



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

22 May 2007

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 **15-16 May 2007** under the chairmanship of Mr. Jacques Moréas (France / AFSSAPS). All PIC/S Participating Authorities were represented, with the exception of Iceland / IMCA and Sweden / MPA. Estonia / SAM participated in the meeting for the first time as a full Member. The EMEA, UNICEF and WHO as well as the competent authorities of Argentina, Malta and South Africa also took part in the meeting.

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 30 Participating Authorities in the PIC/S (Convention (#) and Scheme taken together). The PIC/S Participating Authorities are coming from Australia#, Austria#, Belgium#, Canada, Czech Republic (both Human and Veterinary), Denmark#, Estonia, Finland#, France#, Germany#, Greece, Hungary#, Iceland#, Ireland#, Italy#, Latvia, Liechtenstein#, Malaysia, Netherlands, Norway#, Poland, Portugal#, Romania#, Singapore, Slovak Republic, Spain, Sweden#, Switzerland#, and the United Kingdom#.

Assessment and Reassessment of Authorities

Argentina and South Africa to join PIC/S

The Committee invited South Africa's Medicines Control Council (MCC) and Argentina's National Institute of Medicaments (INAME) to join PIC/S as new Participating Authorities as from 1 July 2007 and 1 January 2008, respectively. Both Inspectorates have been admitted following an evaluation of their GMP system and based on an assessment visit carried out by a delegation of PIC/S, from 3 to 9 September 2006 in South Africa and from 25 November to 1 December 2006 in Argentina. MCC applied for PIC/S Membership on 7 June 2004 and INAME on 26 January 2005.

The Committee noted that France's Agency for Veterinary Medicinal Products (AFSSA - ANMV) had applied for PIC/S Membership on 11 December 2006. A Rapporteur and a Co-Rapporteur were nominated in order to assess the application.

The representative of Malta's Medicines Authority made a presentation of the Maltese GMP inspection system. Malta applied for PIC/S Membership on 2 October 2006.

The Committee reviewed the applications made by Israel's Ministry of Health, Lithuania's Department of Pharmacy, the Thai FDA and the US FDA. Two delegations were appointed by the Committee for the assessment visit in Israel and Thailand, respectively.

The partial reassessment of Iceland's Medicines Control Agency (IMCA) has been completed. The Rapporteur concluded that IMCA had met all PIC/S requirements. The Committee decided that the reassessment could be closed.

New Competent Authority in Belgium

The Committee noted that in Belgium the Federal Agency for Medicines and Health Products (FAMHP) had succeeded to the "Direction Générale des Médicaments" (DGM) as the new PIC/S Competent Authority as from 1 January 2007. FAMHP will be assessed under the EU Joint Audit Programme.

Co-operation with EMEA, DG SANCO, DG Enterprise, EDQM, Heads of Medicines Agencies & WHO's Vaccines Department (IVB)

The Committee noted that the EMEA has replied favourably to PIC/S' proposal to strengthen the co-operation between the two organisations. The proposed fields of co-operation would include the training of inspectors, the participation in meetings, the exchange of information and the evaluation / re-evaluation of competent authorities. Replies to similar proposals to extend co-operation were awaited from DG SANCO**, DG Enterprise**, EDQM**.

WHO's Immunization, Vaccines & Biologicals (IVB) Department agreed in principle to develop an informal co-operation with PIC/S.

The Committee also decided to initiate contacts with the Training Project Team to be set-up by the Heads of Medicines Agency.

Exchange of Information

The Committee discussed a proposal to revise the PIC Scheme (PIC/S 1/95 (Rev. 4)), notably Chapter X on the Exchange of Information. The aim of this revision is to better clarify the scope and modalities of the exchange of information under the Scheme. The proposal will be formally adopted at the next meeting.

Members also agreed to better share information on GMP inspections. They decided to reactivate the list of GMP inspections to be carried out by PIC/S Participating Authorities in order to share information on sites and products to be inspected. They also agreed in principle to the possibility of carrying out "team inspections", subject to the definition of modalities.

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DG SANCO: European Commission's Health and Consumer Protection Directorate-General
DG Enterprise: European Commission's Enterprise and Industry Directorate-General
EDQM: European Directorate for Quality Medicines

Training for inspectors

The Committee noted that the PIC/S Working Group on the Training of Inspectors had met in Geneva on 15 May in the morning. The Working Group...

- noted that the PIC/S Joint Visit Programme had been opened to GCP inspectors;
- reviewed the programme of the 2007 Seminar in Singapore on the Inspection of Solid Dosage Forms;
- discussed the organisation of the 2008 Seminar on GDP in Krakow (Poland);
- reviewed the activities of the different PIC/S Expert Circles.

Guidance Documents

The Committee...

- noted that 22 feedbacks had been received from national and international hospital and pharmacy associations on the second draft of the PIC/S Guide to Good Practices for Preparation of Medicinal Products in Pharmacies (PE 010-1 (Draft 2));
- noted that the PIC/S GMP Guide (PE 009-6) has been revised (new Annex 19) and divided into 2 parts: Part I (GMP principles for the manufacture of medicinal products) and Part II (GMP for active substances used as starting materials);
- adopted the revision of two guidance documents on PIC/S Seminars and Expert Circles, respectively;
- decided to revise the Explanatory Notes for Industry on the Preparation of a Site Master File;
- reviewed the list of guidance documents to be drafted in priority.

In brief

The Committee...

- extended the mandate of Mr. Jacques Moréas (France / AFSSAPS) as PIC/S Chairman until the end of 2008;
- elected Mr. Michel Keller (Switzerland / Swissmedic) as First Deputy Chairman and Mr. Tor Gråberg (Sweden / MPA) as Second Deputy Chairman for the period 2007-2008;
- nominated Malaysia / NPCB as ASEAN Liaison Authority for the period 2007-2008;
- agreed in principle to develop team inspections;
- approved the 2006 accounts and discharged the Chairman for the financial year 2006;
- adopted the 2006 PIC/S Annual Report;
- noted the Summary Record of the first PIC/S - Industry Forum (PS/SR 4/2006);
- agreed in principle to have a joint PIC/S – PDA Conference in 2008;
- confirmed that the next meeting would take place in Singapore on 19 November 2007.