**International Generic Drug Regulator’s Pilot Project**

The International Generic Drug Regulator’s Pilot Project (IGDRP) was created to promote regulatory collaboration and convergence in generic drug regulatory programmes in order to address challenges posed by increasingly heavy workloads, globalization, and the growing complexity of scientific issues.

Following on from its previous meeting in Washington, D.C. in April 2012, IGDRP representatives from the medicines regulatory authorities of Australia, Brazil, Canada, China, Chinese Taipei, Japan, Republic of Korea, Mexico, Singapore, Switzerland and the United States of America, as well as the World Health Organization and the European Directorate for the Quality of Medicines and Healthcare, met in Nanchang, China from 3–4 December 2012.

Representatives discussed worksharing possibilities in the areas of active substance master files (ASMFs)/drug master files (DMFs), exchange of confidential information, inspection of sites conducting bioequivalence and bioanalytical studies, conditions associated with granting biowavers, and pharmaceutical quality issues.

Potential efforts to assist WHO in implementing proposed changes to the WHO Prequalification of Medicines Programme as it moves toward a new operating model were also canvassed, as were the operational possibilities of a number of secure platforms for the sharing of confidential information between agencies. The next meeting of the IGDRP is tentatively scheduled for April or May 2013 in Australia.

**Reference:** Prequalification of Medicines Programme at http://www.who.int/prequal