ICH2017/04F

To:
ICH Assembly

September 1, 2017

FINAL MINUTES
ICH Assembly
May 31 & June 1, 2017, Montreal, Canada

Please find hereafter the final minutes of the Assembly meeting held in Montreal, Canada on May 31 & June 1, 2017.

List of Assembly Participants

ICH Assembly Members

Ms. Lenita Lindström-Gommers	Chair
Dr. Toshiyoshi Tominaga	Vice-Chair
Ms. Tatiana Cambraia Sá Lowande	ANVISA, Brazil
Ms. Bianca Zimon Giacomini Ribeiro	ANVISA, Brazil
Ms. Lila Feisee	BIO
Ms. Kay Holcomb	BIO
Mr. Yuan Lin[1]	CFDA, China
Mr. Wang Xiangyu[1]	CFDA, China
Mr. Georgios Balkamos	EC, Europe
Dr. Tomas Salmonson	EC, Europe
Dr. Spiros Vamvakas	EC, Europe
Mr. Pär Tellner	EFPIA
Ms. Joan Wilmarth Blair	FDA, US
Dr. Theresa Mullin	FDA, US
Dr. Celia Lourenco	Health Canada, Canada
Ms. Catherine Parker	Health Canada, Canada
Dr. Nicholas Cappuccino	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Sun Hee Lee	MFDS, Republic of Korea
Dr. Won Sik Lee	MFDS, Republic of Korea
Dr. Nobumasa Nakashima	MHLW, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Peter K. Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland
Ms. Cordula Landgraf	Swissmedic, Switzerland
Ms. Christelle Anquez-Traxler	WSMI
Ms. Kristin Willemsen	WSMI

ICH Assembly Standing Observers:

Dr. David Jefferys	IFPMA
Mr. Michael Ward	WHO

ICH Assembly Observers:

Dr. Eun Hee Kim	APEC
Mrs. Marieke van Dalen	APIC
Ms. Charunee Krisanaphan	ASEAN
Dr. Celeste Sánchez González	CECMED, Cuba
Dr. Lembit Rägo	CIOMS
Dr. Mario Alanìs Garza	COFEPRIS, Mexico
Ms. Donna Kusemererwa	EAC
Ms. Jane Mashingia	EAC
Dr. Susanne Keitel	EDQM
Mr. Thamer A. Alsubi	GHC

[1] At the Assembly meeting in Montreal under Agenda 3, CFDA, China was welcomed as new ICH Member.

Dr. Hajed M. Hashan	GHC
Ms. Chua Siew Wei	HSA, Singapore
Ms. Janeen Skutnik Wilkinson	IPEC
Dr. Jeanette Lotter	MCC, South Africa
Mr. Tohlang Sehloho	MCC, South Africa
Ms. Sabina Chukumova	National Center, Kazakhstan
Ms. Aliya Kessikova	National Center, Kazakhstan
Dr. Charles Preston	PANDRH
Ms. Fortunate Bhembe	SADC
Dr. Jo-Feng Chi	TFDA, Chinese Taipei
Dr. Churn-Shiouh Gau	TFDA, Chinese Taipei
Dr. Michael Harding	TGA, Australia
Dr. Ian Sharpe	TGA, Australia
Dr. Kevin Moore	USP
Dr. Tina S. Morris	USP

ICH Coordinators:

Ms. Ana Carolina Marino Moreira Araujo	ANVISA, Brazil
Ms. Lila Feisee	BIO
Mr. Georgios Balkamos	EC, Europe
Mr. Pär Tellner	EFPIA
Ms. Amanda Roache	FDA, US
Mr. Nick Orphanos	Health Canada, Canada
Dr. Shinichro Hirose	IGBA
Mr. Mitsuo Mihara	JPMA
Ms. Pan soon Kim	MFDS, Republic of Korea
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
Ms. Camille Jackson	PhRMA
Ms. Christelle Anquez-Traxler	WSMI

ICH Technical Coordinators:

Mr. Milton Bonelli	EC, Europe
Dr. Michelle Limoli	FDA, US
Ms. Chieko Hirose	MHLW/PMDA, Japan

Others:

Dr. Wassim Nashabeh	BIO
Ms. Liu Yuan	CFDA, China
Mr. Martin Harvey Allchurch	EC, Europe
Mr. Faraz Kermani	EFPIA
Mr. Stephan Rönninger	EFPIA
Ms. Pujita Vaidya	FDA, US
Ms. Machiko Sumi	JPMA
Ms. Erina Yamada	JPMA
Ms. Eunkyoung Lee	MFDS, Republic of Korea
Ms. Hanvit Yu	MFDS, Republic of Korea
Mr. Yoshihiro Katsura	MHLW/PMDA, Japan
Ms. Hsiao-Han Chiang	TFDA, Chinese Taipei
Dr. Gabriela Zenhäusern	WHO

ICH Secretariat
Dr. Isabelle Güller
Dr. Véronique Kuntzelmann
Dr. Anne Latrive
Dr. Dawn Ronan

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Opening Discussions

The ICH Assembly meeting in Montreal, Canada held on May 31 - June 1, 2017 was chaired by Mrs. Lindström-Gommers (Chair, EC, Europe) and Dr. Tominaga (Vice-Chair, MHLW/PMDA, Japan).

