ICH PRESS RELEASE

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The Association begins new work on medicines for children and better clinical trials and China Food and Drug Administration joins ICH.

The International Council for Harmonisation (ICH) met in Montreal, Canada on 27 May to 1 June 2017. Among other decisions, the ICH Assembly approved the China Food and Drug Administration (CFDA) as a new Regulatory Member, and Pharmaceutical Inspection Co-operation Scheme (PIC/S) as a new Observer.

With these new parties, there are now 14 members and 23 observers, and full details are available on the ICH website www.ich.org.

Paediatric medicines and modernisation of GCP principles to be new topics for ICH

The ICH Assembly agreed to begin work on two new topics. The first is for a new international harmonised guideline on extrapolation for paediatric medicines. The new Working Group will further advance the use of paediatric extrapolation, which is the focus of the new ICH E11(R1) guideline currently under development. The aim is to provide guidance on incorporating extrapolation methods in an overall approach to paediatric medicinal product development. A harmonised approach to the appropriate use of extrapolation from adult data will improve the speed of access to new drugs for children.

The second new topic is the revision of the 1997 ICH E8 guideline on general considerations for clinical trials. This is part of the strategic 'GCP renovation' announced at the November 2016 Osaka meeting. The revision will look at study design, planning and conduct, with a focus on identifying and supporting a basic set of critical-to-quality factors. Improved clinical trials contribute to public health by generating better evidence to inform regulatory decision-making, by avoiding the need for repeat trials and unnecessary exposure for trial participants, and helping to avoid discontinuation of promising development programs.

Final guidelines

The final M7(R1) addendum to the guideline on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk was adopted by the ICH Assembly at *Step 4* of the ICH process. The addendum provides a list of compounds for which mutagenic potential and the threshold of toxicological concern have been established.

The ICH Assembly adopted at *Step 4* the update of the Questions and Answers on the implementation guide package of the guideline E2B(R3): Electronic Transmission of Individual Case Safety Reports.

Remaining agile as ICH grows

With a view to streamlining the operation of ICH, the Assembly made some revisions to the Articles of Association and rules of procedure. With a growing number of members and observers, the changes include caps on the size of Expert Working Groups to ensure they remain a manageable size and revisions to the criteria for an international organisation to become an Observer. ICH aims to attract and engage with all organisations that are impacted by ICH harmonisation and that can bring value to its work; the revised criteria try to make sure that ICH is engaging with relevant global umbrella organisations at the highest level of representation.

In Montreal, the Assembly also welcomed Standing Observer IFPMA's plan to initially use its seat on ICH Working Groups to facilitate the participation of IFPMA National Association experts in Working Groups.

The next ICH meeting will take place on 11 – 16 November 2017 in Geneva, Switzerland.

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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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