IPRP
International Pharmaceutical Regulators Programme

Public Statement

1st meeting of the IPRP

Kobe, Japan – 2-3 June 2018

The inaugural meeting of the International Pharmaceutical Regulators Programme (IPRP) Management Committe (MC) was held on June 2nd and 3rd 2018 in Kobe, Japan with the participation of 20 IPRP Members and Observers.

The IPRP was launched in January 2018 stemming from the consolidation of the International Generic Drug Regulators Programme (IGDRP) and the International Pharmaceutical Regulators Forum (IPRF). The purpose of IPRP is to create a venue for regulatory authorities and organizations to share information, discuss issues of common concern, discuss emerging scientific areas of relevance to drug development and regulation, and work towards regulatory convergence. IPRP is comprised of representatives from pharmaceutical regulatory authorities and organisations with responsibilities for the regulation of medicinal products for human use or Regional Harmonisation Initiatives (RHIs) that wish to participate.

The first MC meeting focused on the operationalisation of the IPRP through the finalisation and adoption of the IPRP Terms of Reference (ToR). Other foundational elements such as the Strategic Vision, Standard Operating Procedure (SOP) for the MC and Working Groups (WGs), and launch of the new IPRP website will be completed in the coming months. Several IPRP foundational documents will be published on the new website at: www.iprp.global (available shortly).

ANVISA, Brasil and Health Canada, Canada were elected as IPRP MC Chair and Vice-Chair respectively, to serve for a 1-year term.

The meeting involved a report from each of the 8 IPRP WGs on: Nanomedicines, Biosimilars, Gene Therapy, Cell Therapy, Identification of Medicinal Product (IDMP), Quality for Generics and Bioequivalence for Generics, as well as Information Sharing for Generics for the sharing of the European Medicines Agency (EMA) review reports.

The MC endorsed the Reflection Paper on Expectations for Biodistribution Assessments for Gene Therapy Products that will shortly be published on the IPRP website. Furthermore, two other publications are expected to be submitted to the MC for approval in the coming months: a Reflection Paper developed by the Cell Therapy WG on General Principles to Address the Nature and Duration of Follow-up for Subjects of Clinical Trials Using Cell Therapy Products; and a Survey conducted by the Bioequivalence WG for Generics of the Regulatory Requirements for the Acceptance of Foreign Comparator Products by Participating Regulators and Organizations of the IPRP.

Presentations on focus topics including antimicrobial resistance and the opioids crisis in Canada and USA were provided as well as relevant regulatory updates from IPRP Members and Observers. Discussions took place on potential new topics for ICH. Real World Evidence was identified as a topic of interest which need further experience; and a mapping exercise of the data requirements for novel excipients and how they are defined in each region will be carried out by IPRP.

The next IPRP MC meeting will be held on November 11th-12th 2018 in Charlotte, North Carolina, USA.