Adoption of the Agenda

The agenda was adopted without modification.

1. 2016 Annual Report of the Association

The ICH Secretariat presented to the Assembly the ICH 2016 Annual Report on the activities of the Association which covered the activities undertaken by the ICH Management Committee (MC), the MedDRA MC and the ICH Secretariat on behalf of the Association.

Decisions/Actions:

- *The ICH Secretariat will ensure that the hyperlinks within the Annual report match the appropriate versions of the cited documents at that time, and therefore will create an archive section on the ICH website to store previous versions of the procedural documents;*
- *The Assembly approved the 2016 Annual Report on the activities of the Association;*
- *The Annual Report will be published on the ICH website;*
- *Based on the Annual Report, the Assembly also granted discharge to the ICH MC, the MedDRA MC and the ICH Secretariat for the activities undertaken by these bodies in 2016.*

2. Procedural Matters

ICH Articles of Association

The Chair informed the Assembly on several amendments proposed to the ICH Articles of Association which were last updated and approved by the Assembly at the Osaka meeting in November 2016. The changes proposed were aimed at managing the expansion of ICH Membership and Observership while maintaining the efficiency of ICH's harmonisation activities. Amendments made included: revisions to the criteria for an international organisation to become a Member; limiting the number of Observer delegates to Assembly meetings; and revision to the term in office for an Elected MC Representative.

Decisions/Actions:

- *The Assembly approved the proposed changes to the ICH Articles of Association;*
- *The revised ICH Articles of Association will be published on the ICH website.*

Assembly Rules of Procedure

The Assembly was informed on the amendments proposed to the Assembly Rules of Procedure (RoP) which were last updated and approved by the Assembly in November 2016. The Assembly noted that the latest amendments were made to reflect the changes made to the ICH Articles of Association, as well as for clarification and consistency. These changes included: revisions to the criteria for an international organisation to become a Member; changes related to managing the size of delegations to ICH meetings; addition of text regarding ICH Member and Observer names; clarifications regarding the Assembly Chair and Vice Chair role; and adjustment of procedures related to minutes and press releases.

Decisions/Actions:

- *The Assembly approved the proposed changes to the Assembly RoP;*
- *The Revised Assembly RoP will be published on the ICH website.*

Standard Operating Procedures for EWGs/IWGs

The ICH MC presented to the Assembly the v3.0 of the SoP for Working Groups (WGs) approved by the ICH MC in Montreal which includes several procedural clarifications from v2.0 on the attendance of support staff to face to face meetings, sign-off procedures, and the maintenance procedure. Additionally, v3.0 includes provisions to clarify the relevant expertise of prospective WG experts, a procedure for appointing experts to WGs, appointment of *Ad-hoc* Observers to WGs, and a policy on the publication of papers or presentations related to the work of an ICH WG.

WSMI recommended that when an Expert Working Group (EWG) size becomes too big (> 25 experts) the rules of 2 experts/ WG member is strictly observed. If the resulting number is still high, the number of experts per new Member may be limited to one so as to allow more new Members to participate. The chair agreed to take this suggestion into account in the next revision of the SOP.

Decisions/Actions:

- *The Assembly noted the proposed changes to the SOPs v2.0 for WGs and that the ICH MC approved the SOPs v3.0 for WGs at its meeting in Montreal, on May 29, 2017;*
- *The SOPs v3.0 for WGs will be published on the ICH website.*

MC Rules of Procedure

The ICH MC presented to the Assembly the amendments proposed to the MC RoP which were last updated and approved by the MC in November 2016. The latest amendments included changes proposed for consistency with the revisions to the Articles of Association and the Assembly RoP, such as the revision to the term in office for an Elected MC Representative, as well as other changes including the adjustment of procedures related to minutes and summary reports, and the addition of further clarification on the use of the ICH logo.

Decisions/Actions:

- *The Assembly noted some amendments to the MC RoP were adopted by the ICH MC at its meeting in Montreal, Canada on May 29, 2017;*
- *The Assembly noted that the updated MC RoP will be published on the ICH website.*

MedDRA MC Rules of Procedure

Decisions/Actions:

- *The Assembly noted that some minor amendments to the MedDRA MC RoP were adopted by the MedDRA MC at its meeting in Montreal, Canada on May 27, 2017;*
- *The Assembly noted that the updated MedDRA MC RoP will be published on the ICH website.*

IFPMA Role

The IFPMA delegate presented to the Assembly an overview of its engagement in ICH and a process to facilitate the participation of IFPMA National Association experts in WGs.

Decision/Action:

- *The Assembly welcomed the IFPMA proposal on expert appointment in the WGs. An update on the progress of this new process will be provided during the November 2017 meeting in Geneva, Switzerland.*

3. Membership and Observership

The ICH MC presented to the Assembly an overview of applications for Membership/Observership processed since the Osaka meeting in November 2016 and its recommendation on these applications.

