PRESS RELEASE

Minneapolis, MN, USA, June 2014

The International Conference on Harmonisation (ICH) Steering Committee (SC) and its Expert Working Groups (EWGs) met in Minneapolis, MN, USA on May 31-June 5, 2014.

The SC is pleased to announce the decision that Heath Canada (HC) and Swissmedic are now Steering Committee members. In recognition of their historical involvement and commitment to ICH, Health Canada and Swissmedic were invited to become Steering Committee members during the ICH meeting in Osaka, 2013. The invitation came as the SC continued its discussions around a future ICH construct. After further elaboration of the roles and responsibilities envisioned for HC and Swissmedic as SC members, the SC has determined that HC and Swissmedic are now ICH Steering Committee members under a governance model that has been evolving during the discussions on the future of ICH.

As part of those discussions, a broader range of membership and governance reforms have been, and continue to be, considered, including the introduction of greater clarity regarding the distinct and separate roles of the ICH regulatory and industry parties in ICH. The ICH reform discussions have also been addressing parameters for creating a new legal entity for ICH and the future approach to funding. The roles of HC and Swissmedic as SC members conform to these governance principles.

The Steering Committee further progressed the development of the five year ICH strategic plan for future ICH topics in order to improve the strategic oversight on ICH work. A Quality Workshop was organised on June 1, 2014 in Minneapolis, prior to the ICH meeting in order to discuss the strategic way forward and propose key Quality topics for the next 10 years. A list of five future Quality topics was subsequently proposed to the SC for future harmonisation.

Safety Update

The M7 EWG on Assessment and Control of DNA Reactive (mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, reached agreement on the revised draft guideline satisfying all comments received during the public consultation and signed off at *Step 4*. The S5 Informal WG met to develop a Concept Paper, which was requested by the SC.

Efficacy Update

A new EWG created to develop an Addendum to E6, Good Clinical Practices (GCP), met for the first time in Minneapolis and made good progress in developing recommendations to facilitate innovative approaches to GCP. They expect to reach *Step 2* in June 2015.

Quality Update

The Q3D EWG, Guideline for Elemental Impurities, met and plans to reach *Step 4* in September 2014. The Q7 IWG, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, also met to continue their work on developing Q&As to address current issues raised by the use of the Q7 Guideline. The development of a Concept Paper for the new project on lifecycle

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management was endorsed by the SC considering the discussion at the workshop toward the next ICH meeting.

Electronic Standards

The M2 (Electronic Standards for the Transfer of Regulatory Information) met in Minneapolis, as did the M8 EWG (The Electronic Common Technical Document- eCTD). M8 signed-off at *Step 4* of Version 1.26 of the eCTD Change Request Q&A document and continued the development of the new ICH eCTD specification v4.0 ("Next Major Version").

MedDRA

In Minneapolis, ICH agreed the timeframe for the launch of a Call for Tender in mid-August for the contract for the MedDRA Maintenance and Support Services Organization (MSSO). ICH's primary goal is to ensure that there is minimal impact for MedDRA users. Further tender details will be made available on the ICH website in July.

The MedDRA Points to Consider Working Group updated two documents (Term Selection and Data Retrieval and Presentation) which should be completed and released with the new version of MedDRA on September 1, 2014.

The next ICH Steering Committee Meeting and its EWG meetings will be held in Lisbon, Portugal on November 9-13, 2014.

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