ICH Press Release

ICH Global Harmonisation Efforts Continued Through Virtual Meetings

Geneva, 3 June 2020

The International Council for Harmonisation (ICH) met virtually on 27 May, in place of the face-to-face meetings that were to take place in Vancouver, Canada. The meeting was preceded by virtual meetings of the ICH Management Committee and MedDRA Management Committee. ICH's Working Groups have also been progressing their activities virtually.

Further expansion of ICH Membership

The ICH Assembly welcomed TITCK, Turkey as a new Regulatory Member and MOPH, Lebanon as a new Regulatory Observer, bringing the ICH Association to a total of seventeen Members and thirty-two Observers.

Progress on existing ICH Guidelines

The Assembly was updated on the status of ICH's current thirty-four Working Groups, noting the significant milestones reached recently by several Working Groups including:

- *Step 4* of the ICH Process reached in May 2020 for the Q&A v1.3 on the ICH M8 electronic Common Technical Document (eCTD) v4.0.
- *Step 4* of the ICH Process reached in April 2020 for the new ICH S11 Guideline on Nonclinical Safety Testing in Support of Development of Pediatric Medicine.
- *Step 4* of the ICH Process reached in February 2020 for the ICH S5(R3) Guideline on Revision of S5 Guideline on Detection of Toxicity to Reproduction for Human Pharmaceuticals.
- *Step 2* of the ICH Process reached in March 2020 for the ICH Q3C(R8) draft Guideline on Impurities: Guideline for Residual Solvents, which was revised to include the Permitted Daily Exposure (PDE) levels for 2-Methyltetrahydrofuran, Cyclopentyl Methyl Ether and Tertiary Butyl Alcohol.

Agreement on new ICH harmonisation activities

The Assembly was informed on the ICH Management Committee's assessment of New Topic Proposals submitted by ICH Members as part of the 2020 ICH New Topic Process. The Assembly supported work on the following topics:

- Revision of M4Q(R1) Common Technical Document (CTD)
- Structured Product Quality Submissions

Work on M4Q(R1) CTD is foreseen to get underway with the establishment of an informal Working Group towards the end of 2020, with a plan to be drawn-up regarding the initiation of Structured Product Quality Submissions since this topic will be informed by work on M4Q(R1) CTD, and vice versa.

The Assembly additionally supported the establishment of a Discussion Group to further consider the scope and approach of potential new harmonisation activities relating to the following topic proposals:

- General Considerations for Model-Informed Drug Development to support Drug Registration
- ICH E4: Dose Response Information to Support Drug Registration

MedDRA update

The Assembly was updated about MedDRA activities in view of the COVID-19 pandemic which included: an exceptional re-release of MedDRA 23.0 to include ~70 new COVID-19 terms aimed at ensuring that any scientific and medical information from the COVID-19 outbreak can be captured, shared and analysed appropriately; development of a new COVID-19 Standardised MedDRA Query (SMQ); and increased virtual training offerings. With users currently from over 6,200 organisations in more than 125 countries, the

Assembly was also updated on MedDRA Management Committee efforts to support the language needs of users with: release of a new Brazilian Portuguese MedDRA translation in March 2020 which brings to 14 the number of languages in which MedDRA is currently available; and work to begin shortly on a new Swedish MedDRA translation. The Assembly was furthermore informed on other MedDRA Management Committee efforts to support users, including through the development of targeted mappings with other terminologies such as SNOMED.

Training

The Assembly was also updated on ICH training related activities, notably regarding recent ICH Recognised Training Programmes, and the engagement of an accredited non-profit training organisation as ICH's first ICH Training Associate. ICH Training Associates are being put in place to assist ICH in its efforts to address the training needs of its Regulatory and Industry Members and Observers in a strategic manner.

Communication

The publication in May 2020 of a summary of the ICH E6(3) Stakeholder Engagement Approach was welcomed by the Assembly. This work is aligned with ICH's commitment for stakeholder engagement with academic clinical researchers and patients and other stakeholders, as per the Reflection paper on *Renovation of Good Clinical Practice* and the ICH E6(R3) Concept Paper, with a view to ensuring that the guidelines are responsive to the needs of those conducting or participating in clinical trials.

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 Assembly meeting is planned to take place on 17-18 November 2020 in Athens Greece, pending any potential travel restrictions due to the COVID-19 pandemic.

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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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