IPRP
International Pharmaceutical Regulators Programme

Geneva, 6 December 2021

Public Statement
8th Meeting of the IPRP Management Committee

19th & 22th November 2021

The eighth meeting of the Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) was held on the 19th and 22th of November 2021. 24 IPRP Members and Observers were represented in the meeting, which was organised in a virtual setting in view of the COVID-19 pandemic.

As usual in IPRP MC meetings, the 8 IPRP 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 the publication drafted by the Quality WG on *Survey on Administrative Procedures and Terminologies for Quality Variations/Post-approval Changes*. This paper will assist in clarifying differences in Regulators' terminologies and procedural aspects and aims to increase an understanding of the procedures used for changes to APIs and drug products (e.g., categories/levels) for both regulators and the pharmaceutical industry, and will be available shortly on the IPRP website. Additionally, the *Frequently Asked Questions (FAQ)* document of the IDMP WG was updated and will be published on the IPRP website to promote the understanding of IDMP standards in order to support the implementation.

The main focus topics of MC discussion at the meeting were Reliance and e-labelling. The MC is continuing further discussion on technical aspects of Reliance and on identifying steps for concrete action within IPRP, taking into account roles to be played by other fora such as ICMRA (International Coalition of Medicines Regulatory Authorities). The MC reviewed progress on the development of an article informed by the results of the survey conducted among IPRP parties on e-labelling of pharmaceuticals, when the product information is distributed via electronic means. The article is expected to include an overview of e-labelling status amongst IPRP Regulatory Members as well as considerations on the importance of e-labelling and reflections on its future. Publication is expected in 2022.

Additionally, the IPRP Members shared their experiences on challenges encountered within the course of implementation of ICH Guidelines, in particular on ICH Q12 on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management. The MC will keep this topic as an agenda item for the next meetings with the aim of facilitating the implementation of ICH Guidelines.

Finally, the MC noted the results of the survey conducted among IPRP parties on their practices in Environmental Risk Assessment (ERA) and confirmed to discuss more at the next meeting.

The next IPRP MC meeting is planned for the 25th and 26th of May 2022 and is foreseen to be held in person in Athens, Greece, situation permitting.