

Public Statement
14th Meeting of the IPRP Management Committee
6th & 7th November 2024
Montreal, Canada

The fourteenth meeting of the Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) was held on the 6th and 7th of November 2024 in Montreal, Canada. 32 IPRP Members and Observers were represented at the meeting. The MC welcomed three new IPRP MC Members: The Peruvian Regulatory Authority – DIGEMID, Peru; the Uzbekistan Regulatory Authority – CPPS, Uzbekistan; and the Thai Regulatory Authority – Thai FDA, Thailand. NMPA, China participated in this IPRP MC Meeting as an invited Observer.

The following IPRP Working Groups (WGs) provided reports on their achievements over the past months and their future activities: Identification of Medicinal Products (IDMP); Nanomedicines; Cell & Gene Therapy (CGT); Biosimilars; Bioequivalence for Generics (BEG); and Quality. The updates included: news from the Bioequivalence WG for Generics regarding development of Biopharmaceutics Classification System (BCS) Biowaiver Assessment Report Template and Dosage Form Biowaiver Assessment Report Templates for publication on the IPRP website shortly; finalisation of the IDMP Frequently Asked Questions Version 6.0, for publication shortly on the IPRP website, by the IDMP WG; and publication of a summary report in July 2024, on the IPRP website, by the Biosimilars WG on the September 2023 workshop on “Increasing the Efficiency of Biosimilar Development Programs—Reevaluating the Need for Comparative Clinical Efficacy Studies”.

The MC also discussed a number of Focus topics at the Montreal meeting. These included:

- Experiences in the Implementation of ICH Guidelines, including Quality WG considerations on implementation challenges with ICH Quality Guidelines;
- Reliance, with a presentation on the ACCESS Consortium provided by Swissmedic, Switzerland;
- Using Artificial Intelligence (AI), with the use of machine learning and generative large language models in pharmacovigilance presented by HSA, Singapore. Additionally, MHRA, UK presented on the use of AI at the MHRA, UK.

The MC also spent time in Montreal to further discuss IPRP’s strategic vision and stakeholder engagement plan, based on input collected in a survey conducted of IPRP Members and Observers, as well as external stakeholders, with an objective to inform the future strategic direction of IPRP.

Finally, the MC also received a number of regulatory updates from IPRP Members and Observers.

The next meeting the IPRP MC is planned for the 14th and 15th May 2025 in Madrid, Spain.