MEETING REPORT
ICH Steering Committee
12 – 13 November 2014, Lisbon, Portugal
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Opening Discussions
The ICH Steering Committee (SC) meeting in Lisbon, Portugal on 12 – 13 November 2014 was chaired by EU.

Adoption of the Agenda
The agenda was adopted without modification.

1. Membership Update
The SC noted the updated lists of the: ICH Steering Committee Members, Observers and Coordinators; ICH MedDRA Management Board Members and Observer; and RHIs/DRAs/DoH participating in the Global Cooperation session of the SC.

2. Update on MedDRA
The SC received a report on the ICH MedDRA Management Board meeting held on 8 – 9 November, 2014.
The SC noted that the Board approved the 2015 MSSO Subscription Rates with no increase over the 2014 rates. The SC noted that apart from the introduction in 2014 of a new Commercial 6 level (annual revenue > $20 Billion), rates had either decreased or remained flat for the past decade. The SC also noted the status of Special Licences which the Board had granted to regulatory authorities. These allow non-commercial and small commercial organisations with low revenue (usually annual revenue < $10 Million) access to MedDRA without charge in a non-downloadable format within a Regulatory Agency’s electronic tools designed to allow companies to meet their reporting requirements. It was noted that in Lisbon the Board received an update that there were now over 1,000 organisations benefitting from such special licences, which was on top of the 4,000 plus organisations worldwide who have a MedDRA subscription.
The SC noted the importance of training in helping to facilitate the use of MedDRA. In 2014, the MSSO scheduled a total of 79 courses which are provided free to MedDRA users as part of their MSSO subscription. This includes 60 face-to-face training classes and 19 webinars, and represents a 25% increase over the number of courses provided in 2013. The SC noted that a similar scale of training is planned for 2015, with the training offerings to be shortly advertised on the website www.MedDRA.org.
The SC also noted the Board’s further consideration of the recommendations from the Blue Ribbon Panel (BRP) held on the Scope of MedDRA in April 2014 and that in Lisbon it had supported the recommendation to create a 27th SOC (System Organ Class) in MedDRA. The SC noted that the new SOC was recommended by the BRP to group terms that are separate from patient safety and clinical information. The Board agreed in Lisbon to the inclusion of terms related to product quality in this new SOC and that the new SOC should be implemented in MedDRA Version 19.0 in March 2016. This would allow sufficient time for the MSSO to communicate with users.
The SC also noted the recent finalisation of two Factsheets to assist with communication about MedDRA. The Factsheets on Accessing MedDRA and Multilingual MedDRA will be available in paper format from the ICH Secretariat and MSSO, and as a PDF on the ICH and MedDRA websites.

SC Decision/Action:
➢ The SC noted the decisions taken by the MedDRA Management Board on its behalf.
3. Global Cooperation

In Lisbon, Portugal, the Global Cooperation (GC) session saw the participation of representatives from the RHIs of APEC (Asia-Pacific Economic Cooperation), ASEAN (Association of Southeast Asian Nations), EAC (East African Community), GCC (Gulf Cooperation Council), and SADC (Southern African Development Community), and the DRAs of Brazil, China, the Republic of Korea, Russia and Singapore in addition to the DoH of Chinese Taipei. Participants discussed the status of ICH Reforms, the implementation of ICH Guidelines in the ICH regions and beyond and the future ICH strategy for global training.

The RHIs and DRAs/DoH reported on the outcome of their respective discussions during their pre-meetings where they shared views on the ICH Reforms and on ICH Guideline Implementation, including the participation of technical experts in ICH EWGs/IWGs and the need of training on ICH Guidelines.

The GC members noted the organisation of the next ICH/DIA training course on the ICH E2 Series of Pharmacovigilance Guidelines to be held in Algiers, Algeria on 12 – 13 February 2015 following the 1st Maghreb Regulatory Conference to be held on 10 – 11 February 2015. An additional training course will be organised in Dakar, Senegal on April 26, 2015 preceding the 4th African Regulatory Conference.

