ICH Press Release

ICH Assembly Meeting, Fukuoka, Japan, June 2024

Continued Advancement of ICH's Global Harmonisation Efforts

Geneva, 12 June 2024

The Assembly of the International Council for Harmonisation (ICH) met in-person on 4 & 5 June 2024, in Fukuoka, Japan in parallel of meetings of 13 Working Groups, and preceded by meetings of the ICH Management Committee and the MedDRA Management Committee.

The ICH continues to expand and welcomed ANMAT, Argentina and JFDA, Jordan as new ICH Members, bringing ICH to a total of 23 Members and 35 Observers.

ICH Management Committee Elections

In line with ICH procedures, new elections were held for Elected Representatives to the ICH Management Committee, welcoming for a 3-year term Representatives from Regulatory Members: ANVISA, Brazil; MFDS, Republic of Korea; NMPA, China; and SFDA, Saudi Arabia and Industry Members: BIO and IGBA.

New Areas of ICH Harmonisation

The Assembly adopted a new topic for harmonisation at the Fukuoka meeting:

- An Addendum to the Multidisciplinary Guideline M7 on *"Assessment and Control of DNA Reactive (mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk"* to address safety assessment and establishment of appropriate controls for nitrosamine impurities through a staged approach, leveraging the Formal ICH Procedure, as well as to develop a harmonised set of acceptable intakes (AIs) leveraging the M7 Maintenance Procedure.

In addition, the Assembly endorsed a revised ICH Reflection Paper on "*Pursuing Opportunities for Harmonisation in Using Real-World Data to Generate Real-World Evidence, with a focus on Effectiveness of Medicines*", further to the comments received during the public consultation held from June to September 2023. The revised paper, which presents opportunities for development of new ICH Guidelines, as well as the summary of comments received, will be made available on the ICH website.

Progress on ICH Guideline Development and Important Revisions

In addition to receiving reports on progress made at ICH Working Group meetings in Fukuoka, 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 as some new ICH Guidelines:

- The Final ICH M12 Guideline on "*Drug Interaction Studies*" and supporting M12 Questions and Answers (Q&As) were adopted (at *Step 4* of the ICH Process) just prior to the Fukuoka meeting in May 2024. The guideline provides recommendations to promote a consistent approach in designing, conducting, and interpreting enzyme- or transporter-mediated *in vitro* and clinical drug-drug interaction (DDI) studies during the development of a therapeutic product. The supporting Q&As are intended to provide additional clarification and improve harmonization of drug interaction assessment;
- The ICH M14 draft Guideline on "*General Principles on Plan, Design and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of*

Medicines" was endorsed (at *Step 2* of the ICH process) just prior to the Fukuoka meeting in May 2024. This guideline outlines recommendations and high-level best practices for the conduct of these studies, to streamline the development and regulatory assessment of study protocols and reports. These recommendations and practices also seek to improve the ability of the study protocol and/or results to be accepted across health authorities and support decision-making in response to study results;

- The ICH E2D(R1) draft Guideline on "*Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports*" was endorsed (at *Step 2* of the ICH process) in February 2024. This guideline provides recommendations that are harmonised to the extent possible given differences in post-market safety reporting requirements among ICH regions. Where applicable, this guideline notes where local and regional requirements may vary and, as such, marketing authorisation holders (MAHs) should refer to the relevant local or regional regulatory authority's requirements.

Progress on other ICH Documents Developed by ICH Working Groups

The Assembly was updated on the MC approval of the Concept Paper for the new ICH E22 Guideline on *"General Considerations for Patient Preference Studies".*

Revision of Q4B(R1) to Reflect Maintenance by PDG

The Assembly approved the revision of the Q4B(R1) Guideline on *"Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions"*. The revision reflects that responsibility for the maintenance of Q4B and its annexes is handed over to the Pharmacopoeial Discussion Group (PDG). The new procedure takes account of the growth in ICH Regulatory Members in recent years and will give non-PDG pharmacopoeias the option to harmonise their method with the PDG method or to implement the PDG method in parallel of a local method.

Results of New Implementation Survey

The Assembly was presented with the results of the third survey to understand the current level of implementation and adherence to ICH Guidelines within Regulatory Member and Observer countries/regions. The survey results demonstrate good progress made by Regulatory Authorities in implementing ICH Guidelines since the two previous surveys from 2019 and 2021. A summary report will be published on the ICH website.

MedDRA

The number of global MedDRA users continues to grow, currently reaching more than 8,600 user organisations worldwide. ICH supports these users through training and translations. A total of 193 training sessions (135 webinars and 58 in-person) were conducted in 2023 in multiple languages for over 16,000 participants from 99 countries, with a similar level of training planned for 2024. With the recent release of a Finnish MedDRA translation, MedDRA is now available in 21 languages. Work on additional translations is ongoing in close collaboration with regulatory authorities, and several new translations are expected to be released in the coming months.

Training

Significant milestones were reached in Fukuoka by ICH Working Groups, including:

- Finalisation of updates to ICH Q8/Q9/Q10 Training Materials from 2006-2010 on *"Quality Risk Management"* by the Q9(R1) Implementation Working Group, which will be published on the ICH website.

Communication

The next ICH Assembly meeting is planned on 5 and 6 November 2024 in Montréal, Canada.

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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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