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International Pharmaceutical Regulators Forum

Public Summary/Public Statement

International Pharmaceutical Regulators Forum (IPRF) Management Committee holds its fourth meeting in Fukuoka, Japan

Fukuoka, Japan, 9 June 2015

The Management Committee of the International Pharmaceutical Regulators Forum (IPRF) met in Fukuoka on 8 and 9 June 2015. It was the fourth meeting after its establishment in 2013.

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 published on the IPRF website.

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 mandate of the **Nanomedicines Working Group**, which had been developed following the decision of the Committee at the last meeting, to take the topic on board. The work plan for this group is still under development and will be published upon approval within the coming months. The Biosimilars, Gene Therapy and Cell Therapy Working Groups presented their work plans and reported on progress made:

- The **Biosimilars Working Group** has amongst others, initiated work on a "Reflection paper on extrapolation of indications for biosimilars'" to be finalized and published on the IPRF website by beginning of next year. The Biosimilars Working Group has established close collaboration with WHO with the aim of jointly 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 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.

In its effort to increase transparency, IPRF will shortly publish the mandates and current work plans of the Working Groups on its website. Outcomes of their work will also be made available such as high-level summaries of Working Groups' face-to-face meetings.

The IPRF Management Committee is following the activities and developments of other international initiatives in the field of medicinal products in order to identify possible synergies and avoid overlaps. The IPRF Management Committee welcomed the developments of the ICH reform and several IPRF members exchanged their experience on the implementation of ICH guidelines. The International Generic Drug Regulators Programme (IGDRP) or the International Coalition of Medicines Regulatory Authorities (ICMRA) have been launched in the past few years and are currently in development. The IPRF Management Committee was informed on the outcomes of the 8th IGDRP meeting, which was held on 25-28 May 2015 in Pretoria, South Africa. The IPRF Management Committee noted the continued mutual benefit of sharing such updates and decided to discuss options for closer collaboration between the two initiatives at its next meeting. Along the same lines, the IPRF Management Committee also welcomed a presentation from ICMRA and will continue its dialogue with the Coalition.

The Committee received updates from a number of participating regulators and regional harmonization initiatives (RHIs) on new legislation and guidelines, as well as on upcoming trainings and conferences. Topical issues were presented and discussed, such as the implementation of the EU pharmacovigilance legislation and its implications on regulators outside the EU and the Patient-Focused Drug Development initiative of the US-FDA.

The Committee renewed the term for the current Chair and Co-Chair of the Committee, Swissmedic and the Ministry of Health, Labor and Welfare/the Pharmaceuticals and Medical Device Agency of Japan, for another year. Swissmedic will also continue to provide the Secretariat for IPRF.

The next meeting of the IPRF Management Committee will be held in Jacksonville, Florida, US on 7 and 8 December 2015.

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