

Public Statement
12th Meeting of the IPRP Management Committee
1st & 2nd November 2023
Prague, Czech Republic

The twelfth meeting of the Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) was held on the 1st and 2nd of November 2023 Prague, Czech Republic. 29 IPRP Members and Observers were represented at the meeting. The MC welcomed two new IPRP MC Members: The Algerian Regulatory Authority – ANPP, Algeria; and the Jordanian Regulatory Authority – JFDA, Jordan.

The following IPRP Working Groups (WGs) provided reports on their achievements over the past months and their future activities: Nanomedicines; Cell & Gene Therapy; Identification of Medicinal Products (IDMP); Quality; Biosimilars; and Bioequivalence for Generics. Of note was the virtual Biosimilars WG workshop held in September 2023 on *Increasing the Efficiency of Biosimilar Development Programs—Reevaluating the Need for Comparative Clinical Efficacy Studies*. The MC noted that the public session of the workshop was very well attended, with close to 1,700 registrants and that the presentations, as well as a recording of the workshop would be made available shortly on the IPRP website.

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

- Use of Artificial Intelligence in medicines development;
- Experiences with implementation of ICH Guidelines, including a country experience from COFEPRIS, Mexico;
- Reliance, including an update on the WHO Listed Authority (WLA) initiative;
- e-Labeling and e-statutory information of medicinal products.

Other important topics, which the IPRP MC was updated on, included the ongoing work of the International Coalition of Medicines Regulatory Authorities (ICMRA) Pharmaceutical Quality Knowledge Management System (PQ KMS) Working Group, with which IPRP is working, alongside the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) to harmonise pharmaceutical quality knowledge management to improve the availability of high-quality medicines.

At the next meeting the IPRP MC will discuss the revision of the IPRP Strategic Framework, including the IPRP Stakeholder Engagement Plan, besides the continuing topics. The meeting is planned for the 5th and 6th June 2024 in Fukuoka, Japan.