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Subject: International Pharmaceutical Regulators Forum (IPRF)

Agenda item 5a

La Hulpe, Belgium – 4 June 2013

Five years after it met for the first time in June 2008, the Regulators Forum decided to reinforce its role on international cooperation activities between pharmaceutical regulators as the International Pharmaceutical Regulators Forum (IPRF).

The **IPRF** met in La Hulpe, Belgium on 3-4 June 2013 in connection with the ICH Steering Committee meeting. Representatives from 11 Drug Regulatory Authorities/Department of Health (DRAs/DoH)¹, from 5 Regional Harmonization initiatives (RHIs)² and from WHO participated in the meeting.

The **IPRF** will provide members a unique opportunity to leverage the expert scientific knowledge, regulatory and operational experience, on-going technical harmonization work, and information access of other participating regulators. The first goal is to enable all parties 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 regulatory leaders with hands-on operational responsibilities. This information sharing will allow the forum participants to discuss issues at an actionable level of detail. The third goal is to support international regulatory cooperation in areas which are not covered by existing initiatives.

One of the objectives of the **IPRF** will be to identify the need for harmonization, regulatory convergence or for regulatory cooperation, including work-sharing, in specific areas and to refer identified topics to appropriate existing processes or organizations, notably ICH. When identified topics (e.g. “biosimilars”) are not falling under the scope

¹ Australia, Brazil, Canada, China, Chinese Taipei, EU, Japan, Korea, Singapore, Switzerland, U.S.A.

² APEC, ASEAN, EAC, GCC, SADC.

of existing processes or organizations, the **IPRF** may decide to establish working groups, chaired by one of its members, to undertake the work. Three such working groups are already in operation, dealing with: “Cell Therapy”, “Gene Therapy” and “General Principles for Training/Education of GCP inspectors”.

In the same context, the **IPRF** recognizes the importance of the work underway within the International Generic Drug Regulators Pilot (IGDRP) to facilitate the timely authorization of safe and effective generic drugs. The **IPRF** supports collaboration with IGDRP with a view to promoting synergies and saving resources.

The **IPRF** will initially meet face-to-face twice a year, in conjunction with ICH Steering Committee meetings. Switzerland will chair, and Japan will co-chair the IPRF, initially for one year. Switzerland will also provide the Secretariat for the same period. The next meeting of the **IPRF** will be held in Osaka, Japan in November 2013.

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