

ICH Press Release

Continued Advancement of ICH's Global Public Health Mission 30 Years On

Geneva, 25 November 2020

The International Council for Harmonisation (ICH) met virtually on 18 November in place of face-to-face meetings that were to take place in Athens, Greece, and preceded by virtual meetings of the ICH Management Committee and MedDRA Management Committee. The meeting is the second to be held virtually in 2020, a year which also marks 30 years of ICH harmonisation and a continued resolve from ICH Members and Observers to advance ICH's global public health mission against the backdrop of the COVID-19 pandemic.

At the virtual ICH Management Committee meeting, Dr. Theresa Mullin (FDA, United States) and Dr. Nobumasa Nakashima (MHLW/PMDA, Japan) were re-elected as Chair and Vice Chair respectively to serve a one-year term.

Progress on existing ICH Guidelines

ICH's Working Groups have also continued to progress their activities virtually and the Assembly was updated on the status of ICH's current thirty-three Working Groups, and the dedicated efforts of ICH experts to progress their harmonisation activities in the face of pandemic related challenges. The Assembly noted significant milestones reached recently by several Working Groups including:

- ✿ *Step 4* reached for v1.1. of the User Guide of EDQM terminologies for Dose Forms and Routes of Administration for Individual Case Safety Reports in the E2B(R3) message.
- ✿ *Step 2* reached for the ICH Q3D(R2) Guideline for Elemental Impurities which is comprised of extracts of Appendixes 2 and 3 reflecting amendments of the Permitted Daily Exposure (PDEs) for Gold, Silver and Nickel, as well as a new Appendix 5 on Limits for Elemental Impurities by Cutaneous and Transcutaneous Route.
- ✿ *Step 2* reached for the ICH E14/S7B Question & Answer document on Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential, which was accompanied by a public webinar in October 2020 to provide an overview of the high-level principles and rationale behind the new interconnected Questions & Answers to the ICH E14 and S7B Guidelines.
- ✿ *Step 2* reached for the ICH M7 Question & Answer document on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk which is intended to promote further harmonisation in using this guidance in regulation of mutagenic impurities in pharmaceuticals.

New Implementation survey

Following on from the successful 2019 ICH-driven independent third-party survey conducted to understand the level of implementation and adherence to ICH Guidelines within Regulatory Member and Observer countries/regions, the Assembly was updated on the upcoming launch of a new survey until next spring.

Training

The Assembly was also updated on ICH training related activities, notably the recent publication on the ICH website of an Introductory Overview video on ICH Q1 Stability Guidelines developed by ICH's first Training Associate. Plans were also noted for further engagement of accredited non-profit training organisations as ICH Training Associates to assist ICH in its efforts to address the training needs of its Regulatory and Industry Members and Observers in a strategic and sustainable manner.

More patient involvement for drug development

The Assembly gave its support to progress a new ICH Reflection Paper on Patient-Focused Drug Development (PFDD) which identifies key areas where incorporation of the patient's perspective could improve the quality, relevance, safety and efficiency of drug development. 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.

MedDRA update

The Assembly was updated about MedDRA's global uptake amidst the ongoing COVID-19 pandemic, noting 264 new subscribers in 2020 alone bringing the total number of users to over 6,600 organisations in more than 125 countries. Work is ongoing on targeted mappings with other terminologies such as SNOMED-CT, and two new Standardised MedDRA Queries (SMQs) on Immune-mediated/autoimmune disorders and COVID-19, have also been recently included in MedDRA v.23.1. Translations of MedDRA into other languages such as Swedish and remaining languages of the European Economic Area continues.

Communication

While ICH plans for a conference to commemorate its 30th Anniversary in 2020 have been put on hold in view of the pandemic, the Assembly was informed on the development of a publication to celebrate ICH's important milestone which is planned for release in 2021.

The next ICH Assembly meeting is planned as a virtual meeting on 2 June 2021.

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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