

September 26, 2017

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

LIST OF PARTICIPANTS:

ICH Management Committee Members/Observers

Ms. Lenita Lindström-Gommers	EC, Europe
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin (Chair)	FDA, US
Ms. Joan Blair	FDA, US
Ms. Pujita Vaidya	FDA, US
Dr. Celia Lourenco	Health Canada, Canada
Ms. Cathy Parker	Health Canada, Canada
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Toshiyoshi Tominaga (Vice-chair)	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. Mitsuo Mihara	JPMA
Mr. Fumihito Takanashi	MHLW, Japan

Technical Coordinators:

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

Other Participants:

Dr. Tomas Salmonson	EC, Europe
Mr. Martin Harvey Allchurch	EC, Europe

ICH Secretariat:

Dr. Dawn Ronan
Dr. Véronique Kuntzelmann
Dr. Anne Latrive

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin; FDA, US

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

1. ADOPTION OF THE AGENDA

The agenda was adopted without addition.

2. APPOINTMENT OF ELECTED MC REPRESENTATIVES

The MC was updated by the ICH Secretariat on the nominations for Elected MC Representatives which had been received. The MC noted that the objective of the teleconference was to have an in-depth discussion on the eligibility criteria before considering the information provided by each applicant Member. Furthermore, the MC noted that as per the Article 32 of the ICH Articles of Association, the Assembly would need to review the proposals put forward and would then take a decision on the appointment of Elected MC Representatives after consultation of the MC.

The MC noted that to facilitate discussion on the eligibility criteria, a draft document had been developed entitled “Considerations for Assessing the Eligibility Criteria for Appointing Elected Representatives in the ICH Management Committee”. The MC noted that the draft document outlined the eligibility criteria for both Regulatory and Industry Members as presented in the ICH Articles of Association and the MC Rules of Procedures and proposed how to interpret in a consistent and transparent manner criteria such as, in the case of Regulatory Member applicants, having “a good record of implementation of ICH Guidelines”, and in the case of Industry Member applicants, being “regulated or affected by the majority of the ICH Guidelines”. The MC provided their views on the document which they agreed to submit in writing after the teleconference.

MC Actions/Decisions:

- *The MC agreed to provide comments in writing by September 13, 2017 on the document entitled “Considerations for Assessing the Eligibility Criteria for Appointing Elected Representatives in the ICH Management Committee”;*
- *The MC agreed to share the final document with the Assembly along with all nomination applications received and in parallel of this to make its assessment for presentation to the Assembly in a second step;*
- *The MC agreed that on the basis of the final document, the ICH Secretariat should analyse each of the applications, seeking as necessary the support of the Membership Subcommittee, and provide the MC with a summary to support the MC’s assessment.*
- *The MC agreed that the ICH Secretariat share with it the nomination applications received and the initial high-level summary table it had already prepared.*

3. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

The MC was updated by the Membership Subcommittee on the status of applications since the Montreal meeting in June 2017.

4. CONSIDERATION OF OBSERVER REQUESTS TO PARTICIPATE IN ICH WORKING GROUPS (WGs)

The MC discussed the following requests submitted by ICH Observers to participate in ICH WGs:

- GHC's request to appoint an expert to the E19 EWG (current expert count of 28);
- National Center, Kazakhstan's request to appoint an expert to the E8(R1) informal WG (current expert count of 27);
- National Center, Kazakhstan's request to appoint an expert to the Paediatric Extrapolation informal WG (current expert count of 24).

MC Actions/Decisions:

- *The MC agreed that based on considerations including the current WG size (which already exceeds 25) for the E19 EWG and the E8(R1) EWG, it would not be able to support GHC's request to appoint an expert to the E19 EWG or National Center, Kazakhstan's request to appoint an expert to the E8(R1) informal Working Group;*
- *The MC agreed that based on considerations including the current WG size (which is below 25) for the Paediatric Extrapolation informal WG, it could support National Center, Kazakhstan's request to appoint an expert to the Paediatric Extrapolation informal WG;*
- *The MC agreed that Observers approved to participate in WGs should be informed that their participation may need to be revisited in view of new Members seeking to participate to whom preference would need to be given;*
- *The MC acknowledged the need to explore other ways for those Observers unable to directly participate in a WG to be exposed to the development of the ICH Guidelines.*

5. DATES OF NEXT TELECONFERENCES & MEETINGS

The MC noted the dates of the next teleconferences and face-to-face meetings:

❖ **Teleconferences**

September 25	MC Technical/WGs
September 26	MC Policy
October 3	MC Policy
October 11	MC Policy
October 17	MC Policy

❖ **Face-to-Face Meetings**

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