At the GC session, proposed concepts/points for consideration for the development of a plan for the future ICH strategy for global training and for more effectively responding to regional/global training and capacity building needs in partnership with external training providers were presented. Participants received also a presentation regarding the development of an E-learning Center by the APEC Harmonisation Center (AHC); which included a proposal to partner with ICH to develop an ICH E-learning pilot program for regulators and industries on the ICH E2 Series of Pharmacovigilance Guidelines.

SC Decisions/Actions:

- The SC thanked the AHC for its proposal regarding the development of an E-learning Center in collaboration with ICH;
- The SC invited the AHC to refine its proposal based on comments received from the SC.

4. Status Report on Topics

At the start of the meeting in Lisbon, the SC noted the current status of draft ICH Guidelines and predictions for progress towards Step 2a/b and Step 4. Updated information was provided during the SC meeting by the ICH Rapporteurs of the EWGs/IWGs meeting in Lisbon.

5. Q7 IWG: Q&As on Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

The Rapporteur reported to the SC on the outcome of the Q7 IWG meeting held in Lisbon on 9 – 13 November 2014. He presented the recent progress made by the Q7 IWG on the development of the ICH Q7 Questions & Answers (Q&A) document which will include 55 Questions and Answers. It was noted that the 55 Q&As would be circulated to constituencies for a two-month period to collect feedback on the document. All comments received would be subsequently addressed by the IWG with the aim of reaching Step 4 of the ICH process before June 2015. The IWG does not anticipate to meet in June. This will be confirmed in the light of the collected feedback.
SC Decisions/Actions:

- The SC supported the work plan of the Q7 IWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015;
- If finalised before June 2015, the ICH Secretariat will organise a postal sign-off of the Q7 Q&A document.

6. Q12 EWG: ICH Guideline on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

The Rapporteur reported to the SC on the outcome of the first meeting of the Q12 EWG held in Lisbon on 10 – 13 November, 2014 and progress made towards developing the ICH Guideline on Lifecycle Management.

This new ICH Guideline will focus on the harmonisation of change management, leading to better availability and reliability of the supply by enabling companies and regulators to manage Chemistry Manufacturing and Controls changes in a more transparent and efficient manner across the product lifecycle. The Q12 Guideline will cover the following aspects: regulatory dossiers, pharmaceutical quality system, and the post-approval change management plans and protocols. It will apply to pharmaceutical products, including currently marketed chemical, biotechnological and biological products.

The SC noted the EWG progress in Lisbon and discussed the group’s proposed future activities. It was noted that the Q12 EWG will continue to work by email and teleconference with the aim of reaching consensus on a Step 1 Technical Document in June 2015.

SC Decision/Action:

- The SC supported the work plan of the Q12 EWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015.

7. E6(R2) EWG: Addendum to Good Clinical Practice (GCP)

The Rapporteur reported to the SC on the outcome of the E6(R2) EWG meeting held in Lisbon on 10 – 13 November, 2014 and progress made towards developing the E6 Addendum on Good Clinical Practice.

The SC noted that the EWG had revised and agreed on the Addendum structure, concepts and preliminary text. It was noted that the E6(R2) EWG was anticipating to reach Step 2 in June 2015 and Step 4 in November 2016. The EWG proposed to first consider whether it is necessary to consult informally some interested parties before the draft Addendum will go to public consultation under Step 3 of the ICH process in the three ICH Regions. This proposal was supported by the SC.

SC Decisions/Actions:

- The SC supported the work plan of the E6(R2) EWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015.
- The E6(R2) EWG will share with the SC the draft Addendum for information;
- The E6(R2) EWG will consider whether it is considered necessary to consult with other interested parties after Step 1 is reached;
- If so, the E6(R2) EWG will develop a list of organisations that they would consult which will be circulated to the SC for its information.
8. E9(R1) EWG: Addendum to Statistical Principles for Clinical Trials

The Rapporteur reported to the SC on the outcome of the first meeting of the E9(R1) EWG held in Lisbon on 10 – 13 November, 2014 and progress made towards developing the E9 Addendum on *Statistical Principles for Clinical Trials* which is focusing on defining the appropriate estimand for a clinical trial/sensitivity analyses.

