31 July 2020

SUMMARY REPORT
ICH MC Technical TELECONFERENCE
10 July 2020

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

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FINAL REPORT

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

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

1. WELCOMING REMARKS AND ADOPTION OF THE AGENDA

Dr. Theresa Mullin (MC Chair – FDA, United States) welcomed all participants.

The MC agreed that that in view of the discussion scheduled for the MC Policy 1 TC on 30 July on whether to proceed with the ICH meeting in Athens, Greece in November 2020, the MC would postpone until the Policy 1 TC (1) the review of the status reports of the Working Groups (WGs) requesting to meet, as well as (2) making a decision on which WGs' requests to approve.

The agenda was adopted without any further modification.

2. MEDDRA

The MedDRA MC Chair, Mr. Mick Foy (MHRA, UK), updated the ICH MC on the MedDRA MC's recent discussions.

3. ORGANISATION OF THE ATHENS MEETING

The ICH Secretariat provided an update on the organisation of the upcoming ICH meeting to be held in Athens, Greece on 14 – 18 November 2020, and which will include the ICH 30th Anniversary Commemorative event on Saturday, 14 November and the ICH reception the evening of Friday, 13 November. The update of the ICH Secretariat included considerations regarding the capacity of the venue and number of WGs that can meet in parallel, also in view of new social distancing policies due to the COVID-19 situation which have impacted the original planning for the meeting.

***ICH MC Actions/Decisions**:*

- The MC noted that in preparation of the ICH MC Policy 1 TC on 30 July 2020, MC Members and Observers had been invited to share with the ICH Secretariat awareness of any travel restrictions from their respective organisations that would prevent their ICH Representatives / experts from attending the face-to-face meeting;
- The MC tasked the ICH Secretariat to liaise with the Professional Conference Organiser (PCO) and meeting venue ahead of the ICH MC Policy 1 TC on 30 July 2020 on the consequences of cancelling the Athens meeting if this would be determined by the MC to be necessary;
- The MC supported that at the MC Policy 1 TC on 30 July, if the MC would decide to not go ahead with the ICH meeting in Athens, the MC would discuss the impact on the 30th Anniversary Commemorative event and share considerations on whether to postpone the meeting or hold a virtual meeting instead.

4. PREPARATION OF ICH MEETING IN ATHENS: ORGANISATION OF THE WORKING GROUPS

***ICH MC Actions/Decisions*:**

- This MC noted the list of WGs which had requested to meet face-to-face in November 2020, and the list of WGs which had not:
    - <u>WGs requesting to meet face-to-face:</u> E2D(R1) EWG; E6(R3) EWG; E8(R1) EWG; E11A EWG; E19 EWG; E20 EWG; M2 EWG; M7(R2) Maint. EWG/IWG; M10 EWG; M11 EWG; M12

EWG; M13 informal WG; Q2(R2)/Q14 EWG; Q3E informal WG; Q5A(R2) EWG; Q9(R1) informal WG; Q12 IWG; Q13 EWG; S1(R1) EWG; S12 EWG; QDG.

- WGs not requesting to meet face-to-face: Standing Paediatric EWG; E2B(R3) EWG/IWG; E9(R1) EWG; E14/S7B IWG; M1 PtC WG; M4Q(R1) IWG; M8 EWG/IWG; Q3C(R8) Maint. EWG; Q3D(R2) Maint. EWG; S5(R3) EWG; S11 EWG; GDG; PEpiDG.

- The MC supported that at the MC Policy 1 TC on 30 July, the MC would review the WGs requesting to meet taking into consideration criteria for prioritising the WGs' need to meet, and which would include how close the WGs are to finalising Steps/Work Products.

4.1. Items for MC decision related to WGs requesting to meet

The following section relates to WGs that had requested to meet in Athens in November 2020 and which had additional items for MC decision beyond a request to approve a face-to-face meeting in Athens, which as per item #1 above was agreed to be postponed until the Policy 1 TC on 30 July 2020.

4.1.1. M11 EWG: Clinical electronic Structured Harmonized Protocol (CeSHarP) (Rapporteur: Ms. Combs – PhRMA; Regulatory Chair: Dr. Fitzmartin – FDA, United States)

M11 EWG written Status Report:

The M11 EWG continues its work on the development of the M11 draft Technical Document, the clinical protocol template and the Technical Specification document; as well as on the strategic engagement with other key WGs (such as the E9(R1) EWG regarding statistical elements, and M2 EWG regarding data modelling elements).

