September 26, 2016

Minutes
ICH Management Committee Meeting
Lisbon, Portugal
June 13-16, 2016

LIST OF PARTICIPANTS

ICH Management Committee Members & Observers:

Mrs. Lenita Lindström-Gommers	EC *(MC Chair)*	Europe
Dr. Tomas Salmonson	EC	Europe
Dr. Nobumasa Nakashima	MHLW	Japan
Mr. Naoyuki Yasuda	MHLW/PMDA	Japan
Dr. Toshiyoshi Tominaga	MHLW/PMDA	Japan
Dr. Theresa Mullin	FDA	USA
Ms. Joan Blair	FDA	USA
Dr. Richard Bergström	EFPIA	Europe
Dr. Sabine Luik	EFPIA	Europe
Dr. Hironobu Saito	JPMA	Japan
Mr. Takuya Saiki	JPMA	Japan
Mr. Jerry Stewart	PhRMA	USA
Dr. Peter Honig	PhRMA	USA
Ms. Catherine Parker	Health Canada	Canada
Dr. Petra Doerr	Swissmedic	Switzerland
Ms. Cordula Landgraf	Swissmedic	Switzerland
Mr. Mike Ward	WHO	Switzerland

ICH Coordinators

Dr. Sébastien Goux	EC	Europe
Mr. Fumihito Takanashi	MHLW	Japan
Ms. Amanda Roache	FDA	USA
Mr. Pär Tellner	EFPIA	Europe
Mr. Mitsuo Mihara	JPMA	Japan
Ms. Camille Jackson	PhRMA	USA

Technical Coordinators:

Dr. Milton Bonelli	EC/EMA	Europe
Ms. Chieko Hirose	MHLW/PMDA	Japan

Other Participants:

Ms. Emer Cooke	EC/EMA	Europe
Mr. Martin Harvey	EC/EMA	Europe
Mr. Yoshihiro Katsura	MHLW/PMDA	Japan
Mr. Nick Orphanos	Health Canada	Canada
Dr. Michelle Limoli	FDA	USA
Dr. Juliette Toure	FDA	USA

ICH Secretariat:

Dr. Dawn Ronan
Dr. Sarah Adam
Dr. Isabelle Güller

ICH Management Committee Meeting Minutes

Welcome & Adoption of the Agenda

The Management Committee (MC) Chair and Vice-Chair welcomed the Permanent MC Member Representatives and Permanent Observer delegates and the agenda was adopted without modification.

A. ICH Operational Matters

ICH Secretariat Report

The ICH Secretariat provided an update on its activities. This included the seeking of a tax exemption for the ICH Association, and work to address the remaining legal/fiscal points to facilitate the transfer of assets from trustee IFPMA to ICH. The MC noted that there were also some practical points to be addressed prior to the transfer (e.g., acquiring the necessary insurances for staff, contracting an external fiduciary services firm etc…) and that the exact timeframe for the transfer still needed to be confirmed.

The ICH Secretariat also reported on the work which would be undertaken over the coming months to seek several proposals for potential auditors for the Association. The MC noted that the aim would be to make a recommendation to the Assembly at its next meeting in Osaka in November 2016 when the Assembly should appoint auditors for a period of two years.

A proposal was also made by the ICH Secretariat towards increasing operational efficiency which would be of benefit of both the MC and the ICH Secretariat as the Membership and Observership of the ICH Association expands.

Actions/Decisions:

- The MC acknowledged the next steps to be taken to seek the tax exemption for the ICH Association and to address the open points prior to transfer of assets from IFPMA to ICH, and provided its support for the ICH Secretariat to work with the ICH advisors to move this activity forward;
- The MC supported that the ICH Secretariat work to ensure the necessary contracts for the fully independent Secretariat are in place as of the date of the asset transfer;
- The MC supported that the ICH Secretariat seek proposals from several potential auditors with the aim of presenting them to the MC for consideration in September 2016. The MC will recommend an auditor for Assembly approval at its meeting in Osaka in November 2016;
- To improve the efficiency of the work of the MC and the ICH Secretariat, the MC supported a proposal from the ICH Secretariat to reduce the number of documents sent for MC approval and supported that the ICH Secretariat work with the ICH Coordinators to finalise the procedure on documents needing approval, and agreed that actions undertaken by the ICH Secretariat (e.g., follow-up on media enquiries) be reported on at MC meetings.

2015 ICH Secretariat Budget & One-Time Budget Closing Reports

The ICH Secretariat reported on the closure of the 2015 ICH Secretariat Budget and One-time Budget. The MC noted that the latter concerned the fund established by MC Members to support the set-up of the new ICH Association.

