IPRP
International Pharmaceutical Regulators Programme

Geneva, 13 June 2022

Public Statement
9th Meeting of the IPRP Management Committee
25th & 26th May 2022

Athens, Greece

The ninth meeting of the Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) was held on the 25th and 26th of May 2022 in Athens, Greece. 23 IPRP Members and Observers were represented at the meeting, which was organised in a hybrid format with both in-person and virtual participation. The MC welcomed the Egyptian Drug Authority – EDA, Egypt as a new IPRP Member. Dr. Peter Bachmann from EC, Europe and Mr. Diogo Penha Soares from ANVISA, Brazil were re-elected as IPRP MC Chair and Vice-Chair respectively, to serve for another 1-year term from the end of the meeting.

IPRP's 8 Working Groups (WGs) provided a report to the MC on, respectively: Nanomedicines; Cell Therapy; Gene Therapy; Identification of Medicinal Products (IDMP); Quality; Biosimilars; Bioequivalence for Generics; and Pharmacovigilance, presenting their achievements over the past months and their future activities. The MC endorsed publication of an article from the Working Group on Bioequivalence for Generics on *"A Survey of the Criteria Used for the Selection of Alternative Comparator Products by Participating Regulators and Organizations of the International Pharmaceutical Regulators Programme"*.

Focus topics of MC discussion at the meeting included: Reliance; e-Labelling; Environmental Risk Assessment; Challenges in the Implementation of ICH Guidelines; and a new focus topic regarding the Sharing of Experience on Patient Engagement.

- Regarding Reliance, the MC provided support in principle for a Questions and Answers document for publication on the IPRP website that will explain the importance of reliance for the regulatory oversight of medical products working with WHO.
- On the topic of e-labelling, the MC noted development of an article informed by the results of the recent survey conducted amongst IPRP parties. The article entitled *"Electronic product information for human medicines; current situation and future projection: based on surveys of regulatory agencies in IPRP countries/regions"* is planned for publication shortly with financial support for its publication from IPRP as a first case.
- The results of the Environmental Risk Assessment survey amongst IPRP parties in relation to medicinal products were also discussed by the MC, with parties sharing information on requirements in their respective countries/regions.
- The MC also shared experiences regarding approaches to learning about patient's experience with their disease and available treatments, and ways in which patients are engaged to inform regulatory decision making on products to treat that disease.
- The IPRP Members shared their experiences with implementation of ICH Guidelines and agreed an approach for the next meeting to facilitate further discussion of experiences.
- Finally, the IPRP Members shared significant recent regulatory updates.

The next IPRP MC meeting is planned for the 16th and 17th of November 2022 and is foreseen to be held in person in Incheon, Republic of Korea.