IPRP
International Pharmaceutical Regulators Programme

Geneva, 26 June 2023

Public Statement
11th Meeting of the IPRP Management Committee

13th & 14th June 2023

Vancouver, Canada

The eleventh meeting of the Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) was held on the 13th and 14th June 2023 in Vancouver, Canada. 23 IPRP Members and Observers were represented at the meeting. The MC welcomed the Nigerian Drug Authority – NAFDAC, Nigeria as a new IPRP Member. Dr. Petra Doerr from EDQM and Mr. Teruyoshi Ehara from MHLW/PMDA, Japan were elected as new IPRP MC Chair and Vice-Chair to serve for two and one year terms rexpectively.

The following IPRP Working Groups (WGs) provided reports on their achievements over the past months and their future activities: Nanomedicines; Cell Therapy; Gene Therapy; Identification of Medicinal Products (IDMP); Quality; Biosimilars; and Bioequivalence for Generics. Of note was the IPRP MC support for the merging of the Cell Therapy and Gene Therapy WGs moving forward, as well as IPRP MC support for the organization of a virtual public workshop by the Biosimilars WG on 12th and 13th September 2023 on *Increasing the Efficiency of Biosimilar Development Programs – Re-evaluating the Need for Comparative Clinical Efficacy Studies*. Details will be made available on the IPRP website.

The following were discussed as Focus topics discussed at the meeting:

- Experiences with implementation of ICH Guidelines, including the recent Q12 Lifecycle Management Guideline, as well the Q5E and E6(R2) Guidelines;
- Electronic product information (ePI) and future vision for ePI in regulatory processes in Europe;
- A Member experience on Digitalization of Risk Communication;
- Experiences regarding patient stakeholder engagement, and work to collect patient experiences towards enhancing meaningful outcomes;
- Finally, an update to the IPRP Questions & Answers document on Reliance was confirmed for publication on the IPRP website.

The IPRP MC was also updated on the important work, including ongoing pilots, of the International Coalition of Medicines Regulatory Authorities (ICMRA) Pharmaceutical Quality Knowledge Management System (PQ KMS) Working Group, with which IPRP is working, alongside the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) to harmonise pharmaceutical quality knowledge management to improve the availability of high-quality medicines.

The next IPRP MC meeting is planned for the 1st and 2nd November 2023 in Prague, Czech Republic.