

2 June 2018

**SUMMARY REPORT
ICH MC TELECONFERENCE
15 May 2018**

LIST OF PARTICIPANTS

ICH MC Members

Ms. Lenita Lindström-Gommers	EC, Europe
Dr. Spiros Vamvakas	EC, Europe
Dr. Sabine Luik	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin (<i>MC Chair</i>)	FDA, US
Ms. Joan Blair	FDA, US
Ms. Pujita Vaidya	FDA, US
Dr. Celia Lourenco	Health Canada, Canada
Ms. Catherine Parker	Health Canada, Canada
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Toshiyoshi Tominaga (<i>MC Vice-Chair</i>)	MHLW/PMDA, Japan
Dr. Nobumasa Nakashima	MHLW/PMDA, Japan
Dr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland

ICH MC Coordinators

Dr. Georgios Balkamos	EC, Europe
Mr. Pär Tellner	EFPIA
Ms. Amanda Roache	FDA, US
Mr. Mitsuo Mihara	JPMA
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
Ms. Camille Jackson	PhRMA

ICH MC Technical Coordinators:

Dr. Milton Bonelli	EC, Europe
Dr. Michelle Limoli	FDA, US
Ms. Chieko Hirose	MHLW/PMDA, Japan

ICH MC Standing Observers:

Dr. Samvel Azatyan	WHO
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Other Participants:

Mr. Thomas Salmonson	EC, Europe
Mr. Martin Harvey	EC, Europe

ICH Secretariat:

Ms. Nadia Gerweck
Dr. Anne Latrive
Dr. Dawn Ronan

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin, FDA, US

MC Vice-Chair: Dr. Toshiyoshi Tominaga, MHLW/PMDA, Japan

1. ADOPTION OF THE AGENDA

Dr. Theresa Mullin (MC Chair, FDA, US) welcomed all participants. The agenda was adopted without any modification.

2. APPOINTMENT OF ELECTED MC REPRESENTATIVES

The MC noted the applications received for the nomination of the Elected MC Representatives. The MC noted that in line with the ICH Articles of Association, up to eight Elected MC Representatives representing up to four Regulatory Members could be elected, and up to four Elected MC Representatives representing up to two Industry Members could be elected.

MC Action/Decision:

- *The MC noted the Secretariat's preparations for the election to be held at the meeting in Kobe, Japan in June 2018 including the details of the election process.*

3. PROCEDURAL MATTERS

The MC was updated on: revisions to the application forms for Regulatory Membership and Observership for consistency with the proposed revisions to the ICH Articles of Association (AoA) and ICH Assembly Rules of Procedure (RoP) regarding overlapping membership of DRAs and RHIs, as well as a further minor edit to Article 17.1(b) of the Articles of Association for consistency. The MC was further updated on proposed revisions to the Standard Operating Procedures (SOPs) for Working Groups (WGs) for consistency with the proposed revisions to the ICH Assembly Rules of Procedure regarding managing the size of WGs.

MC Actions/Decisions:

- *The MC approved the revisions to the SOPs, pending Assembly approval of the revisions to the ICH AoA and the ICH Assembly RoP at the meeting in Kobe, Japan in June 2018;*
- *The MC approved the provision of the background documents on Procedural Matters to the Assembly ahead of the Kobe meeting including the revisions to: the ICH AoA, the ICH Assembly RoP (with a further minor edit to section 4.1.2 for clarity and consistency), the application forms for Regulatory Membership and Observership, the SOP, as well as a cover note to explain the content of the revisions.*

4. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

The MC was updated by Co-Leads of the Membership Subcommittee on the status of Membership/Observership applications received.

5. FINANCIAL MATTERS

The MC was updated by the ICH Secretariat on the status of the 2017 Audited Accounts/Financial Statements. The MC was further updated by Lead of the Financial Subcommittee on the preparation for the discussions on Financial Matters to be held at the meeting in Kobe, Japan in June 2018.

MC Actions/Decisions:

- *The MC noted that the final report of the Auditor on the 2017 Audited Accounts/Financial Statements is pending and would be provided shortly;*

- *The MC approved the provision of the background documents on Financial Matters to the Assembly ahead of the Kobe meeting including the 2017 ICH Closing Cost Report (pre- and post- asset transfer), and the draft 2019 ICH budget (shared with the Assembly in Geneva as part of the 5-year projection);*
- *The MC agreed to discuss and review the mandate of the Financial Subcommittee as well as other MC Subcommittees at the Kobe meeting.*

6. NEW TOPICS AND STRATEGIC DISCUSSIONS

The MC was updated on the status of the revised draft Reflection Paper on *Advancing Pharmaceutical Quality Standards* including considerations on the remit of an Informal Quality Discussion Group (IQDG).

The MC was updated on the status of the draft Reflection Paper on *Vaccines*.

MC Actions/Decisions:

- *The MC supported the provision of the revised draft Reflection Paper on Advancing Pharmaceutical Quality Standards as a PhRMA Reflection Paper to the Assembly ahead of the Kobe meeting;*
- *The MC agreed to further discuss the establishment of an IQDG at the MC meeting with a view to providing a recommendation to the Assembly at the Assembly meeting in Kobe;*
- *The MC supported the provision of the draft Reflection Paper on Vaccines as an EC, Europe Reflection Paper to the Assembly ahead of the Kobe meeting.*

7. IMPLEMENTATION

The MC was updated by Co-Lead of the Implementation Subcommittee on the preparation for the discussions on Implementation to be held at the meeting in Kobe, Japan in June 2018.

MC Actions/Decisions:

- *The MC approved the provision of the background documents on ICH implementation to the Assembly ahead of the Kobe meeting including the ICH Guideline implementation table, the case studies on E2D and M8 implementation, and the draft proposal for the ICH implementation survey;*
- *The MC agreed to further discuss the definitions of the degrees of implementation at the MC meeting in Kobe with a view to further sharing considerations with the Assembly at the Assembly meeting in Kobe.*

8. COMMUNICATION

The MC was updated by the Lead of the Communication Subcommittee on the preparation for the discussions on Communication to be held at the meeting in Kobe, Japan in June 2018.

MC Action/Decision:

- *The MC noted that the Communication Subcommittee would not provide any background documents to the Assembly ahead of the Kobe meeting.*

9. TRAINING

The MC was updated by the Lead of the Training Subcommittee on the preparation for the discussions on Training to be held at the meeting in Kobe, Japan in June 2018.

MC Action/Decision:

- *The MC noted that the Training Subcommittee would not provide any background documents to the Assembly ahead of the Kobe meeting.*

10. ORGANISATION OF THE KOBE MEETING

The MC was updated by the ICH Secretariat on the preparation of the Kobe meeting.

MC Action/Decision:

- *The MC supported the provision of the background documents to the Assembly within the Assembly Agenda Papers package by 23 May 2018.*

11. NEXT TELECONFERENCES AND MEETINGS

Face-to-Face Meetings

10-15 November 2018	Charlotte, North Carolina, USA
1-6 June 2019	Europe (location to be confirmed)
16-21 November 2019	Asia (location to be confirmed)

12. ANY OTHER BUSINESS