

## **International Pharmaceutical Regulators Forum (IPRF) takes on board nanomedicines and concludes work on implementation of Good Clinical Practices**

Lisbon, Portugal, 11 November 2014

**The Management Committee of the International Pharmaceutical Regulators Forum (IPRF) met in Lisbon on 10 and 11 November 2014. It took note of the work done by the Working Group on the General Principles for the Education and Training of GCP Inspectors, which had achieved its mandate and adopted a proposal to establish a new Working Group on nanomedicines. The Management Committee also stressed the need to increase transparency of the IPRF activities and will adopt corresponding measures.**

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 amended Terms of Reference (ToR) of the IPRF, which had been updated reflecting the establishment of the Management Committee as one of the outcomes of the last meeting in June 2014.

In order to provide additional guidance on operational aspects not detailed in the ToR, the Management Committee discussed the IPRF working procedures. These will, 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 and will be finalized based on the discussions and input provided at the meeting.

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 approved the establishment of a working group on nanomedicines, which incorporates an existing International Regulators Nanomedicines Working Group, consisting of representatives from US-FDA, Health Canada, EMA, MHLW/PMDA (Japan) and observers from Swissmedic (CH) and TGA (Australia). It received a report of the work of the Biosimilars Working Group. The Gene Therapy and Cell Therapy Working Groups, which had been established already a few years ago under the

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“Regulators Forum”, reported on progress made and presented their mandates and work plans according to the new templates under the IPRF.

The Working Group on General Principles for the Education and Training of GCP Inspectors, chaired by MHLW/PMDA (ICH E6; GCP) accomplished its work; an article on the results of the work of the group has been published in the DIA Journal “Therapeutic Innovation and Regulatory Science” (October 2014).

The IPRF Management Committee was informed on the outcomes of the 7<sup>th</sup> International Generic Drug Regulators Pilot (IGDRP) meeting, which was held on 5-7 November 2014 in Singapore. The IPRF Management Committee noted the continued mutual benefit of sharing such updates and the great progress that had been made. The IGDRP concluded its first three years as a “pilot” and recommended to continue under the current arrangements for another two years.

The IPRF Management Committee welcomed a presentation from the International Coalition of Medicines Regulatory Authorities (ICMRA). Possible mechanisms for communication and sharing of information between the two initiatives were discussed and will be exchanged with the ICMRA, considering also the need to avoid duplication of work.

The IPRF Management Committee finally decided to enhance efforts to increase transparency about the work of the initiative. More information will be made public on the IPRF website, such as mandates and work products of IPRF Working Groups. In addition, further dissemination of outcomes through publications in journals, such as the one on the ICH E6 Working Group, will be considered on a case-by-case basis. Also, it was decided that IPRF working groups could develop reflection or consideration papers, outlining the available regulatory information and approaches in the different work areas.

The next meeting of the IPRF will be held in Fukuoka on 7 and 8 June 2015.

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