16 July 2020

SUMMARY

of

MC SESSION ACTIONS AND DECISIONS

ICH Management Committee Virtual Meeting

13, 25 and 26 May 2020

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
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ICH MC Members

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ICH MC Coordinators

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A. Adoption of the Agenda

At the MC TCs on 13, 25 and 26 May 2020, Dr. Theresa Mullin (MC Chair - FDA, United States) welcomed all participants. The agenda was adopted without modification.

B. Q4B Maintenance

MC discussion on 13 May 2020

The MC discussed the Pharmacopoeial Discussion Group (PDG)'s modified proposal for maintenance and revision of the ICH Q4B Annexes, and additional comments/considerations shared by MC Members since the MC Policy 3 TC on 22 April 2020.

ICH MC Action/Decision:

- The MC agreed to hold a joint discussion with PDG, at which time it would share its considerations on PDG's proposal.

MC joint discussion with PDG on 26 May 2020

PDG presented to the MC their proposal to modify the process for the revision of the Q4B Annexes, and the MC shared its considerations with PDG further to which PDG provided the MC with clarity on their process, highlighting the opportunities which exist for engagement of the pharmacopoeias of the non-Founding ICH Regulatory Members and ICH Industry Members.

ICH MC Action/Decision:

- The MC and PDG agreed that the PDG would provide the MC an overview of their proposed process for reviewing the Q4B Annexes, in which the opportunities for engagement of the pharmacopoeias of the non-Founding ICH Regulatory Members and ICH Industry Members would be mapped.

C. New Topic Proposals

The MC was informed by the Co-Leads of the New Topics Subcommittee on the 2020 New Topic cycle and feedback received from the Quality Discussion Group (QDG) on topics #12 on *Structured Product Quality Submissions* and #13 on the *revision of M4Q(R1) CTD*, as agreed at the Policy 3 TC held on 22 April 2020.

ICH MC Actions/Decisions:

- The MC supported both proposals #12 and #13 for recommendation to the ICH Assembly for endorsement, with an informal WG on topic #13 to be established first, once the Q13 EWG will have reached *Steps 1/2*, which is currently anticipated in the November 2020 timeframe. The future M4Q(R2) informal WG with possible support from the QDG will be tasked to further develop a plan on the overlap of these two topics that will minimize delay of topic #12 while having topic #13 best inform the work to be done on topic #12;
- The MC supported the planned update to be given to the Assembly at its TC on 27 May 2020.

Revised Reflection Paper: Patient-Focus Drug Development (PFDD)

The MC was updated on work by FDA, United States and EC, Europe on revising the draft Reflection Paper on *Patient-Focus Drug Development* (PFDD).

ICH MC Action/Decision:

- The MC noted that a revised Reflection Paper would be shared with the MC in the July timeframe, with the aim of submitting a Reflection Paper for Assembly consideration at its meeting in Athens in November 2020.

Strategic Framework

The MC was updated on the finalisation of the Strategic Framework document which lists already agreed topics, either endorsed New Topic proposals with a delayed start or topics included in an endorsed Reflection Paper, with the categorization of topics as "short-term" or "long-term".

ICH MC Actions/Decisions:

- The MC approved the final version of the Strategic Framework document and supported that it would be shared with the Assembly electronically with an explanatory note;
- The MC agreed that going forward, the Strategic Framework document would be maintained by the ICH Secretariat, to be updated when Reflection Papers are endorsed or New Topics are endorsed with a delayed start, seeking input from the MC as appropriate.

D. Financial Matters

ICH MC Financial Subcommittee

The MC was informed by the MC Financial Subcommittee Chair on the outcome of discussions within the ICH MC Financial Subcommittee and with the MedDRA MC Financial Subcommittee on the sustainable funding and financial management of the ICH Association, as well as on the update prepared for sharing with the Assembly presenting the outcome of financial discussions.

