ICH announces organisational changes as it marks 25 years of successful harmonisation

Geneva, 26 October 2015

The International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation (ICH) held the inaugural meetings of its new Assembly [and Management Committee] on 23 October 2015.

The reforms build on a 25-year track record of successful delivery of harmonised guidelines for global pharmaceutical development, and their regulation. The changes announced today build on that success and will reinforce the foundations of ICH to make it better-equipped to face the challenges of global pharmaceutical development and regulation.

The reforms will mean that ICH is a truly global initiative, expanding beyond the current ICH members. More involvement from regulators around the world is welcomed and expected, as they will be invited to join counterparts from Europe, Japan, USA, Canada and Switzerland as ICH regulatory members. This is matched by the possibility of wider inclusion of global industry sectors affected by ICH harmonisation. The reforms strengthen ICH as the leading platform for global pharmaceutical regulatory harmonisation, and one that brings together in a transparent manner all key regulatory authorities and industry stakeholders.

The changes give ICH a more stable operating structure through the establishment of an ICH association, a legal entity under Swiss law. The association establishes the new Assembly as the over-arching governing body that will be instrumental in facilitating future growth through the participation of new members.

At the end of the inaugural meeting, ICH Assembly members declared “The fundamentals of what the ICH parties are trying to achieve are not changed, but the reforms to the process and organisation were needed to adapt to changes in how medicines are developed and regulated. These changes mark an exciting moment for us to help harmonise and streamline the global drug development process for the benefit of patients around the world.”

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NOTES FOR EDITORS

1. Current ICH membership includes the following 5 regulators: Health Canada (Canada), European Commission (EU), Ministry of Health Labor and Welfare/Pharmaceuticals and Medical Devices Agency (Japan), Swissmedic (Switzerland), Food and Drug Administration (USA). It also includes the following 3 industry members: European Federation of Pharmaceutical Industries and Associations (EU), Pharmaceutical Research and Manufacturers of America (USA) and Japan Pharmaceutical Manufacturers Association (Japan).
2. ICH has developed over 60 Guidelines to-date on Quality, Safety, Efficacy and Multidisciplinary topics, in addition to products including Electronic Standards for the Transfer of Regulatory Information (ESTRI), the Common Technical Document (CTD & eCTD), and the Medical Dictionary for Regulatory Activities (MedDRA).
3. This press release, together with more information on 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.