IPRP
International Pharmaceutical Regulators Programme

Geneva, 1 December 2022

Public Statement
10th Meeting of the IPRP Management Committee
16th & 17th November 2022

Incheon, Republic of Korea

The tenth meeting of the Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) was held on the 16th and 17th of November 2022, Incheon, Republic of Korea. 25 IPRP Members and Observers were represented at the meeting.

IPRP's 8 Working Groups (WGs): Nanomedicines; Cell Therapy; Gene Therapy; Identification of Medicinal Products (IDMP); Quality; Biosimilars; Bioequivalence for Generics; and Pharmacovigilance, provided a report to the MC on their achievements over the past months and their future activities.

Focus topics: Reliance; Experiences in the Implementation of ICH Guidelines; Experience Sharing on Patient Engagement; and statutory electronic product Information of Medicinal Products were discussed at the meeting:

- The IPRP MC discussed the important topic of sameness of medicinal product in the context of reliance. The verification of sameness (as defined in the WHO Good Reliance Practices document) is an essential step for any reliance approaches in order to check that the product for which a dossier has been received by the relying authority has "identical essential characteristics" as the one received by the reference authority. Regarding manufacturing sites as they constitute key quality attributes for the medical product, the expectation from regulators is that the product should have the same manufacturing site(s) reviewed by the reference authority. Per WHO Good Reliance Practices, any differences between the dossier submitted to the reference authority and the relying authority should be clearly identified upfront by the manufacturer/marketing authorization holder and should be assessed by the National Regulatory Authority;

- The IPRP MC Members shared their experiences with implementation of ICH Guidelines, with specific focus on Quality, including the older Q1 ICH Stability Guidelines and the more recent Q12 Lifecycle Management Guideline. Regarding Q12, Regulators shared similar experiences, including stepwise approaches to implementation and training considerations;

- The IPRP MC Members also shared experiences regarding patient stakeholder engagement, including approaches for engagement of patients in different scenarios, such as during the pandemic which highlighted the importance of communication in a non-technical way;

- The IPRP MC was also informed on the latest technical advances in Europe on e-Labelling and electronic product information (ePI) under Health Level Seven's (HL7's) Fast Healthcare Interoperability Resources (FHIR), and the broader use of FHIR as a common technical standard for structuring and exchanging product information.

Finally, the MC also discussed a new topic on using Artificial Intelligence (AI) to Monitor Products Sold Online, and also received a number of regulatory updates from IPRP Members.

The next IPRP MC meeting is planned for the 13th and 14th of June 2022 and is foreseen to be held in Vancouver, Canada.