ICH MC Actions/Decisions:

- The MC noted that it was invited to provide any comment in writing shortly after the TC on the update for the Assembly, with a view to sharing the document with the Assembly in advance of its TC on 27 May 2020;
- The MC supported the setting-up of a future standing ICH Finance Subcommittee including Representatives from the ICH MC and the MedDRA MC and reporting to the ICH MC and MedDRA MC. The MC noted that this approach had also been supported by the MedDRA MC;
- The MC agreed that the ICH Finance Subcommittee would review financial documents and provide recommendations on financial matters to the ICH MC and MedDRA MC, and may also provide support on contract or procurement processes. The MC noted that the Assembly is ultimately responsible for the approval of financial matters;
- The MC noted the early draft charter for the ICH Finance Subcommittee and agreed to provide comments in writing within two weeks of the TC, with a view to finalise in the June timeframe;
- The MC supported that the ICH Secretariat develop an overview of the current ICH and MedDRA financial cycles as per the procedures, with a view to informing the new process and timeline to be included in the charter.

2019 Closing Expense Reports, 2021 ICH Budget & 5-Year Plan

The MC was informed by the ICH Secretariat on the 2019 ICH Closing Expense Report and the updating of the 2021 ICH budget and 5-Year Plan on the basis of 2019 experience/status of activities.

ICH MC Actions/Decisions:

- The MC approved the provision to the Assembly of the updated 2021 ICH budget for approval in May 2020, as well as the 5-Year Budget Plan and the 2019 ICH Closing Expense Report for information;
- The MC noted that, following the MC decision taken at the Policy 3 TC on 22 April to propose the use of a webconferencing tool upon request to the ICH Working Groups (WGs), the ICH Secretariat had received expressions of interest from 4 WGs and is proceeding with the setting-up of the licenses. Going forward, the ICH Secretariat will give all WGs the possibility to have access to this webconferencing tool for the duration of their activities

E. Meetings

Cancellation of the ICH MC interim meeting of March 2020

The MC was informed by the ICH Secretariat on feedback received from the Professional Conference Organiser (PCO) regarding the possibilities for the rescheduling of the ICH MC interim meeting of March 2020.

ICH MC Actions/Decisions:

- The MC agreed to hold an MC interim meeting in Brussels in March 2021 prior to / after the DIA Europe meeting scheduled to be held in Basel, Switzerland on 17 to 19 March 2021;
- The MC supported that the ICH Secretariat send a poll to the MC to identify suitable dates, further to which the venue should be booked.

ICH Meeting in Athens in November 2020

The MC discussed contingency planning for the ICH meeting in Athens in November 2020 in view of the global COVID-19 situation.

ICH MC Actions/Decisions:

- The MC supported that at the MC Policy 1 TC on 30 July 2020 the MC would review the situation and any impact on the organisation of the ICH meeting in Athens in November 2020;
- The MC supported that the PCO would be invited to join part of the TC to report to the MC directly.

Next Meetings

The MC was informed by the ICH Secretariat on the organisation of 2021 and 2022 meetings.

ICH MC Actions/Decisions:

- The MC confirmed the following date for the November 2022 meeting: 12 to 16 November 2022, noting the location will be confirmed in November 2020;
- The MC noted that the contracting of the venues for the 2021 meetings would be finalised shortly by the PCO.

Call for tenders

The MC was informed by the ICH Secretariat on preparations for the conduct of the call for tenders for the contracting of a PCO for the organisation of ICH biannual meetings from 2023.

ICH MC Action/Decision:

- The MC agreed, in view of the short time available at the TC, that the proposed planning would be re-discussed after the TC.

F. Oversight of Working Groups

Impact of COVID-19 on harmonisation activities

The MC was informed by the ICH Secretariat on the feedback received from WGs on the impact of COVID-19 on their timelines.

ICH MC Action/Decision:

- The MC noted that at the time of the TC on 13 May 2020, approximately half of the WGs who had provided feedback to the ICH Secretariat reported that they did not foresee any delays, with delays expected by the other half of the WGs ranging from 3 to 6 months.

WGs to meet in Athens in November 2020

The MC discussed the timeline for the MC to approve WGs to meet face-to-face at the ICH meeting in Athens in November 2020, which would normally have been decided upon at the end of the ICH Assembly meeting.

ICH MC Actions/Decisions:

- The MC supported that a Coordinators TC would be held on Thursday, 18 June, and a MC Technical TC on 10 July, in order to review (1) the progress of the WGs further to their teleconferences in May which were held in lieu of WG face-to-face meetings, and (2) the requests of WGs to meet at the ICH meeting in Athens in November 2020;
- The MC further noted that it would decide at the MC Policy 1 TC on 30 July whether to continue or cancel the ICH meeting in Athens in view of the then current situation with COVID-19.