Steps 1 and 2a/b on the Guideline, Template, Basis of Requirements, and Technical Description are expected by September 2021.

Steps 1 and 2 on the Full Technical Specification for Electronic Exchange are expected by February 2022.

The Coordinator for PhRMA provided an update on the activities of the M11 EWG, in addition to the written status report, which included:

- An update regarding discussions between the Rapporteurs of the M11 EWG and the E9(R1) EWG about support needed for the M11 EWG on statistical elements;
- Interest expressed from the M11 EWG to use an alternative webconferencing tool to the one currently made available to WGs by the ICH Secretariat.

***ICH MC Actions/Decisions*:**

- This MC supported that experts from the E9(R1) EWG provide support to the M11 EWG, as needed, on statistical elements, until the E9(R1) would have finalised its activities and would be subsequently disbanded, further to which experts from the E20 EWG would provide support to the M11 EWG;
- The MC supported that the Coordinator for PhRMA liaise with the M11 EWG with a view to the group providing to the ICH Secretariat their considerations on different webconferencing tools, including, if possible, licensing aspects.

4.1.2. M13 informal WG/ EWG: Bioequivalence for Immediate-Release Solid Oral Dosage Forms (informal WG Lead/acting Rapporteur: Dr. Zhang - FDA, United States; Regulatory Chair: Dr. Welink – EC, Europe)

Further to Assembly approval of the M13 Concept Paper outline at the ICH meeting in November 2019, the M13 informal WG was established in February 2020 to develop a Concept Paper and Business Plan.

The MC noted that the M13 informal WG had finalized the M13 Concept Paper and Business Plan.

ICH MC Actions/Decisions:

- The MC approved the M13 Concept Paper and Business Plan, with a minor editorial amendment to the Business Plan, and the establishment of the M13 EWG;
- The MC noted that the membership of the M13 informal WG would be transferred to the EWG;
- Further to approving the M13 Concept Paper and Business Plan, the MC noted that the Assembly would subsequently be informed and invited to endorse acting Rapporteur as Rapporteur.

4.1.3. Q3E informal WG/EWG: Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics (informal WG Lead/acting Rapporteur: Mr. Kiehl - PhRMA; informal Regulatory Chair: Dr. Rodriguez – FDA, United States)

Further to Assembly approval of the Q3E Concept Paper Outline at the ICH meeting in November 2019, the Q3E informal WG was established in February 2020 to develop a Concept Paper and Business Plan.

The MC noted that the Q3E informal WG has finalized its work on the development of the Q3E Concept Paper and Business Plan.

ICH MC Actions/Decisions:

- The MC approved the Q3E Concept Paper and Business Plan and the establishment of the Q3E EWG;
- The MC noted that the membership of the Q3E informal WG would be transferred to the EWG;
- The MC noted that PhRMA would submit to the ICH Secretariat the nominee for the role of Q3E Rapporteur, and that subsequently the Assembly would be invited to endorse PhRMA's nomination.

4.2. <u>WGs which have not requested to meet in Athens</u>

The following section relates to the WGs that have not requested to meet in Athens in November 2020.

ICH MC Action/Decision:

- The MC noted the written status reports for the WGs not requesting to meet (provided below), as well as items for the MC's consideration regarding the following WGs: E14/S7B (item # 4.2.3); M4Q(R1) (item # 4.2.); M11 (item 4.2.8) and S5(R3) (item #4.2.11).

4.2.1. Standing Paediatric EWG (Rapporteur: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Yao – FDA, United States)

<u>Standing Paediatric EWG written Status Report:</u>

The group remains available for expert consultation and guidance to WGs charged with developing new or revised guidance which may be of relevance to paediatric drug development.

The Standing Paediatric EWG did not receive any request for paediatric advice from WGs and the group remains available for expert consultation and guidance to WGs charged with developing new or revised guidance which may be of relevance to paediatric drug development.

4.2.2. 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)

<u>E2B(R3) EWG/IWG written Status Report:</u>

The E2B(R3) EWG/IWG continues its work, including on the development of the Modules II and III training materials.

Additionally, further to a discrepancy noted in the ICSR BFC Specification document, the WG is working to correct the document.

