ICH Press Release

ICH Assembly Virtual Meeting, November 2021

Continued Advancement of ICH's Global Harmonisation Efforts

Geneva, 25 November 2021

The International Council for Harmonisation (ICH) met virtually on 17 and 18 November. The Assembly meeting was preceded by virtual meetings of the ICH Management Committee and MedDRA Management Committee.

Further expansion of ICH Membership and Observership

The ICH Assembly welcomed COFEPRIS, Mexico as a new ICH Member, in addition to three new ICH Observers: EDA, Egypt, Indonesian FDA, Indonesia and SECMOH, Ukraine, bringing ICH to a total of 19 Members and 35 Observers.

Elections

The Management Committee and Assembly Chair and Vice-Chair elections were also held during the meeting which saw the following appointments:

- Ms. Lenita Lindström-Gommers (EC, Europe) was re-elected as Assembly Chair and Dr. Gabriela Zenhaeusern (Swissmedic, Switzerland) was elected as Assembly Vice-Chair to serve a two-year term;
- Dr. Theresa Mullin (FDA, United States) and Dr. Nobumasa Nakashima (MHLW/PMDA, Japan) were re-elected as Management Committee Chair and Vice Chair respectively to serve a two-year term.

Progress on existing ICH Guidelines and harmonisation activities

ICH's Working Groups have also continued to progress their activities virtually and the Assembly was updated on the status of ICH's Working Groups. The Assembly noted significant milestones reached recently by several Working Groups including:

- *Step 4* reached for the Electronic Common Technical Document (eCTD) v4.0 Question & Answer Document v1.6 and eCTD v3.2.2 Question & Answer Document v1.32 in November 2021.

- *Step 4* reached for the ICH E8(R1) Guideline on General Considerations for Clinical Studies in October 2021.

- *Step 2* reached in November 2021 for the ICH Q9(R1) draft Guideline on Quality Risk Management (QRM) which is intended to provide important additional guidance on four specific areas: the levels of subjectivity in risk assessments and in QRM outputs; the product availability risks; the lack of understanding as to what constitutes formality in QRM work; and the lack of clarity on risk-based decision-making.

- *Step 2* reached in October 2021 for the ICH M7(R2) draft Guideline and Addendum on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk which is intended to provide useful information regarding the acceptable limits of known mutagenic impurities/carcinogenic and supporting monographs.

- *Step 2* reached for the ICH Q13 draft Guideline on Continuous Manufacturing of Drug Substances and Drug Products in July 2021.

In addition, the Assembly approved a report from the Quality Discussion Group outlining future opportunities for ICH Quality Guidelines to support continual improvements and innovation in manufacturing technologies and approaches that would be subsequently published on the ICH website.

New areas of ICH harmonisation

The ICH Assembly supported and endorsed the revised New Topic proposal and associated Concept Paper Outline on General Considerations for Model-Informed Drug Development (MIDD) for establishment of a M15 informal WG.

In addition, and further to the New Topic proposal approved by the Assembly in May 2020, the finalisation by the M4Q(R2) informal WG and endorsement by the ICH Management Committee of the ICH M4Q(R2) Concept Paper and Business Plan for the Revision of the M4Q(R1) Common Technical Document (CTD) on Quality guidance was noted by the Assembly.

New topic selection process

The ICH Assembly decided to proceed with the New Topic selection process cycle in 2022. Considering the current COVID-19 influence and the delay with some existing topics, the Assembly will seek topic candidate(s) with high public health impact and in specific areas. The Assembly will also seek more efficient WG management to progress work on more ICH Guidelines.

Training

The Assembly was also updated on ICH training related activities, and gave its support for an expedited approach to address the training needs of ICH Members and Observers as part of a 5-year strategic plan focused on expanding work with ICH Training Associates to develop online training materials for all ICH Guidelines, in addition to offering tailored training.

MedDRA

The Assembly was updated on the steady uptake of MedDRA, noting over 600 new subscribers in 2021 to-date, bringing the total number to over 7,400 organisations in more than 130 countries. In support of users' language needs, work continues to translate MedDRA into several additional European languages and initiate work for an Arabic translation. Russian translations of the Points-to-Consider documents on *MedDRA Term Selection* and *MedDRA Data Retrieval and Presentation* have also been recently made available. Work is ongoing on targeted mappings with other terminologies, and a new Standardised MedDRA Query (SMQ) on *Sexual dysfunction* has been included in the MedDRA v.24.1 September release. Based on interest expressed, a new SMQ *Noninfectious myocarditis* is also being developed.

Communication

The Assembly noted the ICH 30th Anniversary Publication published on the ICH website in October 2021, providing an overview of ICH's history and current work, as well as views of different stakeholders on how ICH has contributed to better health and ICH's future directions in the next 10 years. An informative leaflet on ICH will also be finalised shortly after the meeting.

The next ICH Assembly meeting is planned on 24 - 25 May 2022.

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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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