of the EAC Medicines Regulation Harmonisation (EAC MRH) project to be achieved within five years, such as the implementation of CTD for registration of medicines, the establishment of a common integrated Information Management System (IMS) and the implementation of a Quality Management System (QMS) in all partner states. Ms. Mashingia also reported to the GCG on EAC MRH Project’s high level official launch in Arusha, Tanzania on March 30, 2012 which was attended by most of the ICH parties and other stakeholders. Since then, the first regional Steering Committee meeting for EAC-MRH Project was held on May 28-29, 2012, in Bujumbura, Burundi. Among other deliberations, the meeting considered and approved terms of reference for the four technical working groups (CTD, GMP, IMS and QMS) and calendar of activities for the project. The GCG wished success in the establishment and coordination of the EAC MRH project.

**African Medicines Registration Harmonisation (AMRH)** – Dr. Rägo (WHO) updated the GCG on the AMRH initiative, and highlighted the importance of the different roles and responsibilities of the consortium of partners which includes: the New Partnerships for Africa's Development (NEPAD) and Pan African Parliament (PAP), the World Health Organization (WHO), the Bill & Melinda Gates Foundation (BGMF), the UK Department for International Development (DFID), the Clinton Health Access Initiative (CHAI). Dr. Rägo added that starting with EAC, the regional economic Communities will lead the work towards harmonisation and aligning of regulatory procedures between countries. The 14th International Conference of Drug Regulatory Authorities (ICDRA) recommendations for Medicines Regulatory Authorities were also presented to the GCG.

Mr. Mhetwa (SADC) informed the GCG that the SADC region was currently finalising a Memorandum of Understanding with NEPAD for the Harmonisation of Medicines Registration in the SADC region with the aim to launch the project by the end of 2012.

5. **Overview of ICH E2C(R2) Guideline on Periodic Benefit-Risk Evaluation Report**

Dr. Spooner (E2C(R2) Rapporteur, EU) presented to the GCG on the development of the draft ICH E2C(R2) Guideline on Periodic Benefit-Risk Evaluation Report (PBRER), and on the current activities of the E2C(R2) Expert Working Group (EWG) to which the DRAs of China, Korea, Singapore in addition to the DoH of Chinese Taipei have each nominated one technical expert to participate. The GCG noted the main objectives of the EWG (revision of the PSUR and gap analysis of E2E and E2F Guidelines); and the outcome of the public consultation conducted in spring 2012 in the three ICH regions and beyond was presented. Key messages for this new guidance were also noted, and maximisation of positive impact for public health was discussed with the GCG, RHIs and DRAs/DoH.

Dr. Luik (GCG Co-Chair, EFPIA and former E2C(R2) Rapporteur) welcomed the active participation of technical experts from the DRAs of China, Korea, Singapore in addition to the DoH of Chinese Taipei. She also highlighted the importance to have as many countries as possible involved in the Guideline development in order to create a PBRER which could be used globally.
6. **Training and Capacity - Building**

- **APEC Life Sciences Innovation Forum (LSIF)**
  - **Regulatory Harmonisation Steering Committee (RHSC) Activities** – Mr. Ward (Health Canada) presented to the GCG the strategic approach to promote regulatory convergence by defining priority work areas. Mr. Ward reported on the outcome of the APEC LSIF Regulatory Harmonisation SC (RHSC) meeting held in Singapore on March 28-30, 2012 including recent measures to promote greater engagement with all APEC economies. The GCG noted the mutual interest in medical device regulatory activities between RHSC and the International Medical Device Regulators Forum (IMDRF). Future RHSC activities included the endorsement of a revised governance structure; the organisation of workshops (on Pharmacovigilance, Combination Products, Advanced Good Review Practice and MRCT) and the launch of the Good Clinical Practices Inspection roadmap led by Thailand.

