IPRP
International Pharmaceutical Regulators Programme

Geneva, 19 June 2024

Public Statement
13th Meeting of the IPRP Management Committee

5th & 6th June 2024

Fukuoka, Japan

The thirteenth meeting of the Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) was held on the 5th and 6th of June 2024 in Fukuoka, Japan. 29 IPRP Members and Observers were represented at the meeting. Dr. Asmaa Fouad from EDA, Egypt was elected as the new IPRP MC Vice-Chair, replacing Mr. Teruyoshi Ehara from MHLW/PMDA, Japan, to serve for a two year term from the end of the Fukuoka meeting, alongside the current IPRP Chair Dr. Petra Doerr from EDQM.

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; Biosimilars; Bioequivalence for Generics; and Quality. The updates included: news from the Bioequivalance WG for Generics regarding the publication in March 2024 of an article on "Bioequivalence Study Designs" in the Journal of Pharmacy & Pharmaceutical Sciences; work on a summary report, for publication shortly 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"; and Quality WG involvement with activities of the International Coalition of Medicines Regulatory Authorities (ICMRA) Pharmaceutical Quality Knowledge Management System (PQ KMS) Working Group.

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

- Patient-orientated and electronic product information;
- Experiences in the Implementation of ICH Guidelines, with discussion of the outcome of the recent survey conducted by ICH (via a third-party survey provider) to assess the current level of implementation and adherence to ICH Guidelines within Regulatory Member and Observer countries/regions, many of who are also represented at IPRP;
- Reliance practices and cooperation;
- Artificial Intelligence (AI) in medical products development, with presentation on the 2024 AI Regulatory and International Symposium (AIRIS) held in February 2024 in Seoul, Republic of Korea, co-hosted by MFDS, Republic of Korea and FDA, United States.

The MC also spent time in Fukuoka to discuss IPRP's strategic vision and stakeholder engagement plan, reviewing input collected in a survey conducted of IPRP Members and Observers, as well as external stakeholders. The MC will reflect on the outcome of the survey which will be used 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 6th and 7th November 2024 in Montréal, Canada.