Decisions/Actions:

ICH Membership Applications

- *The Assembly approved the following Membership application:*
    - *CFDA, China*
- *The Assembly did not approve the Membership application from the following organisation:*
    - *BPTF;*

ICH Observership Applications

- *The Assembly approved the following Observership application:*
    - *PIC/S;*
- *The Assembly did not approve the Observership applications from the following organisations:*
    - *BPTF;*
    - *AAPS;*
    - *AAHRPP;*
    - *HPCUS;*
    - *SINDUSFARMA.*

4. Financial Matters

The ICH MC updated the Assembly on ICH financial matters including; 2016 Financial Audit; 2016 costs; 2018 ICH budget; multi-year budget planning; cash flow; and development of a proposal for a participation fee for non-membership fee paying ICH meeting participants.

Decisions/Actions:

- *The Assembly agreed that the ICH Secretariat will provide support services to the International Pharmaceutical Regulators Forum ('IPRF') activities as of January 2018. Support to IPRF activities will be conducted and financed separately from support to ICH activities;*
- *The Assembly approved the 2016 Closing ICH Financial Statements;*
- *The Assembly approved the 2016 Audited Accounts of the ICH Association;*

- *The Assembly approved the 2018 ICH Budget and the publication of a short version of this on the ICH website.*

5. New ICH Topic Proposals & Strategic Discussions

New Topic Proposals

The ICH MC presented to the Assembly for its consideration and approval its recommendation to adopt the following 2 new topics: *Revision of E8 on General Considerations for Clinical Trials* and *Paediatric Extrapolation.*

Decisions/Actions:

- *The Assembly endorsed the two topics recommended for harmonisation including the Revision of E8 on General Considerations for Clinical Trials and Paediatric Extrapolation.*
- *The Assembly noted the Concept Paper outlines for the following 2 new ICH topics which were recommended by the MC to the Assembly for its approval:*
  - *Revision of E8 on General Considerations for Clinical Trials (proposed by FDA, US)*
  - *Paediatric Extrapolation (proposed by FDA, US)*
- *The Assembly adopted the Concept Paper outline on Revision of General Considerations for Clinical Trials (code: ICH E8(R1)) and agreed on the establishment of an informal WG (with FDA, US nominated as Lead) to finalise the Concept Paper and develop a Business Plan ahead of the MC Teleconference to be held in September 2017;*
- *The Assembly adopted the Concept Paper outline on Paediatric Extrapolation (ICH code to be confirmed) and agreed on the establishment of an informal Working Group (with FDA, US nominated as Lead) to finalise the Concept Paper and develop a Business Plan ahead of the MC Teleconference to be held in September 2017;*
- *The ICH Secretariat will launch the nomination process amongst ICH Members for the establishment of the 2 informal WGs;*
- *ICH Members and ICH Observers interested to participate in the activities of these new WGs were invited to consult the applicable RoP and SOPs regarding the nomination process for the different categories of Members and for Observers;*
- *The Assembly supported FDA, US as the future Rapporteur for the ICH E8(R1) EWG and also for the second group (ICH code to be confirmed) once established;*
- *The Founding Regulatory Members and the Standing Regulatory Members will confirm the need for respective Regulatory Chairmanship for these 2 new EWGs once established;*
- *The Assembly noted plans to refine the New Topic proposal process and that the MC would in future aim to send the Assembly all proposals submitted, not only those being recommended (1 month ahead of the ICH meeting), and to be followed no later than 2 weeks before the next ICH Meeting with the MC's considerations with respect to the prioritisation of each topic and justification of the MC's considerations.*

Strategic Discussions

The ICH MC updated the Assembly on: the status of work by a feasibility group set-up after the November 2016 meeting to further consider the topic *Compliance of Reliability for Electronic Records;* the response received from the public consultation on the *GCP Renovation* Reflection Paper; work to develop a Quality Reflection Paper; and general considerations regarding progression of strategic topics.

Decisions/Actions:

- *The Assembly noted that the Feasibility Group on the topic Compliance of Reliability for Electronic Records will be closed;*
- *The Assembly noted the comments received from the public consultation on the GCP Renovation Reflection Paper and supported the next steps;*
- *The Assembly noted the ongoing MC work on the development of a Quality Strategic Reflection Paper and plans for development of further Reflection Papers on strategic topics including vaccines and generic medicines as a possibility for discussions. The status of these strategic topics will be informed to the Assembly at its next meeting in Geneva, with any finalised Reflection Papers to be shared ahead of the meeting.*

6. Communication

Communication Activities

The ICH MC provided an update to the Assembly on current communication activities including development of a transparency policy and stakeholder engagement plan, as well as recent updates to the ICH website.

