IPRP
International Pharmaceutical Regulators Programme

Geneva, 28 May 2025

Public Statement
15th Meeting of the IPRP Management Committee

14th & 15th May 2025

Madrid, Spain

The fifteenth meeting of the Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) was held on the 14th and 15th of May 2025 in Madrid, Spain. 31 IPRP Members and Observers were represented at the meeting. The MC welcomed three new IPRP MC Members: the Paraguayan Regulatory Authority – DINAVISA, Paraguay; the Kuwaiti Regulatory Authority – MOH, Kuwait; and the Salvadoran Regulatory Authority – SRS, El Salvador. NMPA, China participated in this IPRP MC Meeting as an ad-hoc Observer.

Dr. Petra Doerr from EDQM was re-elected as the IPRP MC Chair to serve for a two-year term from the end of the Madrid meeting, with Dr. Asmaa Fouad (EDA, Egypt) continuing in her role of MC Vice-Chair.

The following IPRP Working Groups (WGs) provided reports on their achievements over the past months and their future activities: Identification of Medicinal Products (IDMPWG); Nanomedicines (NWG); Cell & Gene Therapy (CGTWG); Biosimilars (BWG); Bioequivalence for Generics (BEWGG); and Quality (QWG). The updates included the finalisation of the following milestones for publication on the IPRP website:

- IDMP Frequently Asked Questions Version 7.0 developed by the IDMPWG;
- Executive Summary on Survey on the Implementation of the IPRP Quality Assessment Tools developed by the QWG.

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

- Experiences in the Implementation of ICH Guidelines, including sharing experiences with the implementation of the M4Q(R2) Guideline and FDA, United States' experiences with M8 eCTD v4.0. Additionally, EDA, Egypt shared lessons learned from their training funded by ICH under the ICH Regulatory Training process;
- Reliance practices and cooperation, with a presentation on Reliance terminology presented by WHO and Reliance in the EU system, by EC, Europe;
- Artificial Intelligence (AI) regulatory challenges on the use of AI to design individualised cancer immunotherapies by MHRA, UK.

The MC also continued discussions on IPRP's strategic vision, with the aim of shaping the organisation's future direction. A strategic vision document as well as revised Terms of Reference are expected to be finalised at the next MC meeting. The importance of establishing a clear communication plan to enhance IPRP's visibility was also emphasised. The proposed communication strategy and updated stakeholder engagement plan will also be further explored at the next MC meeting.

The activities of the International Coalition of Medicines Regulatory Authorities (ICMRA) and initiatives related to building a Pharmaceutical Quality Knowledge Management (PQKM) capability were shared with the MC. Finally, the MC also received a number of regulatory updates from IPRP Members and Observers.

The next IPRP MC meeting is planned for the 19th and 20th November 2025 in Singapore.