

Ref.: MC2016/37

October 25, 2016

**SUMMARY REPORT
ICH MC TELECONFERENCE
September 30, 2016**

LIST OF PARTICIPANTS:

ICH Management Committee Members/Observers

Mrs. Lenita Lindström-Gommers	EC	Europe
Dr. Tomas Salmonson	EC	Europe
Mr. Richard Bergström	EFPIA	Europe
Dr. Theresa Mullin	FDA	USA
Ms. Cathy Parker (Vice-Chair)	Health Canada	Canada
Dr. Celia Lourenco	Health Canada	Canada
Dr. Masafumi Yokota	JPMA	Japan
Dr. Takuya Saiki	JPMA	Japan
Dr. Toshiyoshi Tominaga (Chair)	MHLW/PMDA	Japan
Mr. Naoyuki Yasuda	MHLW/PMDA	Japan
Dr. Nobumasa Nakashima	MHLW	Japan
Dr. Peter Honig	PhRMA	USA
Mr. Jerry Stewart	PhRMA	USA
Dr. Petra Doerr	Swissmedic	Switzerland

ICH Coordinators

Mr. Pär Tellner	EFPIA	Europe
Ms. Amanda Roache	FDA	USA
Dr. Celia Lourenco	Health Canada	Canada
Mr. Mitsuo Mihara	JPMA	Japan
Mr. Fumihito Takanashi	MHLW	Japan
Ms. Camille Jackson	PhRMA	USA

Technical Coordinators:

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

Other Participants:

Mr. Martin Harvey	EC/EMA	Europe
Dr. Michelle Limoli	FDA	USA
Dr. Yoshihiro Katsura	MHLW/PMDA	Japan

ICH Secretariat:

Dr. Dawn Ronan
Dr. Sarah Adam
Dr. Isabelle Güller
Ms. Coralie Angulo

SUMMARY REPORT

MC Chair: Dr. Toshiyoshi Tominaga, MHLW/PMDA

MC Vice-Chair: Ms. Cathy Parker, Health Canada

1. ADOPTION OF THE AGENDA

The agenda was adopted without any comments.

APPROVAL OF THE MC REPORTS

MC Actions/Decisions:

- *The MC approved the recent MC Meeting (MC2016/25F) and Teleconference (MC2016/26F) Reports and their publication on the ICH website;*
- *The ICH Secretariat will proceed with the publication of these reports on the ICH website.*

2. ORGANISATION OF OSAKA MEETING

The MC discussed the organisation of the Osaka Meeting and noted that the Assembly Agenda Papers will be shared electronically with the Assembly on October 26, 2016.

MC Actions/Decisions:

- *The MC noted the draft agenda for the Assembly meeting and was invited to provide comments to the ICH Secretariat by October 5, 2016;*
- *The MC discussed the organisation of the Briefing session for ICH experts to be held in Osaka on November 7 and supported that a presentation be delivered by Dr. Mullin (FDA) which could also include a reference to the version 1.0 of the Standard Operating Procedures for EWGs/IWGs;*
- *The ICH Secretariat will prepare the draft 2017 Annual Work Plan, and the draft Multi-Annual Strategic Plan to be circulated to the MC ahead of Osaka and will be updated in Osaka based on the outcome of New Topic/Strategic discussions;*
- *The MC discussed the potential ways for reporting on implementation of ICH Guidelines by Members and suggested that in Osaka ICH Members and Observers should be informed about how this reporting is envisaged to be done at the Montreal meeting in June 2017.*

3. ICH ACTIVITIES AND NEXT STEPS

❖ ICH PROCEDURAL MATTERS

The MC was updated on the proposed amendment to the ICH Articles of Association and the Assembly RoP.

The MC was also updated on comments received on the version 2.0 of the SOP for EWGs/IWGs which was circulated to the MC on September 12. The MC confirmed the timeframe for next steps once MC approval is confirmed (circulation of SOP to the Assembly for its information and publication on the ICH public website).

MC Actions/Decisions:

Articles of Association and Assembly RoPs

- *On October 7, at its teleconference, the MC will be invited to approve in principle the updated Assembly RoP and the revised Articles pending legal review for subsequent sharing with the Assembly on October 26 for its consideration and approval in Osaka in November 2016;*

Standard Operating Procedures

- *The MC noted the proposed changes received on the version 1.0 of the SOP for EWGs/IWGs following the Lisbon meeting and that further discussion was needed within the Subcommittee regarding some of the comments received;*
- *The MC agreed that the SOP version 1.0 be published on the ICH website ahead of the Osaka meeting, and that the SOP subcommittee meets in Osaka (for 2 hours) to review/address all comments received on the document to be included in the next version of the SOP (version 2.0);*
- *In Osaka, the updated SOP document (version 2.0) will be presented for MC consideration and approval;*
- *In Osaka, the MC will be invited to confirm whether upon MC approval of the SOP version 2.0 document, the SOP Subcommittee would be disbanded.*

❖ ICH FINANCIAL MATTERS

The Lead of the Financial Subcommittee updated the MC on the activities of the subcommittee in preparation of the Assembly meeting.

MC Actions/Decisions:

- *The MC supported the revised Membership Fee Proposal (dated September 23, 2016) which will be circulated to the Assembly on October 26 ahead of the Osaka meeting for approval for implementation in 2018;*
- *The MC supported including a note in the Membership/Observership application forms on the timing for payment of the fee;*
- *The MC approved the revised Donation Policy for inclusion in the Assembly RoP for Assembly approval;*
- *It was confirmed to the MC that to date no changes are considered necessary to the Draft 2017 Budget;*
- *Ahead of Osaka, the Financial Subcommittee will provide its recommendation to the MC on proposals received from potential auditors for recommendation to the Assembly for appointment;*
- *In Osaka, the MC noted that the MedDRA Management Committee will invite Assembly approval of the 2017 MedDRA Budget.*

❖ ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

The Leads of the Membership Subcommittee updated the MC on all Membership/Observership applications currently under consideration.

The MC was also updated on the finalisation of the document 'Value of Membership'.

MC Action/Decision:

- *The MC discussed next steps concerning the document 'Value of Membership' (focusing on advantages for regulatory authorities) and agreed that a letter be prepared by the Secretariat to be sent to all Observers and that information also posted on the ICH website to summarize the value of Membership;*

4. ANY OTHER BUSINESS

MC Action/Decision:

- *The MC noted that the sign-off of the hotel contract for the Canada meeting in spring 2017 was completed, and it supported that the ICH Secretariat will submit the signed contract to the hotel.*