

9 May 2019

SUMMARY
of
MC SESSION ACTIONS AND DECISIONS
**ICH Management Committee Interim Meeting
1-2 April 2019, Brussels, Belgium**

List of Participants

ICH Management Committee Members Representatives

Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Ms. Lenita Lindström-Gommers	EC, Europe
Dr. Milton Bonelli	EC, Europe
Mr. Pär Tellner	EFPIA
Ms. Joan Blair	FDA, United States
Dr. Theresa Mullin (<i>Chair</i>)	FDA, United States
Ms. Pujita Vaidya	FDA, United States
Dr. Celia Lourenco	Health Canada, Canada
Dr. Léo Bouthilier	Health Canada, Canada
Dr. Dorothy Toh (<i>via TC</i>)	HSA, Singapore
Ms. Siew Wei Chua (<i>via TC</i>)	HSA, Singapore
Dr. Nick Cappuccino	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Kyung Won Seo	MFDS, Republic of Korea
Dr. Nobumasa Nakashima (<i>Vice-Chair</i>)	MHLW/PMDA, Japan
Dr. Junko Sato	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Mr. Xiaoling Qin	NMPA, China
Dr. Peter Honig	PhRMA
Ms. Camille Jackson	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland
Ms. Cordula Landgraf	Swissmedic, Switzerland

ICH Assembly Member Representative:

Mr. Harald Enzmann	EC, Europe
--------------------	------------

ICH Management Committee Standing Observers Delegates:

Dr. David Jefferys	IFPMA
Ms. Sharon Olmstead	IFPMA
Ms. Emer Cooke	WHO

ICH Management Committee Coordinators:

Dr. Georgios Balkamos	EC, Europe
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, United States
Dr. Shinichiro Hirose	IGBA
Mr. Mitsuo Mihara	JPMA
Ms. Pansoon Kim	MFDS, Republic of Korea
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
Mr. Yang Wang	NMPA, China
Ms. Camille Jackson	PhRMA

ICH Management Committee Technical Coordinators:

Dr. Milton Bonelli	EC, Europe
Dr. Michelle Limoli	FDA, United States
Dr. Yasuhiro Kishioka	MHLW/PMDA, Japan

ICH Management Committee Additional Participants:

Dr. Agnes Saint-Raymond	EC, Europe
-------------------------	------------

Ms. Minyoung Lim
Ms. Sayaka Kurihara
Mr. Jerry Stewart

ICH Secretariat:
Dr. Anne Latrive
Dr. Dawn Ronan

MFDS, Republic of Korea
MHLW/PMDA, Japan
PhRMA

ICH Secretariat
ICH Secretariat

Table of Content

Welcome & Adoption of the Agenda.....	1
A. New Topic Proposals	1
B. Implementation.....	1
C. Procedural Matters	2
D. General Operational Matters	2
E. Financial Matters	3
F. Training	3
G. Reflection Papers.....	3
H. Oversight of Working Groups.....	4
I. Any Other Business.....	5
J. Dates of Next meetings	5

ICH MANAGEMENT COMMITTEE INTERIM MEETING MINUTES

MC Chair: Dr. Theresa Mullin, FDA, United States

MC Vice Chair: Dr. Nobumasa Nakashima, MHLW/PMDA, Japan

Welcome & Adoption of the Agenda

Mrs. Anne Bucher, Director General DG SANTE, and Dr. Andrzej Rys, Health systems, Medical Products and Innovation Director, DG SANTE, as well as Dr. Mullin (MC Chair, FDA, United States) and Dr. Nakashima (MC Vice Chair, MHLW/PMDA, Japan) welcomed MC Member Representatives and Standing Observer delegates.

MC Decision/Action:

- The MC adopted the agenda without any modification.

A. New Topic Proposals

The MC was informed on the process for MC assessment of New Topic proposals and on the evaluations and priority ranking scoring provided by the MC Members ahead of the meeting.

MC Decisions/Actions:

- The MC agreed on the categorisation of New Topic proposals for recommendation to the ICH Assembly in June 2019;
- The MC supported that a draft summary of MC assessments with short rationale would be circulated shortly after the meeting with a view to the MC approving a final version at the MC Policy 3 TC on 12 April 2019 for provision to the ICH Assembly;
- The MC supported that the Secretariat would circulate to the Assembly Members and Observers at least one month ahead of the meeting in Amsterdam in June 2019 the following documents:
 - Final package of New Topic proposals;
 - Summary of MC assessments;
 - Consolidation of evaluation forms for each topic outlining every MC Member position.
- The MC agreed to have further discussion at the meeting in Amsterdam on the capacity of ICH in consideration of the New Topic proposals, namely on the number of WGs which can work simultaneously (e.g., 25 WGs) and meet at face-to-face meetings (e.g., 15).