Action/Decision:

- The MC approved the 2015 ICH Secretariat Budget and One-time Budget Closing Reports.

B. ICH Rules of Procedure

The MC was updated by the Lead of the Rules of Procedure (RoP) Subcommittee on the status of the Assembly, MC and MedDRA MC RoP. The MC discussed the latest version of the MC RoP document agreed that there were several amendments needed to the Assembly RoP which should be raised for consideration by the Assembly.

Actions/Decisions:

- The MC supported the MC RoP document as final for publication on the ICH public website with the understanding that the MC RoPs would need to be updated to include a section on meeting organization and the review of new topics at a later time;
- The MC supported the proposed revisions to the Assembly RoP document for presentation to the Assembly for consideration and approval;
- The MC noted that the MedDRA MC RoP were under discussion by the recently established MedDRA MC and the aim was to finalise these ahead of the Osaka meeting in November 2016.

C. Standard Operating Procedures for EWGs/IWGs

The Lead of the Standard Operating Procedures (SOPs) for EWGs/IWGs Subcommittee reported on work to finalise version 1.0 of the SOPs for EWGs/IWGs. The Lead highlighted the comments which several MC Members had submitted prior to the Lisbon meeting and which needed to be reflected in the document.

Actions/Decisions:

- The MC supported version 1.0 of the SOPs for EWGs/IWGs pending the addressing of the comments raised by MC Members prior to and in Lisbon;
- The MC agreed that the final version 1.0 should be shared with the MC after which it will be finalised for publication on the ICH public website.

D. ICH Financial Matters

The Lead of the Financial Subcommittee provided an update on the activities of the Financial Subcommittee and sought MC views on items including: new membership fees, concept of a participation fee; draft 2017 ICH budget; and development of an ICH donation policy.

Actions/Decisions:

- The MC supported the presentation of a proposal to the Assembly for a fee range of between CHF 19,200 to CHF 48,000;
- The MC supported the presentation of the concept of a participation fee to the Assembly for its views and for the finance subcommittee to assess the implications for administration of a participation fee;
- The MC supported the provision to the Assembly of the 2016-2018 ICH Secretariat Budget;
- The MC agreed to further discuss in Osaka in November 2016 the donation policy and items of relevance for the 2017 ICH Secretariat Budget;
- The MC supported that the finance subcommittee assist in the assessment of audit reports in the future;
- The Financial Subcommittee will work with the Communications Subcommittee to develop communications on the items being published on the financial section of the website such as new member fees and budgets.

E. ICH Membership and Observership Applications

The Lead of the Membership Subcommittee provided an update on the activities of the Membership Subcommittee including an overview of all applications for Membership/Observership received to-date. The MC took under consideration interest expressed since January 2016 when the application forms had been made available on the ICH website. The MC noted that some applications needed follow-up with applicants to clarify aspects of their submission.

The ICH Secretariat updated the MC on the invitation to the Lisbon Assembly meeting of several applicants whose applications had been provisionally assessed and considered by the Management Committee as fulfilling the membership criteria.

The MC finalised its assessment and prepared recommendations for the Assembly for a number of applications. The MC also agreed that it would not be appropriate to comment on or communicate the status of applications that have not yet been finalised and approved for recommendation to the Assembly.

Actions/Decisions:

- The MC agreed to recommend the following Membership applications to the Assembly for approval:
    - The International Generics and Biosimilar Association (IGBA);
    - The World Self-Medication Industry (WSMI).
- The MC agreed to recommend the following Observership applications to the Assembly for approval :
    - The European Directorate for the Quality of Medicines & HealthCare (EDQM);
    - The Council for International Organizations of Medical Sciences (CIOMS);
    - The Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS, Mexico);
    - The International Pharmaceutical Excipient Council (IPEC)
    - The United States Pharmacopeia (USP).
- The MC agreed to recommend BIO to the Assembly for Observership;
- The MC agreed to recommend to the Assembly not to approve the application for Observership received from the Centers for Medicare and Medicaid Services (CMS) which the MC concluded was not eligible;
- The MC agreed to progress the other pending applications as soon as feasible.

F. ICH Communication

The Lead of the Communication Subcommittee updated the MC on the activities of the Communication Subcommittee including: work to finalise the Q&As on Membership and Observership which were recently published on the ICH public website; the development of a general slide deck on ICH which could be used by Members and Observers invited to present on ICH; and the development of a Transparency Policy, as well as a Communication and Stakeholder Engagement Plan.