Decisions/Actions:

- *The Assembly approved the one-year Communication and Stakeholder engagement plan for 2017-2018, including website improvement plan;*
- *The Assembly supported the ongoing work of the Communications Subcommittee and the ICH Secretariat;*
- *The Assembly noted that the Communication Subcommittee may ask some EWGs to identify stakeholders for specific ICH Guidelines and to contribute to special communication packages;*
- *The Assembly agreed to publication of a set of Q&As on transparency on the ICH website;*
- *The Assembly agreed to the publication on the ICH website of new documents not currently shared with stakeholders;*
- *The Assembly supported publication on the ICH website of photographs and short biographies of Assembly and MC Member Representatives and Observer delegates along with their names (already published) on the ICH public website;*
- *The Assembly supported publication on the ICH public website of the names of the Regulatory Chairs and Rapporteurs (including nominating party, name of representative and role) for all active EWGs/IWGs, effective immediately, and noted that the MC planned further discussion as a second step of options including publication of the names of experts from new EWG/IWGs or from all active EWGs/IWGs.*[2]

[2] **Post-meeting note**: Following the Montreal meeting, the MC agreed to the publication on the ICH website of the names of all experts of EWGs/IWGs along with a disclaimer to clarify that Expert Working Groups members are appointed by their nominating ICH Member or Observer party and are responsible for representing the views of that party, which may not necessarily reflect their personal views.

ICH Regional Public Meetings

The Assembly was invited to share information on any ICH Regional Public Meetings in their respective regions prior to/following the ICH meeting in Montreal.

The Assembly noted the organisation of a joint FDA, US/Health Canada, Canada public meeting held in Silver Spring, MD, US on April, 24 2017, to which participants were also able to participate by webcast. Health Canada, Canada will be hosting the next one in October 2017. Additionally, FDA, US will be co-chairing a session on ICH with PhRMA at the upcoming DIA meeting on June 21, 2017 in Chicago, IL, US.

The Assembly noted the organisation by MHLW/PMDA, Japan and JPMA of a regional public meeting to be held on June 30, 2017.

The Assembly also noted the organisation of an ICH information day by ANVISA, Brazil in May 2017 and the initiative to organise a regional public meeting one month ahead of each ICH meeting.

Decision/Action:

- *The Assembly agreed to keep the ICH Secretariat informed on the organisation of any ICH Regional Public Meetings for communication via the ICH website.*

7. Training

The ICH MC provided an update to the Assembly on the progress of the pilot supported in Osaka in November 2016 for the Training Subcommittee to partner with a small group of training providers.

Decisions/Actions:

- *The Assembly noted the Terms of Reference of the ICH 2017 Training Pilot which had been endorsed by the MC;*
- *The Assembly noted the progress of the pilot and that a further update would be provided at the next meeting in Geneva in November 2017.*

8. Update on MedDRA

The Assembly received a report on the ICH MedDRA Management Board/Management Committee (MB/MC) meeting held on May 27 – 28, 2017. The Assembly noted while the MedDRA MC had been established in April 2016, until MedDRA is transferred to the new ICH Association, the MedDRA MB will remain operational and the MedDRA MC will only have responsibilities for MedDRA issues which pertain to the new ICH Association.

The report covered the following matters: expansion of MedDRA use; training; cooperation effort with WHO; tools to facilitate MedDRA's use; and development of Standardised MedDRA Queries (SMQs) including status of SMQ development and collaboration with CIOMS.

The Assembly was updated on the continued growth of MedDRA subscribers throughout the world, with currently over 5,000 organisations in 103 countries, reflecting the successful adoption of MedDRA as a worldwide standard in the protection of public health. The Assembly noted the importance of training in helping to facilitate the use of MedDRA and that the MSSO provides free training to Regulators and other MedDRA users as part of their MedDRA subscription package, with training available in several forms: face-to-face training; webinars; and e-learning tools/videocasts. The Assembly heard that in 2016 the MSSO provided free training to almost 4,500 people which included 715 Regulators from the following countries: Canada, Czech Republic, France, Germany, Mexico, Republic of Serbia, the Netherlands, the United Kingdom, and the United States. It was noted that a similar scale

of training is planned for 2017, with all training offerings advertised on the website www.meddra.org, and including first-time training organised in Russia in June 2017.

The Assembly also noted the cooperating effort with the WHO and its Collaborating Centre Uppsala Monitoring Centre (UMC), which resulted in joint MSSO MedDRA and UMC WHODrug user group meetings in India (February 2017), in China (September 2017), and a MedDRA presentation scheduled at the 2017 WHO Annual Meeting of National Pharmacovigilance Centres (NPCs) in Uganda (November 2017).

The Assembly was informed of the release of a new Self-Service application in April 2017 which is a web-based application which allows users to obtain subscription information; add/delete/change point of contact; and change of password. The Assembly was also informed on the development of a Patient Friendly term list (~1,500 LLTs) that is going under pilot testing in the UK MHRA's Yellow Card application as a part of the WEB-RADR project, for future use in apps and web portals. The results will be presented to the MedDRA MB/MC at the 2017 November meeting.

The Assembly was also updated on ICH's work with CIOMS to develop Standardised MedDRA Queries (SMQs). In Montreal, the MedDRA MB acknowledged the significant contributions of the CIOMS SMQ Working Group and the development to-date of 101 SMQs, as well as one new SMQ on *Infective pneumonia* that will go into production in v20.1 on 1 September 2017.