B. Implementation

The MC was updated by the Lead and Co-Lead of the Implementation Subcommittee on the conduct of the ICH Implementation Survey which was launched with a deadline for responses by 29 March 2019.

CIRS (Centre for Innovation in Regulatory Science), as the independent third-party conducting the survey, further presented to the MC the proposed templates for reporting on the survey results.

MC Decisions/Actions:

- The MC approved the Work Plan of the ICH Implementation Subcommittee;
- The MC supported the proposed templates for reporting of the survey results to the Assembly with minor revisions for clarity;

- The MC noted that the results of the survey would be presented to the MC and to the Assembly at the next ICH meeting in Amsterdam in June 2019;
- The MC agreed to discuss next steps in communication to the public following the ICH meeting in Amsterdam in June 2019;
- The MC noted that a new Lead of the Implementation Subcommittee would need to be appointed in June 2019, upon the stepping down of the current Lead.

C. Procedural Matters

- **Management of ICH Working Groups Size**

The MC was updated on the revised proposal for a new approach for managing the size of ICH Working Groups (WGs) further to comments shared by MC Members ahead of the meeting

MC Decisions/Actions:

- The MC supported the revised proposal regarding managing the size of ICH WGs;
- The MC supported that the ICH Secretariat reflect the necessary changes in ICH's procedural documents to align with the proposal with a view to seeking the appropriate MC and/or Assembly approval of these procedural documents by/at the time of the Amsterdam meeting.

- **Reflection Papers**

The MC discussed refining the purpose and process for future ICH Reflection Papers.

MC Decisions/Actions:

- The MC agreed the need to refine the process for development of Reflection Papers as part of a more structured multi-year strategic plan of near and long-term planning for Q, S, E and M ICH topics, to reflect more linkage to the new topic selection process, and inclusion of a pre-Reflection Paper discussion step to ensure MC input prior to initiation of Reflection Paper development;
- The MC supported working in Amsterdam to structure this process with the MC to consider ahead of the meeting the planning process and questions which should be raised as part of pre-reflection paper discussion.

- **Discussion Groups**

The MC discussed the need for procedures for ICH Discussion Groups.

MC Decisions/Actions:

- The MC agreed the need to clarify the procedures regarding to ICH Discussion Groups with development of clear remits including specific tasks and timelines for each Discussion Group;
- The MC supported the development for further discussion in Amsterdam of a general principles document regarding procedures for ICH Discussion Groups.

D. General Operational Matters

- **Cooperation with other organisations and signing of contracts**

The MC was informed on considerations regarding the need for clarification within ICH procedural documents of the respective roles of the Assembly, the MedDRA MC and of the ICH MC regarding cooperation with other organisations, particularly with respect to cooperation requiring the signing of contracts.

MC Decision/Action:

- The MC noted that the ICH Secretariat will work to propose a revision to ICH procedural documents to address the need identified for additional clarity with a view to seeking the appropriate MC and/or Assembly approval of these procedural documents by/at the time of the Amsterdam meeting.

E. Financial Matters

The MC discussed comments received on the draft considerations document regarding the development of a plan for the use of surplus funds on strategic activities. The MC agreed that the main focus should be activities related to training and support of ICH Guideline implementation.

The MC furthermore discussed the use of funds in 2020 and beyond with a view to multi-year budget planning.

MC Decision/Action:

- The MC supported that the MC and Assembly Chairs work together with the ICH Secretariat to refine the strategic proposal regarding the use of surplus funds and develop a budget plan in line with the objectives outlined in the proposal and the amounts provisionally discussed at the interim meeting for potential allocation to different activities.

F. Training

The MC was updated by the Lead and Co-Lead of the Training Subcommittee on the materials prepared by the Subcommittee, with the support of the ICH Secretariat, for the Call for Expression of Interest (including eligibility criteria, development of Terms of Reference and Response Form etc...) from Training Associates who ICH would potentially contract with to: develop training materials for ICH ownership; deliver training; and provide consultancy services to ICH.

MC Decisions/Actions:

- The MC supported minor adjustments to the Terms of Reference and the Response form and to proceed with the launch on 5 April 2019 of the Call for Expression of Interest from Training Associates;
- The MC approved the proposed communication plan for the Call for Expression of Interest from Training Associates with agreement to: publish the Terms of Reference and Response Form on the ICH website; to request the Members and Observers of the ICH Assembly to promote the call among their collaborators; to communicate through ICH social media channels; and inform about the call those training providers who have already provided/been approved to provide ICH Recognised Training Programmes;
- The MC supported the proposed timeline for the Call for Expression of Interest from Training Associates to launch on 5 April 2019, with the call to close on 3 May 2019 with a view to facilitating review of applications ahead of the Amsterdam meeting in June 2019;
- The MC confirmed the participants to the Review Committee.