Action/Decision:

- In the interest of time, the MC agreed to further discuss via teleconference after the Lisbon meeting items including the slide deck on ICH, draft Transparency Policy, and draft Communication and Stakeholder Engagement Plan.

G. New Topics

The Lead of the New Topics Subcommittee provided the MC with an update on the activities of the New Topics Subcommittee, including collection of new topic proposals, as well as the development of a process and framework for the selection of new ICH technical topics to be used in future ICH meetings.

The MC noted the new topic proposals which had been submitted by several of the Members prior to the Lisbon meeting. All topics were ranked by each Member according to priority and the MC agreed to recommend to the Assembly for approval those with the highest priority rankings.

Actions/Decisions:

- The MC agreed to recommend two new topic proposals to the Assembly for approval. One on biopharmaceutics classification system-based biowaivers (M9), proposed by the EC/EMA, and the other on bioanalytical method validation (M10), proposed by MHLW/PMDA;
- The EC and MHLW/PMDA agreed to each propose a Rapporteur to the Assembly for the M9 and M10 topics respectively;
- The MC agreed that if approved by the Assembly, the ICH Secretariat should send a nomination request to all Members and Standing Observers inviting them to nominate experts to the two informal Working Groups which would be tasked with finalising the Concept Papers and developing Business Plans;
- The MC agreed to highlight that Observers would have the possibility to request that the Assembly consider in Osaka in November 2016 any interest they might have to appoint experts to these new Working Groups in line with Article 17(5) of the ICH Articles of Association;
- The MC agreed that Regulatory Chairs for each of these new Working Groups could be confirmed by the MC after the Lisbon meeting;
- The MC also agreed to further consider the new topic proposals on adaptive clinical trials (proposed by PhRMA) and safety data collection (proposed by FDA) since many Members had also ranked these proposals highly;
- The MC agreed to present to the Assembly the yearly cycle, for new topic selection at the nominal stage (except current topic selection process);
- The MC agreed to also present to the Assembly a general outline on the organisation of ICH Strategic discussions on selected topics, separate from nominal new topics selection, with a recommendation that proposals are developed for strategic discussions in Osaka on Good Clinical Practice (GCP) (to be led by FDA) and on compliance of reliability for electronic data (to be led by JPMA and supported by FDA).

H. Training

The Lead of the Training Subcommittee updated the MC on the activities of the Training Subcommittee including the development of an options paper on an ICH training strategy.

Action/Decision:

- The MC agreed to further reflect on the options paper on an ICH training strategy proposed by the Training Subcommittee and to further discuss the proposed options at a MC teleconference following the Lisbon meeting.

I. Implementation of ICH Guidelines

Time did not allow for the MC to discuss potential mechanisms for reporting on implementation of ICH Guidelines be all Members.

Action/Decision:

- The MC postponed discussion of potential mechanisms for reporting on implementation of ICH Guidelines by Members and will aim to have this discussion in preparation of the Osaka meeting in November 2016.

J. Oversight of Expert Working Groups and Implementation Working Groups

Groups Meeting in Lisbon

- ***E2B(R3) IWG: Revision of the Electronic Submission of Individual Case Safety Report***

The MC received an update from the E2B(R3) Rapporteur on the status of its discussions with EDQM regarding it being the maintenance organisation for Dosage Forms and Routes of Administration TermIDs for E2B(R3), and on the unconstrained use of EDQM Dosage Forms and Routes of Administration TermIDs for E2B(R3).

Action/Decision:

- The MC supported the E2B(R3) IWG provide a similar update to the Assembly.

Groups Not Meeting in Lisbon

- ***M2 EWG: Electronic Standards for the Transfer of Regulatory Information***

The MC received a report on behalf of the M2 EWG which was not meeting in Lisbon on a proposed new M2 operating model that would provide more structure to M2 activities. The MC extended its appreciation to the M2 EWG for the thoughtful proposal in response to the MC's request with which it generally agreed.

Action/Decision:

- The MC supported the continuation of the M2 EWG and agreed to communicate the MC's considerations on the proposed new M2 operating model to their respective M2 experts.

- ***Q3D IWG: Guideline for Elemental Impurities***

The MC noted that since the publication of the Q3D ICH Guideline the Q3D IWG had received many questions related to the dermal route of administration. In response the IWG proposed to develop PDEs for this route of administration. The Q3D IWG proposed to the MC that this be done in the context of the Q3D maintenance procedure by updating in the Q3D Guideline the method for establishing exposure limits in Appendix 1 and adding the PDEs and permitted concentrations of elemental impurities in Appendix 2 to include the dermal route of administration. Additionally, the individual safety assessments for each of the 24 compounds would be updated to include the dermal route of administration.

