

23 October 2017

**SUMMARY REPORT  
ICH MC TELECONFERENCE  
26 September 2017**

## LIST OF PARTICIPANTS:

### ICH Management Committee Members/Observers

Ms. Lenita Lindström	EC, Europe
Dr. Spiros Vamvakas	EC, Europe
Dr. Sabine Luik	EFPIA
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
Mr. Jerry Stewart	PhRMA
Ms. Cordula Landgraf	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, Japan
Ms. Camille Jackson	PhRMA

### Technical Coordinators:

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

### Other Participants:

Dr. Tomas Salmonson	EC, Europe
Dr. Martin Harvey	EC, Europe
Dr. Sarah Adam	IFPMA
Dr. Gabriela Zenhäusern	WHO

### 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 modifications, but with a reordering of topics (item 5 was discussed first, and then followed the order 2, 3, 4, 6, 7).

### **2. ADOPTION OF THE MINUTES OF THE MONTREAL MEETING AND OF THE REPORT OF THE PREVIOUS TELECONFERENCE**

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

- *The MC approved as final the MC minutes of the Montreal meeting (MC2017/07) and publication on the ICH website;*
- *The MC approved the Report of the teleconference held on 6 September 2017 and publication on the ICH website.*

### **3. 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 Actions/Decisions:***

- *The MC agreed to further consider the next steps for the document at its next TC on 3 October;*
- *The MC agreed that the applications for elected MC Representatives received from the ICH Members should be shared with all Members of the Assembly.*

### **4. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS**

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

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

- *The MC agreed that the initial assessment of applications for elected MC Representatives would be led by the Secretariat with input from the Membership Subcommittee as necessary.*

### **5. NEW TOPIC PROPOSALS AND STRATEGIC DISCUSSIONS**

The MC was updated on the progress of the New Topics Subcommittee, in particular with regards to amending the processes for New Topics, Strategic Reflection Papers and strategy of harmonisation. The MC noted that all MC Members are represented in the New Topics Subcommittee and that all MC Members would need to be represented on the subcommittee going forward.

### ***New Topics proposals***

The MC noted that, in the revised New Topics process, New Topics proposals should be submitted to the Secretariat at the latest on 15 December 2017.

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

- *The MC supported allocating between 60 minutes and 120 minutes at both the MC and Assembly meetings on New Topics Proposals and Strategic Discussions;*
- *The MC supported the organisation of an interim meeting for the New Topics Subcommittee to begin on Monday 26 March 2018 in London, UK, hosted by EC, Europe and noted that the schedule and exact number of days (between 1 and 3) should be further discussed. The MC also noted that the Financial Subcommittee is working on elaborating a proposal for the organisation of an MC interim meeting, to be discussed at the Geneva meeting.*
- *The MC endorsed the updated supporting documents put together by the New Topics Subcommittee describing the New topics selection process.*

### ***Strategic discussions***

The MC noted that the updated Quality Reflection Paper on Advancing Pharmaceutical Quality Standards had been received and that a very preliminary draft Reflection Paper on Vaccines would also be circulated by mid-October, for discussion at the Geneva meeting. The MC noted that one or two additional suggestions for future strategic priorities may also be submitted later, for discussion at the Geneva meeting.

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

- *The MC supported the intent of inviting Assembly Members to propose topics to be included in the long-term strategy of the ICH organisation (e.g. strategic priorities and Reflection Papers) for preliminary discussion by the MC for recommendation and subsequent decision by the Assembly and endorsed the supporting documents put together for this purpose by the New Topics Subcommittee. The MC also agreed that further reflection was needed on how to organise the discussions of the Assembly to enable more engagement and participation of the Assembly Representatives and Delegates;*
- *The MC supported that the Quality Reflection Paper on Advancing Pharmaceutical Quality Standards will be discussed at the MC TC on 17 October with comments to be provided to the Secretariat by 10 October, with the aim of providing it to the Assembly in the Agenda Papers Package ahead of the Geneva meeting.*

## **6. COMMUNICATION**

The MC was updated on the activities undertaken since the Montreal meeting, notably in relation to the implementation of the Transparency policy.

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

- *The MC agreed that pending biographies and photos from MC and Assembly Members Representatives and Observers Delegates should be sent to the ICH Secretariat as soon as possible in order to be published on the ICH website ahead of the Geneva meeting, in line with the transparency policy approved by the Assembly at the Montreal meeting;*
- *The MC agreed on the principle of issuing an interim press release to update stakeholders on ICH guidelines having reached key milestones since the Montreal meeting and on the publication of experts' names on the ICH website.*

## 7. DATES OF NEXT TELECONFERENCE AND MEETINGS

### ❖ Teleconferences

<b>3 October</b>	MC Policy
<b>11 October</b>	MC Policy
<b>17 October</b>	MC Policy

### ❖ Face-to-Face Meetings

<b>11-16 November 2017</b>	Geneva, Switzerland
<b>2-7 June 2018</b>	Kobe, Japan
<b>November 2018</b>	USA ( <i>date &amp; location to be confirmed</i> )