

Public Statement

6th meeting of the IPRP Management Committee

19th-20th November 2020

The Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) held its sixth meeting on the 19th and 20th of November 2020, with the participation of Representatives from 25 out of the 32 IPRP Members and Observers. For the second time in 2020, the meeting was organised in a virtual format due to the COVID-19 pandemic.

Following the departure of the previous IPRP MC Vice-Chair, the MC elected Dr. Peter Bachmann from EC/EMA, Europe to serve the remainder of the annual term which ends in June 2021.

IPRP Members and Observers shared the latest significant updates on pharmaceutical regulation in their regions, as well as their respective responses to the COVID-19 pandemic. The main focus topic of the meeting was Reliance, the act by which one regulatory authority takes into account and give significant weight to assessments performed by another regulatory authority or other trusted institution in reaching its own decision. The MC agreed to continue advancing discussion on this topic within IPRP in the coming year. The publication of an article on the outcome of a survey developed by the World Health Organization (WHO) and conducted amongst IPRP parties on their experiences of Reliance is expected in the coming months and a second publication is foreseen in 2021 focusing on Reliance in the context of a Public Health Emergency.

The MC reviewed the outcome of the pilot project of the Information-Sharing Working Group (WG) for Generics for the sharing of information on the evaluation of Generic Drug applications and agreed to confirm the closure of the pilot project and the WG. The MC will take into account the experience gained with the pilot to the other IPRP activities and continue moving forward on this topic as part of its broader discussion on Reliance.

Highlights of the meeting also included reports from the IPRP WGs on Nanomedicines, Gene Therapy, Cell Therapy, Identification of Medicinal Products (IDMP), Quality, Biosimilars, Bioequivalence for Generics, and Pharmacovigilance, on their progress and planned activities for 2021. The MC endorsed the final mandate and 2021 work plan of the Pharmacovigilance WG, which will be available shortly on the IPRP website. The Pharmacovigilance WG was established earlier this year to leverage knowledge-sharing and advance pharmacovigilance collaboration between IPRP members. The MC also noted the progress and milestones reached electronically by WGs, including the finalisation by the Bioequivalence WG for Generics of an article on *Biowaivers for dosage forms (oral and injectable products)*, which has been submitted for publication in a peer review journal.

The next IPRP MC meeting is planned for the 7th and 8th of June 2021 and will be held again in a virtual setting.