WGs for ICH MC discussion

- ***E2B(R3) EWG/IWG: Revision of the Electronic Submission of Individual Case Safety Reports (Rapporteur: Dr. Misu – MHLW/PMDA, Japan; Regulatory Chair: Mr. Chen – FDA, United States)***

The MC was informed by the Coordinator for MHLW/PMDA, Japan of a discrepancy noted in the ICSR BFC Specification document.

ICH MC Action/Decision:

- The MC noted that the WG would correct the ICSR BFC Specification document.

- ***E6(R3) EWG: Good Clinical Practice (Rapporteur: Dr. M. El Zarrad – FDA, United States; Regulatory Chair: Dr. Sweeney – EC, Europe)***

The MC was provided with an update by the Coordinator for FDA, United States on the progress made by the E6(R3) EWG on the engagement of stakeholders as per the plan approved by the MC on 9 March 2020, which involves both (1) direct engagement with stakeholders during EWG meetings; and (2) the organisation by MC Members of meetings for the engagement of regional stakeholders.

ICH MC Actions/Decisions:

- The MC noted that as part of the direct engagement process, the group had compiled a list of stakeholders, and that in June 2020 the group would start reaching out to them to invite them to discuss with the group at its TCs;
- The MC noted that as part of the regional stakeholder engagement process, the following regional public virtual meetings were being organised:
    - 3 June 2020, organised by EC, Europe;
    - 4-5 June 2020, organised by FDA, United States.

- ***E14/S7B IWG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (Rapporteur: Dr. Strauss – FDA, United States; Regulatory Chair: TBD)***

The MC was updated by the Coordinator for FDA, United States on the progress made by the group on the development of the first stage of Q&As.

ICH MC Actions/Decisions:

- The MC noted the group's considerations, that once finalised, the Q&As should undergo public consultation, instead of going directly to *Steps 3* and *4* as the group had been initially considering;
- The MC noted the group's considerations to organise a virtual public meeting in October/November 2020 during the public consultation on the first stage of Q&As, and the MC supported that the E14/S7B IWG submit a written proposal for its further consideration.

- ***M7(R2) Maintenance EWG/IWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (Rapporteur: Dr. Froetschl – EC, Europe)***

The MC was updated by the ICH Secretariat on progress made by the M7(R2) Maintenance EWG/IWG on the M7Q&A and M7(R2) draft Guideline. The MC was further informed of the group's considerations to publish, as a support document to the M7 Q&A, an extract of the M7(R2) draft Guideline showing an update of the listing of the HIV treatment duration in view of clinical treatment advances, as this update is already referred to in the M7Q&A.

ICH MC Action/Decision:

- The MC supported that once *Step 1* of the M7Q&A is finalised, the Assembly be invited to (1) sign-off *Steps 2a/b* of the M7Q&A, and (2) pre-approve the change related to the HIV treatment duration, so that it may be published alongside the M7Q&A as a support document.

- ***Q2(R2)/Q14 EWG: Analytical Procedure Development and Revision of Q2(R1) Validation of Analytical Procedures (Rapporteur: Dr. Hiyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Keire – FDA, United States)***

The MC was informed by the Coordinator for EC, Europe of EC, Europe's considerations that the group should proceed to make a recommendation to the MC on whether they would provide two separate draft Technical Documents (i.e. for Q2(R2) and Q14) or one combining both in sufficient advance of *Step 1* sign-off.

ICH MC Action/Decision:

- The MC supported that MHLW/PMDA, Japan liaise with the Q2(R2)/Q14 Rapporteur so that the group would make a recommendation to the MC on whether one Q2(R2)/Q14 Technical document or two separate Technical documents would be developed.

- ***Establishment of Q9(R1) informal WG: Quality Risk Management (informal WG Lead: Mr. O'Donnell - EC, Europe; Regulatory Chair: Mr. Alex Viehmann - FDA, United States)***

The MC was informed by the ICH Secretariat that the requests to nominate experts from Industry and Observers to the Q9(R1) informal WG had been approved by all MC Members electronically, and that an additional request had been received from Swissmedic, Switzerland after the deadline.

