PRESS RELEASE

Fukuoka, Japan, June 2015

The International Conference on Harmonisation (ICH) Steering Committee (SC) and its Expert Working Groups (EWGs) met in Fukuoka, Japan from June 5-11, 2015. The meeting was hosted by the Ministry of Health, Labour and Welfare and the Japan Pharmaceutical Manufacturers Association.

The SC agreed on the key issues relating to the reform of ICH in terms of the Articles of Association, funding model and membership. An important part of the reform effort is establishing a formal organisation with a new approach to membership, governance and shared funding among ICH members. During a special session on June 10, Interested Parties were updated on the future of ICH, including issues regarding membership and governance of the new association. All participants welcomed the goals of the reform and recognised the intended roles of the Assembly as well as the Management Committee. Most participants indicated their interest for becoming ICH members or observers and the different intended eligibility criteria were discussed.

The new ICH Association under Swiss law is expected to be established over the coming months with the aim of being operational starting in 2016.

Twelve working groups met in Fukuoka and achieved important progress towards their respective objectives. The Question & Answer (Q&A) document on the Q7 Guideline on *Good Manufacturing Practices for Active Pharmaceutical Ingredients (APIs)* has been signed off at *Step 4* in Fukuoka and is thus ready for implementation in the ICH regions.

In addition, two documents, the draft Addendum to the M7 Guideline on *Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk* document and the draft Addendum to E6 on *Good Clinical Practice* have reached *Step 2b* and will be submitted to public consultation. More details on the progress achieved by the different groups is provided hereunder.

Safety Guidelines Update

The M7 EWG reached agreement on the draft Addendum to the Guideline *Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk*. The SC signed off the *Step 2a/2b document* in Fukuoka. thus releasing this document for public consultation.

A new EWG, S5(R3), was created to revise the Guideline on *Detection of Toxicity to Reproduction for Medical Products and Toxicity to Male Fertility* and met in Fukuoka for the first time. This group made good progress in reviewing and revising the current guidance in developmental and reproductive toxicity studies and expects to reach *Step 2* by June 2017.

It was also the first meeting of the S11 EWG tasked to develop a new ICH Guideline on *Nonclinical Safety Testing in Support of Development of Paediatric Medicines*.

Efficacy Guidelines Update

The EWG developing an Addendum to E6 on *Good Clinical Practice* to promote innovative approaches to clinical trial design, management, oversight and conduct made good progress and reached *Step 2a/2b*. The draft document that will take the format of an integrated addendum will now be submitted to public consultation.

The EWG developing an Addendum to E9 on *Choosing the Appropriate Estimand and Defining Sensitivity Analyses in Clinical Trials*, met to focus on harmonising improved clinical trial planning, conduct, analysis and interpretation.

The E11 EWG worked to develop an Addendum to the Guideline on *Clinical Investigation of Medicinal Products in the Pediatric Population* and made good progress towards the draft *Step 1* technical document. *Step 2* for this topic is expected in December 2015.

The E14 Discussion Group (DG) met to develop a Concept Paper to revise the ICH E14 Guideline on the Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs. During the meeting in Fukuoka, the SC endorsed the Concept Paper on the revision of the Q&A 5.1 on Concentration-Response Modelling for regulatory decision making thereby allowing experts to initiate this revision.

The group working on the development of the E17 Guideline on *Multi-regional Clinical Trials* progressed towards developing the *Step 1* technical document.

The E18 EWG on *Genomic Sampling Methodologies for Future Use* made progress towards a *Step 2* document which is expected in December 2015. This Guideline will clarify points to consider in collecting genomic samples in clinical trials, resulting in further implementation of genomic research for the benefit of all stakeholders.

Quality Guidelines Update

The Q7 Implementation Working Group (IWG) on *Good Manufacturing Practices for APIs* reached agreement on the *Step 3* Q&A document ahead of the Fukuoka meeting. The SC approved this document for release by signing off *Step 4* in Fukuoka.

The SC also signed-off on *Step 2a/2b* of the Q3C(R6) Guideline for Residual Solvents including two solvents: Triethylamine and Methyl Isobutyl Ketone. The Q3C maintenance EWG had reached agreement on this document ahead of the Fukuoka meeting

The Q12 EWG on *Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management* met for the second time in Fukuoka. This group is expected to finalise its *Step 1* technical document in June 2016.

The ICH SC approved an interim face-to face meeting of the Q11 IWG to develop Q&As on *Selection and Justification of Starting Materials for the Manufacture of Drug Substances* in September 2015.

Multidisciplinary Guidelines Update

The M2 EWG on *Electronic Standards for the Transfer of Regulatory Information (ESTRI)* met in Fukuoka, making progress on a variety of issues.

The M4E(R2) EWG working on the revision of the *Common Technical Document (CTD) Efficacy* Guideline to provide greater specificity on the format and structure of benefit-risk information also made progress to finalise a draft of its *Step 1* technical document.

The M8 EWG on *electronic Common Technical Document (eCTD)* met in Fukuoka and the SC signed-off at *Step 4* of Version 1.27 of the eCTD Change Request Q&A document and endorsed that the M8 would update the Granularity Document based on Q&A from CTD-Quality and change requests M8 received. The M8 EWG reconciled all of the comments received on the draft eCTD Implementation Guide v.4.0 during *Step 3*.

The next ICH meeting will be held in Jacksonville, Florida, USA on December 5 - 10, 2015.

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