

10 April 2018

**SUMMARY REPORT
ICH MC TELECONFERENCE
20 March 2018**

LIST OF PARTICIPANTS

ICH MC Members

Ms. Lenita Lindström-Gommers	EC, Europe
Dr. Spiros Vamvakas	EC, Europe
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin (<i>Chair</i>)	FDA, US
Ms. Joan Blair	FDA, US
Ms. Pujita Vaidya	FDA, US
Ms. Catherine Parker	Health Canada, Canada
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Nobumasa Nakashima	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. Nick Orphanos	Health Canada, Canada
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 Standing Observer:

Dr. David Jefferys	IFPMA
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Other Participants:

Mr. Martin Harvey Allchurch	EC, Europe
Dr. Yoshihiro Katsura	MHLW/PMDA, Japan
Dr. Gabriela Zenhäusern	WHO

ICH Secretariat:

Dr. Dawn Ronan
Dr. Anne Latrive

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin, FDA, US

1. ADOPTION OF THE AGENDA

Dr. Mullin (MC Chair, FDA, US) welcomed all participants. The agenda was adopted with some reordering of agenda items.

2. APPOINTMENT OF ELECTED MC REPRESENTATIVES

The MC was updated on all applications received, including updated applications, for the nomination of the Elected MC Representatives. The MC noted that in line with the ICH Articles of Association, at the election planned for the Kobe meeting in June 2018, 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.

3. PROCEDURAL MATTERS

Revisions to the ICH Articles of Association and Rules of Procedure

The MC was updated on proposed revisions to the ICH Articles of Association and the ICH Assembly Rules of Procedure regarding overlapping membership of RHIs and DRAs to avoid the situation of dual representation at the ICH Assembly, as well as other revisions regarding managing the size of ICH Working Groups (WGs). Regarding the latter, the MC also noted some general considerations shared for further MC discussion.

The MC also noted that further proposed revisions would be circulated shortly for MC consideration regarding changes to the Rules of Procedure to clarify the roles of the ICH MC, MedDRA MC and ICH Assembly with respect to MedDRA financial matters.

Proposal for Pilot for ICH WG Consultation with ICH Members without Experts on the WG

The MC noted the proposal for MC consideration for a pilot for ICH WG consultation with ICH Members unable to appoint experts to a WG. The MC noted that the proposal had been made in view of the recent MC decision to close the ICH E8(R1) EWG to new Members in view of the large size of the WG and the current status of work.

Under the proposal, as a pilot, the ICH E8(R1) EWG would consult with other interested ICH Members by providing an opportunity for the other interested ICH Members to review the draft ICH Guideline and submit questions to the WG prior to sign-off at *Step 1*. The interested ICH Members would then be invited to participate in a webconference with the WG where the draft technical document would be presented and any questions submitted would be discussed. The MC noted that this process would be of particular benefit to ICH Regulatory Members who are expected to implement ICH Guidelines and who may wish to conduct their own regional public consultation.

MC Actions/Decisions:

- *The MC agreed to provide comments in writing on the proposed revisions to the ICH Articles of Association and ICH Assembly Rules of Procedure to the ICH Secretariat by 3 April 2018;*
- *The MC agreed to try to find an opportunity to further discuss managing the size of WGs at the forthcoming interim MC meeting in London on 26-27 March;*
- *The MC supported launching the pilot for ICH E8(R1) EWG consultation with other interested ICH Members prior to the ICH E8(R1) Guideline reaching Step 1.*

4. OVERSIGHT OF THE WORKING GROUPS

MC Action/Decision:

- *The MC supported that the ICH E19 EWG be closed to new expert nomination requests in view of the large size of the WG and the current status of work.*

5. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

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

6. FINANCIAL MATTERS

The MC was updated the Lead of the Financial Subcommittee. The MC noted ongoing activities including selection of a Professional Conference Organiser (PCO) and considerations regarding the selection process for the location of future ICH meetings.

The MC noted that a contract had been negotiated the most suitable candidate PCO further to ICH's solicitation of proposals and PCO selection process. The MC noted that the contract had undergone review by the Financial Subcommittee, the ICH Secretariat and the ICH lawyer.

With respect to the selection process for the location of future ICH meetings, the MC noted that the approach proposed by the Financial Subcommittee was to continue with the previously agreed three-region rotation (North America/South America, Europe/Africa, Asia) and within a region with more than one ICH Member to direct the PCO to identify the three best options (based on the agreed selection criteria) looking across ICH Member countries/regions, with one of the options to come from the country/region of a Founding or Standing ICH Member. The MC noted that it would then be for the MC to take a final decision based on the report of the PCO.

