

4 May 2018

**SUMMARY REPORT  
ICH MC TELECONFERENCE  
10 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. 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. 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

### Other Participants:

Mr. Martin Harvey Allchurch	EC, Europe
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### 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. Mullin (MC Chair, FDA, US) welcomed all participants. The agenda was adopted without modification.

### 2. APPOINTMENT OF ELECTED MC REPRESENTATIVES

The MC noted all applications received for the nomination of the Elected MC Representatives.

#### *MC Action/Decision:*

- *The MC noted the need to provide Assembly Members with the applications received prior to the meeting in Kobe, Japan in June 2018, and agreed to work to provide its recommendation in accompaniment.*

### 3. 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 supported to further discuss the revisions to the ICH Articles of Association and the ICH Assembly Rules of Procedure at the next MC Policy 5 TC on 25 April 2018;*
- *The MC supported that the revision to the ICH MedDRA MC Rules of Procedures be shared with the ICH MC Chair and Vice-Chair and the MedDRA MC Chair prior to being circulated to the MedDRA MC for approval and subsequently to the ICH MC for its support.*

### 4. FOLLOW-UP FROM THE INTERIM MEETING

#### *New Topics Subcommittee*

##### *New Topics proposals*

The MC was updated on the outcome of the Subcommittee interim meeting held on 26 and 27 March 2018, including the development of the New Topics assessment summary table to be shared with the Assembly ahead of the meeting in Kobe.

The MC was updated on considerations related to the type of expertise that will be needed for the proposed new work of ICH S7B/E14 based on the CiPA initiative.

#### *MC Actions/Decisions:*

- *The MC noted that the New Topics Subcommittee will assess on a yearly basis the need for holding an interim meeting, in particular in view of the number of New Topics proposals received for the year;*

- *The MC noted that MC Members had the possibility to amend their New Topic evaluation forms by 25 April 2018;*
- *The MC supported that the final New Topics assessment summary table be shared with the Assembly ahead of its meeting in Kobe, Japan in June 2018, along with a compilation of the evaluation forms provided by the MC Members for each New Topic;*
- *The MC noted the considerations on the need for non-clinical expertise for the proposed new work of ICH S7B/E14, which includes in silico method and in vitro iPS derived cardiomyocytes method etc. and agreed to invite revision of Member representation in the E14/S7B DG on a voluntary basis.*

### Reflection Paper

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

### **MC Actions/Decisions:**

- *The MC noted the proposed revisions to the draft Reflection Paper on Generic Drug Harmonisation and that the MC was invited to support its circulation to the Assembly as an FDA, US paper, noting further MC discussion is needed, unless there would be any major issue raised by 24 April 2018;*
- *The MC noted the next steps for the draft EC, Europe Reflection Paper on Vaccines and that the need for any revisions to the current version would be defined in May 2018, further to any comments received from IPRP Members by 30 April 2018.*

### Implementation, Training and Communication Subcommittees

#### **MC Action/Decision:**

- *The MC noted that at the MC Policy 5 TC on 25 April 2018, the Leads of the Implementation, Training and Communication Subcommittees will be invited to provide an update on the outcome of their interim meetings and any request for MC input ahead of the meeting in Kobe, Japan in June 2018.*

## **5. PREPARATION OF THE KOBE MEETING**

The MC was updated by the ICH Secretariat on timelines ahead of the Kobe meeting and requests received for WG joint meetings and for caucus meetings.

#### **MC Action/Decision:**

- *The MC noted the following joint meetings would be held: the E2B(R3) EWG/IWG with the M2 EWG; the E8(R1) EWG with the E19 EWG; and the E8(R1) EWG with the Communication Subcommittee;*
- *The MC noted those Members who had requested rooms for caucus meetings;*
- *The MC noted the following key dates in preparation of the Kobe meeting:*
  - *By 26 April: All participants should be registered online;*
  - *By 4 May: All background documents for the Assembly meeting should be provided to the Secretariat for MC review prior to inclusion in the Assembly Agenda papers;*
  - *By 9 May: The draft Assembly Agenda will be circulated to the Assembly for comments;*
  - *By 11 May: The draft MC Agenda will be circulated to the MC for comments;*
  - *By 15 May: All background documents for the MC meeting should be provided to the Secretariat for inclusion in the MC Agenda papers.*

## **6. NEXT TELECONFERENCES AND MEETINGS**

### **Teleconferences**

25 April 2018	Policy 5
15 May 2018	Policy 6

### **Face-to-Face Meetings**

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

## **7. ANY OTHER BUSINESS**

The MC was updated on the conduct of the joint FDA, US and Health Canada, Canada ICH public meeting held on 6 April 2018 and the conduct of an ICH information day in coordination with EC, Europe at the DIA meeting to be held in Basel, Switzerland on 19 April 2018.