The SC noted that the group reached consensus regarding their understanding of an ‘estimand’ and its role in clinical trial planning, conduct, analysis and interpretation, and the role of sensitivity analyses in this pathway. Consensus on the target audience and the accessibility of the guideline text was also reached during this first meeting. In addition, several technical / conceptual questions and topics were identified by the EWG.

The Rapporteur stressed the importance to obtain input from other statisticians and non-statisticians once the Addendum will be developed. The SC noted that the discussions around this subject might impact other ICH Guidelines such as the E17 and M4E Guidelines. The importance of quantifying the impact of a new framework on clinical operations (e.g. protocol writing, data collection, reporting) was also highlighted. Future work of the E9(R1) EWG will include the development of technical definitions and simple case studies to help facilitate discussion within the EWG.

The E9(R1) EWG will continue to work by email and teleconference with the aim of reaching consensus on a *Step 1 Technical Document* in advance of June 2015.

**SC Decision/Action:**

- The SC supported the work plan of the E9(R1) EWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015.

9. E11(R1) EWG: Addendum to Pediatric Drug Development

The Rapporteur reported to the SC on the outcome of the first meeting of the E11(R1) EWG held in Lisbon on 10 – 13 November, 2014 and progress made towards developing the E11 Addendum on *Pediatric Drug Development*.

The SC noted that consensus was achieved amongst the ICH Parties on the format of the Addendum to the ICH E11(R1) Guideline. The Addendum will contain an introduction and also references to the existing E11 Guideline, in addition to new/updated sub-sections.

The group agreed on a principal approach for the following seven topic areas: Commonality of Content (new topic), Ethical Issues in Pediatric Studies (updated topic), Age Classification and Pediatric Subsets (updated topic), Clinical Trial Methodology (updated topic), Extrapolation of Data (new topic), MID3/Modeling & Simulation (new topic), and Pediatric Formulations (updated topic).

The SC noted that the objective of this guideline is to advance the understanding of pediatric drug development. The Rapporteur commented that pediatric product development is multi-disciplinary and therefore, the ICH E11 Guideline could not encompass the full scope of relevant considerations. The SC recognised the importance to consider pediatric in several areas of adult drug development and supported the recommendation of the E11 EWG for reflection on the need for pediatric specific information during the development of all relevant new ICH Guidelines or the revision of existing ICH Guidelines.

The SC discussed the proposed timelines suggested by the group for reaching *Step 1* in spring 2015 and suggested that these be re-considered early next year after the group has further progressed its work.
**SC Decisions/Actions:**

- The SC supported the work plan of the E11(R1) EWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015;
- Based on its progress by early next year, the E11(R1) EWG will revise its work plan with updated timeframes for reaching Step1 and Step 2a/b;
- The SC recommended that other EWGs/IWG should reflect on whether they could include considerations related to pediatrics in their respective guideline.

**10. E17 EWG: ICH Guideline on Multi-Regional Clinical Trials**

The Rapporteur reported to the SC on the outcome of the E17 EWG meeting held in Lisbon on 10 – 13 November, 2014 and progress made towards developing a new ICH Guideline on Multi-Regional Clinical Trials.

The SC noted that during the week, the group discussed and shared regional perspectives regarding which topics should be included in the E17 Guideline. It was noted that consensus was reached on the table of contents and that the group already initiated the drafting of some sections for this new guidance. The SC highlighted two important points to be addressed in the E17 Guideline – how to define a region, and the selection of comparators. The SC also noted the importance of the E17 Guideline to improve the current situation of global drug development and to promote simultaneous regulatory submissions in multiple countries/regions.

The E17 EWG will continue to work by email and teleconference with the aim of reaching consensus on a Step I Technical Document in June 2015.

**SC Decisions/Actions:**

- The SC supported the work plan of the E17 EWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015;
- The SC recommended that the E17 EWG should reflect on whether they could include considerations related to pediatrics in their guideline.