MC Actions/Decisions:

- *The MC supported the selection of the PCO further to ICH solicitation of proposals and PCO selection process and agreed that ICH signatories proceed to sign-off the contract;*
- *The MC supported Europe and Asia as the locations for the June and November 2019 meetings respectively, and the approach proposed by the Financial Subcommittee for the selection process for the location of these and future ICH meetings.*

7. COMMUNICATION

The MC was updated by as the Lead of the Communication Subcommittee on the work plan of the Subcommittee and the agenda for the 1-day Subcommittee meeting at the interim MC meeting on Monday, 26 March 2018 (09h30-18h00). The MC noted that the agenda for the interim meeting included discussion of: the GCP stakeholder engagement proposal; considerations related to webcasting parts of ICH Assembly meetings; review of outstanding actions from the 2017-2018 work plan; and identification of topics for the 2018-2019 stakeholder engagement plan.

MC Action/Decision:

- *The MC supported the work plan of the Communication Subcommittee and the agenda for its meeting on 26 March 2018.*

8. IMPLEMENTATION

The MC was updated by the Leads of the Implementation Subcommittee on the work plan of the Subcommittee and the agenda for the 1-day Subcommittee meeting at the interim MC meeting on Tuesday, 27 March 2018 (10h45-18h00). The MC noted that the agenda for the interim meeting included discussions on definitions of full and partial implementation, presentations on ongoing activities, discussion on elements/criteria for the survey, and preparations for the Kobe meeting.

MC Action/Decision:

- *The MC supported the work plan of the Implementation Subcommittee and the agenda for its meeting on 27 March 2018.*

9. TRAINING

The MC was updated by the Lead of the Training Subcommittee on the work plan of the Subcommittee and the agenda for the 1-day meeting of the Training Subcommittee on Tuesday 27 March (8h30-18h00). The MC noted that the agenda for the interim meeting included discussions on the Mission/Vision Statement for the Subcommittee, consideration of feedback from ICH Training Partners, and definition of goals and planning for online training.

MC Action/Decision:

- *The MC supported the work plan of the Training Subcommittee and the agenda for its meeting on 27 March 2018.*

10. NEW TOPICS AND REFLECTION PAPERS

The MC was updated by the Lead of the New Topic Subcommittee on the work plan of the Subcommittee and the agenda for the 1.5-day meeting of the Subcommittee on Monday 26 March (9h30-18h00) and Tuesday 27 March (8h30-10h30) 2018. The MC noted that the agenda for the interim meeting would include a review of the outcome from scoring and prioritisation of ICH new topic proposals by Subcommittee Members, with sessions grouped by Quality, Safety, and Efficacy and Multidisciplinary topics, followed by preparation of recommendations for the ICH Assembly.

The MC noted that the agenda for the meeting also included time for discussion of Reflection Papers currently under development and strategic priorities, as well as a consideration at the end of the meeting on the value of the meeting to the new topic selection process. With respect to the discussion on Reflection Papers, the MC noted that an update would be given on the status of development of: the Reflection Paper on Quality; the Reflection Paper on Generics; and the Reflection Paper on Vaccine.

Regarding the Reflection Paper on Generics which had been circulated to the MC for comments, the MC was briefed on the types of comment received. Interest was also expressed for the comments received to be shared electronically with the MC. As a next step, and envisioning further discussion by the MC, the Assembly and the IPRP would be necessary, it was proposed to make only minor revisions to the Reflection Paper at this time before sharing with the Assembly for discussion in Kobe, Japan in June 2018.

MC Actions/Decisions:

- *The MC supported the work plan of the New Topics Subcommittee and the agenda for its meeting on 26-27 March 2018;*
- *The MC supported that a revised version of the Reflection Paper on Generics be circulated to the MC by end of the first week in April, with the envisioned revisions to already be outlined at the interim meeting on 27 March;*
- *The MC supported the aim of providing the Assembly with the revised Reflection Paper on Generics for discussion at its meeting in Kobe, Japan in June 2018 and agreed to further discuss the preparation of this Assembly agenda item at the interim meeting.*

11. ORGANISATION OF THE INTERIM MEETING

The MC was updated on the organisation of the interim meeting of the MC Subcommittees on 26-27 March 2018 hosted by the EMA in London. The MC noted that as of 20 March 2018, the participant list was considered as final with the names to be provided to the EMA for the preparation of badges and name plates.

MC Action/Decision:

- *The MC supported the overall timetable for the interim meeting and the agendas of each Subcommittee.*
- *The ICH Secretariat will circulate shortly to the participants the meeting documents, as well as dial-in details for those joining remotely.*

12. NEXT TELECONFERENCES AND MEETINGS

MC Teleconferences

22 March 2018	Technical
10 April 2018	Policy 4
25 April 2018	Policy 5
15 May 2018	Policy 6

Interim MC Subcommittee Face-to-Face Meeting

26-27 March 2018	London, UK
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Face-to-Face ICH Meetings

2-7 June 2018	Kobe, Japan
10-15 November 2018	Charlotte, USA
18-23 May or 1-6 June 2019	Europe (date and location to be confirmed)
16-21 November 2019	Asia