ICH Press Release

ICH Assembly Meeting, Vancouver, Canada, June 2023

New Areas of Harmonisation Adopted

Alongside Significant Advancement of Ongoing Activities

Geneva, 20 June 2023

The Assembly of the International Council for Harmonisation (ICH) met in-person on 12 & 13 June 2023, in Vancouver, Canada in parallel of meetings of 14 Working Groups, and preceded by meetings of the ICH Management Committee and the MedDRA Management Committee.

ICH continues to grow, and it was with great pleasure that ICH welcomed EDA, Egypt as the first African Regulatory Authority to join ICH as a Member, along with NAFDAC, Nigeria as a new ICH Observer. This brings ICH to a total of 21 Members and 36 Observers.

Mr. Naoyuki Yasuda was also announced as the new ICH Management Committee Vice-Chair, being elected to serve until the end of the next ICH meeting in October/November 2023 following the mid-term departure of the previous Vice-Chair, Dr. Nobumasa Nakashima.

New Areas of ICH Harmonisation

The Assembly adopted three new topics for harmonisation at the Vancouver meeting, with the starting timeframe to be determined in a subsequent step:

- *"General Considerations for Patient Preference Studies"* – a new ICH Efficacy Guideline which will provide considerations for a systematic approach to designing, conducting, analyzing and presenting Patient Preference Studies, when studies are considered important to be conducted to supplement information about the assessment of a product or inform drug development and related decisions;
- *"Nonclinical Safety Studies for Oligonucleotide-based Therapeutics"* – new ICH Safety Guideline which will clarify regulatory expectations on nonclinical safety evaluation of various Oligonucleotide-based treatment options by providing a common understanding of the applicable requirements;
- *"Bioequivalence for Modified-Release Products"* – a new ICH Multidisciplinary Guideline which represents an important next step for harmonisation of bioequivalence standards for more complex dosage forms, with several elements being harmonised under the M13 series of guidelines, which are currently under development being transferrable to this new guideline.

In addition, the Assembly decided to progress a new ICH Reflection Paper titled "*International Harmonisation of Real-World Evidence Terminology and Convergence of General Principles Regarding Planning and Reporting of Studies Using Real-World Data, with a Focus on Effectiveness of Medicines*". The paper, which presents opportunities for development of new ICH Guidelines, will be made available on the ICH website for public consultation recognising the value of broader input on this topic.

New ICH Discussion Group

The Assembly was also informed of the formation of a new ICH "*Cell and Gene Therapies"* Discussion Group *(CGTDG)* which will serve as a technical discussion forum for issues related to ICH harmonisation efforts in the field of CGT products. The CGTDG is charged with developing a roadmap of potential harmonisation areas focusing on CGT modalities of relatively high maturity.

Progress on ICH Guideline Development and Important Revisions

The Assembly was updated on the approval of the Concept Paper for the new ICH E21 Guideline on *"Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials"*. In addition to receiving reports on progress made at ICH Working Group meetings in Vancouver, the Assembly also noted significant milestones reached by several Working Groups since the last ICH meeting, which included eagerly awaited important updates to some older ICH Guidelines, as well two new ICH Guidelines:

- The Draft ICH E6(R3) Guideline on "*Good Clinical Practice (GCP)"* was endorsed (at *Step 2* of the ICH process*)* just prior to the Vancouver meeting in May 2023. The guideline is composed of principles and two planned annexes that expand on the principles with specific details for different types of clinical trials. The draft Principles and Annex 1 reached *Step* 2, while the draft Annex 2 is under development;
- The Final Revised ICH M7(R2) Guideline on the *"Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk"* and accompanying Addendum entitled *"Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes"* were adopted (at *Step 4* of the ICH process*)* in April 2023. These documents were published alongside a new Questions and Answers document to provide additional clarification, promote convergence and improve harmonisation of the considerations for assessment and control of DNA reactive (mutagenic) impurities found in ICH M7(R2);
- The new Final ICH S12 Guideline on "*Nonclinical Biodistribution Considerations for Gene Therapy Products"* was adopted (at *Step 4* of the ICH Process) in March 2023. The guideline provides guidance on the conduct of nonclinical biodistribution studies in the development of gene therapy products that mediate their effect by the expression (transcription or translation) of transferred genetic materials, and harmonised recommendations to facilitate the development of gene therapy products while avoiding unnecessary use of animals, in accordance with the 3Rs (reduce/refine/replace) principles;
- The Final Revised ICH Q9(R1) Guideline on "*Quality Risk Management"* was adopted (at *Step 4* of the ICH process) in January 2023, and provides guidance on the principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality and make limited and specific adjustments to specific chapters and annexes of the earlier Q9 guideline;
- Updated ICH E2B(R3) Questions and Answers (Version 2.4) for the ICH E2B(R3) Guideline on "*Electronic Transmission of Individual Case Safety Reports (ICSRs)"* were adopted (at *Step 4* of the ICH process) in January 2023;
- Finally, the Draft ICH M13A Guideline on *"Bioequivalence for Immediate-Release Solid Oral Dosage Forms"* was endorsed (at *Step 2* of the ICH process) in December 2022. This new guideline is the first in the foreseen ICH M13 Guideline series to describe the scientific and technical aspects of study design and data analysis to support bioequivalence assessment for orally administered immediate-release solid oral dosage forms.

Training

The Assembly was also updated on ICH training related activities, including progress of work by ICH Training Associates to develop materials on ICH E2, E6(R3), E8(R1), E17, M4, Q1, Q3, Q5 and the ICH Q8 to Q12 series of Guidelines, as well as work by ICH Working Groups to develop training materials. This included a significant milestone reached in Vancouver by the ICH Q9(R1) Working Group, with finalisation of training materials on six topics in support of the implementation of the recent ICH Q9(R1) Guideline on "*Quality Risk Management*". The Assembly also noted the finalisation in January 2023 of the training video *"Module I - Introduction to E2B(R3):* Electronic Transmission of Individual Case Safety Reports".

Patient Stakeholder Engagement

The Assembly noted ICH efforts in relation to patient stakeholder engagement and the organisation of a session at the forthcoming DIA Annual Meeting in Boston, United States of America on 28 June 2023 on *"ICH Work to Harmonize Requirements for Safe and Effective Medicines: What's in It for Patients?"*.

MedDRA

2022 was another important year for the growth of the MedDRA user community, with an 11% growth rate over the previous year. Currently reaching over 8,300 user organisations worldwide within 134 countries, the MedDRA Management Committee remains dedicated in supporting MedDRA globally. This includes the training of over 19,000 participants from 109 countries in 7 languages within 2022, as well as expansion in 2023 of local in-region support in Latin America and to Africa/Middle East. With the release of a new Arabic MedDRA translation in January 2023, MedDRA is now available in 19 languages and continues to respond to the needs of communities worldwide.

The next ICH Assembly meeting is planned on 31 October and 1 November 2023 in Prague, the Czech Republic.

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NOTES FOR EDITORS

This press release, together with more information on the ICH 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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