

9 November 2017

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

## LIST OF PARTICIPANTS:

### ICH Management Committee Members

Ms. Lenita Lindström-Gommers	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
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
Dr. Petra Doerr	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
Dr. Milton Bonelli	EC, Europe

### Other Participants:

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

### ICH Secretariat:

Ms. Coralie Angulo
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.

### 2. APPROVAL OF THE AGENDA FOR THE ASSEMBLY MEETING

The MC noted the draft Assembly Agenda for the Geneva meeting circulated to the MC on 5 October 2017 and the comments received. A revised version of the draft was circulated to the MC on 12 October 2017.

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

- *The MC endorsed the draft Assembly Agenda for the Geneva meeting, to be circulated to the Assembly by 18 October 2017;*
- *The MC noted that the Agenda Papers Package will be circulated to the Assembly by 1 November 2017;*
- *The MC supported that the Assembly Agenda be published on the ICH public 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 supported the final version of the document entitled “Considerations for assessing the eligibility criteria for appointing Elected Representatives in the ICH Management Committee”, dated 12 October 2017, and that it would be circulated to the Assembly Members along with the package of the nomination applications received;*
- *The MC supported that any additional information needed from applicants will be requested by the Secretariat after sending the Considerations document and the Package of nomination applications, with a deadline to reply ahead of the next MC Policy TC 5 scheduled on 31 October 2017.*

### 4. OVERSIGHT OF THE WORKING GROUPS

#### • **Paediatric Extrapolation informal WG**

The MC noted the Concept Paper and the Business Plan developed by the WG and circulated to the MC on 5 October 2017.

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

- *The MC endorsed the Concept Paper and the Business Plan of the Paediatric Extrapolation informal WG and the establishment of an Expert Working Group;*
- *The MC agreed that further discussion will be held at the Geneva meeting to define the ICH code of the Paediatric Extrapolation WG.*

- **E8(R1) Informal WG: General Considerations for Clinical Trials**

The MC noted the progress made by the group towards finalising the Concept Paper and the Business Plan ahead of the next MC Policy TC 5 scheduled on 31 October 2017.

- **Q12 EWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management**

The MC noted the two documents circulated by EC, Europe on 12 October 2017, a proposal aimed at addressing the findings of the EC, Europe's legal review within the *Step 1 Q12 Technical Document* and a background for discussion.

**MC Action/Decision:**

- *The MC supported that EC, Europe circulate an alternative proposal to address the findings of the EC, Europe's legal review within the Step 1 Q12 Technical Document, to be discussed at the next MC Policy TC 5, scheduled on 31 October 2017.*

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

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

The MC was further updated by the Secretariat on the proposed revisions to the Membership page of the ICH website, as well as to the Membership Q&As and application forms, in order to reflect the updated procedures adopted in Montreal in June 2017.

**MC Action/Decision:**

- *The MC supported the proposed revisions to the Membership page of the ICH website, as well as to the Membership Q&As (with a minor modification) and the application forms, and that the Secretariat proceed with publishing the revised documents on the ICH website.*

## **6. REFLECTION PAPERS**

### **Quality Reflection Paper on Advancing Pharmaceutical Quality Standards**

The MC was updated on the comments received and subsequent revisions made to the Quality Reflection Paper.

**MC Actions/Decisions:**

- *The MC supported the circulation of the draft document entitled "Quality Reflection Paper on Advancing Pharmaceutical Quality Standards", dated 17 October 2017, to the Assembly within the Agenda Papers by 1 November 2017;*
- *The MC supported further discussion of the draft Quality Reflection Paper with the Assembly at the Geneva meeting.*

### **Vaccines Reflection Paper**

The MC was updated on the first comments received on the Vaccines Reflection Paper.

**MC Action/Decision:**

- *The MC tasked EC, Europe to engage further with subject matter experts to clarify or refine the project scope in view of MC comments, in order to present a revised version of the Vaccines Reflection Paper at the Geneva MC meeting.*

## **7. ICH WORK PLAN AND MULTI-ANNUAL STRATEGIC PLAN**

The MC noted the draft 2018 Work Plan and draft Multi-Annual Strategic Plan prepared by the ICH Secretariat.

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

- *The MC agreed to review the draft 2018 Work Plan and draft Multi-Annual Strategic Plan and provide any comments by 25 October 2017;*
- *The MC supported in principle that both the draft 2018 Work Plan and the draft Multi-Annual Strategic Plan would be circulated to the Assembly within the Agenda Papers by 1 November 2017 following review and any comments.*

## **8. FINANCIAL MATTERS**

The MC was updated on the revisions to the 5-year Budget Projection 2018-2022 and to the 2018 ICH Budget, dated 11 October 2017. The MC was further updated by the Secretariat on the additional costs integrated into the 5-year Budget Projection 2018-2022 and 2018 ICH Budget.

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

- *The MC supported that the revised 5-year budget projection for 2018-2022 as well as the revised 2018 ICH Budget would be circulated to the Financial Subcommittee for approval along with the explanatory website-related costs summary;*
- *The MC agreed that, subject to obtaining the approval of the Financial Subcommittee, the documents would be circulated to the Assembly within the Agenda Papers by 1 November 2017.*

## **9. ORGANISATION OF THE GENEVA ASSEMBLY MEETING**

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

- *The MC confirmed its support for the Assembly Agenda Papers package to be circulated by 1 November 2017.*

## **10. DATES OF NEXT TELECONFERENCE AND MEETINGS**

### **❖ Teleconferences**

**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*)