Decision/Action:

- *The Assembly noted the decisions taken by the MedDRA Management Board/Management Committee.*

9. General Operational Matters

The ICH Secretariat updated the Assembly on general operational matters including: the status of transfer of assets of the former ICH (International Conference on Harmonisation) from IFPMA to the new ICH Association; considerations on future ICH meeting organisation in view of the expansion of ICH Membership and Observership; organisation of elections at the next Assembly meeting in Geneva, Switzerland in November 2017 for the election of the next Assembly Chair and Vice Chair, as well as the election of Elected MC Representatives.

Decisions/Actions:

- *The Assembly noted the status of the transfer of assets of the former ICH (International Conference on Harmonisation) from IFPMA to the new ICH Association which was expected to be completed shortly;*
- *ICH Assembly Members and Observers noted some ICH meeting logistical challenges associated with the expansion of ICH Membership and Observership, and acknowledged the need to more strictly adhere to the rules and procedures (i.e., in the Articles, RoPs & SOPs) on the numbers of Member Representatives and Observer delegates able to attend ICH Assembly, ICH Management Committee and Working Group meetings;*
- *The Assembly noted the organisation of elections at the next Assembly meeting in Geneva, Switzerland in November 2017 for the election of the next Assembly Chair and Vice Chair, as well as the election of Elected MC Representatives;*
- *The Assembly noted that nominations for Assembly Chair and Vice Chair may be submitted to the ICH Secretariat any time prior to the next ICH Assembly meeting in Geneva in November 2017, while nominations for Elected MC Representatives should be submitted no later than July 15, 2017 using the nomination forms available from the ICH Secretariat.*

10. Implementation of ICH Guidelines

The ICH Secretariat presented the table developed to facilitate monitoring by the Assembly of the status of ICH Guideline implementation by ICH Regulatory Members.

Decisions/Actions:

- *The Assembly noted the table developed by the ICH Secretariat to facilitate monitoring by the Assembly of the status of ICH Guideline implementation by ICH Regulatory Members and Observers;*
- *The Assembly noted that the standing Assembly agenda item on ICH Guideline implementation (which the table has been developed to support) should be used as an opportunity to discuss and share experiences related to guidelines which have been found challenging to implement;*
- *The Assembly supported further discussions at the Geneva meeting in November 2017 on ICH Guideline implementation, as well as on the presentation of implementation information within the table. The Assembly also noted that the ICH Secretariat was considering options for the maintenance and updating of the table.*

REPORTS ON CURRENT TOPICS

11. Status Report on Topics

At the start of the meeting in Montreal, the Assembly noted the current status of draft ICH Guidelines and predictions for progress towards *Step 2a/b* and *Step 4*. Updated information was provided during the Assembly meeting by the ICH Rapporteurs of the EWGs/IWGs meeting in Montreal.

Regarding requests from EWGs/IWGs to meet at the next ICH meeting in Geneva on November 11-16, 2017, the Assembly noted that any such requests would be taken under consideration by the MC and that a list of EWG/IWGs agreed by the MC to meet face-to-face in Geneva will be made available to the Assembly, and also on the ICH website, following the MC teleconference to be held in September 2017. It was also agreed that in order to facilitate logistics and organisation, confirmation of face to face meeting of EWGs/IWGs may occur sooner via mailing.

12. S1(R1) EWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline

The Rapporteur reported on the outcome of the S1(R1) EWG meeting held on May 29-June 1, 2017 and progress made towards the collection and review of confidential submissions of Carcinogenicity Assessment Documents (CADs) and summary report submissions by sponsors to Drug Regulatory Authorities (DRAs) within each region. So far, 40 CADs were received (36 were reviewed) including 17 aligned as Category 3, which makes the target of 20 aligned Category 3 CADs by December 2017 likely to be achieved.

The Assembly noted that the S1(R1) document is expected to reach *Step 1* and *Step 2a/b* in June or November 2018.

Decision/Action:

- *The Assembly endorsed the work plan of the S1(R1) EWG for activities to be undertaken.*

13. S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals

The Rapporteur reported to the Assembly on the outcome of the S5(R3) EWG meeting held on May 28-June 1, 2017 and progress made towards revising the S5(R2) Guideline with potential addition of a readily revisable appendix/annex.
The Assembly noted that the S5(R3) EWG was expecting to reach *Steps 1* and *2a/b* electronically in June 2017.

Decisions/Actions:

- *The Assembly noted that the Experts of S5(R3) EWG will proceed with an electronic sign-off under Step 1 of the Technical Document in June 2017;*
- *Thereafter the Assembly Members will be invited to endorse Step 2a of the Technical Document electronically;*
- *The Regulatory Members of the Assembly will be invited to endorse Step 2b of the Technical Document electronically;*
- *The Assembly endorsed the work plan of the S5(R3) EWG for activities to be undertaken.*

14. S11 EWG: Nonclinical Safety Testing in Support of Development of Paediatric Medicines

The Rapporteur reported to the Assembly on the outcome of the S11 EWG meeting held on May 29-June 1, 2017 and the progress made towards developing the S11 draft Technical Document by October 2017 to be shared with EWG Member constituencies for a one month period ahead of the November meeting.
The Assembly noted that the S11 EWG was expecting to reach *Steps 1* and *2a/b* by the November 2017 meeting.

