ICH Press Release

Kobe, Japan, June 2018

ICH continues membership expansion, and advances harmonisation work in electronic standards and pharmaceutical quality

Geneva, 22 June 2018

The International Council for Harmonisation (ICH) met in Kobe, Japan on 2 – 7 June 2018. In one of the remaining steps of implementing the 2015 reforms of ICH, the Assembly elected additional members to the Association's Management Committee. The Founding and Standing Members are now joined on the Management Committee by five newer ICH Members. CFDA, China, HSA, Singapore and MFDS, South Korea join the current regulatory members and BIO and IGBA join the current industry members.

Among other decisions, the ICH Assembly approved TFDA, Chinese Taipei as a new Regulatory Member. The Assembly also approved MMDA, Moldova, NPRA, Malaysia, SCDMTE, Armenia and TİTCK, Turkey as new Observers. With these new parties, there are now 16 ICH Members and 27 Observers, and full details are available on the ICH website www.ich.org.

ICH continues delivery across broad range of topics in drug development and maintenance

With the work of implementing the ICH reforms now largely completed, there was substantial progress at the Kobe meeting with the finalisation of 6 ICH harmonised guidance documents, as well as 2 draft guidance documents.

The following guidance documents were adopted by the Assembly at the Kobe meeting (*Step 4* of the ICH process):

- Revision of Q&As for the Electronic Submission of Individual Case Study Reports (E2B(R3));
- eCTD v3.2.2 Q&A and Specification Change Request Document v1.31 (M8);
- eCTD v4.0 Implementation Package v1.2 (M8);
- eCTD v4 Q&A and Specification Change Request Document v1.2 (M8);
- Specification for Submission Formats for CTD v1.2 (M8);
- Finally, it was noted that Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals (S9) were adopted through written procedure in April 2018.

The Assembly also noted the publication of revised recommendations on Electronic Transfer of Regulatory Information (ESTRI) (M2).

The following draft guidance documents were adopted for public consultation (*Step 2b* of the ICH process):

- Biopharmaceutics Classification System-based Biowaivers (M9);
- It was noted that the Guideline on Elemental Impurities: Revision to Cadmium inhalation Permitted Daily Exposures (Q3D(R1)) was endorsed through written procedure in May 2018.

ICH prepares for future new topics

The Assembly agreed to begin work on three new topics for ICH harmonisation:

- Analytical Procedure Development and Revision of Q2(R1) Analytical Validation (Q2(R2)/Q14);
- Continuous manufacturing (Q13);
- Clinical electronic Structured Harmonised Protocol ('CeSHarP') (M11).

Work will now begin on developing formal concept papers and work plans.

Two other new topics were also adopted with a delayed starting timeframe:

- Adaptive Clinical Trials;
- Drug interaction Studies.

The Assembly also discussed future strategic areas for harmonisation by endorsing a strategic reflection paper entitled Advancing Biopharmaceutical Quality Standards to Support Continual Improvement and Innovation in Manufacturing Technologies and Approaches.

Training and stakeholder engagement to enhance implementation and adherence

As the global impact of ICH grows, there is an increased focus on training and stakeholder outreach. The Assembly noted the development of training tools for regulators, industry and other stakeholders involved in drug development, to ensure consistent implementation and approaches to ICH guidelines. The training strategy will be delivered through trusted partners' programmes across the ICH regions, in addition to efforts of the ICH Expert Working Groups to develop their own training materials for guidelines.

In parallel, there are efforts to fully map the implementation of ICH guidelines by current and future ICH Members. Once completed, the outcome will be published on the ICH website so that all stakeholders can identify how ICH guidelines are implemented in their region.

The next ICH meeting takes place on 10-15 November 2018 in Charlotte, NC, USA.

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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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