ICH MC Actions/Decisions:

- The MC agreed that although the standard procedure would be for the MC to review Swissmedic, Switzerland's late request at the next MC Technical TC, as the request had been received prior to the formal launch of the WG, the MC would review the request. Furthermore, the MC approved Swissmedic, Switzerland's request to appoint an expert;
- The MC noted that the ICH Secretariat would proceed with finalising the establishment of the Q9(R1) informal WG.

- ***Establishment of Q12 IWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (Rapporteur: Ms. Boam – FDA, United States; Regulatory Chair: Ms. Kruse – EC, Europe)***

The MC was informed by the ICH Secretariat on feedback received from Members and Observers regarding the establishment of the Q12 IWG.

ICH MC Actions/Decisions:

- The MC approved the request to appoint an expert received from PIC/S;
- The MC noted that the ICH Secretariat would proceed with finalising the establishment of the Q12 IWG.

- ***Generic drug Discussion Group (GDG) (Rapporteur: Dr. Tampal – FDA, United States; Regulatory Chair: Dr. Welink – EC, Europe)***

The Coordinator for FDA, United States presented to the MC the summary report prepared by the GDG, which had reached the end of its term, and their request (1) to extend the term of the GDG for another year and (2) to forward the GDG's considerations for the E6(R3) Guideline to the E6(R3) EWG.

ICH MC Actions/Decisions:

- The MC supported that the term of the GDG be extended by up to one year (i.e. until June 2021), with a view to disbanding the group earlier if they would finalize its activities sooner, and with the frequency of its TCs to be reduced to every other month;
- The MC supported that the GDG's recommendations on the E6(R3) Guideline be shared with the E6(R3) EWG.

- ***Development of a standard template for comments from public consultations***

The MC was updated by the Coordinator for EC, Europe on progress made by the Coordinators of the Founding Regulatory Members on the development, as agreed by the MC at its meeting in Singapore in November 2019, of a standard template for compiling comments received during the public consultation period to help facilitate their review by ICH WGs.

ICH MC Action/Decision:

- The MC noted that it would be further updated on progress at a subsequent TC and supported that, to inform the development of the common template, the ICH Secretariat should reach out to all Coordinators of Regulatory Members to enquire about their process and templates for collecting comments during the public consultation period.

G. Preparation of the Assembly Teleconference

The MC was informed by the ICH Secretariat on the preparation of the Assembly TC on 27 May 2020.

ICH MC Actions/Decisions:

- The MC supported that the revised agenda and package of background documents be shared with the Assembly, and noted that, to facilitate Assembly discussion at the TC, the Assembly would be invited to share comments/questions on documents in advance;
- The ICH MC noted that the ICH Assembly Chair and Vice Chair had prepared with the ICH Secretariat the agenda item on Membership & Observership applications and that, in line with the procedures, an open vote would be organised;
- The MC noted that the agenda for the Assembly TC would be published shortly on the ICH website.

H. Implementation

The MC was updated by the Implementation Co-Leads on the progress made on the Free-Text Analysis and on the revision of the proposal for the Phase 2b Survey.

ICH MC Actions/Decisions:

- The MC noted that the agreement for the Free-Text Analysis was being reviewed by the ICH Secretariat;
- The MC supported that the Phase 2b Survey follow the same questions and format as the Phase 2a survey conducted in 2019;
- The MC supported that the scope of the Phase 2b Survey be limited to determining whether Regulatory Members would meet the eligibility criteria for the MC Elections in 2021, and that the survey be limited to non-Founding and non-Standing Regulatory Members, with Regulatory Observers invited to participate on a voluntary basis;
- The MC supported that the Tier 2 Guidelines be included in the survey, and that the ICH Secretariat invite the MC to share considerations on the Tier 3 Guidelines to include;
- The MC acknowledged that IFPMA develop a proposal to facilitate participation of local manufacturers from new regulatory Member regions in the Phase 2b Survey.

I. Training

ICH Training Associates

The MC was updated by ICH Secretariat on the status of contracting ICH Training Associates. The MC was furthermore updated by the Training Co-Lead on the next steps planned by the Training Subcommittee to develop a mechanism to evaluate the deliverables of ICH Training Associates.

