



Press Release

November 2003

PIC/S COMMITTEE MEETING, GENEVA, SWITZERLAND

A joint meeting of the Committee of Officials, established under the terms of the Pharmaceutical Inspection Convention (PIC), and the Committee set up under the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) was held in Geneva (Switzerland) on **11 and 12 November 2003** under the chairmanship of Ms. Lilian Hamilton (Sweden / Medical Products Agency). All PIC/S Participating Authorities were represented with the exception of Denmark and Portugal. The EMEA¹, Estonia¹ and Latvia¹ also participated in the meeting.

¹ Observer to PIC/S Committee

Latvia invited to join the Scheme

The Committee invited Latvia's State Pharmaceutical Inspection (SPI) to join PIC/S as a new Participating Authority as from 1 January 2003.

SPI has been admitted following an evaluation of its GMP system and a visit in December 2000 to assess the local GMP inspection and licensing system. A follow-up visit took place in March this year to ensure that SPI had implemented all recommendations, in particular changes to its licensing system and the GMP compliance of industry. SPI applied to join PIC/S back in 1996.

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international agreements 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 26 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 Australia*, Austria*, Belgium*, Canada, Czech Republic, Denmark*, Finland*, France*, Germany*, Greece, Hungary*, Iceland*, Ireland*, Italy*, Liechtenstein*, Malaysia, Netherlands, Norway*, Portugal*, Romania*, Singapore, Slovak Republic, Spain, Sweden*, Switzerland*, and the United Kingdom*.

Closer co-operation with the EU / EMEA / EDQM

In order to optimise its co-operation with the **EMEA** and avoid a duplication of efforts, the Committee discussed a proposal to conclude a "co-operation agreement" with the **EMEA Ad Hoc Group of GMP Inspectors**. The scope of the agreement would be to define the respective roles and obligations of both parties with regard to the harmonisation of **GMP** and the assessment (or reassessment) of **GMP** inspectorates under the respective programmes.

While waiting for the conclusion of the agreement, the Committee agreed to immediately co-operate with the **EU Heads of Agencies** and the **EMEA Ad Hoc Group of GMP Inspectors** with a view to mutually accept results under the **EU Heads of Agencies' Joint Audit Programme (JAP)** and the **PIC/S Joint Reassessment Programme (JRP)**.

The Committee - with the exception of Canada - also agreed to co-operate with the **European Commission** with a view to accept the results of audits carried out under **Mutual Recognition Agreements (MRAs)** or pre-MRA visits such as those to be carried out by the Commission in the 10 Accession Countries in 2004.

The Committee was given a presentation by Ms. Corinne Pouget of **European Directorate for the Quality of Medicines (EDQM)** on a recently launched programme regarding certificates of suitability for **Active Pharmaceutical Ingredients (APIs)**. The programme may lead to a closer co-operation with **EDQM**.

Joint Reassessment Programme (JRP)

The Committee reviewed reports on the reassessment of **Australia's Therapeutic Goods Administration (TGA)**, **Greece's National Organization for Medicines (EOF)** and **Romania's National Medicines Agency (NMA)**. It was informed that preparations for the reassessment of **Italy's Dipartimento per la Valutazione dei Medicinali e la Farmacovigilanza (DVMF)** and the **Norwegian Medicines Agency (NOMA)** were under way. The Committee decided to wait until early 2004 before starting with the planned reassessment of **Germany** (subject to the mutual acceptance of result between **JAP** and **JRP**). With regard to the planned reassessment of the **Slovak State Institute for Drug Control**, it also decided to give priority to the Commission's pre-MRA visit to the **Slovak Republic** and to check whether it could be combined with the **JRP**.

Evaluation of membership applications

The Committee discussed a proposal to streamline the current **Guidelines for Accession** and to introduce a time element, in particular deadlines for the submission of information by applicants. The revised proposal will be submitted to the Committee's approval at its next meeting.

The Committee also reviewed the following membership applications:

On the basis of a progress report presented by Estonia's State Agency of Medicines, the Committee decided that the follow-up visit by a **PIC/S Delegation** to **Estonia** would take place by spring 2004, if possible in conjunction with the pre-MRA inspection by the Commission.

The Committee agreed to send a PIC/S Delegation to assess Poland's GMP inspection system in general and the Main Pharmaceutical Inspectorate in particular. The visit should be coupled with the pre-MRA inspection by the Commission.

The Committee invited the Rapporteur on the membership application of the Czech Institute for State Control of Veterinary Biologicals and Medicaments (ISCVBM) to check with the Commission whether the ISCVBM would also be subject to a pre-MRA inspection and whether PIC/S could join the EU inspection team.

The Committee invited the Chairperson to write to the National Laboratories for Foods and Drugs (NLFDD) of Chinese Taipei and to request a clear and detailed action plan on the implementation of the PIC/S recommendations, which had still not been submitted although a PIC/S Delegation visited Taipei in May 2002.

The Committee requested the Rapporteur to provide a written evaluation of the membership application made by Lithuania's Department of Pharmacy in time for the next meeting.

The Committee examined the application made by UNICEF to become an Observer to PIC/S. As UNICEF qualifies in principle for observer status, the Committee also appointed a Rapporteur to evaluate its application.

International Medicinal Inspectorates Database

The Committee discussed a report made by the Director of the International Medicinal Inspectorates Database (IMID). Since the IMID was established on 1 July 2003, 11 PIC/S Authorities have joined the IMID. In order to assist the Director in the launching phase, the Committee agreed to revive the Working Group on the IMID and asked it to discuss a number of issues, which have arisen since the IMID was launched.

