IPRP
International Pharmaceutical Regulators Programme

Geneva, 20th November 2018

Public Statement
2nd meeting of the IPRP

Charlotte, NC, USA – 11th-12th November 2018

The second meeting of the International Pharmaceutical Regulators Programme (IPRP) Management Committe (MC) was held on the 11th and 12th of November 2018 in Charlotte, NC, USA with the participation of 19 IPRP Members and Observers.

With the MC welcoming in Charlotte its newest Member the Turkish Medicines and Medical Devices Agency (TITCK, Turkey), IPRP now has 23 Members and 2 Observers. The MC reaffirmed the inclusive membership of IPRP, comprised of regulatory authorities and organisations with responsibilities for the regulation of medicinal products for human use or related Regional Harmonisation Initiatives (RHIs) that wish to participate.

The meeting in Charlotte marked the end of the first year of the existence of the IPRP, which 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 operationalisation of the IPRP was finalised with the endorsement of its stakeholder engagement plan to be published shortly on the newly launched IPRP website, www.iprp.global. Other IPRP foundational documents are already published on the website, including the Terms of Reference (ToR), Standard Operating Procedure (SOP), and Strategic Vision. Please visit the new website for the latest achievements of IPRP, including publications of the IPRP Working Groups (WGs) and outcomes of the IPRP MC meetings. The IPRP Secretariat can also be reached via the contact form of the website for any external inquiry.

The meeting involved a report from 7 of the 8 IPRP WGs, specifically: Nanomedicines, Biosimilars, Gene Therapy, Cell Therapy, Identification of Medicinal Product (IDMP), Quality for Generics and Bioequivalence for Generics, with several milestones achieved. The MC endorsed the Reflection Paper of 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" to be published on the IPRP website. Several other publications are also expected in the coming months including: a survey on liposomal product recommendations developed by the Nanomedicines WG, a Frequently Asked Questions (FAQ) by the IDMP WG, a survey on administrative procedures and terminologies for Quality-related post-approval changes by the Quality WG for Generics, and an assessment report template for additional strength biowaivers (immediate release dosage forms) by the Bioequivalence WG for Generics.

A main focus topic of the meeting was *reliance*, the act by which one regulatory authority takes into account the work performed by another regulatory authority or other trusted institution in reaching its own decision, which has been seen by an increasing number of countries as an important means of improving the efficiency of regulatory operations. In this spirit, the MC has agreed to further use IPRP as a forum for discussion of best practices related to reliance and to assist the WHO in developing further guidance and tools through the experience of IPRP members.

The IPRP Members also shared their experiences on challenges encountered within the course of implementation of ICH Guidelines and discussed case studies related in particular to the implementation of ICH Guidelines on electronic standards. Recognising the importance of ICH guideline implementation and the need for further discussion, the MC agreed to keep this topic as a standing agenda item for IPRP meetings going forward.

The next IPRP MC meeting will be held on the 2nd and 3rd of June 2019 in Amsterdam, the Netherlands.