PRESS RELEASE

PIC/S CELEBRATES 40TH ANNIVERSARY

US FDA Commissioner, Dr. Margaret Hamburg, calls for closer and more global co-operation on GMP at PIC/S’ 40th Anniversary

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) celebrated its 40th anniversary at a landmark symposium in Geneva (Switzerland) on 31 May 2011. PIC/S is a technical arrangement between 39 Competent Authorities in the field of GMP inspections of pharmaceutical manufacturing sites. The symposium was opened by PIC/S Chairman, Mr. Tor Gråberg (Sweden / MPA), who underlined the need for PIC/S to further promote co-operation based on communication, mutual trust and harmonisation.

Over 160 participants from all continents participated in the event, including Competent Authorities from Argentina, Australia, Brazil, China, Chinese Taipei, Croatia, most EU/EEA Member States, Georgia, Hong Kong SAR, Indonesia, Iran, Israel, Japan, Malaysia, New Zealand, Nigeria, Russia, Singapore, Saudi Arabia, South Africa, South Korea, Switzerland, Thailand, Turkey, Uganda, Ukraine, and USA. The long list demonstrates that the organisation, created by 10 European Authorities back in 1971, has now become truly global. PIC/S co-operates with the European Commission and has partnership agreements with the European Medicines Agency (EMA), EDQM, UNICEF and WHO; it also co-operates with non-profit organisations like ISPE and PDA and industry associations such as APIC, EFPIA, IFPMA, in the field of training.

The 40th Anniversary symposium coincided with the first-time attendance of the Ukrainian State Inspectorate for Quality Control of Medicines (SIQCM) and the US Food and Drug Administration (FDA) as full Members of the Organisation. US FDA Commissioner, Dr. Margaret Hamburg, delivered a key note address to the symposium and called upon all Regulatory Authorities to co-operate more closely and share information on GMP inspections, in particular in third countries. PIC/S’ main advantage over a Mutual Recognition Agreement is that it is not legally binding, thus allowing Participating Authorities to co-operate and share information informally (subject to confidentiality) while keeping complete control over imported medicinal products. For more information on PIC/S’ 40th Anniversary, see www.picscheme.org.