Steps 3 and 4 of the revision of the EDQM User Guide incorporating the mapping table for RoA between ICH and EDQM terms is expected to be finalised by July 2020.

Training Material Module II is expected to be finalised by the second half of 2020.

The voice-over presentation for Training Material Module I is expected to be finalised by September 2020.

Training Material Module III is expected to be finalised by September 2020.

4.2.3. E9(R1) EWG: Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses (Rapporteur: Dr. Petavy – EC, Europe; Regulatory Chair: Dr. Ando – MHLW/PMDA, Japan)

E9(R1) EWG written Status Report:

Steps 3 and 4 were reached at the ICH meeting in Singapore, and the E9(R1) EWG is working on the development of training materials and video.

The E9(R1) EWG continues to work on the development of training materials.

The E9(R1) training slide decks are expected to be finalised in the second half of 2020.

4.2.4. 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: TBC)

E14/S7B IWG written Status Report:

The E14/S7B IWG continues its work regarding the Q&A document and the Integrated Risk Assessment for E14/S7B.

The Technical Coordinator for FDA, United States presented the E14/S7B IWG's proposal to hold a virtual public meeting in October 2020 on the first stage of Q&A document.

***ICH MC Action/Decision*:**

- The MC approved the E14/S7B IWG's proposal to hold a virtual public meeting in October 2020. As a result, the E14/S7B Q&A document will be published on the ICH website following *Step 2* sign-off, and the public consultations organised by each ICH Regulatory Member would be left open until after the completion of the E14/S7B virtual public meeting. The ICH Secretariat will inform the Assembly when initiating *Step 2a/b*.

Step 1 and 2 a/b of the first stage of Q&As are expected by July 2020.

4.2.5. M1 PtC WG: MedDRA Points to Consider (Rapporteur: Dr. Winter – EFPIA; Regulatory Chair: Dr. Brajovic – FDA, United States)

M1 PtC WG written Status Report:

In October 2019, the ICH MC and Assembly approved the translations in Chinese, Korean, and Spanish (in addition to English and Japanese) of the Points to Consider (PtC) documents; and a change in frequency for the release of the PtC documents from twice to once a year effective March 2020.

The M1 PtC WG continues its work on the update of the Points to Consider documents and on the revision of the Companion document, which is expected to be finalised by July 2020.

Release of second edition of the 'Companion document', is expected in July 2020.

Release of Chinese, Korean, and Spanish translations of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (based on MedDRA Version 23.0) is expected in October 2020.

4.2.6. M4Q(R1) IWG: (CTD-Quality) IWG: Addressing CTD-Q-Related Questions (Rapporteur: Dr. Schmuff – FDA, United States)

At the Virtual meeting on Wednesday, 27 May 2020, the Assembly endorsed the proposal "Revision of M4Q(R1) CTD on Quality guidance", with an informal WG to be established in the November 2020 timeframe after the Q13 draft Guideline has reached Step 2a/b. Furthermore, a Concept Paper outline will be provided for Assembly endorsement by November 2020.

M4Q(R1) IWG written Status Report:

No questions were so far received following the implementation of the revised M4 Granularity Document which would need to be addressed by the M4Q(R1) IWG, and the M4Q(R1) IWG therefore remains in a dormant state.

The Technical Coordinator for FDA, United States presented to the MC the views of FDA, United States, as the Member holding the M4Q (R1) Rapporteurship, on how best to establish the new M4Q(R2) informal WG, pending the Q13 draft Guideline reaching *Steps 2 a/b*, in view of the existing IWG and whether the expertise needed for the new WG would be the same.

***ICH MC Action/Decision*:**

- The MC supported that further to the Q13 draft Guideline reaching *Step 2a/b*, and the Assembly endorsing the M4Q(R2) Concept Paper outline, the ICH Secretariat would launch a Call for Expression of Interest to nominate experts to the M4Q(R2) informal WG, at which time Members with experts on the existing M4Q(R1) IWG would be invited to inform the ICH Secretariat on whether they would transition their experts to the new M4Q(R2) informal WG. Furthermore, as a result of this decision, when launching the Call for Expression of Interest to nominate experts to the M4Q(R2) informal WG, the ICH Secretariat will:
    - invite FDA, United States, as proposing party for this new topic, to nominate the M4Q(R2) informal WG Lead;
    - launch a Call for Expression of Interest to nominate the M4Q(R2) informal Regulatory Chair;
    - confirm whether the M4Q(R1) IWG will then be disbanded.