- **APEC Harmonisation Center (AHC) Activities** – Dr. K.L. Park (APEC) presented to the GCG an overview of the APEC Harmonisation Center (AHC) activities conducted in 2011, including the outcome of the Asia Regulatory Conference held on April 26-28, 2011, the AHC workshop on Medical Devices held on June 4-5, 2011, the ICH Quality by Design (Q8/Q9/Q10) workshop held in Seoul on October 4-5, 2011 and the fourth Multi-Regional Clinical Trials Tokyo Workshop held on November 1-2, 2011. The GCG noted also the outcome of the 2012 Biosimilars workshop held on April 3-5, 2012 including its discussions and recommendations. A summary of a Regulators’ meeting conducted during the 2012 Biosimilars workshop including priority issues was also highlighted. Dr. K.L. Park informed the GCG also of the organisation in 2012 of additional AHC international workshops on Pharmacovigilance, RHSC awareness, Combination Products and MRCT.

- **Future GCG Training**
  - **ASEAN** – Dr. Javroongrit (ASEAN) informed the GCG that the training request submitted by the Drug Administration of Vietnam (DAV) in September 2011 to organise a Quality workshop on ICH Guidelines had been withdrawn by Vietnam. Dr. Javroongrit also informed the GCG of ASEAN’s interest to organise training on MedDRA for the ASEAN region and/or for each individual ASEAN Member State.
  
  - **China** – Ms. Zhou Fang (DRA of China, Skype) presented a request by the Chinese Food and Drug Administration for a 2-day workshop to be held in October 2012 in Beijing, China on MedDRA and electronic submissions (ICSR, eCTD standards and M5 topic). Dr. Ronan (ICH Secretariat) informed the GCG that this request which was submitted to the ICH Secretariat had been circulated to the MedDRA Management Board for its review and consideration. The GCG welcomed China’s request and noted that the ICH Secretariat will coordinate with both the SC and the Board to organise this training.

- **GCG Training Strategy Proposal** – Mr. Ward (Health Canada) presented to the GCG an ICH Training proposal developed by the Training Working Group (TWG), for which the objective is to promote a better global understanding and use of ICH Guidelines. The outcome of the TWG’s discussions were highlighted including the need to perform a gap analysis on existing training materials, the importance of a modular approach to meet the needs of different regions and economies, and the use of modern communication technologies. Considerations, resources and best practices were also discussed.
The GCG welcomed the ICH training proposal and noted the proposed next steps including the development of a work plan for the activities of the TWG, the review of the training materials available on the ICH website, the assessment of remote learning tools and the role of the GCG in this project.

Dr. Tominaga (MHLW/PMDA) commented on the challenges which would be faced in order to operationalise this proposal (e.g., resources implicated, different audience needs, etc).

**Actions/Decisions:**

- The ICH Secretariat will coordinate with both the SC and the MedDRA Management Board to organise a 2-day workshop to be held in October 2012 in Beijing, China on MedDRA and electronic submissions;
- The Training Working Group will continue to work by email and webconference on proposed next steps (e.g., development of a prioritised workplan, assess the materials available on ICH website, assessment of remote learning tools).

7. **Multi-Regional Clinical Trials – China/Korea/Japan Tripartite Cooperation**

Dr. Tominaga (MHLW/PMDA) presented to the GCG some background information on Multi-Regional Clinical Trials (MRCT), on APEC regulatory convergence for medical products on pharmaceuticals and more specifically on the APEC roadmap to promote MRCT (a MHLW/PMDA proposal endorsed by the RHSC in March 2011). The GCG noted the outcome of a first workshop on MRCT held on September 13-15, 2010 in Seoul, Korea. Several recommendations from a second workshop held on November 1-2, 2011 in Tokyo, Japan concerning development strategy, statistical study design and case study on oncology area were also described.

