ICH Press Release

Singapore November 2019

Continued Advancement in Global Harmonisation Efforts

as ICH Prepares for 30 Year Commemoration

Geneva, 27 November 2019

The International Council for Harmonisation (ICH) met in Singapore from 16 – 20 November 2019, bringing together over 450 participants from ICH's sixteen Members and thirty-two Observers. The meeting saw the convening of fourteen ICH Working Groups, which included six new Working Groups who met to progress work on recently approved new topic proposals.

At the meeting, the Assembly reviewed the status of activity of all thirty-two of ICH's Working Groups, including those not meeting in Singapore; received a report from the MedDRA Management Committee; and was updated on several important recent ICH activities in relation to implementation and communication.

A number of elections were also held in Singapore which saw the following appointments:

- Ms. Lenita Lindström-Gommers (EC, Europe) and Dr. Celia Lourenco (Health Canada, Canada) were re-elected by the Assembly as its Chair and Vice Chair respectively to serve a two-year term;
- Dr. Theresa Mullin (FDA, United States) and Dr. Nobumasa Nakashima (MHLW/PMDA, Japan) were re-elected by the ICH Management Committee as Chair and Vice Chair respectively to serve a one-year term; and
- Representatives from ANVISA, Brazil were elected by the Assembly to the ICH Management Committee.

Key milestones reached by several ICH Working Groups

Particularly noteworthy was the adoption by the Regulatory Members of the Assembly of the new ICH Q12 Guideline (*Step 4* of the ICH process) on the Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management, which was finalised in Singapore by the Q12 Working Group. This guideline, complementary to ICH Quality Guidelines Q8 through Q11, aims to promote innovation and continual improvement in the pharmaceutical sector, and strengthen quality assurance and reliable supply of product, including proactive planning of global supply chain adjustments.

The Assembly also welcomed the finalisation of work by two Working Groups not meeting in Singapore, which saw the Regulatory Members of the Assembly adopting (*Step 4* of the ICH process) the E9(R1) Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses and the new ICH M9 Guideline Biopharmaceutics Classification System-based Biowaivers. Both represent important areas of work, with the E9(R1) Addendum aiming to improve the planning, design, analysis and interpretation of clinical trials by providing a structured framework and harmonised standards on the choice of estimand, while M9 provides recommendations to support biopharmaceutics classification of medicinal products and waiver of bioequivalence studies.

Several new Working Groups also advanced work in Singapore on their respective new topics with the finalisation of Concept Papers and Business Plans on:

- E6(R3): Good Clinical Practice
- E2D(R1): Post Approval Safety Data Management: Definition and Standards for Expedited Reporting
- E20: Adaptive Clinical trials
- Q5A(R2): Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
- S12: Nonclinical Biodistribution Studies for Gene Therapy Products
- M12: Drug Interaction Studies

Agreement on new ICH harmonisation activities

The Assembly revisited two new topic proposals which it had supported in principle at the last ICH biannual meeting in June 2019. This included the new topic proposal on Bioequivalence for Immediate-Release Solid Oral Dosage Forms (M13) and a proposal for the revision of the ICH Q9 Guideline on Quality Risk Management. The Assembly approved the Concept Paper Outlines for both topics, with the revision of ICH Q9 to have a delayed start time in view of other ongoing quality work, while a new Working Group would be established without delay to initiate work on finalising the concept paper and business plan for the M13 topic. The Assembly was furthermore updated that a new Working Group would now be established to initiate work on the new topic proposal on ICH Q3E Guideline Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics, which had been adopted in June 2019 with a delayed start time.

Supporting MedDRA's continued global uptake

The Assembly was updated about MedDRA's increasingly global uptake and efforts by the MedDRA Management Committee to support the growing number of users from over 6,000 organisations in more than 125 countries. These users currently have access to MedDRA in 13 language translations, with Russian and Korean the most recent translations added. The Assembly was informed on the expanded number of MedDRA training offerings available to users and additionally noted MedDRA Management Committee efforts to enable terminology interoperability. Particularly noteworthy in this regard is ongoing coordination with: SNOMED International to develop a mapping with SNOMED (as part of the IMI WEB-RADR 2 project); and IMDRF (International Medical Device Regulators Forum) regarding a mapping developed with its adverse event terminology.

Monitoring ICH Guideline implementation

With monitoring the progress of international harmonisation and coordinating efforts in this regard being an important ICH focus, the Assembly welcomed ICH's publication in November 2019 on the ICH website of the results of the recent survey undertaken to understand the state of ICH Guideline implementation by ICH Regulatory Members and Observers.

Training

The Assembly was also updated on ICH training related activities, notably as regards recent ICH Recognised Training Programmes, and efforts to engage appropriate accredited non-profit training organisations to assist ICH in its efforts to address the training needs of its Regulatory and Industry Members and Observers in a strategic manner.

Communication

In relation to ICH stakeholder communication, the Assembly was updated on the recent ICH Global Meeting on the draft revised E8(R1) Guideline on General Considerations for Clinical Trials held at the headquarters of FDA, United States in Silver Spring, MD, USA on 31 October 2019. This meeting, forming part of the "GCP renovation" plan was well received, being attended in person by 100 participants, with close to 500 participating remotely through the live streaming of the event. The meeting was successful in soliciting input from a broad range of non-ICH Member and Observer stakeholders on the draft E8(R1) Guideline which recently completed public consultation in the ICH regions. Further to this positive experience with E8(R1) outreach, the Assembly also discussed opportunities for other Working Groups to gather stakeholder input through similar outreach activities.

The Assembly was furthermore updated on plans to commemorate in 2020 ICH's 30th Anniversary with the organisation of a conference to be held back-to-back with ICH's biannual meeting in November 2020 in Athens, Greece. Further details will be available shortly on the ICH website.

The next ICH meeting will take place on 23-27 May 2020 in Vancouver, Canada.

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NOTES FOR EDITORS

This press release, together with more information on the Guidelines mentioned above and the work of ICH, can be found on its website: www.ich.org

For further information, please contact the ICH Secretariat at pressrelease@ich.org

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