**11. E18 EWG: ICH Guideline on Genomic Sampling Methodologies for Future Use**

The Rapporteur reported on the outcome of the first meeting of the E18 EWG held on 10 – 13 November, 2014 and progress made towards developing a new ICH Guideline on Genomic Sampling Methodologies for Future Use.

The SC noted that the new E18 Guideline would focus on technical aspects of genomic sampling, highlighting the value and importance of defining an appropriate methodology for genomic sample collection for future use. The Rapporteur explained the advantage and limitation of prospective and retrospective genomic analysis, and that the E18 guidance would be applicable to pre- and post-approval studies. The Rapporteur also presented a draft table of contents for the guideline covering the following areas: collection of samples; handling and storage of samples; generation, use and handling of genomic data; privacy/confidentiality; emerging topics.. The SC noted that issues of bio-bank management would be out of the scope of the E18 Guideline.

The E18 EWG will continue to work by email and teleconference with the aim of reaching consensus on a Step I technical document in June 2015.

**SC Decisions/Actions:**

- The SC supported the work plan of the E18 EWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015;
The SC recommended that the E18 EWG should reflect on whether they could include considerations related to pediatrics in their guideline.

12. M4E(R2) EWG: Revision of CTD-Efficacy Guideline

The Rapporteur reported on the outcome of the first meeting of the M4E(R2) EWG held on 10 – 13 November, 2014 and progress made towards revising the CTD-Efficacy Guideline.

The SC noted that general guidance exists in the M4E(R1) Guideline regarding the expected content of CTD Section 2.5.6 “Benefits and Risks Conclusions”. However, no further guidance has been suggested that could aid industry in structuring their benefit-risk assessment so far. In addition, regulators observe variability taken by applicants in presenting benefit-risk information. It was noted that the M4E(R2) EWG is tasked with standardising the content and presentation of benefit-risk information in regulatory submissions; and such standardisation should increase efficiency in communication of the benefit and risk assessment between industry and regulators.

The SC noted that M4E(R2) EWG reached consensus in Lisbon on general principles for the revision of the CTD-Efficacy Guideline including on a new sub-structure for Section 2.5.6.

The SC discussed the proposed timelines suggested by the group for reaching Step 4 in November 2015 and suggested that these be re-considered early next year after the group has further progressed its work.

**SC Decisions/Actions:**

- The SC supported the work plan of the M4E(R2) EWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015;
- The M4E(R2) EWG will provide revised timelines to the SC ahead of its spring webconference.

13. M2 EWG: Electronic Standards for the Transfer of Regulatory Information

The Rapporteur reported on the outcome of the M2 EWG meeting held on 10 – 13 November, 2014. The role of the M2 EWG is to maintain the technical ‘bigger picture’ with respect to ICH work, ensure ICH awareness, and enable technical harmonisation.

The SC noted the proposed work plan for major activities to be undertaken between Lisbon and the next meeting in Fukuoka, Japan in June 2015 as follows: performing assessment of technology activity impacts and opportunities for ICH topics; updating ESTRI website Content; monitoring SDO activity and assessing relevance of new SDO activities; preparing Technology Watch report for the SC; advancing ESTRI activities for DOCX testing, redaction “current state” evaluation, and structured content approaches across ICH regions.

**SC Decisions/Actions:**

- The Regulatory SC members signed-off the ICH M2 File Format Criteria document;
- The SC approved the work plan and major activities between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015.


The Rapporteur reported on the outcome of the M8 EWG/IWG meeting held on November 9 (pm) – 13, 2014 and progress made towards reaching Step 2a/b of the eCTD Implementation Guide.
The report included an update on:

- Preparation for the Step 2a/b eCTD v4.0 Implementation Guide and accompanying documents;
- Assessment of Change Requests deferred to v4.0 development
- Review of CTD-Q related Change Requests;

Proposal to assign Granularity Document update based on appropriate experts’ decision. The SC noted the work plan of the M8 EWG including proposed timeframes for initiating the consultation period (Step 3) and for finalising the eCTD version 4.0 (Step 4) in March 2015 and November 2015, respectively.

