PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

6 May 2002

PRESS RELEASE

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) took place in Geneva (Switzerland) on **23 and 24 April 2002** under the chairmanship of Ms. Lilian Hamilton (Sweden / Medical Products Agency). Thirty-four delegates and observers from twenty-five Inspectorates and two Agencies took part in the meeting. Latvia, the EMEA and WHO attended the meeting as observers.

Greece and Malaysia

The Committee welcomed the representatives of the Greek National Organization for Medicines (NOM) and the Malaysian National Pharmaceutical Control Bureau (NPCB), who attended the meeting for the first time as Members (both NOM and NPCB acceded to PIC/S on 1 January 2002).

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*.

Recommendations by Strategy Group

The Committee endorsed all recommendations made the Strategy Group at its meeting in London on 4 and 5 February 2002. The Strategy Group made important recommendations to the Committee with regard to organisation, goal and future activities (see below).

PIC/S goal

The Committee adopted a goal for PIC/S, which reads as follows:

> To lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products.

This goal is to be achieved by:

- Developing and promoting harmonised GMP standards and guidance documents;
- Training competent authorities, in particular inspectors;
- Assessing (and reassessing) inspectorates;
- Facilitating the co-operation and networking for competent authorities and international organisations.

International Medicinal Inspectorate

The Committee fully supported the creation – within PIC/S – of a non-profit International Medicinal Inspectorate (IMI). The IMI, whose concept was developed by Mr. Jean Lambert of Canada (Health Products and Food Branch Inspectorate), will carry out cost-recovered GMP inspections to establishments located outside of the jurisdictions covered by the PIC/S members. It will focus on the inspection of Active Pharmaceutical Ingredients (APIs) as well as medicinal products. The IMI will constitute the prototype of a model quality system inspectorate and start gradually its operations by July 2003. Industry and international health organisations are expected to be the main beneficiaries of the IMI.

WHO Global Alliance for the Quality of Medicines

The Committee decided to fully support the WHO Global Alliance for the Quality of Medicines, which aims at ensuring the quality, safety and efficacy of pharmaceuticals worldwide through partnership and international co-operation. PIC/S will be one of the strategic partners of the Global Alliance.

PIC/S Executive Bureau

To alleviate the burden on the Chair, the Committee decided to create an Executive Bureau consisting of the Chairperson, the First and Second Deputy Chairpersons as well as two new Bureau Members, who will be elected at the next meeting. One of the two new Bureau Members will be in charge of monitoring new membership applications while the other Bureau Member will be the PIC/S-EU Liaison Officer. The Executive Bureau will meet in-between Committee meetings.

Joint Reassessment Programme

The Committee confirmed its decision to launch the pilot phase of the PIC/S Joint Reassessment Programme (JRP) and to strive for a single evaluation system to be recognised by PIC/S, the EU Heads of Agencies as well as MRA partners. It nominated the auditors in charge of evaluating during the pilot phase the Inspectorates from Romania and Sweden (second half of 2002) and Australia and Greece (first half of 2003). It also established a Compliance Group in charge of monitoring the JRP.

Chinese Taipei, Estonia and Poland

A PIC/S Delegation will visit the National Laboratories for Foods and Drugs (NLFD) of Chinese Taipei from 29 April to 3 May 2002. The visit will focus on the assessment of the local GMP inspection and licensing system.

A follow-up visit to Estonia will be carried out by a PIC/S Delegation in autumn 2002 following the entry into force of the local GMP legislation.

The evaluation of the application made by the Main Pharmaceutical Inspectorate of Poland was sent for comments to the Polish Authorities. A reply by the latter is awaited.

The Czech Institute for State Control of Veterinary Biologicals and Medicaments has expressed an interest in joining PIC/S. The Czech Institute is the second veterinary agency to express such an interest in PIC/S after the UK Veterinary Medicines Directorate (VMD).

Training for inspectors

The Committee was informed on past and future **PIC/S seminars** for GMP inspectors:

- The Canadian Health Products and Food Branch Inspectorate (HPFBI) updated Members on the final preparations for the 2002 seminar on "The Interface Between Good Clinical Practice (GCP) and GMP in the Manufacture and Audit of Clinical Trial Products" (Montebello, Quebec, 8-11 October 2002).

- The Slovak State Institute for Drug Control (SIDC) presented a revised draft programme for the 2003 seminar on the Inspection of Quality Control Laboratories (Bratislava, 4-6 June 2003).

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

- The 9th meeting of the "Expert Circle on Human Blood and Tissue" will be organised by the French Agency for the Safety of Health Products French (AFSSAPS) in St. Denis (France) from 19 to 21 June 2002. It will be devoted to questions related to the inspection of human tissues.

- The 4th meeting of the Expert Circle on Medicinal Gases will be held in Helsinki (Finland) in late May or early June 2003.

- The 5th meeting of the Expert Circle on Hospital Pharmacy took place in Reykjavik (Iceland) on 15 April 2002. It was organised by the Icelandic Medicines Control Agency (IMCA) and attended by 17 countries. The next meeting will be organised in London on 21-22 October 2002.

- The first meeting of the Expert Circle on Biotechnology, due to take place in Denmark on 29-30 April 2002, was postponed. However, an Expert Meeting on Biotech will be arranged by the Danish Medicines Agency later this year.

- The first meeting of the Expert Circle on Computerised Systems will be hosted by the Medicines Control Agency in London (UK) on 12-13 June 2002.

New / revised PIC/S guidance documents

The Committee revised the Standard Operation Procedure on the Editing of PIC/S Documents (PI 001-1) in order to better distinguish "PIC/S internal documents" (i.e. recommendations for the guidance of inspectors) from "PIC/S external documents" (i.e. GMP Guides, which industry must follow).

The Committee also adopted the following internal documents:

- Recommendation on Isolators Used for Aseptic Processing and Sterility Testing (PI 014-1);

- Aide-Memoire on the Inspection of Utilities (PI 009-1);

- Standard Operating Procedure on Rapid Alert System (PI 010-1);

- Guidelines on the Acceptance and Status of Observers to the PIC/S Committee (PS/W 3/2002);

All these documents will enter into force on 1 July 2002 and made available on the PIC/S web site.

The following documents were also discussed at the Committee meeting:

- Annexes 1 and 13 to the PIC/S GMP Guide (revision in parallel with the EU);
- Annex 16 of the EU GMP Guide on "Certification of a Qualified Person and Batch Release" (the Committee decided not to adopt this EU specific Annex, which is applicable to EU/EEA Members States only);
- Revision of the Explanatory Notes for Industry on the Preparation of a Site Master File (PH 4/93);
- Standard Operating Procedure on PIC/S Inspection Report Format and Classification of Deficiencies (PI 013 (Draft)).

PIC/S on line

Several projects regarding the PIC/S web site (http://www.picscheme.org) are currently under way (password protected "bulletin board" for inspectors, extranet, etc.).

Next meeting

The Committee will meet later this year in Montebello (Canada) on 8 October 2002 in connection with the 2002 PIC/S Seminar.

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