IPRP
International Pharmaceutical Regulators Programme

Geneva, 4 December 2025

# Public Statement
# 16th Meeting of the IPRP Management Committee

**19-20 November 2025**

**Singapore**

The sixteenth meeting of the Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) was held on 19-20 November 2025 in Singapore. 39 IPRP Members and Observers were represented at the meeting. The MC welcomed three new IPRP MC Members: The Dominican Regulatory Authority – DIGEMAPS, Dominican Republic; the Filipino Regulatory Authority – Philippine FDA, Philippines; and the Tunisian Regulatory Authority – DPM, Tunisia. NMPA, China participated in this IPRP MC Meeting as an ad-hoc Observer.

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 MC also discussed a number of Focus Topics at the Singapore meeting. These included:

- Experiences in the Implementation of ICH Guidelines, including discussions on challenges and lessons learned in implementing ICH E17. EC, Europe framed the discussion on adequate and consistent implementation, and MHLW/PMDA, Japan presented its experience with E17. Members also exchanged views on mechanisms that support harmonisation and practical steps for improving implementation;
- Reliance practices and cooperation, with extended discussions on reliance and worksharing approaches. Presentations were delivered on a database of reliance-based pathways (FRPath Project), on the perspective on international reliance by Health Canada, Canada, updates on reliance from the ICMRA Summit by TGA, Australia, and national approaches to reliance from ANVISA, Brazil and CPED, Israel. WHO presented on the WLA framework as a sustainable mechanism for regulatory reliance;
- Artificial Intelligence (AI), focusing on the use of AI in medicines regulation and therapeutic development. Presentations included FDA, United States on AI for drug and biological products, EDA, Egypt on AI in vaccine development, MFDS, Republic of Korea on outcomes from the AI Regulatory & International Symposium (AIRIS 2025), and SFDA, Saudi Arabia on the AI tools developed and used in SFDA for various purposes.

The MC also noted a presentation by MPA, Sweden on the Regulatory Agencies Global Network Against AMR (RAGNA), an initiative launched during the Swedish Presidency of the Council of the European Union in 2023 to strengthen international collaboration among regulatory agencies in addressing antimicrobial resistance (AMR) through a One Health approach.

The MC finalised the review of the strategic vision and Terms of Reference, following the discussions at the Madrid meeting, and adopted them. The main changes include a reflection of the focus on reliance in the mission and purpose of IPRP, refining the communication strategy, and strengthening stakeholder engagement. The MC also discussed the Communication Plan, summarising the visibility and outreach activities for 2026. Finally, the MC also received a number of written regulatory updates from IPRP Members and Observers.

The next meeting of the IPRP MC is planned for 3-4 June 2026 in Rio de Janeiro, Brazil.