Dr. I. S. Park (DRA of Korea) presented to the GCG on the China/Korea/Japan Tripartite Cooperation on MRCT for which Japan coordinates joint research projects on ethnic factors, Korea coordinates the information exchange focusing on clinical trials and China directs MRCT guidelines. The GCG noted the information collected by Korea FDA from PMDA and China SFDA to further establish a comparison table including information exchange categories. Dr. I. S. Park presented the objectives and future directions of studies on ethnic difference of pharmaceutical products in Korea to investigate the feasibility of sharing clinical data in China, Korea and Japan.

Dr. Uyama (MHLW/PMDA) presented to the GCG on Japanese experiences of MRCT data review. An overview of current situations of MRCTs in Japan was provided to the GCG. Dr. Uyama presented also the results of scientific studies for MRCT-based drug approval when using the drugs Gefitinib and Edoxaban, and also the outcome of prospective global pharmaco-kinetics studies conducted in China, Korea, Japan and USA. The GCG noted that a new guidance on *Basic Principles on Global Clinical Trials (Reference Cases)* will be published in the future to promote understanding of the already existing MHLW/PMDA 2007 notification and to reflect Japan’s recent accumulated data.

Dr. Yang (DRA of China) presented to the GCG (by Skype teleconference) on current activities conducted in China related to the China/Korea/Japan Tripartite Cooperation on MRCT including
the current development of the “China-Japan-Korea Regional Clinical Trial Guideline which is expected to be finalised by the end of 2012, examples of drugs application and approval for MRCT in China, and challenges faced.

8. **Outcome of the GCG Survey**

The GCG noted the outcome of the GCG survey which was conducted for the second time on an anonymous basis amongst RHIs and DRAs/DoH to solicit their opinions and get feedback on the GCG. All new comments received were compiled and integrated in a document which was subsequently renamed GCG 142R. Overall, a total of 4 RHIs out of 6, and 6 DRAs/DoH out of 8 completed the survey.

In conclusion, RHIs and DRAs/DoH are pleased with both the GCG and the Regulators Forum and made also several constructive comments on how to improve future meetings.

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<td>The RHIs and DRAs/DoH were invited to send to the ICH Secretariat any comments/proposal regarding the organisation of future GCG meetings and any GCG-related activities.</td>
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9. **RHI and DRA/DoH meeting Reports on the Future of the GCG**

**RHI Meeting** – Dr. Javroongrit (ASEAN) reported on the outcome of the RHI meeting held on Sunday June 3, 2012 from 13h30 to 17h30, where RHIs finalised their Reflections Paper on the future of the GCG and discussed the need to revisit the current GCG Terms of Reference (ToR) endorsed by the SC in November 2003. The GCG acknowledged the value of this proposal.

Prof. Bawazir (GCC) presented to the GCG the RHI Reflections Paper entitled *Improving RHI Participation in ICH GCG*; where RHIs highlighted the importance of the GCG and suggested to increase the training efforts and to consider funding of additional existing RHI representatives to attend ICH meetings in order to maintain the level of participation and continuity of RHI participation in the GCG meetings. The following proposals for improvement were also presented to the GCG: for the GCG to develop a guiding document for RHI activities and the establishment of a work plan for ICH Guideline implementation in the different regions.

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<td>Subject to SC approval, the RHIs will be submitting an updated ToR to the GCG and SC for consideration at the next meeting to be held in San Diego, CA on November 13, 2012.</td>
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**DRA/DoH Meeting** – In Fukuoka, the DRAs/DoH met together for the first time in parallel of the RHI meeting on Sunday, June 3, 2012 from 13h30 to 17h30 to discuss and finalise their decisions.

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1 At the Steering Committee meeting held in Fukuoka, on June 7, 2012, the SC agreed to continue the current process of funding the participation of one representative per RHI in the ICH meetings.
Reflections Paper on the future of the GCG entitled: Proposal of the Establishment of a DRA/DoH Group (see also agenda item 10 below).

