

2 November 2017

**SUMMARY REPORT
ICH MC TELECONFERENCE
3 October 2017**

LIST OF PARTICIPANTS:

ICH Management Committee 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>Vice Chair</i>)	MHLW/PMDA, Japan
Dr. Nobumasa Nakashima	MHLW, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Ms. Cordula Landgraf	Swissmedic, Switzerland

ICH MC Coordinators

Mr. 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, Japan
Ms. Camille Jackson	PhRMA

Technical Coordinators:

Ms. Chieko Hirose	MHLW/PMDA, Japan
Ms. Michelle Limoli	FDA, US

Other Participants:

Dr. Martin Harvey	EC, Europe
Dr. Yoshihiro Katsura	MHLW/PMDA, Japan
Dr. Sarah Adam	IFPMA

ICH Secretariat:

Dr. Véronique Kuntzelmann
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. Mullin (MC Chair, FDA, US) welcomed all participants. The agenda was adopted without any comments.

2. APPOINTMENT OF ELECTED MC REPRESENTATIVES

The MC was updated on the comments received from MC Members on the proposed document entitled “*Considerations for assessing the eligibility criteria for appointing Elected Representatives in the ICH Management Committee*” and the main changes made in view of these comments.

MC Action/Decision:

- *The MC agreed on adding an introduction to the Considerations document to explain that it has been developed to outline the deliberations of the MC aimed at ensuring an objective and fair assessment of the applications.*

3. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

The MC was updated on the status of Membership/Observership applications.

4. IMPLEMENTATION OF ICH GUIDELINES

The MC was updated on the preparation of the Assembly’s discussion on the implementation of ICH Guidelines including the update of information on the ICH public website. The MC noted that the implementation of ICH Guidelines is a standing agenda item of the Assembly meeting.

MC Actions/Decisions:

- *The MC supported that the Assembly Chair and Vice-Chair prepare the Assembly discussion to focus on some ICH Guidelines for which the implementation could be challenging and on how to overcome the potential obstacles;*
- *The MC supported that the Assembly discuss the implementation states of ICH Guideline as fully versus partially implemented;*
- *The MC agreed that new Regulatory Members should note the intent to publish on the ICH website information regarding implementation alongside information from Founding and Standing Regulatory Members;*
- *The MC agreed to allocate 60 min to discuss the ICH Guideline implementation during the Assembly meeting in Geneva;*
- *The MC noted that the Founding Industry Members will present on their ICH Guideline implementation survey to the Assembly and to the MC during the Geneva meeting;*
- *The MC supported that the Implementation Table would be shared with the Members and Observers of the Assembly as a background document to be included in the Agenda Papers ahead of the Geneva meeting, with Members being given an opportunity to update the table ahead of circulation.*

5. GENERAL OPERATIONAL MATTERS

The MC was updated by the ICH Secretariat on the following general operational matters: the ongoing work in preparation for the asset transfer from IFPMA to ICH; the preparation of a draft ICH work plan and a draft ICH Multiannual strategic plan to be circulated to the MC shortly with the intent to be included in the Assembly Agenda papers package for the Geneva meeting; and the preparation of Elections of MC Chair/Vice Chair and Assembly Chair/Vice Chair to take place at the Geneva meeting.

MC Action/Decision:

- *The MC supported that, for logistical reasons, the Secretariat would solicit the names of candidates for MC Chair/Vice Chair and Assembly Chair/Vice Chair by 6 November, even though names can be put forward until the last minute, in line with the procedures. The MC agreed that names of a candidate can be put forward by a Member other than the Member of the candidate, provided the candidate is agreeable to their name being put forward.*

6. FINANCIAL MATTERS AND MEETING ORGANISATION

The MC was updated on the progress made on: options explored to organise an ICH MC Interim Meeting and its impact on budget; preparation of a 5-year budget projection; considerations related to the future use of a Professional Conference Organiser (PCO) which would also include the implementation of a participation fee. The MC noted the progress made to solicit PCO proposals and that proposals had been received and were being assessed in order to submit a recommendation to the MC at the Geneva meeting. The MC additionally noted that the IPRF-IDGRP Secretariat transition is part of the implementation plan of the ongoing IPRF-IDGRP consolidation.

MC Action/Decision:

- *The MC supported the items to be presented to the MC at the Geneva meeting.*

7. PROCEDURAL MATTERS

The MC was updated on the proposed revisions for the EWG/IWG SOP. The MC noted the ongoing development process of the SOP v4.0 including revisions for clarity on the appointment of Regulatory Chair, the role of Additional Expert, and the publication of experts' names.

The MC noted that no revision of the Articles of Association or Assembly RoP was expected ahead of the Geneva meeting. The MC additionally noted that printed booklets of the Articles of Association will be distributed to Members and Observers at the Geneva meeting.

MC Actions/Decisions:

- *The MC supported the development of the SOP v4.0, noting the need to keep the procedures of reasonable length, and that the SOP v4.0 would be for MC endorsement ahead of the Geneva meeting with the aim of being shared with the Assembly;*
- *The MC supported that a potential revision of the MC RoP related to the use of ICH logo (Section 9.7) and the processes for New Topics (section 9.2.1) may be proposed at a later point.*

8. TRAINING

The MC was updated on the ICH Training Pilot 2017 and the feedback expected during the Geneva meeting. The MC noted the revamping of the ICH public website to display the ICH Recognised Training Programmes included in the ICH Training Pilot 2017.

MC Action/Decision:

- *The MC supported the presentation to the Assembly during the Geneva meeting on the outcome of the ICH Training Pilot 2017 and MC discussion of proposals for future training including financial considerations.*

9. DATES OF NEXT TELECONFERENCE AND MEETINGS

❖ **Teleconferences**

17 October MC Policy

31 October MC Policy

❖ **Face-to-Face Meetings**

11-16 November 2017 Geneva, Switzerland

2-7 June 2018 Kobe, Japan

November 2018 USA (*date & location to be confirmed*)

10. ANY OTHER BUSINESS

The MC also noted that the interim press release prepared by the Communications Subcommittee would be circulated shortly by the Secretariat to the MC for one-week tacit approval.