

ICH PRESS RELEASE
Lisbon, Portugal, 11-16 June 2016

ICH increases its global reach, moves forward on global drug development

The International Council for Harmonisation (ICH) met in Lisbon, Portugal, 11-16 June 2016, bringing together regulators and industry from around the world. Building on the objective to establish itself as a truly global platform for harmonisation for better health, ICH formally welcomed 2 new Members and 14 Observers representing regulatory authorities, regional health initiatives and pharmaceutical industry.

In addition to the 5 regulatory authorities and regional health initiatives announced in December 2015, ICH welcomed the following as new Observers:

- Association of Southeast Asian Nations (ASEAN)
- Biotechnology Innovation Organisation (BIO)
- Central Drugs Standard Control Organization (CDSCO, India)
- Council for International Organizations of Medical Sciences (CIOMS)
- Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS, Mexico)
- East African Community (EAC)
- European Directorate for the Quality of Medicines & HealthCare (EDQM)
- Health Sciences Authority (HSA, Singapore)
- International Pharmaceutical Excipient Council (IPEC)
- Ministry of Food and Drug Safety (MFDS, South Korea)
- Roszdravnadzor (Russia)
- Food and Drug Administration (TFDA, Chinese Taipei)
- Therapeutic Goods Administration (TGA, Australia)
- United States Pharmacopeia (USP)

Moreover, two new pharmaceutical industry bodies were welcomed, with International Generics and Biosimilars Association (IGBA) and World Self-Medication Industry (WSMI) accepted as Members¹.

Benefit-risk assessment, global drug development and other highlights

With advances for public health in mind, highlights of the meeting included adoption of a final revised ICH guideline on format and structure of benefit-risk information in the common technical document (ICH M4E (R2)). Given the importance of benefit-risk assessment for drug regulation, this is expected to support regulatory decision-making through a more consistent description of information coming from clinical trial data, as well as other factors such as disease severity and availability of other treatment options. Recognising the increasing role of the patient voice in drug development and regulation, the revised guideline also opens the possibility to include information about patient perspectives, for example information from patient preference studies. This revised guideline will now be implemented by each of the ICH regulatory members. Another highlight was the endorsement of a draft guideline on multi-regional clinical trials (ICH E17). With the move to global development of medicines, the guideline is intended to support the

¹ The list of all ICH Members and Observers is available on the [ICH website](#).

planning and design of multi-regional clinical trials, a reduction in unnecessary duplication of studies and the subsequent acceptability to regulators of data from those trials. The draft guideline will now be released for stakeholder consultation, with adoption of the final guideline planned for 2017.

The guideline on good clinical practice (ICH E6) was adopted in 1996. Designed to bring the guideline up to date, an integrated addendum (ICH E6 (R2)) reached *Step 3* of the ICH process, with expert consensus on the principles and content. With formal adoption expected later in 2016, the addendum is designed to modernise ICH E6 to enable implementation of innovative approaches to clinical trial design, management, oversight, conduct, documentation, and reporting that will better ensure human subject protection and data quality.

ICH also endorsed a draft question and answers document aimed at clarifying the 2009 ICH guideline on non-clinical evaluation of anticancer products (ICH S9 Q&A) that will now be released for stakeholder consultation. The questions and answers are intended to clarify the scope and implementation of the guideline, and support the development and evaluation of medicines for faster access for patients with serious and life-threatening cancers.

New topics for international harmonisation

Two new topics for international harmonisation were endorsed by the Assembly. The first is the development of a guideline on biopharmaceutical classification system-based biowaivers. The aim of the future ICH M9 Guideline is to achieve worldwide harmonisation of the applicability of biowaivers and the data needed to support such applications. The public health benefits include reducing unnecessary clinical trials, and facilitating the production and availability of good quality medicines especially in low and middle-income countries.

The second new topic is related to bioanalytical method validation, for which recent regulatory requirements have been introduced in EU, Japan and USA. The proposed ICH M10 Guideline will address the discrepancies between these provisions and those from other ICH regulatory members. A harmonisation approach will promote rational and effective studies and facilitate global drug development, thereby advancing the mission of ICH.

For further details on progress made on other guidelines at the meeting, please see the ICH Assembly Report published on the ICH website.

The next ICH meetings will be held on 5-10 November 2016 in Osaka, Japan, and in Spring 2017 in Montreal, Canada, to be hosted by Health Canada for the first time.

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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