**SC Decisions/Actions:**

- The SC endorsed the M8 recommendation to allow M8 to update the Granularity document;
- The M8 IWG will ask the CTD-Q experts to review the proposed update to the Granularity document;
- The M8 Experts signed-off Step 1 of the eCTD v2.0 Implementation Guide;
- The ICH Secretariat will organise a postal signed-off for the Step 2a Implementation Guide v2.0 at the level of the SC members;
- Once Step 2a is reached, the ICH Secretariat will launch the postal sign-off for the Step 2b Implementation Guide v2.0 at the level of the Regulatory SC members;
- The SC endorsed the work plan and timelines for Step 3 and Step 4 of the eCTD version 4.0;
- The SC endorsed the work plan of the M8 EWG/IWG for work to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015.

15. EWGs/IWGs/Discussion Groups not Meeting in Lisbon, Portugal

- **S1 EWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline**

  The S1 EWG did not meet in Lisbon.

  The SC noted the current activities of the S1 EWG including the progress made towards the collection and review of confidential submissions of Carcinogenicity Assessment Documents (CADs) by sponsors to Drug Regulatory Authorities (DRAs) within each ICH region.

  The SC noted that the ICH S1 Guideline was expected to reach Step 2 in November 2017 depending on the outcome of the CAD assessment.

  **SC Decision/Action:**

  - The SC supported the work plan of the S1 EWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015.

- **S3A IWG: Q&As on Note for Guidance on Toxicokinetics**

  The SC noted the endorsement of the S3A Concept Paper for the establishment of an IWG which will initiate work by email and teleconference to develop a Questions and Answers document to the ICH S3A Guideline.

  The SC noted that the ICH S3A Q&A document was expected to reach Step 2 in March 2015.
SC Decision/Action:

- The ICH Secretariat will launch the nomination process for the establishment of the S3A IWG.

S9 IWG: Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals

The SC noted the endorsement of the S9 Concept Paper for the establishment of an IWG which will initiate work by email and teleconference to develop a Q&A document to the ICH S9 Guideline.

The SC noted that the ICH S9 Q&A document was expected to reach Step 2/Step 4 in June 2015.

SC Decision/Action:

- The ICH Secretariat will launch the nomination process for the establishment of the S9 IWG.

M7 EWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

The M7 EWG did not meet in Lisbon.

The SC noted the current activities of the M7 EWG including the progress made towards developing the M7 Addendum on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.

The SC noted that the ICH M7 EWG Guideline was expected to reach Step 2a/b in February 2015.

SC Decision/Action:

- The SC supported the work plan of the M7 EWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015.

Q3C(R5) Maintenance EWG: Maintenance of the Guideline for Residual Solvents

The Q3C(R5) Maintenance EWG did not meet in Lisbon.

The SC noted the current activities of the Q3C(R5) EWG and progress made towards addressing the request received for ICH to consider undertaking maintenance of the ICH Q3C(R5) Guideline to include three solvents: Formaldehyde, Triethylamine and Methyl Isobutyl Ketone.

SC Decision/Action:

- The Q3C Maintenance EWG will provide a work plan to the SC ahead of its spring webconference to be held in March 2015 for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015.

Q3D EWG/IWG: Guideline for Metal Impurities

The Q3D Guideline reached Step 4 with sign-off by Regulatory SC members in Lisbon. The SC also noted the endorsement of the Q3D Concept paper and Business Plan for the establishment of an IWG which will work by email and teleconference on the development of a training package on the Q3D Guideline.

SC Decisions/Actions:

- The Regulatory SC members signed-off the Step 4 of the ICH Q3D Guideline;
- The SC acknowledged that this completed the Q3D EWG’s work;
The ICH Secretariat will organise a webinar for RHIs/DRAs/DoH on ICH Q3D Guideline in Q1 2015;
The ICH Secretariat will launch the nomination process for the establishment of the Q3D IWG.

