IPRP
International Pharmaceutical Regulators Programme

Geneva, 14 June 2019

Public Statement
3rd meeting of the IPRP

Amsterdam, the Netherlands – 2nd & 3rd June 2019

The third meeting of the International Pharmaceutical Regulators Programme (IPRP) Management Committee (MC) was held on the 2nd and 3rd of June 2019 in Amsterdam, the Netherlands. A total of 22 IPRP Members and Observers from across the world participated in the meeting.

The MC welcomed the National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT, Argentina) and the Iran National Regulatory Authority (NRA, Iran) as new Members in Amsterdam. With these newest Members, IPRP now has 26 Members and 2 Observers globally. Dr. Junko Sato from MHLW/PMDA, Japan and Ms. Hacer Coşkun Çetintaş from TITCK, Turkey were elected as IPRP MC Chair and Vice-Chair respectively, to serve for a 1-year term.

The purpose of the meeting was to review progress of the IPRP Working Groups (WGs), share information on regional pharmaceutical regulation, and to discuss emerging regulatory topics.

The meeting involved a report from the 8 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, Bioequivalence for Generics and Information-Sharing for Generics. A Frequently Asked Questions document prepared by the IDMP WG was approved and will be published shortly on the IPRP website to support the implementation and promote the understanding of IDMP standards. The MC also endorsed the article developed by the Bioequivalence WG for Generics on *Differences and Commonalities amongst Requirements for Additional Strength Biowaivers for Immediate Release Solid Oral Dosage Forms*, which will be submitted for publication. The Assessment Report Template on *Additional Strength Biowaivers for use by Regulatory Authorities*, another deliverable of the Bioequivalence WG for Generics, is already available on the IPRP website.

In the meeting, information was shared, including comparing statutory and regulatory frameworks among regulators, to better identify and understand potential opportunities for *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 MC discussed the outcome of a survey developed by the World Health Organization (WHO) and conducted among IPRP parties on their experiences, challenges, perceived benefits and opportunities of reliance. The MC agreed to continue discussion at its next meeting with a focus on key considerations for reliance.

Another focus topic of the meeting was real-world evidence and the use of non-conventional data sources for pharmacovigilance purposes. Acknowledging the possible benefits that information sharing on this topic could bring to IPRP Regulators, but also its associated technical challenges, the MC agreed as a first line of action to pursue a scoping exercise to explore to what extent this topic could be undertaken within IPRP. Outcomes of the exercise and next steps for this line of work will be further discussed at the next MC meeting.

The next IPRP MC meeting will be held on the 20th and 21st of November 2019 in Singapore.