4.2.7. M8 EWG/IWG: The Electronic Common Technical Document (eCTD) (Rapporteur: Mr. Gray – FDA, United States; Regulatory Chair: Ms. Puusaari – EC, Europe)

M8 EWG/IWG written Status Report:

The M8 EWG/IWG continue its work to monitor the status of implementation of eCTD v4.0.

If Change Requests are received, Steps 3 and 4 are expected in November 2020 on the eCTD v3.2.2 Q&As and the Specification Change Request Document v1.32, and/or the eCTD v4.0 Q&As and Specification Change Request Document v1.4.

4.2.8. Q3C(R8) Maintenance EWG: Maintenance of the Guideline for Residual Solvents (Rapporteur: Dr. McGovern – FDA, United States)

Q3C(R8) Maintenance EWG written Status Report:

The Q3C(R6) Guideline was published in October 2019 on the ICH website, effectively reinstating the PDE for ethyleneglycol to 6.2 mg/day (620 ppm), along with a cover statement to explain the reason for the

reversion. Furthermore, the revised monograph for the PDE of ethyleneglycol was published on the ICH website in January 2020 as part of Support Document #2.

Step 2b on the Permitted Daily Exposure (PDE) levels for the solvents 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol was reached in March 2020, and the new PDEs were published for public consultation in the ICH regulatory regions.

Steps 3 and 4 are expected by second half of 2020.

4.2.9. Q3D(R2) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities (Rapporteur: Dr. Hirose – MHLW/PMDA, Japan)

Q3D(R2) Maintenance EWG written Status Report:

The Q3D(R2) Maintenance EWG has finalised the draft Addendum on cutaneous and transdermal routes of administration and correction of the PDEs of Gold (all routes), Silver (parenteral) and Nickel (inhalation).

Steps 1 and 2a/b of the Q3D(R2) are expected to be reached in July 2020.

4.2.10. S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals (Rapporteur: Dr. Waxenecker – EC, Europe)

S5(R3) EWG written Status Report:

Steps 3 and 4 for the S5(R3) Guideline were reached electronically in February 2020.

The S5(R3) EWG finalised the *Step 4* training presentation which was published on the ICH website.

As per the maintenance process endorsed in March 2019, the S5(R4) Maintenance EWG will stay in a dormant state until 1 year after Step 4, i.e. Q1 2021.

The Coordinator for EC, Europe presented to the MC the S5(R3) EWG's proposal for the establishment of the S5(R4) Maintenance EWG.

***ICH MC Action/Decision*:**

- This MC supported that the membership of the S5(R3) EWG be directly transferred to the S5(R4) Maintenance EWG.

4.2.11. S11 EWG: Nonclinical Safety Testing in Support of Development of Paediatric Medicines (Rapporteur: Dr. Brown – FDA, United States; Regulatory Chair: Dr. van der Laan – EC, Europe)

S11 EWG written Status Report:

The S11 draft Guideline reached Step 4 in April 2020.

The S11 EWG continues its work on the finalisation of the S11 Training Materials.

The S11 Training Materials are expected by June 2020.

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

GDG written Status Report:

At the MC TC on 25 May 2020, the MC supported that the term of the GDG be extended by up to one year, with a view to disbanding the group earlier if they would finalise its activities sooner, and with the frequency of its TCs to be reduced.

The GDG is working on updating their Work Plan, and on further scoping of identified topics for potential future harmonisation and to build consensus on their sequencing and timing for any topics identified.

The Technical Coordinator for FDA, United States informed the MC of a question raised by the Rapporteur regarding any ICH policy on the development of publications following a suggestion raised within the GDG.

***ICH MC Action/Decision*:**

- The MC agreed that development of a publication for a journal was outside of the remit of the GDG and may best be an activity undertaken as a non-ICH activity by those experts interested, since it would be difficult to undertake this as a GDG activity.

4.2.13. Pharmacoepidemiology Discussion Group (PEpiDG) (Rapporteur: Dr. Uyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Ball – FDA, United States)

PEpiDG written Status Report:

The PEpiDG continues its work on the prioritisation of proposed topics based on feasibility, needs and importance for harmonisation.

The list of potentially harmonisable areas in ICH is expected by June 2020.