M4Q IWG: Addressing CTD-Q Related Questions/Change Requests Raised by eCTD

The M4Q IWG did not meet in Lisbon.
The SC noted the current activities of the M4Q (CTD-Quality) IWG and the progress made towards addressing the questions received related to CTD-Q from the M8 IWG which is working on the eCTD.

SC Decision/Action:
- The SC supported the work plan of the M4Q IWG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015.

E14 Discussion Group: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs

The E14 Discussion Group did not meet in Lisbon.
The SC noted the current activities of the E14 Discussion Group and progress made by the Discussion Group on the development of timelines for the different topics mentioned in the E14 Discussion Group proposal.

SC Decisions/Actions:
- The SC supported the work plan of the E14 Discussion Group for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015;
- The E14 Discussion Group will provide timelines to the SC ahead of the SC spring webconference to be held in March 2015 for the different topics mentioned in the E14 Discussion Group proposal.

M1 PtC WG: MedDRA Points to Consider (PtC) Working Group

The M1 PtC WG did not meet in Lisbon.
The SC noted the current activities of the M1 PtC WG and the outcome of the recent interim meeting held in London, UK on 10 – 12 November, 2014, which included work to provide input on the EU’s Good Practice Guide on Coding and Reporting of Medication Errors - Technical Guidance.

SC Decisions/Actions:
- The SC noted the report of the M1PtC WG interim meeting recently held in London, UK;
- The SC supported the work plan of the M1 PtC WG for activities to be undertaken between the Lisbon meeting and the next meeting in Fukuoka, Japan in June 2015.

16. Communication about ICH

ICH Reforms
Interested stakeholders and regulators participated in a SC Special Session on ICH Reforms on Sunday, 9 November, 2014 where they were informed on the state-of-play of the ICH Reforms and invited to share their views. All participants welcomed the objectives of the
Reforms and the intention to increase the involvement of interested regulators and key stakeholders in ICH.

The RHIs and DRAs/DoH who attended the GC session of the SC meeting noted that the SC had continued to make progress in Lisbon on the ICH reforms and hoped to reach conclusion shortly on the reforms.

The SC will inform interested stakeholders and regulators on the outcome of these discussions which the SC hopes to reach conclusion on very shortly.

**ICH Regional Public Meetings**

The SC noted the organisation by JPMA of a Regional Public Meeting to be held in Tokyo, Japan on 11 December, 2014. The SC also noted the outcome of a M7 workshop organised by JPMA which was held in Tokyo, Japan on 29 September, 2014; and the organisation by JPMA and the Pharmaceutical and Medical Device Regulatory Science Society of Japan (PMRJ) of two additional workshops on ICH M8 and ICH M7/ICH Q3D which would be held in Tokyo, Japan on 9 March, 2015 and 7 April, 2015 respectively.

The SC also noted that the EU/EMA was considering whether it could organise a Regional Public Meeting in spring 2015.

**Dates of Next Meetings for 2015**

<table>
<thead>
<tr>
<th>Dates</th>
<th>Location</th>
</tr>
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<tbody>
<tr>
<td>6 – 11 June 2015</td>
<td>Fukuoka, Japan</td>
</tr>
<tr>
<td>Autumn 2015</td>
<td>USA (date and location to be confirmed)</td>
</tr>
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**EWG/IWGs Meeting in Fukuoka, Japan**

A list of EWG/IWGs which will meet face-to-face at the next ICH meeting in Fukuoka, Japan on 6 – 11 June 2015 will be made available on the ICH public website following the SC webconference to be held in spring 2015.

**17. Any Other Business**

**ICRMA**

The SC received a general presentation on the International Coalition of Medicines Regulatory Authorities (ICMRA). The SC appreciated the efforts of ICMRA for providing this information and welcomed the involvement of Medicine Regulatory Authorities at executive level to support the development of international collaboration in a strategic manner.

**SC Decision/Action:**

- The SC will follow-up with ICMRA in the coming days to extend its thanks for the presentation and to provide information on the ICH reform and harmonisation activities.