**PHARMACEUTICAL INSPECTION CONVENTION**
**PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME**

14 February 2005

# PRESS RELEASE

## PIC/S COMMITTEE MEETING
## GENEVA, SWITZERLAND

A joint Committee meeting of the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) was held in Geneva (Switzerland) on **8 and 9 February 2005** under the chairmanship of Mr. Hans Smallenbroek (Netherlands / Inspectorate of Health Care). With the exception of Greece and Hungary, all PIC/S Participating Authorities were represented. The Czech Veterinary Institute, Poland, the EMEA* and WHO* also participated in the meeting.

### Czech Veterinary Institute invited to join the Scheme

The Committee invited the Czech Institute for State Control of Veterinary Biologicals and Medicaments (ISCVBM) to join PIC/S as a new Participating Authority as from 1 July 2005.

The Czech Institute is the first veterinary Agency to join PIC/S. It has been admitted following an evaluation of its GMP system and based on a pre-MRA inspection report by the European Commission, which was shared with PIC/S. The Czech Institute for State Control of Veterinary Biologicals and Medicaments applied for PIC/S membership back in September 2002. It is independent from the Czech State Institute for Drug Control (SÚKL), responsible for medicinal products for human use, which has been a PIC/S Member since 1997.

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities which provide together an active and constructive co-operation in the field of GMP. Their purpose is the networking between competent authorities, the development and maintenance of mutual confidence, the exchange of information and experience in the field of GMP and related areas and the mutual training of inspectors.

There are currently 27 Participating Authorities in the PIC/S (Convention and Scheme taken together). All countries, which are parties to the Convention (#), are members of the Scheme. The PIC/S Participating Authorities are from Australia#, Austria#, Belgium#, Canada, Czech Republic, Denmark#, Finland#, France#, Germany#, Greece, Hungary#, Iceland#, Ireland#, Italy#, Latvia, Liechtenstein#, Malaysia, Netherlands, Norway#, Portugal#, Romania#, Singapore, Slovak Republic, Spain, Sweden#, Switzerland#, and the United Kingdom#.

* Observer to PIC/S Committee

**Argentina applies for PIC/S membership; US FDA signals intention to join**

The Committee appointed a Rapporteur (Australia) and a Co-Rapporteur (Italy) to evaluate the membership application received by Argentina's Instituto Nacional de Medicamentos (INAME). Argentina is the first Latin American country to apply for PIC/S membership.

It noted the decision taken by the US Food and Drug Administration (FDA) to seek PIC/S membership as part of its 21st Century Initiative on the Regulation of Pharmaceutical Manufacturing. An application has, however, not been submitted yet.

The Committee discussed the report made by the PIC/S Delegation, which inspected Poland's Main Pharmaceutical Inspectorate (MPI) on 20-24 September 2004. It appointed a new Rapporteur (Netherlands), who was invited to evaluate the encouraging replies given by the MPI to the Delegation's main recommendations.

It decided to invite UNICEF, who has applied to become an Observer to PIC/S, for a hearing at the next Committee meeting and appointed a new Rapporteur (Switzerland). It also briefly reviewed other membership applications: Estonia's State Agency of Medicines, Israel's Ministry of Health, Lithuania's Department of Pharmacy, South Africa's Medicines Control Council and the Ukraine's Ministry of Health.

**Italy's AIFA successfully reassessed; next: UK MHRA**

The Committee took note that the reassessment of Italy's Agenzia Italiana del Farmaco (AIFA) had been successfully completed. It was also informed on the forthcoming follow-up visit to Romania's National Medicines Agency (NMA) following its reassessment in November 2002 and on the on-going reassessment of the Norwegian Medicines Agency (NOMA)

To avoid an unnecessary duplication of efforts, it agreed to accept evaluations made by the Commission and Canada under their Mutual Recognition Agreement (MRA) as equivalent to a reassessment under the PIC/S Joint Reassessment Programme (JRP). It decided to concentrate on the re-evaluation of older Members which had undergone significant structural changes starting with the UK's Medicines and Healthcare Products Regulatory Agency (MHRA). An audit team comprising Sweden, Malaysia and Portugal was appointed.