The MC approved the PEpiDG to operate for a 2-year term. The PEpiDG is expected to have completed its work by early 2022.

5. ESTABLISHMENT OF THE MIDD DG

At the Assembly Virtual Meeting on 27 May 2020, the Assembly supported in principle the New Topic proposals on "General Considerations for Model-Informed Drug Development (MIDD) to support Drug Registration and on ICH E4 on Dose Response Information to Support Drug Registration" and approved as a first step the establishment of a Discussion Group (DG) on MIDD. Further to this, a call for expression of interest to nominate experts was launched by the ICH Secretariat with a deadline of 8 July.

The MC noted a challenge for FDA, United States to immediately appoint experts to the MIDD DG in view of other priorities and its request to delay the start of MIDD DG work.

***ICH MC Actions/Decisions*:**

- This MC supported postponing the start of MIDD DG work until January 2021;
- To enable the MIDD DG to begin work without delay in January 2021, the MC supported continuing with the Call for Expression of Interest to nominate experts to the MIDD DG, but with the deadline to be extended to 18 September 2020. Further to this decision, the ICH Secretariat would also finalise the Call for Expression of Interest/appointment of the MIDD Regulatory Chair.
- Furthermore, as a result of the MC's decisions, the ICH Secretariat will inform the Assembly of the delayed start of the MIDD DG and the extension of the call for expression of interest to nominate experts.

6. Q4B ANNEXES

The ICH Secretariat informed the MC on the feedback from the Pharmacopeial Discussion Group (PDG) regarding the timeline for providing an overview of the 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.

***ICH MC Action/Decision*:**

- This MC noted that the PDG would provide further feedback regarding the Q4B Annex mapping exercise to the MC by the time of the ICH meeting in November 2020.

7. MEMBER/OBSERVER REQUESTS TO NOMINATE EXPERTS TO WGS

7.1. MEMBER REQUESTS TO NOMINATE EXPERTS TO WGS

The ICH Secretariat updated the MC on the Member expert nomination request received.

***ICH MC Action/Decision*:**

- This MC supported that PhRMA be provided with up to 2 seats on PEpiDG.

7.2. OBSERVER REQUESTS TO NOMINATE EXPERTS TO WGS

The ICH Secretariat updated the MC on the Observer expert nomination requests received.

***ICH MC Actions/Decisions*:**

- The MC supported the request from APIC to appoint an expert on the Q3E informal WG;
- The MC supported the request from EDQM to appoint an expert on the Q5A(R2) EWG.

8. ESTABLISHMENT OF PLENARY WORKING PARTIES

***ICH MC Action/Decision*:**

- The MC noted the overview table (below) of WGs with Plenary Working Parties (PWPs).

WG	Member/Observer	Timeline for next *Steps 1* or *Steps 3*	PWP next step
E20	CPED, Israel	*Step 1 by November 2021*	*To be involved prior to Step 1 sign-off*
E2D(R1)	Health Canada, Canada	*Step 1 by November 2021*	
E6(R3)	CPED, Israel	*Step 1 by January 2022*	
	SFDA, Saudi Arabia		
M12	Health Canada, Canada	*Step 1 by November 2021*	
	SFDA, Saudi Arabia		
Q3E	Swissmedic, Switzerland	TBD	
	Health Canada, Canada		
Q5A	CPED, Israel	*Step 1 by November 2021*	
Q9(R1)	Health Canada, Canada	TBD	
S12	SFDA, Saudi Arabia	*Step 1 by May 2021*	

9. DATES OF NEXT TELECONFERENCES AND ICH FACE TO FACE MEETINGS

Teleconferences

- 30 July 2020 ICH MC Policy 1
- 23 September 2020 ICH MC Policy 2
- 19 October 2020 ICH MC Policy 3

Face-to-Face Meetings

- 14 - 18 November 2020 in Athens, Greece (with ICH 30th Anniversary event on Saturday 14 November 2020);

- 15 - 16 March 2021, MC Interim meeting in Brussels, Belgium
- 29 May - 2 June 2021 in Incheon, Republic of Korea (final confirmation pending);
- 13 - 17 November 2021 in Vancouver, Canada (final confirmation pending);
- 21 – 25 May 2022 or 11 –15 June 2022 in Europe (location & dates to be confirmed);
- 12 –16 November 2022 in Asia (location to be confirmed)