Dr. Rothenfluh (DRA of Australia) presented to the GCG the DRAs/DoH Reflections Paper on the future of GCG entitled Establishment of a DRA/DoH Group where the ToR of the DRA/DoH Group were described. The GCG noted the proposed objectives of the Group including to share: (1) information about implementation of ICH Guidelines, (2) experience in applying ICH Guidelines in non-ICH countries, (3) information about education needs and programmes; and (4) to identify regulatory issues to raise with and/or seek advice from Regulators Forum. A proposed process flow for the DRA/DoH Group was described and some recommendations for the GCG Steering Committee members were presented.

10. Recent Development/Challenges of RHIs and DRAs/DoH on ICH-related Matters

**Australia** – Dr. Rothenfluh (DRA of Australia) provided background information to the GCG on the Therapeutic Goods Administration (TGA) including its organisation and the preliminary results of the implementation in November 2010 of a new process for the prescription of medicines business. The TGA regulatory framework and reviewing medicines labels requirements were also presented. The GCG noted that the Australian and New Zealand Governments have agreed to proceed with a joint scheme for regulation of therapeutic goods (Australia-New Zealand Therapeutic Goods Authority). A 3-staged approach over a period of up to 5 years has been adopted in June 2011 to progressively achieve this goal. Dr. Rothenfluh described also in more details the first deliverables for the next 12 months, including the development of common recalls and adverse events portals for therapeutic products, the development of a common early warning system, and the development of an integrated capability to conduct Good Manufacturing Practices audits by early 2013.

**ASEAN** – Dr. Javroongrit (ASEAN) provided background information on the ASEAN community including its structure and main objectives. The Pharmaceutical Product Working Group (PPWG) scope and current activities were presented (e.g., implementation of ASEAN Common Technical Dossier and ASEAN Common Technical Requirement; and other harmonised products on Quality, Safety and Efficacy). The GCG noted also the organisation of the 19th PPWG Meeting to be held in Bangkok, Thailand on July 2-6, 2012.

**GCC** – Prof. Bawazir (GCC) provided background information to the GCG on the Cooperation Council for the Arab States of the Gulf including its organisation and recent activities for 2012. The GCG noted the outcome of the first Saudi International Regulatory and Registration workshop held on February 26-28, 2012 where drug regulation and registration, clinical trials, pharmacovigilance, technology transfer and manufacturing compliance were discussed. The outcome of the following workshops was also noted: a Good Clinical Practices – ‘train the trainer’ workshop held on March 3-7, 2012 in Riyadh; a USP’s Science and Standards Symposium held on May 27, 2012 at SFDA headquarters in Riyadh and the recent joint Information Technology / GCC-DR meeting held on May 29-30 in Riyadh, where the practical technological aspects of eCTD implementation were discussed.

**SADC** – Mr. Mthetwa (SADC) provided background information to the GCG on the SADC Pharmaceutical Harmonisation Programme including its priority work areas and challenges faced.

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2 At the SC meeting held in Fukuoka, on June 7, 2012, the SC agreed with the request made by DRAs/DoH for the establishment of a DRA/DoH Group which the ICH Secretariat would support for the organisation of webconferences (as required) and a face-to-face meeting at the time of each ICH meeting.
through the harmonisation process and steps undertaken so far towards SADC regional harmonisation. Mr. Mthetwa reported to the GCG on the outcome of the training on the ICH Q7 Guideline on *Good Manufacturing Practice for APIs* held on June 27-30, 2011 in Arusha, Tanzania. The organisation of a Flagship Course on *Pharmaceutical Reform* held on July 10-16, 2011 in Cape Town, South Africa and two FDA-SADC *Good Clinical Practices (GCP)* training courses held on August 29-September 2, 2011 in Pretoria, South Africa were also noted. The GCG noted the proposed SADC training plan for 2013 – 2014 and the suggested project proposal for 2013 on harmonisation of registration of medicines in SADC in collaboration with the NEPAD agency.

