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March 9, 2017

**SUMMARY REPORT
ICH MC TELECONFERENCE
February 13, 2017**

LIST OF PARTICIPANTS:

ICH Management Committee Members

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

ICH Standing Observers

Dr. David Jefferys	IFPMA	Switzerland
Dr. Sarah Adam	IFPMA	Switzerland

ICH Coordinators

Ms. Amanda Roache	FDA	USA
Mr. Nick Orphanos	Health Canada	Canada
Mr. Mitsuo Mihara	JPMA	Japan
Mr. Fumihito Takanashi	MHLW	Japan
Ms. Camille Jackson	PhRMA	USA

ICH Technical Coordinators

Dr. Michelle Limoli	FDA	USA
Ms. Chieko Hirose	MHLW/PMDA	Japan
Ms. Pujita Vaidya	FDA	USA

Other Participants:

Mr. Martin Harvey Allchurch	EC/EMA	Europe
Dr. Yoshihiro Katsura	MHLW/PMDA	Japan

ICH Secretariat

Dr. Dawn Ronan
Dr. Isabelle Güller

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin, FDA

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

1. ADOPTION OF THE AGENDA

2. ORGANISATION OF MONTREAL MEETING

The MC noted the following key dates for the preparation of the Montreal meeting:

- ❖ **May 1:** The draft Assembly Agenda will be circulated to the Assembly;
- ❖ **May 17:** The Assembly Agenda Papers Package, including background documents, will be circulated to the Assembly (with exception of New Topic Proposals which should be sent to the Assembly 4 weeks ahead of Assembly meeting i.e., by ~ May 1).

3. ICH MC ACTIVITIES

❖ ICH MEMBERSHIP AND OBSERVERSHIP

Membership & Observership Applications

An update was provided by PhRMA as lead of the Membership Subcommittee on the Membership Subcommittee's consideration of recently received applications and confirmed follow-up steps.

The MC noted that several of the Observer applications raised similar questions to those discussed in Osaka on how to ensure ICH expands in a manageable way considering the growing interest in ICH from many organisations.

MC Action/Decision:

- *The MC noted that the Membership Subcommittee would follow-up with some of the applicants to seek clarifications.*

Related Procedural Matters

The MC was briefed by (the EC, as lead on this subject on proposed changes to the ICH Articles of Association and Assembly Rules of Procedure aimed at ensuring ICH expands in a manageable way. Proposed changes included tightening the eligibility criteria for international pharmaceutical industry organisations and international organisations to become Observers, and limiting the number of representatives/delegates that Members and Observers can appoint (for the Assembly).

The MC noted other proposed changes related to preparing for an enlarged MC and amending the provisions related to the transition period.

MC Actions/Decisions:

- *In view of comments shared at the teleconference, the EC will work on the proposal to amend the ICH Articles of Association and Assembly Rules of Procedure;*
- *Ahead of the next MC teleconference when a more substantial discussion on procedures is planned, a revised version of the ICH Articles of Association and Assembly Rules of Procedures will be shared with the MC for comments with a view to preparing a proposal for the Assembly in Montreal.*

❖ NEW TOPICS AND STRATEGIC DISCUSSIONS

An update was provided by the EC as Lead of the New Topics Subcommittee on the next steps for the New Topic Subcommittee's consideration of the 16 New Topic Proposals submitted by the mid-January 2017 deadline. The MC noted that a teleconference of the Subcommittee would be held on February 14, when the Subcommittee would discuss next steps to prepare the submission to the Assembly ahead of Montreal of a short-list of proposals. The MC noted the Subcommittee would also discuss a proposal from PhRMA to utilise the concept of ICH themes to enhance prioritisation.

The MC noted that at the following Subcommittee teleconference on February 22, **E**fficacy and **M**ultidisciplinary proposals would be discussed, followed by **Q**uality proposals on February 24. Teleconferences have been scheduled at the end of March to discuss prioritisation.

4. DATES OF NEXT TELECONFERENCES AND MEETINGS

Teleconferences Ahead of Montreal Meeting:

March 2, 2017	Coordinators Teleconference
March 9, 2017	MC TC (Policy/Procedures)
March 29, 2017	MC TC (Technical WGs)
April 13, 2017	MC TC (Policy/Procedures)
May 16, 2017	MC TC (Policy/Procedures)

Face-to-Face ICH Meetings:

May 27 – June 1, 2017	Montreal, Canada
November 11-16, 2017	Geneva, Switzerland
June 2-7, 2018	Kobe, Japan