The International Medicinal Inspectorates Database (IMID) aims at establishing - on a voluntary basis - a database containing information on GMP inspections carried out (or to be carried out) by IMID participating Regulatory Authorities. The IMID exclusively targets medicinal products (finished products, active pharmaceutical ingredients (APIs) and investigational medicinal products), which have been manufactured in non-PIC/S countries. The main aim of the IMID is to alleviate the workload of PIC/S Members with regard to third-country inspections. This is to be achieved by sharing information on the GMP compliance status of manufacturing sites. The IMID will result in a reduction in the number of inspections, in particular of duplicative inspections.

There are currently 11 Participating Authorities in the IMID: Australia, Belgium, Canada, Czech Republic, France, Hungary, Iceland, Netherlands, Romania, Singapore, and Sweden. For more information on the IMID, see <http://www.picscheme.org/IMID/imid.htm>

Elections

The Committee elected Mr. Hans Smalldenbroek from the Netherlands' Inspectorate of Health Care as Chairman for 2004-2005. Ms. France Dansereau of Canada's Health Products and Food Branch Inspectorate (HPFBI) was elected First Deputy Chairperson while Mr. Jacques Morénas of the French Health Products Safety Agency (AFSSAPS) was elected Second Deputy Chairman for the same period. As due to the election of Mr. Morénas as Second Deputy Chairman, one of two positions for Member of the Executive Bureau became vacant, the Committee elected Dr. Vassiliki Revithi of Greece National Organization of Medicines (EOF) as new Member of the PIC/S Executive Bureau.

In brief

The Committee.....

- accepted a proposal to revise the PIC Scheme to allow the Secretariat to register PIC/S as an Association under the Swiss law;
 - supported a proposal aiming at obtaining an observer status for PIC/S in ICH (International Conference on the Harmonisation);
 - adopted the 2004 budget;
 - was briefed on the meeting of the Working Group on the Training of Inspectors (see Annex);
 - noted that the Chairperson had written to the European Commission enquiring whether the EU Member States had the competence to join a treaty establishing an international organisation with similar activities as those carried out by PIC/S currently;
 - agreed to harmonise the PIC/S recommendation on Quality System Requirements for Pharmaceutical Inspectorates (PI 002) with the recently adopted EU document on the same subject in order to ensure consistency between the two documents;
 - noted that the Chairperson of the PIC/S Committee and the Chairman of the Standing Committee of the Convention on the Control and Marking of Articles of Precious Metals had signed a Memorandum of Understanding regarding secretariat services;
 - accepted a proposal to introduce, among other things, a password-protected page on the PIC/S web site (<http://www.picscheme.org>) where Committee Members could download PIC/S Secretariat documents;
 - agreed that the next meeting would take place in El Vendrell (Spain) on 14-15 June 2004 in conjunction with the 2004 PIC/S Seminar.
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Training for inspectors

The PIC/S Working Group on the Training of Inspectors met on 11 November 2003 under the chairmanship of Mr. Hans Smallembroek (Netherlands / IGZ). The present and former Chairpersons of the PIC/S Committee, the organisers of the 2002, 2003, 2004 and 2005 seminars and an EMEA representative attended the meeting.

The Working Group reviewed the operation of the **PIC/S Joint Visits Programme**. It established seven new groups and modified the composition of three existing groups. Twenty-nine joint visit groups are now operational.

The Working Group discussed the evaluation of the 2002 and 2003 (including the finalisation of aide-memoires deriving from the seminars) and reviewed the scientific programmes for the 2004 and 2005 **PIC/S seminars** for GMP inspectors:

- The 2004 seminar on the Inspection of Active Pharmaceutical Ingredients will be organised by the Spanish "Agencia Española del Medicamento" (AEM) in El Vendrell (Tarragona) on 16-18 June 2004.
- The 2005 seminar on "Primary packaging material, labelling and the prevention of mix-ups (including counterfeit packaging and labelling)" will be organised by Romania's National Medicines Agency (NMA) in Bucharest in September 2005.

The Working Group reviewed past and future meetings of **PIC/S Expert Circles**:

- The 10th meeting of the Expert Circle on Human Blood and Tissue, organised by the Hungarian National Institute of Pharmacy (NIP), took place in Visegrad (Hungary) from 8 to 11 September 2003. The next meeting will be organised by Germany (BMG, ZLG & Paul-Ehrlich-Institut) in Langen in September 2004.
- The 4th meeting of the Expert Circle on Medicinal Gases, organised by Finland's National Agency for Medicines, was held in Hämeenlinna (Finland) on 9-11 June 2003. The next meeting is scheduled for 2005 in the Czech Republic.
- The 7th meeting of the Expert Circle on Hospital Pharmacy, will be organised by the "Gesundheitsamt" of the City of Cologne (Germany) on 29-30 March 2004.
- The 2nd meeting of the Expert Circle on Computerised Systems, organised by Australia's Therapeutic Goods Administration (TGA), took place in Canberra on 17-18 February 2003. The next meeting will be organised by Swissmedic in Switzerland in the course of 2004.
- The second meeting of the Working Group on Biotechnology, organised by the Danish Medicines Agency, was held in Brønshøj (Denmark) on 29 August 2003.

The Working Group also discussed a new guideline on the organisation of Expert Circles and the revision of the aide-memoire on the organisations of Seminars. It also discussed the co-ordination of training activities with the EMEA.

The next meeting of the Working Group will be held in Geneva on 2 November 2004.