The Committee agreed in principle to harmonise the tool used for the evaluation and re-evaluation of PIC/S Members on the basis of the MRA evaluation procedure of Canada's Health Products and Food Branch Inspectorate (HPFBI). As a similar tool should also be used under the EU's Joint Audits Programme (JAP), it should facilitate the mutual recognition of audit results between the EU JAP and the PIC/S Joint Reassessment Programme (JRP).

**PIC/S officially recognised as an Association by Switzerland**

The Committee took note that the registration procedure of PIC/S as a fully independent and publicly recognised Association under the Swiss law had been successfully completed and published in the Official Journal.

It also followed the advise given by legal experts[1] of the Swedish and Swiss Ministries of Foreign Affairs to remain an Association for the time being rather than turning into an International Organisation, as there was a risk that PIC/S would otherwise loose its flexibility and dynamism.

The Committee also noted with satisfaction that PIC/S' financial situation was sound. The 2004 accounts, which were the first accounts of PIC/S since it became independent on 1st January 2004, were positive and even showed a surplus.

**Training for inspectors**

The Committee discussed preparations for the 2005 and 2006 **PIC/S seminars** for GMP inspectors as well as forthcoming Expert Circle meetings (see "activity calendar" on the PIC/S web site). It took note of a comparison made by the former First Deputy Chairperson on seminar costs (registration and hotel), which showed that PIC/S seminars had not become more expensive contrary to allegations made by PIC/S Observers at the previous Committee meeting.

It reviewed the programme for the 2005 Seminar on "Primary packaging material, labelling and the prevention of mix-ups", which will be organised by Romania's National Medicines Agency and take place in Bucharest on 14-16 September 2005.

It approved the creation of a new Expert Circle on Active Pharmaceutical Ingredients (APIs). A first meeting will be organised the French Health Products Safety Agency (AFSSAPS) in Paris on 10-12 October 2005.

It finally adopted the revision of the Aide-Memoire on the Organising of Seminars (PI 003-2) and a new Guideline for PIC/S Expert Circles (PI 022-1). Both documents will enter into force on 1 May 2005.

**Elections**

The Committee elected Mr. Jacques Morénas of France's Health Products Safety Agency (AFSSAPS) as First Deputy Chairman for the year 2005 in replacement of Ms. France Dansereau (Canada) who had retired. Mr. Johann Kurz (Austria / Federal Ministry for Health and Women) was elected Second Deputy Chairman for the year 2005. Ms. Eija Pelkonen (Finland / National Agency for Medicines) and Mr. Michel Keller (Switzerland / Swissmedic) were elected as Members of the Executive Bureau for 2005-2006 in replacement of Dr. Vassiliki Revithi (Greece) and Dr. Martin Valchář (Czech Republic).

The Committee bid farewell to Ms. Dansereau, Dr. Revithi and Dr. Valchář and thanked them for their very active involvement in PIC/S and their important contribution in the Executive Bureau.

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[1] These experts were invited to a joint meeting of the PIC/S Executive Bureau and the Working Group on the International Organisation Status (Geneva, 10 November 2004)

**In brief**

The Committee…

- agreed to a proposal by the Executive Bureau to work out a Road Map for PIC/S;
- noted that the PIC/S web site had been upgraded and now included an activity calendar, a page for announcing forthcoming training events; an electronic version of the brochure presenting the International Medicinal Inspectorates Database (IMID); and a password-restricted page for Members of the Committee;
- agreed to a proposal by the Chairman to nominate Ms. France Dansereau, former Deputy Chairperson, as the Chairman's Special Representative to GMP conferences which he was unable to attend in 2005;
- welcomed Mr. André Kovacs, who had been recruited in November 2004 in order to assist the PIC/S Secretary on a full-time basis, and bid farewell to Ms. Denise Cormier, the previous Assistant to the PIC/S Secretary, who had retired at the end of last year;
- decided that the next meeting would take place in Bucharest (Romania) on 12-13 September 2005 in conjunction with the 2005 PIC/S Seminar.

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