i-p-r-f.org
International Pharmaceutical Regulators Forum

Public Summary/Public Statement

Second International Pharmaceutical Regulators Forum (IPRF) Meeting held in Minneapolis, US

Minneapolis, MN, US, 3 June 2014

The Management Committee of the International Pharmaceutical Regulators Forum (IPRF) met in Minneapolis, MN, US, on 2 and 3 June 2014. It was the second meeting of this group, following on the work from the first meeting in November 2013 in Osaka, Japan.

The IPRF provides to its members a unique opportunity to leverage the expert scientific knowledge, regulatory and operational experience and on-going technical harmonization work of other members. The goals, scope, objectives, governance, collaborative mechanisms and communications are reflected in the Terms of Reference (ToR) of the IPRF that were adopted at the first meeting in Osaka. The participants decided at the meeting to establish their group as the Management Committee of the IPRF. The ToR will be revised accordingly.

In order to provide additional guidance on operational aspects not detailed in the ToR, the Management Committee discussed a first draft of working procedures. These would, for example, include provisions on the preparation and organization of meetings, on the procedures for ensuring the oversight of the working groups as well as on communication.

One of the objectives of the IPRF is to identify the need for regulatory harmonization or convergence, as well as for regulatory cooperation, including work-sharing, in specific areas. The IPRF Management Committee discussed nanomedicines as a potential new work area for discussion of regulatory challenges. It received a first report of the newly established Biosimilars Working Group. The Gene Therapy, Cell Therapy and Good Clinical Practices (ICH E6) Working Groups also reported on progress made. Both the Biosimilars Working Group and the Cell Therapy Working Group will hold a face-to-face meeting in the first half of July 2014 in Seoul and Singapore, respectively. Both are conducted in conjunction with international conferences in the topic areas.

The IPRF also maintains several contact lists (Safety information, GCP, GMP inspections and MedDRA) to facilitate exchange of information. These lists are updated on a regular basis by the IPRF Secretariat with leading members.

i-p-r-f.org
International Pharmaceutical Regulators Forum

Public Summary/Public Statement

The IPRF Management Committee was informed on the outcomes of the 6th International Generic Drug Regulators Pilot (IGDRP) meeting, which was held on 26 - 28 May 2014 in Yilan, Chinese Taipei. The IPRF Management Committee noted the continued mutual benefit of sharing such updates.

The IPRF Secretariat informed the Management Committee about the launch of the IPRF public website (www.i-p-r-f.org). The website will serve as the primary source of information on the IPRF activities.

It was agreed that Swissmedic, Swiss Agency for Therapeutic Products, would continue as the Chair and Secretariat of IPRF together with the Ministry of Health, Labor and Welfare (MHLW), Japan as Co-Chair.

The next meeting of the IPRF will be held in Lisbon, Portugal in November 2014.

For further information, please contact: *secretariat.IPRF@swissmedic.ch*