11. **Good Review Practices**

Dr. Tzou (DoH of Chinese Taipei) provided an overview to the GCG on the project of implementation of Good Review Practices (GRevPs) for which Chinese Taipei is the lead amongst APEC economies. The GCG noted that a draft 2020 roadmap for GRevPs on medical products (step-wise approach) has been endorsed and funded by APEC RHSC in December 2010. Dr. Tzou reported on the outcome of a survey for gap analysis which was circulated to APEC economies to assess the current status of GRevPs on medical products in 2011. The GCG noted the outcome of the first workshop on GRevPs held in Taipei on October 12-14, 2011 including its recommendations. The GCG noted also the organisation of a 2012 Advanced GRevPs workshop in Taipei to be held on November 6-8, 2012. Next steps for the GRevPs project were presented including the completion of framework documents on GRevPs, the establishment of an annual curriculum, and the creation of a possible framework and pilot study on the exchange and use of regulatory information.

12. **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** – A calendar of training events has been posted on the ICH public website under the tab *training/other resources* which includes information on training possibilities for all. On this page was also made available all the presentations of the 14th Center for Drug Evaluation and Research (CDER) Forum for International Drug Regulatory Authorities which was held on April 16-20, 2012 in College Park, Maryland and focused on Drug Safety Identification, Evaluation, Monitoring and Analysis during Clinical Trials, FDA Application Review and Postmarket Monitoring and Analysis.

The audio presentation of the recent webinar on the ICH S2 (R1) Guideline on *Genotoxicity Testing* held in March 2012 has been published on the ICH website, under the tab *Safety Guidelines*.

**Step 2/Step 4 Webinars** – Further to the email circulated to the RHIs and DRAs/DoH regarding the organisation of future webinars on *Step 2/Step4* ICH Guidelines on May 25, 2012; the Secretariat confirmed the forthcoming organisation of the following two webinars on:

- ICH E14 Guideline on *Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs* (including the development of the E14 Q&A document);
- ICH Q11 Guideline on *Development and Manufacture of Drug Substances* which reached *Step 4* on May 1, 2012.
The Secretariat will be using Elluminate *Live!* which allows greater participation and at no line cost for participants through Voice over IP. Recordings have also been made of the various past webinars with posting on the ICH website to add to the resource materials.

**Action/Decision:**

- The Secretariat will organise two webinars on ICH E14 and ICH Q11 Guidelines.

**Step 2 Guidelines for Consultation** – The ICH Secretariat sent letters to the RHIs and DRAs/DoH on April 12, 2012 inviting them to comment on the ICH E2C(R2) Guideline which reached *Step 2* in February 2012. Comments on the draft guidance were received from the Saudi FDA (GCC), the DRA of China and the DoH of Chinese Taipei, and subsequently shared with the E2C(R2) Expert Working Group.

**Participation of RHIs/DRAs/DoH in ICH Technical Working Groups** – To date, fifteen (15) technical experts have been nominated from China (on Q3D, S10, M7 and E2C), Chinese Taipei (on Q3D and E2C), Korea (on Q3D, S1, S10, M7 and E2C), and Singapore (on M7 and E2C) to participate in the activities of ICH technical Working Groups.

**Special Session of the ICH MedDRA Management Board** – The Special Session of the Board held for RHIs/DRAs/DoH took place on June 3 (9h30–12h00) and was attended by the majority of RHIs/DRAs/DoH in attendance of the Fukuoka meeting. The agenda for the session was developed based on feedback from previous Special Sessions. Ms. Sutcliffe (Health Canada) gave to the RHIs and DRAs/DoH a brief overview of MedDRA and ICH. Saudi Experience with MedDRA was presented by Prof. Bawazir (GCC); reasons for considering the need for interoperability with other terminologies was presented by Mr. Mick Foy (MHRA) and Dr. Dawn Ronan (ICH Secretariat) presented Board considerations on the need for mappings with other terminologies e.g., SNOMED-CT, ICD-10.

13. **Any Other Business – Closing Remarks**

**Dates of the Next GCG Meeting**

November 13, 2012  San Diego, CA, USA