Decisions/Actions:

- *The Assembly supported that the S11 EWG consults EWG Member constituencies on a preliminary draft by October 2017, with feedback received to be considered ahead of the Geneva meeting where the group aims to reach Steps 1 and 2 a/b;*
- *The Assembly endorsed the work plan of the S11 EWG for activities to be undertaken.*

15. Q11 IWG: Q&As on Selection and Justification of Starting Materials for the Manufacture of Drug Substances

The Rapporteur reported to the Assembly on the outcome of the Q11 IWG meeting held on May 29-June 1, 2017 and progress made to address comments received on the draft Q&As document during public consultation that ended in April 2017.
The Assembly noted that the Q11 IWG was expecting to reach *Steps 3* and *4* electronically in July 2017.

Decisions/Actions:

- *The Assembly noted that the Regulatory Experts of the Q11 IWG will sign-off electronically Step 3 of the Q&As in July 2017;*
- *Thereafter the Regulatory Members of the Assembly will be invited to adopt the Step 4 of the Q&As electronically.*
- *The Assembly endorsed the work plan of the Q11 IWG for activities to be undertaken.*

16. Q12 EWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

The Rapporteur reported to the Assembly on the outcome of the Q12 EWG meeting held on May 29-June 1, 2017 and progress made towards reaching *Step 1* of the Q12 Technical Document in Montreal.

The Assembly noted that the Technical Document still needed to go through EC, Europe legal review, and therefore the Members of the Assembly would decide on endorsing *Step 2a/2b* once the legal review is completed, by mid-September 2017.

Decisions/Actions:

- *The Q12 Experts signed-off Step 1 of the Q12 Technical Document;*
- *The Assembly endorsed the nomination of the new Rapporteur;*
- *The Assembly endorsed the work plan of the Q12 EWG for activities to be undertaken.*

17. E9(R1) EWG: Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses

The Rapporteur reported to the Assembly on the outcome of the E9(R1) EWG meeting held on May 29-June 1, 2017 and the progress made towards developing the E9(R1) draft Addendum.

The Assembly noted that the E9(R1) EWG was expecting to reach *Steps 1* and *2a/b* electronically in June 2017.

Decisions/Actions:

- *The Assembly noted that the Experts of E9(R1) EWG will proceed with an electronic sign-off under Step 1 of the Technical Document in June 2017;*
- *Thereafter the Assembly Members will be invited to endorse Step 2a of the Technical Document electronically;*
- *The Regulatory Members of the Assembly will be invited to endorse Step 2b of the Technical Document electronically;*
- *The Assembly noted that the MC supported the development of communication material;*
- *The Assembly endorsed the work plan of the E9(R1) EWG for activities to be undertaken.*

18. E11(R1) EWG: Addendum to Paediatric Drug Development

The Rapporteur reported to the Assembly on the outcome of the E11(R1) EWG meeting held on May 29-June 1, 2017 and the progress made towards developing the final Addendum and addressing the comments received during the regional public consultation completed in April 2017.

The Assembly noted that the E11(R1) EWG was expecting to reach the *Steps 3* and *4* by August 2017.

Decisions/Actions:

- *The Assembly noted that the Regulatory Experts of E11(R1) EWG will proceed with an electronic sign-off under Step 3 of the Addendum by July 2017;*
- *Thereafter the Regulatory Members of the Assembly will be invited to adopt Step 4 of the Addendum electronically;*
- *The Assembly endorsed the work plan of the E11(R1) EWG for activities to be undertaken.*

19. E17 EWG: Multi-Regional Clinical Trials

The Rapporteur reported to the Assembly on the outcome of the E17 EWG meeting held on May 29-June 1, 2017 and the progress made towards addressing the comments received from the regional public consultation completed in January 2017 and developing the final E17 Guideline.

The Assembly noted that the E17 EWG was expecting to reach the *Steps 3* and *4* during the Geneva meeting.

The Assembly noted that the E17 EWG was expecting to have 5 days or 6 days face to face meeting in Geneva in order to deal with a lot of comments and aim to reach *Step 4*.

Decision/Action:

- *The Assembly endorsed the work plan of the E17 EWG for activities to be undertaken.*

20. E19 Informal WG: Optimization of Safety Data Collection

The Rapporteur reported to the Assembly on the outcome of the first E19 informal WG meeting held on May 29-June 1, 2017 and the progress made towards finalising the Concept Paper and the Business Plan.

The Assembly noted that the E19 informal WG was expecting to reach the *Steps 1* and *2a/b* by November 2018.

