



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

12 June 2003

PRESS RELEASE

**PIC/S COMMITTEE MEETING
BRATISLAVA, SLOVAK REPUBLIC**

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) took place in Bratislava (Slovak Republic) on **2 and 3 June 2003** under the chairmanship of Ms. Lilian Hamilton (Sweden / Medical Products Agency). With the exception of Singapore, unable to attend due to SARS¹, all PIC/S Members were represented. The EMEA*, Estonia*, Latvia*, Poland, South Africa and WHO* also participated in the meeting. All in all, forty delegates from thirty Inspectorates and two Agencies took part in the meeting.

International Medicinal Inspectorates Database

The Committee adopted the statute of the International Medicinal Inspectorates Database (IMID), which 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 (for more information on the IMID, see <http://www.picscheme.org/IMID/imid.htm>)

The IMID will start operating as from 1 July 2003. With the exception of Germany and the United Kingdom, all other PIC/S Participating Authorities have expressed an interest in the IMID.

¹ Severe Acute Respiratory Syndrome

* Observer to PIC/S Committee

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*.

Joint Reassessment Programme

The Committee decided to conclude the pilot phase of the PIC/S Joint Reassessment Programme (JRP) following the positive experience made during the reassessment of Romania and Sweden (second half of 2002) as well as Australia (first half of 2003). It also revised and simplified the procedure for the JRP, allowing auditors to make use of other evaluation reports (e.g. under a Mutual Recognition Agreement). It selected the next Authorities to be reassessed and their respective auditors. Finally, the Committee also supported the proposal to merge the JRP with the Joint Audit Programme launched by the EU Heads of Agencies in order to avoid unnecessary duplications between the two programmes.

Evaluation of Membership Applications

A follow-up visit by a PIC/S Delegation to Latvia took place in March 2003. On the basis of the Delegation's recommendations, the Committee agreed to invite Latvia's National Inspection System to accede to PIC/S by 1 January 2004. However, Latvia will have to report beforehand on changes to the licensing system, its ability to honour membership obligations and the GMP compliance of industry,

A follow-up visit by a PIC/S Delegation to Estonia was postponed for the second time, thus prompting the Committee to request a progress report by Estonia's State Agency of Medicines before the next Committee meeting.

The Committee reviewed the membership application made by Poland's Main Pharmaceutical Inspectorate. It decided to leave Poland sufficient time to implement the recent legislative changes before sending a delegation to assess the Polish GMP inspection system.

The Committee examined the membership application made by the Czech Institute for State Control of Veterinary Biologicals and Medicaments and decided to proceed with an evaluation visit in autumn 2003, possibly in conjunction with a similar visit to be carried out by the EU in the context of a PECA² Agreement with the Czech Republic. The Czech Institute is the first veterinary agency to apply for PIC/S membership (the Czech State

² Protocol to European Conformity Assessment and Acceptance for Industrial Products

Institute for Drug Control, responsible for medicines for human use, is already a PIC/S Member).

Some progress was reported on the application by the National Laboratories for Foods and Drugs (NLFD). However, a number of important questions still need to be addressed, in particular why a 3-5 years long transitional period is needed by the NLFD to adopt the PIC/S GMP Guide (or equivalent) – a basic requirement for any PIC/S membership applicant.

South Africa's Medicines Regulatory Authority reported that it would update its membership application shortly, thus resuming with the interrupted application process.

New Membership Applications (Lithuania, Oman, Russia, Ukraine)

A preliminary assessment of the application made by Lithuania's Department of Pharmacy was given to the Committee. Three new but incomplete applications were received by the Secretariat: one from Oman's Ministry of Health, one from the Ministry of Health of the Russian Federation and one from the Ukrainian Ministry of Health. The representatives of Oman, Russia and the Ukraine were also met in the margin of the PIC/S 2003 Seminar (see Annex).

Training for inspectors

The Committee was informed on **PIC/S seminars** for GMP inspectors, in particular:

- the 2003 seminar on the Inspection of Quality Control Laboratories (Bratislava, 4-6 June 2003), organised by the Slovak State Institute for Drug Control (SIDC), see Annex.
- the 2004 seminar on the Inspection of Active Pharmaceutical Ingredients, organised by the Spanish "Agencia Española del Medicamento" (AEM), which will take place near Barcelona (Spain) on 16-18 June 2004.

Information was also provided on **PIC/S Expert Circles**:

- The 4th meeting of the Expert Circle on Medicinal Gases, organised by Finland's National Agency for Medicines, will be held in Hämeenlinna (Finland) on 9-11 June 2003.
- The 10th meeting of the Expert Circle on Human Blood and Tissue, organised by the Hungarian National Institute of Pharmacy (NIP), will take place in Visegrad (Hungary) from 8 to 11 September 2003.
- The 6th meeting of the Expert Circle on Hospital Pharmacy, organised by the Medicines and Healthcare Products Regulatory Agency (MHPRA), in London (UK) on 21-22 October 2002.

- The 2nd meeting of the Expert Circle on Computerised Systems, organised by Australia's Therapeutic Goods Administration (TGA), in Canberra on 17-18 February 2003.
- The second meeting of the Working Group on Biotechnology, organised by the Danish Medicines Agency, will be held in Brønshøj (Denmark) on 29 August 2003.

New / revised PIC/S guidance documents

The Committee adopted the following documents:

- Guide to Inspections of Source Plasma Establishments and Plasma Warehouses (PI 008-1); Site Master File for Source Plasma Establishments (PI 019-1); and Site Master File for Plasma Warehouses (PI 020-1). These documents will enter into force on 15 July 2003;
- PIC/S Guidance on Best Practices for Computerised Systems in Regulated "GxP" Environments (PI 011-1), which will enter into force on 1 September 2003;
- Annex 1 to the PIC/S GMP Guide (revision in parallel with the EU), which will be adopted by written procedure and enter into force at the same time as in the EU;
- Annex 13 to the PIC/S GMP Guide³ (revision in parallel with the EU), which will enter into force at the same time as in the EU.

PIC/S on line

The Committee was informed on the initial draft of a "Questions & Answers" document with regard to the interpretation of the PIC/S GMP Guide, which will be posted on the PIC/S web site (<http://www.picscheme.org>) once completed.

Next meeting

The Committee agreed to meet later in the year in Geneva (Switzerland) on 11 and 12 November 2003 (one day and a half meeting).

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³ without references to the EU legislation

2003 PIC/S SEMINAR - BRATISLAVA

The joint meeting of the PIC/S Committee was followed by a Seminar on “The Inspection of Quality Control Laboratories” (Bratislava, Slovak Republic, 4-6 June 2003), organised by the Slovak State Institute for Drug Control (SIDC).

The PIC/S Seminar was attended by 95 participants from 36 countries. This number also includes invited inspectors and speakers from a number of non PIC/S countries or agencies such as Cyprus, EMEA*, Estonia*, FDA, Latvia*, Lithuania, Macedonia, New Zealand, Oman, Poland, Russia, Serbia, South Africa, Ukraine, UNICEF, and WHO*.

The Seminar focused on:

- (i) experts discussions on current regulatory issues related to GMP in pharmaceutical quality control laboratories;
- (ii) the harmonisation of inspection standards and practices; and
- (iii) the drafting of guidance documents, in particular an Aide Memoire on the inspection of pharmaceutical quality control laboratories.

The collected papers presented at the Seminar will be made available on a CD-ROM (orders can be addressed to the PIC/S Secretariat).

* Observer to PIC/S Committee