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International Pharmaceutical Regulators Forum

The International Pharmaceutical Regulators Forum (IPRF) progresses work on future strategy

October 14, 2016

The Management Committee of the International Pharmaceutical Regulators Forum (IPRF) met in Lisbon, Portugal, June 12-13, 2016. It continued a strategy development process that had been initiated at the meeting in December 2015. 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 work of IPRF has evolved since its establishment. With the regulatory environment changing in a dynamic manner IPRF is expected to develop, if it wants to continue to provide value for members and external stakeholders. Therefore, the Management Committee had initiated a strategy development process at the meeting in Jacksonville, and the final outcomes will be adopted at the Management Committee meeting in November 2016. At the Meeting in June, the Management Committee completed the strategy analysis and developed the future business model for the initiative. The following guiding principles were agreed for the design of IPRF's strategy:

- Increase value/benefits for members (and stakeholders) to ensure IPRFs long-term viability
- Increase efficiency for members (e.g. by supporting consolidation of initiatives)
- Further increase institutional maturity (and therewith ensure sustainability)
- Fill-in the gaps for international collaboration on pharmaceuticals and avoid duplication with existing initiatives
- Promote openness and transparency

One of the objectives of the IPRF is to identify the need for regulatory harmonization and convergence, as well as for regulatory cooperation, including work sharing, in specific areas. The Management Committee supported the engagement of IPRF in the implementation of the **Identification of a Medicinal Product (IDMP)**, a suite of ISO standards for data elements, formats and terminologies for the unique identification of and the exchange of information on medicines. The creation of a working group was endorsed in principle, pending a review of the revised mandate.

IPRF currently operates four working groups, which reported on progress made and presented their accomplishments based on the deliverables of their work plans:

- The **Biosimilars Working Group** finished its work on a template for "Public Assessment Summary Information for Biosimilar (PASIB)" taking into consideration the feedback received by various stakeholders during a two months consultation period. The final documents are published on the IPRF website together with four PASIB examples. Further PASIBs will follow as biosimilars get approved in the various jurisdictions.

  The final draft "Reflection paper on extrapolation of indications for biosimilar marketing authorisation'" was presented to the Management Board and is now open for public feedback on the IPRF website for a two months period.
- The **Gene Therapy Working Group's** primary objective is to gain a common understanding of the regulatory framework including laws, regulations and available guidance as well as of the classification of gene therapy products in participating regions. The findings are in the process of being put together for publication on the IPRF website.
- The **Cell Therapy Working Group** has been gathering information on the categorization of cell therapy products and the degree of regulatory oversight in the participating regions. The group has identified factors to be considered in the nature and duration of patient follow-up after receiving a cell therapy product and is drafting a concept paper for an IPRF considerations paper.
- The **Nanomedicines Working Group** has finalized its work on an "Information sharing and mapping" document compiling information about legislative requirements, new or planned guidance documents and categorization in its members' various jurisdictions. The document is published on the IPRF website.

The IPRF Management Committee was informed on the outcomes of the 10th International Generic Drug Regulators Programme (**IGDRP)** meeting, which was held May 9-12, 2016 in Strasbourg, France. The IPRF Management Committee acknowledged the progress made by IGDRP and agreed to establish a joint group with IGDRP to develop options for the future cooperation between the two initiatives.

An update from International Coalition of Medicines Regulatory Authorities (**ICMRA)** was also presented to the IPRF Management Committee. In this context, the Management Committee agreed to a report from the Biosimilars Working Group on the results of the evaluation of a number of issues raised by ICMRA on the topic for possible inclusion in the group's work plan.

A number of participating regulators and regional harmonization initiatives (RHIs) updated the other participants on new legislation and guidelines, as well as on upcoming trainings and conferences.

After three years with Dr. Petra Doerr (Swissmedic) as chair and Dr. Naoyuki Yasuda (MHLW/PMDA) as the co-chair stepped down from their responsibilities. The Management Committee unanimously elected Joan Blair (US-FDA) as the new chair and Patrícia Pereira Tagliari (ANVISA) as the new co-chair, effective September 15, 2016. The US-FDA is also taking over the secretariat from Swissmedic starting October 1, 2016.

The next meeting of the IPRF Management Committee will be held in November 6-7, 2016 in Osaka, Japan.

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Link to website: www.i-p-r-f.org