Actions/Decisions:

- The MC supported the Q3D IWG's proposal that additional routes of administration are included in the Q3D Guideline in the context of the maintenance procedure;
- The MC agreed that this work could be undertaken by the current Q3D IWG.

Participation of Observers in EWGs/IWGs

Article 17(5) of the ICH Articles of Association states the Assembly may, on the basis of recommendation by the MC, invite Observers to appoint experts in Working Groups. Further to this the MC noted that ICH Observer MFDS had submitted a request to participate in the Q12 EWG.

Action/Decision:

- The MC agreed to recommend approval of the participation of a MFDS expert in the Q12 EWG to the Assembly.

K. ICH 2015 Annual Report

The MC noted that the ICH 2015 Annual Report had been shared with the Assembly prior to the Lisbon meeting and the Assembly would be invited to approve this in Lisbon for publication on the ICH public website.

L. ICH Annual Work Plan and Multi-Annual Strategic Plan

The MC noted that the ICH 2016 Annual Work Plan and Multi-Annual Strategic Plan had been shared with the Assembly prior to the Lisbon meeting and the Assembly would be invited to approve these documents in Lisbon for publication on the ICH public website. The MC also noted that a MedDRA 2016 Work Plan had been developed by the MedDRA Management Committee/MedDRA Management Board and would be shared with the Assembly in Lisbon for approval.

M. IPRF Update

The MC received an update on IPRF (International Pharmaceutical Regulators Forum) activities and was presented a possible proposal for cooperation with ICH for the provision of Secretariat services for both the IPRF and IGDRP (International Generic Drug Regulators Program).

Action/Decision:

- The MC supported the possible proposed cooperation and that these activities would be financed through contributions from IPRF and IGDRP Regulatory Members;

N. Organisation of Assembly Meetings

Procedures Related to Meeting Organisation

The MC discussed the respective roles of the host, the MC and the ICH Secretariat with respect to the organisation of ICH meetings, particularly where the ICH Association needs to enter into the contracts (e.g., venue, meeting planner etc…) and/or make payments.

Actions/Decisions:

- The MC agreed that the meeting host should be responsible for the selection of the venue and the negotiation of the necessary contracts;
- To enable MC approval of contracts over CHF 100,000, the MC agreed that Members with previous experience hosting ICH meetings should review the contracts prior to the provision of MC authorisation for the ICH Association to sign off;
- The MC supported that the ICH Secretariat work with the host to clarify ICH meeting requirements and supported the proposal for the ICH Secretariat to develop a package with input from former ICH meeting hosts which could be provided to future hosts to brief them on ICH meeting requirements;
- The MC supported that where a host has itself entered into the necessary contracts and will directly make payments, the ICH Secretariat could provide a letter to confirm that the ICH Association will reimburse the host to the amount approved in the ICH Budget.

Organisation of 2017 and 2018 Meetings

Health Canada provided an update on the organisation of the spring 2017 meeting in Montreal, Canada, the final dates for which still need to be confirmed. Swissmedic and MHLW/PMDA and JPMA kindly volunteered to host the autumn 2017 and spring 2018 meetings respectively.

Actions/Decisions:

- The MC acknowledged Swissmedic as the host of the autumn 2017 meeting in Switzerland;
- The MC supported MHLW/PMDA and JPMA as the host of the spring 2018 meeting in Japan.

EWGs/IWGs Meeting in Osaka, Japan

The MC discussed the requests made by EWGs/IWGs to meet face-to-face at the next ICH meeting in Osaka on November 5 – 10, 2016 and made provisional planning.

Action/Decision:

- The MC agreed to finalise the list of EWG/IWGs which will meet in Osaka in November 2016 at the autumn 2016 Management Committee teleconference.

Dates/Location of Next Meetings for 2016/2017

November 5-10, 2016	Osaka, Japan
Spring 2017	Montreal, Canada

Any Other Business

Ad hoc Stakeholders meeting on ICH E6 Integrated Addendum to Good Clinical Practice (GCP)

The MC noted the hosting in Lisbon by the EC/EMA of an *Ad hoc* Stakeholders meeting on the E6 Addendum on June 6, 2016 which had been organised in response to a communication sent to both ICH and the EMA, and was attended by several trialists from the MoreTrials initiative.

Actions/Decisions:

- The MC noted the valuable input provided by the stakeholder experts and was supportive of reflecting on a process which would allow ICH to dialogue with interested stakeholders in a consistent manner;
- The MC supported the development of a reflections paper to facilitate MC discussion on this prior to the Osaka meeting.