IPRP
International Pharmaceutical Regulators Programme

Geneva, 4 December 2019

Public Statement
4th meeting of the IPRP

Singapore – 20th & 21st November 2019

The fourth meeting of the International Pharmaceutical Regulators Programme (IPRP) Management Committee (MC) was held on the 20th and 21st of November 2019 in Singapore. Representatives from 25 IPRP Members and Observers from across the world participated in the meeting.

Three new Members were welcomed by the MC: the Center for Pharmaceutical and Enforcement Division of Israel (CPED), the National Pharmaceutical Regulatory Agency of Malaysia (NPRA) and the Saudi Arabia Food and Drug Agency (SFDA). With these newest Members, a total of 29 Members and 2 Observers are now participating in IPRP cooperation activities.

The purpose of the meeting was to review progress of the IPRP Working Groups (WGs), to share information on regional pharmaceutical regulation, and to discuss emerging regulatory topics including in particular Real-World Evidence and Reliance. PIC/S was invited as an ad-hoc Observer participant for this meeting and presented to the MC areas of PIC/S activities in international cooperation relevant to IPRP activities.

The meeting involved a report from the IPRP WGs on activities and achievements since their last report to the MC: Nanomedicines, Biosimilars, Gene Therapy, Cell Therapy, Identification of Medicinal Product (IDMP), Quality for Generics, and Bioequivalence for Generics. The MC reviewed the work conducted by the pilot project of the Information-Sharing WG for Generics for the sharing of information on the evaluation of Generic Drug applications and agreed in view of its completion to propose the closure of the project by the time of the next meeting.

Following-on from discussions held at the previous meeting on real-world evidence and the use of non-conventional data sources for pharmacovigilance purposes, the MC decided to proceed with the establishment of a Pharmacovigilance Working Group with a mandate to leverage knowledge-sharing and opportunities to advance collaboration in the area of pharmacovigilance between IPRP members. This WG will initiate activites after the meeting to develop its work plan and define steps to be taken to enhance the area of pharmacovigilance through collaborations and knowledge-sharing on appropriate methodologies to use and analyze structured and unstructured data, and to complement traditional spontaneous reporting systems through this process, when necessary.

The MC also discussed the outcome of the survey developed by the World Health Organization (WHO) and conducted among IPRP parties on their experiences of Reliance, the act by which one regulatory authority takes into account the work performed by another regulatory authority or other trusted institution in reaching its own decision. The results of the survey were already shared on the IPRP website and will inform the development of an article to be published in 2020. The MC will continue further discussion on this topic at its next meeting.

The next IPRP MC meeting will be held on the 27th and 28th of May 2020 in Vancouver, Canada.