Decisions/Actions:

- *The Assembly noted that the group will soon complete the Concept Paper and Business Plan for MC endorsement;*
- *After endorsement of the Concept Paper and the Business Plan, the E19 informal WG will be converted into E19 EWG;*
- *The ICH Secretariat will launch the nomination process amongst ICH Members for the establishment of the EWG;*
- *ICH Members and ICH Observers interested to participate in the activities of this new WG were invited to consult the applicable RoP and SOPs regarding the nomination process for the different categories of Members and for Observers;*
- *The Assembly supported FDA, US as the future Rapporteur for the ICH E19 EWG once established;*
- *The Founding Regulatory Members and the Standing Regulatory Members will confirm a Regulatory Chair for this new EWG once established;*
- *The E19 EWG will provide a work plan to the MC ahead of its teleconference to be held in September 2017 for activities to be undertaken.*

21. E2B(R3) EWG/IWG: Revision of the Electronic Submission of Individual Case Safety Reports

The Rapporteur reported to the Assembly on the E2B(R3) EWG/IWG meeting held on May 29-June 1, 2017 and the progress made towards developing the annexes to the Individual Case Safety report (ICSR) Implementation Guide (IG) on the use of European EDQM terminologies for Dose Form and Route of Administration, and UCUM lists, as well as the outcomes of discussion with the M2 EWG on the maintenance process for external terminologies.

Decisions/Actions:

- *The Assembly supported the group to nominate a terminology maintenance Point of Contact for dealing with future terminology maintenance issues;*
- *The E2B(R3) EWG/IWG Regulatory Experts signed-off Step 3 of the additional Q&As v2.1 in the Implementation Guide Package;*
- *The Regulatory Members of the Assembly adopted Step 4 of the additional Q&As v2.1 in the Implementation Guide Package;*
- *The E2B(R3) Experts signed-off the E2B Code List #26;*
- *The Assembly endorsed the E2B Code List #26;*
- *The Assembly noted that these documents will be published on the ESTRI website;*
- *The Assembly endorsed the work plan of the E2B EWG/IWG for activities to be undertaken.*

22. M2 EWG: Electronic Standards for the Transfer of Regulatory Information

The Rapporteur reported to the Assembly on the M2 EWG meeting held on May 29-June 1, 2017 and the progress made towards developing the ICH project opportunities proposal, defining the maintenance process for external terminologies and evaluating existing ICH topics for technical opportunities.

Decisions/Actions:

- *The Assembly noted the revision of the ICH-HL7 agreement;*
- *The Assembly noted that the group will soon complete a Redaction Points to Consider document for its endorsement electronically;*
- *The Assembly endorsed the work plan of the M2 EWG for activities to be undertaken.*

23. M9 EWG: Biopharmaceutics Classification System-based Biowaivers

The Rapporteur reported to the Assembly on the outcome of the M9 EWG meeting held on May 29-June 1, 2017 and the progress made towards developing the draft Technical Document.

The Assembly noted that the M9 EWG was expecting to reach *Steps 1* and *2a/b* by June 2018.

Decision/Action:

- *The Assembly endorsed the work plan of the M9 EWG for activities to be undertaken.*

24. M10 EWG: Bioanalytical Method Validation

The Rapporteur reported to the Assembly on the outcome of the M10 EWG meeting held on May 29-June 1, 2017 and the progress made towards developing the draft Technical Document.

The Assembly noted that the M10 EWG was expecting to reach *Steps 1* and *2a/b* by June 2018.

Decision/Action:

- *The Assembly endorsed the work plan of the M10 EWG for activities to be undertaken.*

25. EWGs/IWGs/Discussion Groups Not Meeting in Montreal

❖ *S3A IWG: Q&As on Note for Guidance on Toxicokinetics*

The S3A IWG did not meet in Montreal.

The Assembly was updated on the current activities of the S3A IWG and the progress made by the group to address comments on the draft S3A Q&As in the respective ICH regions.

Decision/Action:

- *The Assembly noted the progress made by the group to reach Steps 3 and 4 electronically by July 2017.*

❖ *S9 IWG: Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals*

The S9 IWG did not meet in Montreal.

The Assembly was updated on the current activities of the S9 IWG and the progress made towards developing the S9 draft Q&As.

The Assembly noted that the S9 IWG was expecting to reach *Steps 3* and *4* by November 2017.

Decision/Action:

- *The S9 IWG will provide a work plan to the MC ahead of its teleconference to be held in September 2017 for activities to be undertaken.*

❖ *M7(R1) Maintenance EWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk*

The M7(R1) Maintenance EWG did not meet in Montreal.

The Assembly was updated on the status of the finalisation of the draft M7(R1) Addendum and its sign-off at *Step 3 by* M7(R1) EWG Regulatory Experts.

Decisions/Actions:

- *The M7(R1) Regulatory Experts signed-off electronically Step 3 of the Addendum in May 2017, ahead of the Montreal meeting;*
- *The Regulatory Members of the Assembly adopted Step 4 of the Addendum;*
- *The Assembly noted the rotation to a new Regulatory Rapporteur in line with the SOP Annex #4 Maintenance Procedure prior to the next stage of work;*
- *The M7(R1) Maintenance EWG will provide a work plan to the MC ahead of its teleconference to be held in September 2017 for activities to be undertaken.*

❖ *Q3C(R7) Maintenance EWG: Maintenance of the Guideline for Residual Solvents*

The Q3C(R7) Maintenance EWG did not meet in Montreal.