ICH MC Actions/Decisions:

- The MC noted that a first Training Associate agreement had been signed to deliver training on ICH Q1, with the delivery of the first training materials expected in August 2020;
- The MC noted that the Training Subcommittee was looking into creating four "Technical Advisory Groups" to cover the Efficacy, Quality and Safety topics, as well as Electronic Standards.

ICH Training Subcommittee

The MC was updated by the Training Co-Lead on the Training Subcommittee activities, including approval of face-to-face and online ICH Recognised Training Programmes and support provided to WGs developing training materials.

ICH MC Actions/Decisions:

- The MC approved v1.2 of the Procedure for Organisations Interested in Developing an ICH Recognised Training Programme and v1.3 of the Terms of Reference for Training Providers for an ICH Recognised Training Programme, and the MC noted the documents would subsequently be published on the ICH website;
- The MC supported that the Training Subcommittee explore the availability of accurate translations of training materials on ICH Guidelines, with a view to possibly posting a link to such materials on the ICH website;
- The MC supported the provision to the Assembly of the written report providing an update on Training activities.

J. Collaboration with PIC/S

The MC was informed by the MC Chair on the status of the pilot programme for more routine engagement between ICH and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) on ICH Quality Guideline work with relevance to both Regulatory assessor and Inspector disciplines, focusing on Q12 and the future Q9(R1) Guidelines.

ICH MC Action/Decision:

- The MC noted that the pilot programme could now be considered as initiated with the launch of the Q12 IWG work.

K. Communication

ICH 30th Anniversary

The MC was updated by the ICH Secretariat on the status of registration of the Assembly Members and Observers to the 30th Anniversary Commemorative event to be held on the margins of the ICH meeting in Athens on Saturday, 14 November 2020, as well as to the reception the evening prior; and on the progress made by the Organising Subcommittee to identify the remaining speakers/panelists.

ICH MC Actions/Decisions:

- The MC noted that the Assembly had been informed that the deadline to register to the ICH 30th Anniversary Commemorative event had been extended to 30 June;
- The MC noted that the Organising Subcommittee was in the process of identifying/confirming participation of the last remaining 4 speakers/panelists;

- The MC noted that it would decide at the MC Policy 1 TC on 30 July whether to continue or cancel the event in view of the then current situation with COVID-19.

ICDRA Meeting

The MC was informed that WHO was looking into whether to postpone the International Conference of Drug Regulatory Authorities (ICDRA) meeting to be held in New Delhi, India on 28 September – 2 October 2020[1] in view of the COVID-19 pandemic.

ICH MC Action/Decision:

- The MC agreed to postpone discussion on identifying a speaker for the ICH presentation at the ICDRA meeting until further updates on the status of the ICDRA meeting would be made available.

Press Release

ICH MC Action/Decision:

- The MC agreed that a Press Release would be issued following the Assembly TC on 27 May to communicate on progress of ICH and MedDRA activities.

L. General Operational Matters

Report of the ICH Secretariat

The MC was informed by the ICH Secretariat on its written report on General Operational Matters including: status of trademark registrations, status of websites and IT tools, and level of participation of Members and Observers in ICH.

ICH MC Action/Decision:

- The MC noted the written report of the ICH Secretariat.

O. Next Meetings

Teleconferences

The MC noted the scheduling of teleconferences in preparation of its next meeting in Athens in November 2020, as per the below:

- (FYI) Thursday, 18 June 2020 – Coordinators TC
- Friday, 10 July 2020 – MC Technical TC
- Thursday, 30 July 2020 – MC Policy 1 TC
- Wednesday, 23 September 2020 – MC Policy 2 TC
- Monday, 19 October 2020 – MC Policy 3 TC

Face-to-face Meetings

The MC noted the scheduling of the next face-to-face meetings, as per the below:

• 14-18 November 2020	Athens, Greece
• 15-16 March 2021	MC Interim meeting in Brussels, Belgium
• 29 May - 2 June 2021	Incheon, Republic of Korea (final confirmation pending)

[1] Post-meeting note: At the time of the Assembly « Vancouver » TC on Wednesday, 27 May 2020, the Assembly was informed by WHO that the ICDRA meeting was postponed to 2021.

• 13-17 November 2021	Vancouver, Canada (final confirmation pending)
• 21-25 May 2022 or 11-15 June 2022	Europe (location & dates to be confirmed)
• 12-16 November 2022	Asia (location to be confirmed)