G. Reflection Papers

- ***Draft Reflection Paper: Model Informed Drug Development (MIDD) (PhRMA)***

The MC was informed by PhRMA on the revisions to be made to the PhRMA draft Reflection Paper on MIDD.

MC Decision/Action:

- The MC noted that a revised draft Reflection Paper on MIDD would be shared by PhRMA ahead of the MC Policy 3 TC on 12 April 2019.
- **Revised 3 Draft Reflection Paper: Strategic Approach to International Harmonization of Technical Scientific Requirements for Pharmacoepidemiological Studies Submitted to Regulatory Agencies to Advance More Effective Utilization of Real-World Data (MHLW/PMDA, Japan)**

The MC was informed by MHLW/PMDA, Japan on comments received from MC Members on its revised draft Reflection Paper on *Strategic Approach to International Harmonization of Technical Scientific Requirements for Pharmacoepidemiological Studies Submitted to Regulatory Agencies to Advance More Effective Utilization of Real-World Data*, which had been circulated to the MC in March 2019.

MC Decision/Action:

- The MC noted that MC Members would provide further feedback to MHLW/PMDA, Japan shortly, to be taken into consideration for further revision of the draft Reflection Paper.
- **ICH Reflection Paper: Further Opportunities for Harmonization of Standards for Generic Drugs**

The MC was informed by FDA, United States, as the Member holding the Rapporteurship of the Informal Generic drugs Discussion Group (IGDG), on efforts to assess the work already done by other initiatives.

MC Decision/Action:

- The MC noted that considerations would be shared by FDA, United States in the coming weeks regarding efforts by the IGDG to assess the work already done by other initiatives.

H. Oversight of Working Groups

- **Establishment of the Informal Generic drugs Discussion Group (IGDG) (Rapporteur: Dr. Tampal – FDA, United States; Regulatory Chair: Dr. Welink – EC, Europe)**

The MC was informed by the ICH Secretariat of expressions of interest received for the nomination of experts to the IGDG. The MC noted the request forms received from Industry Members and Observers, as well as the overview table prepared by the ICH Secretariat with the number of requests per Member/Observer.

MC Decisions/Actions:

- The MC approved the requests of Industry Members and Observers;
- The MC approved WHO's request for an exception to the rules to enable the appointment of a second WHO expert in view of the importance for the IGDG of the work undertaken by WHO in this area.
- **Member requests to nominate experts to WGs**

MC Decision/Action:

- The MC approved both TFDA, Chinese Taipei's and ANVISA, Brazil's requests to each nominate 1 expert to the M7(R2) Maintenance EWG/IWG.

▪ Observer requests to nominate experts to WGs

MC Decisions/Actions:

- The MC agreed that in general when a WG size is larger than 25 but less than 30, the Rapporteur of the WG should be consulted on any requests received to nominate experts, to provide a recommendation on whether additional experts can be accommodated within the group;
- The MC approved TITCK, Turkey's request(s) to nominate experts to the following WGs: E2B(R3) EWG/IWG, M1 PtC WG, M8 EWG/IWG, Q3C(R8) Maintenance EWG, S1(R1) EWG, S11 EWG;
- The MC noted that further follow-ups would be conducted with the Rapporteurs of other WGs which TITCK, Turkey had expressed interest in, but were already larger in size, to receive their feedback on whether additional experts can be accommodated within the group.

I. Any Other Business

The MC was informed by the ICH Secretariat on a request received from an ICH Observer for an additional participant to the Assembly meeting in Amsterdam and the justification provided in support of the request.

MC Decision/Action:

- The MC acknowledged the interest of the ICH Observer, but considered that there was in this circumstance not sufficient justification to warrant an additional participant.

J. Dates of Next meetings

Teleconferences

12 April 2019	ICH MC Policy 3
8 May 2019	ICH MC Policy 4

Face-to-Face Meetings

1-6 June 2019	Amsterdam, The Netherlands
17-21 November 2019*	Singapore
24-28 May 2020*	Vancouver, Canada (to be confirmed)
15-19 November 2020*	Europe (location to be confirmed)
30 May - 3 June 2021*	Asia (location to be confirmed)

**Note: The new meeting schedule is implemented for meetings from November 2019 onwards, with the ICH meeting week starting on Sunday.*