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International Pharmaceutical Regulators Forum

Public Summary/Public Statement

First International Pharmaceutical Regulators Forum (IPRF) Meeting held in Osaka, Japan

Osaka, Japan, 12 November 2013

The International Pharmaceutical Regulators Forum (IPRF) met in Osaka, Japan, on 11 and 12 November 2013, in connection with the ICH Steering Committee meeting. It was the first full meeting of this group, after the decision of the Regulators Forum to reinforce its role – five years after the initial meeting – as the IPRF.

The IPRF provides members a unique opportunity to leverage the expert scientific knowledge, regulatory and operational experience, on-going technical harmonization work, and information access of the other members. The first **goal** is to enable all members to identify new approaches and specific best practices, and develop smart strategies for dealing with the challenges of the globalization of the pharmaceutical industry. The second goal is to provide a global overview of the different regulatory developments at national and international level and enable open sharing of information and ideas among regulators. The third goal is to support international regulatory cooperation in areas which are not covered by existing initiatives.

These goals along with provisions such as the scope, the objectives, the governance, collaboration mechanisms and communication are reflected in the Terms of Reference of the IPRF, that were adopted at the meeting.

One of the objectives of the IPRF is to identify the need for harmonization or regulatory convergence, as well as for regulatory cooperation, including work-sharing, in specific areas. Three such working groups are already in operation: Gene Therapy, Cell Therapy and Good Clinical Practices (ICH E6). The progress made in these three groups was reported at the meeting. The IPRF took special note of the report provided by the GCP working group on the “General Principles for Training and Education of GCP inspectors”, which is one of the deliverables of the working group and is going to be published. The IPRF also maintains several contact lists (safety information, GCP and GMP inspections) to facilitate exchange of information. These lists are updated on a regular basis by the IPRF Secretariat.

Biosimilars had been identified as a topic of interest to the members already at the last meeting. At its meeting in Osaka, the IPRF decided to establish a working group on biosimilars, which will be chaired by the Korean Ministry of Food and Drug Safety.

Sharing best practices in switching medical terminologies in the coding of Adverse Event Reports (ADRs) from WHOArt to MedDRA was another topic that was discussed. Several members have been or are running projects in this area – experience from which other members, who are considering this change could benefit from. PANDRH and Health Canada shared information on a secure platform for information sharing within the Americas, which is currently under development by PAHO (Regional Platform on Access and Innovation for Health Technologies; PRAISsec).

The IPRF welcomed a report on the outcomes of the last International Generic Drug Regulators Pilot (IGDRP) meeting, which was held in October 2013 in Geneva, Switzerland. The IPRF will continue to interact with IGDRP – based on mutual sharing of information - with a view to promoting synergies and saving resources.

The IPRF Secretariat provided information on the work to set up an IPRF website, which should go live end of 2013. The website will serve as primary source of information on the IPRF activities aiming at making as much information as possible available in the public domain.

The next meeting of the IPRF will be held in Minneapolis, USA in June 2014, in conjunction with the ICH Steering Committee Meeting.

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