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International Pharmaceutical Regulators Forum

Public Summary/Public Statement

The International Pharmaceutical Regulators Forum (IPRF) reviews progress and initiates work on future strategy

Jacksonville, FL, 15 December 2015

The Management Committee of the International Pharmaceutical Regulators Forum (IPRF) met in Jacksonville, Florida, US, on 7 and 8 December 2015. Within the two and a half years after its establishment, the initiative has achieved substantial progress. In order to define the future direction, the Management Committee embarked on a strategy development process, which should be completed in June 2016.

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 has decided to elaborate a **strategy** for the initiative for the next five years. The process was initiated at the meeting in Jacksonville, and will be concluded at the next meeting in June 2016.

One of the objectives of the IPRF is to identify the need for regulatory harmonization/convergence, as well as for regulatory cooperation, including work-sharing, in specific areas. The Management Committee heard a first proposal on a potential future engagement of IPRF in supporting 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 proposal will be further developed based upon the inputs from the IPRF members and tabled for decision at the next meeting of the Management Committee.

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** has continued its work on a template for “Public Assessment Summary Information for Biosimilar (PASIB)” and on a “Reflection paper on extrapolation of indications for biosimilars’” to be finalized and published on the IPRF website by 2nd quarter of

next year. The Biosimilars Working Group has held a workshop with WHO to advance work on developing training material to establish biosimilar comparability.

- 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. A compilation of findings will be posted shortly 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 results are expected to be published in a White Paper or journal article by the end of this year. The Management Committee adopted an updated work plan for the group that will be published on the IPRF website.
- The **Nanomedicines Working Group** is in the process of finalizing 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 will be published on the IPRF website.

The IPRF Management Committee also discussed the implications resulting from the establishment of the **ICH Association**, especially for those regulators considering to become members or observers of the Association.

The IPRF Management Committee was informed on the outcomes of the 9th **IGDRP** meeting, which was held on 2-5 November 2015 in Seoul, South Korea. The IPRF Management Committee acknowledged the progress made by IGDRP and discussed the need for engaging in a close dialogue to discuss options for future collaboration. This dialogue should also include the International Coalition of Medicines Regulatory Authorities (ICMRA), which is operating a generics working group.

An update on the outcomes of the **ICMRA** meeting, held on 11-13 November 2015 in Mexico-City, was also presented to the IPRF Management Committee. In this context, the Management Committee agreed to task the Biosimilars Working Group to evaluate 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) informed the other participants on new legislation and guidelines, as well as on upcoming trainings and conferences. Presentations on **current topics** included an information from MHLW/PMDA on their new international strategy, and an update from the EMA on EU collaboration models and on the Article 58 procedure.

The next meeting of the IPRF Management Committee will be held in Lisbon, Portugal, on 13 and 14 June 2016.

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