IPRP
International Pharmaceutical Regulators Programme

Geneva, 22 June 2021

Public Statement
7th Meeting of the IPRP Management Committee

7th-8th June 2021

The Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) held its seventh meeting on the 7th and 8th of June 2021. Representatives from 27 IPRP Members and Observers joined the meeting which was organised in a virtual setting in view of the COVID-19 pandemic.

The IPRP welcomed as its newest Member the Medicines and Healthcare products Regulatory Agency of the United Kingdom (MHRA). With this continued expansion in membership, a total of 31 Members and 2 Observers globally are currently cooperating within IPRP. Dr. Peter Bachmann from EC/EMA, Europe and Mr. Diogo Penha Soares from ANVISA, Brazil were elected as IPRP MC Chair and Vice-Chair respectively, to serve for a 1-year term after this meeting.

Focus topics for MC discussion at the meeting included: Reliance, e-labelling and Environmental Risk Assessment (ERA). Following-on from discussions held at the previous meetings on Reliance, the MC noted that a second article on Reliance focusing on the context of a Public Health Emergency is expected for publication by the end of the year. The MC will continue further discussion on technical aspects of Reliance within IPRP and the MC will take into account the recently published WHO Good Reliance Practices. The MC reviewed the preliminary results of a survey conducted among IPRP parties on e-labelling of pharmaceuticals, when the product information is distributed via electronic means, including on use of this concept by the various regulators. The timeframe to answer the survey will be extended and, with the establishment of a drafting group, its results will inform the development of an article on e-labelling expected to be published by 2022. Finally, the MC shared views on Environmental Risk Assessment (ERA), the process by which relevant regulators ensure that the potential influence of pharmaceuticals on the environment are studied and adequate precautions are taken in case specific risks are identified. Considering the relevance of this topic, the MC agreed to continue the discussion in IPRP, exchange experiences and share practices on ERA. A survey will be conducted among IPRP parties on regional practices. More in-depth MC discussion will be considered at the next meeting.

Additionally, the IPRP Members shared their experiences on challenges encountered within the course of implementation of ICH Guidelines, in particular on electronic standards. In view of the importance of ICH Guideline implementation and the need for further discussion, the MC will keep this topic as an agenda item for the next meetings.

Highlights of the meeting also included reports from the 8 IPRP Working Groups (WGs) on 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 the *Quality Assessment Report – Full Dossier Template* developed by the Quality WG, which provides a common template for the assessment of technical information contained in Common Technical Document (CTD) Module 3 and will assist regulators in the review of applications for marketing authorisation. This template completes the suite of IPRP Quality regulatory tools for the assessment of Quality information related to drug substances and drug products, and will be available shortly on the IPRP website.

The next IPRP MC meeting is planned for the 22nd and 23rd of November 2021 in a virtual format.