

25 May 2018

**SUMMARY REPORT
ICH MC TELECONFERENCE
25 April 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. Celia Lourenco	Health Canada, Canada
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Toshiyoshi Tominaga (<i>MC Vice-Chair</i>)	MHLW/PMDA, Japan
Dr. Naoyuki Yasuda	MHLW/PMDA, Japan
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:

Mr. David Jefferys	IFPMA
--------------------	-------

Other Participants:

Dr. Gabriela Zenhäuser	WHO
------------------------	-----

ICH Secretariat:

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 with a reshuffling of the order or items.

2. PREPARATION OF THE KOBE MEETING

The MC was updated by the ICH Secretariat on the development of the draft 2017 Annual Report of the Association and the development of the draft Assembly agenda for the meeting in Kobe, Japan in June 2018.

MC Action/Decision:

- *The MC noted that the draft 2017 Annual Report of the Association and the draft Assembly agenda would be circulated shortly;*
- *The MC noted the following key dates in preparation of the meeting:*
 - *By 26 April: All participants are to register on the online platform;*
 - *By 4 May: All background documents for the Assembly meeting are to be provided to the Secretariat for MC review prior to inclusion in the Assembly Agenda papers;*
 - *By 9 May: The draft Assembly Agenda is circulated to the Assembly;*
 - *By 11 May: The draft MC Agenda is circulated to the MC;*
 - *By 15 May: All background documents for the MC meeting are to be provided to the Secretariat for inclusion in the MC Agenda papers.*

3. APPOINTMENT OF ELECTED MC REPRESENTATIVES

The MC noted all applications received for the nomination of the Elected MC Representatives and was updated by the ICH Secretariat on the preparations for the election to be held at the meeting in Kobe, Japan in June 2018. 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.*

4. PROCEDURAL MATTERS

Revisions to the ICH Articles of Association and Rules of Procedure

The MC was updated on proposed revisions including: 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; revisions to the ICH Assembly Rules of Procedure regarding managing the size of ICH Working Groups (WGs); and revision to the ICH MedDRA MC Rules of Procedures to clarify the roles of the ICH MC, MedDRA MC and ICH Assembly with respect to MedDRA financial matters.

MC Actions/Decisions:

- *The MC agreed to put forward the proposed revisions to the ICH Articles of Association and the ICH Assembly Rules of Procedure for consideration by the ICH Assembly for approval at the meeting in Kobe, Japan in June 2018;*
- *The MC noted that the revision to the ICH MedDRA MC Rules of Procedures to clarify the roles of the ICH MC, MedDRA MC and ICH Assembly with respect to MedDRA financial matters had been approved by the MedDRA MC on 19 April 2018 and that the MedDRA MC would further discuss the operationalisation of the procedures at the meeting in Kobe, Japan in June 2018.*

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. NEW TOPICS

New Topics proposals

The MC was updated by the Lead of the New Topic Subcommittee on development of the New Topics assessment summary table and compilation of evaluation forms to be shared with the Assembly ahead of the meeting in Kobe.

MC Action/Decision:

- *The MC supported the New Topics assessment summary table and compilation of evaluation forms and their subsequent circulation to the Assembly for comments by 25 May 2018.*

Reflection Paper

The MC was updated on the comments received from the MC on the draft FDA, US Reflection Paper on Generic Drug Harmonisation and next steps ahead of the meeting in Kobe.

MC Action/Decision:

- *The MC supported the circulation of the draft Reflection Paper on Generic Drug Harmonisation to the Assembly as an FDA, US paper to collect comments by 24 May 2018.*

7. IMPLEMENTATION

The MC was updated by the Lead of the Implementation Subcommittee on the activities of the Implementation Subcommittee including on the development of a draft document on the definitions of the degrees on implementation, as well as on next steps for the implementation survey.

MC Actions/Decisions:

- *The MC noted the report of the Implementation Subcommittee interim meeting and action items expected ahead of the meeting in Kobe, Japan in June 2018;*
- *The MC noted that the Subcommittee would further provide an updated work plan ahead of the meeting in Kobe, Japan in June 2018;*
- *The MC supported to further discuss this topic at the next MC Policy 6 TC on 15 May 2018 including the draft document on the definitions of the degrees on implementation, case studies on M4/M8 and on E2D to be presented to the Assembly, and the status of the implementation survey project proposal;*
- *The MC supported to allocate at least 60 minutes for the agenda items on implementation at both the Assembly and the MC meetings in Kobe, Japan in June 2018.*

8. COMMUNICATION

The MC was updated on the activities of the Communication Subcommittee. The MC noted the outcome of the recent meeting of the Subcommittee and that MC input was requested to enable the Subcommittee to work on the development of the 2018-2019 Communication Plan for the ICH Assembly meeting in Kobe, Japan.

MC Action/Decision:

- *The MC agreed to provide comments to the ICH Secretariat via email on the items for input and to schedule further discussion at the next MC TC on 15 May, 2018.*

9. TRAINING

The MC was updated by the Lead of the Training Subcommittee on the outcome of the recent meeting of the Subcommittee. The MC noted that the Subcommittee developed a mission and vision statement and agreed upon major work objectives, which included: development of online training programmes; conduct of a gap analysis for priority Tier 3 ICH Guidelines; supporting the E9 EWG, E17 IWG and Q11 IWG to develop training materials; establishing a process to review existing and new training programmes; and establishing procedures to develop training for new ICH Guidelines. The MC noted several points on which MC input was sought, including on the completion of a prioritisation of Tier 3 ICH Guidelines which had been initiated by the MC but had still to be completed. The MC Vice Chair requested that the Training Subcommittee update their 2016 survey of the Assembly members regarding the priority training needs for Tier 3 guidelines.

MC Action/Decision:

- *The MC supported completing work on the Tier 3 ICH Guideline prioritisation and for the Training Subcommittee, supported by the ICH Secretariat, to survey the Assembly to determine which Tier 3 ICH Guidelines would be priorities for training.*

10. ARTICLE ON VACCINES PREPARED BY IFPMA AND DCVMN

The MC was updated on an analysis undertaken by IFPMA and DCVMN on “Challenges for the registration of vaccines in emerging countries: differences in dossier requirements, application and evaluation processes”.

MC Action/Decision:

- *The MC supported that this topic be discussed at the Assembly meeting in Kobe, Japan, in June 2018 under the agenda item on Implementation of ICH Guidelines.*

11. NEXT TELECONFERENCES AND MEETINGS

Teleconferences

15 May 2018	Policy 6
-------------	----------

Face-to-Face Meetings

2-7 June 2018	Kobe, Japan
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)