

Public Statement 5th meeting of the IPRP

28th May 2020

The Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) held its fifth meeting on the 28th of May 2020. Representatives from 25 IPRP Members and Observers joined the meeting which was organised in a virtual setting.

The IPRP welcomed as its newest Member the Food and Drug Administration of Indonesia, Badan POM. With this continued expansion in membership, a total of 30 Members and 2 Observers from across the world are currently cooperating within IPRP. Dr. Junko Sato from MHLW/PMDA, Japan and Ms. Hacer Coşkun Çetintaş from TITCK, Turkey were re-elected by consensus as IPRP MC Chair and Vice-Chair respectively, to serve for a further 1-year term.

The meeting included reports from the IPRP Working Groups (WGs) on Nanomedicines, Gene Therapy, Cell Therapy, Identification of Medicinal Product (IDMP), Quality, Biosimilars, Bioequivalence for Generics, and Pharmacovigilance, presenting their achievements since the last meeting and their future activities. The MC endorsed the *Guidance for Quality Assessors - Drug Product*, developed by the Quality WG, which will provide guidance and assistance to Quality Assessors in the assessment of the technical information contained in the Drug Product Quality Module (Module 3.2.P) and will facilitate the preparation of Quality Assessment Reports. This document will be available shortly on the IPRP website.

IPRP Members and Observers shared the latest updates on pharmaceutical regulation in their regions as well as actions put in place and specific responses to the COVID-19 pandemic. The MC also discussed next steps for the publication of the outcome of the survey developed by the World Health Organization (WHO) and conducted among IPRP parties on their experiences of 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. The publication of an article on this topic is expected before the end of 2020.

The next IPRP MC meeting is planned for the 18th and 19th of November 2020 in Athens, Greece.