The Assembly was updated on the group's recommendation on whether to undertake Q3C maintenance in relation to five new proposals received.

The Assembly noted that the Q3C(R7) Maintenance EWG was expecting to reach *Steps 1* and *2a/b* by November 2017.

Decisions/Actions:

- *The Assembly noted the MC recommendation on five new proposals received by the Q3C(R7) Maintenance EWG;*
- *The Assembly endorsed the MC recommendation to develop PDEs on the following three proposals: 2-methyltetrahydrofuran, cyclopentylmethylether, and tert-butanol, and not to pursue work on isopentane and trichloroethylene;*

- *The Assembly endorsed the work plan of the Q3C(R7) Maintenance EWG for activities to be undertaken by the EWG.*

❖ *Q3D(R1) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities*

The Q3D(R1) Maintenance EWG did not meet in Montreal.

The Assembly was updated on the development of Permitted Daily Exposures and permitted concentrations of elemental impurities for products administered by the cutaneous and transdermal route for all 24 elements included in the Q3D Guideline.

The Assembly noted that the Q3D(R1) Maintenance EWG was expecting to reach *Steps 1* and *2a/b* by May 2018.

Decisions/Actions:

- *The Assembly endorsed the nomination of the new Rapporteur;*
- *The Q3D(R1) Maintenance EWG will provide a work plan to the MC ahead of its teleconference to be held in September 2017 for activities to be undertaken.*

❖ *E14/S7B Discussion Group (DG): The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs*

The E14/S7B DG did not meet in Montreal.

The Assembly noted the current activities of the E14/S7B DG including its proposal to review advances in science and methods related to the clinical assessment of QT prolongation and to monitor the progress of the discussion of the Comprehensive In vitro Proarrythmia Assessment Initiative. The Assembly noted that the E14/S7B DG recommendation on whether to reopen the E14 Guideline for a complete revision was expected by early 2018.

Decisions/Actions:

- *The Assembly endorsed the nomination of the new Rapporteur;*
- *The E14/S7B Discussion Group will provide a work plan to the MC ahead of its teleconference to be held in September 2017 for activities to be undertaken.*

❖ *E18 EWG: Genomic Sampling and Management of Genomic Data*

The E18 EWG did not meet in Montreal.

The Assembly noted the current activities of the E18 EWG, including progress made towards finalising the E18 Guideline and reaching *Steps 3* and *4* by June 2017.

Decisions/Actions:

- *The Assembly endorsed the nomination of the new Rapporteur;*
- *The Assembly noted that the Regulatory Experts of the E18 EWG will sign-off electronically Step 3 of the Guideline in June 2017;*
- *Thereafter the Regulatory Members of the Assembly will be invited to adopt the Step 4 of the Guideline electronically.*

❖ *M1 PtC WG: MedDRA Points to Consider*

The M1 PtC WG did not meet in Montreal.

The Assembly noted the current activities of the M1 PtC WG including the updating with each MedDRA release of the two PtC documents on Term Selection and Data Retrieval and Presentation, as well as the development of a companion document to the PtC Documents.

Decisions/Actions:

- *The Assembly endorsed the nomination of the new Rapporteur;*

- *The M1 PtC WG will provide a work plan to the MC ahead of its teleconference to be held in September 2017 for activities to be undertaken.*

❖ ***M4Q(R1) (CTD-Quality) IWG: Addressing CTD-Q-Related Questions***

The M4Q(R1) EWG did not meet in Montreal.

The Assembly noted that the M4Q(R1) (CTD-Quality) IWG had completed its work regarding the revision of the Granularity Document with the M8 EWG, and acknowledged the potential for questions to be received following the implementation of the M4 Granularity document.

Decision/Action:

- *The Assembly noted that the M4Q(R1) is in a dormant stage and will not be requested to provide a work plan to the MC ahead of its teleconference to be held in September 2017.*

❖ ***M8 EWG/IWG: The Electronic Common Technical Document: eCTD***

The M8 EWG/IWG did not meet in Montreal.

The Assembly noted the current activities of the M8 EWG/IWG including updating the eCTD v3.2.2 and v4.0 Q&As based on change requests received.

Decisions/Actions:

- *The Assembly noted the request for postal sign-off on eCTD v3.2.2 Q&As in June 2017, as well as the status of implementation of the eCTD v4.0 Implementation Package;*
- *The Assembly noted that the Regulatory Experts of the M8 EWG/IWG will sign-off electronically Step 3 of the Q&As in June 2017;*
- *Thereafter the Regulatory Members of the Assembly will be invited to adopt the Step 4 of the Q&As electronically;*
- *The M8 EWG/IWG will provide a work plan to the MC ahead of its teleconference to be held in September 2017 for activities to be undertaken.*

26. Organisation of Next Meetings

DATES/LOCATION OF NEXT MEETINGS FOR 2017/2018

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