



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

12 June 2006

**PRESS RELEASE**

**PIC/S COMMITTEE MEETING  
DÜSSELDORF, GERMANY**

A joint Committee meeting of the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) took place in Düsseldorf (Germany) on **29 and 30 May 2006** under the chairmanship of Mr. Jacques Morénas (France / French Agency for the Safety of Health Products). All PIC/S Participating Authorities were represented with the exception of Canada and Finland. The EMEA\*, UNICEF\* and WHO\*, the competent authorities from Argentina, Estonia\*, New Zealand, Thailand, South Africa, and USA also participated 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 29 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#, 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#.

**Thailand applies for membership**

The Committee discussed the application of Thailand's Food and Drug Administration (Thai FDA) to PIC/S, which was received on 24 February 2006. It also reviewed the evaluation report prepared by the Rapporteur and Co-Rapporteurs. Representatives from the Thai FDA made a presentation on the Thai GMP system and replied to questions raised by Members of the Committee. The PIC/S Chairman was mandated to visit the Thai FDA at the end of the year to discuss the membership application.

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\* Observer to PIC/S Committee

## **Assessment and Reassessment of other Authorities**

The membership applications of Argentina's National Institute of Medicaments (INAME), South Africa's Medicines Control Council (MCC) and USA's Food and Drug Administration (US FDA) were reviewed in the presence of their representatives ("hearing"). Assessment visits have been scheduled to South Africa in September 2006 and to Argentina in November 2006. An evaluation report on the US FDA's application, to be submitted by the Rapporteur and Co-Rapporteurs, is awaited. The Committee also discussed the application made by Estonia's State Agency of Medicines (SAM) and decided that a follow-up visit to Estonia would be carried out in 2006.

The Committee took note that the team in charge of the reassessment of United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) had made its visit and that the report was on its way. The reassessment of Iceland's Medicines Control Agency (IMCA), Switzerland's Agency for Therapeutic Products (Swissmedic) and Liechtenstein's "Kontrollstelle für Arzneimittel" (KA) would be based on Canadian reports and be launched shortly. An update was also made on the implementation of corrective measures by Greece's National Organization for Medicines (EOF) and Romania's National Medicines Agency (NMA).

In addition, the Committee decided to:

- waive the reassessment of the Czech Republic's State Institute for Drug Control (SÚKL), Hungary's National Institute of Pharmacy (NIP) and the Slovak Republic's State Institute for Drug Control (SIDC), provided that EU and Canadian reports were shared with PIC/S;
- reassess Austria following the creation of a new competent agency, the Austrian Medicines and Medical Devices Agency (AGES PharmMed);
- reassess Australia's Therapeutic Goods Administration (TGA) once its merger with New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) would become effective (1<sup>st</sup> July 2007).

## **Training for inspectors: meeting of the Working Group**

The PIC/S Working Group on the Training of Inspectors met in Düsseldorf on 28 May 2006. It reviewed the programme of the 2007 PIC/S Seminar on the "Inspection of the Manufacture of Solid Dosage Forms", which would be held in Singapore on 21-23 November 2007.

It also reviewed the forthcoming Expert Circle meetings:

- PIC/S Expert Circle on Computerised Systems (Düsseldorf, Germany, 29-30 May 2006)
- PIC/S Expert Circle on Hospital Pharmacy (Lisbon, Portugal, 6-7 June 2006)
- PIC/S Expert Circle on Human Blood and Tissue (Utrecht, Netherlands, 22-22 September 2006)
- PIC/S Expert Circle on Active Pharmaceutical Ingredients (APIs) (United Kingdom, last quarter of 2006)

It decided to revise the PIC/S Guideline for Expert Circles (PI 022-1) in order to introduce (i) a deadline to submit invitations and programmes for each Expert Circle meeting and (ii) criteria to define the notion of “expert”.

Following a proposal made by the Working Group on Training, the Committee decided to suspend the Expert Circle on Medicinal Gases until further notice but to create a Working Group on Good Distribution Practices (GDP).

### **2008 PIC/S Seminar in Poland**

Poland’s Main Pharmaceutical Inspectorate (MPI) generously offered to organise the 2008 Seminar on “Good Distribution Practices”.

### **Guidance Documents**

The Committee agreed to revise the format of the PIC/S GMP Guide (PE 009-4) in line with the EU GMP Guide: Chapter 1 to 9 would become Part I while the Guide on APIs (PE 007-2) would become Part II of the revised PIC/S GMP Guide.

It noted that additions to Chapter 6 of the PIC/S GMP Guide would enter into force on 1 June 2006 and agreed, in principle, to adopt Annex 19 of the EU GMP Guide to the PIC/S GMP Guide.

The Committee also adopted the PIC/S Aide-Memoire on Medicinal Gases (PI 025-1).

### **Relations with other Organisations**

The Committee discussed a proposal to amend the PIC/S Guidelines for Observer Status (PS/W 3/2002) in order to redefine the status of Observers within PIC/S. A revised proposal will be submitted at the next meeting of the Committee.

Following a presentation on WHO’s Department of Immunization, Vaccines and Biologicals (IVB), the Committee decided to co-operate with this department.

It also agreed to hold a half-day meeting with industry and professional associations in Geneva (Switzerland) on 23 November 2006.

It has also been decided to seize the opportunity of the 2007 PIC/S Seminar in Singapore to hold a forum with Regulatory Authorities of the Association of South East Asian Nations (ASEAN).

### **In brief**

The Committee noted that...

- the PIC/S Blueprint has been successfully adopted by the PIC/S Committee by written procedure. This document aims at reviewing PIC/S’ mission and at defining its objectives for the next decade. It is available on the PIC/S website ([www.picscheme.org](http://www.picscheme.org));
- the PIC/S Secretariat moved to new offices in Geneva (Switzerland). The postal address remains, however, unchanged;

- all PIC/S assessment and reassessment tools had been harmonised;
- a position paper had been sent to the EEA Heads of Medicines Agencies' concerning their "Strategy Paper on the European Medicines Regulatory Network";
- the PIC/S Executive Bureau had adopted its Rules of Procedures.

The Committee also...

- approved the 2005 accounts and discharged the former Chairman for the financial year 2005;
- adopted the 2005 PIC/S Annual Report;
- decided that the next meeting would take place in Geneva (Switzerland) on 21-22 November 2006.

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## 2006 PIC/S SEMINAR – DÜSSELDORF

The joint meeting of the PIC/S Committee was followed by a Seminar on “Quality Risk Management and related ICH topics” which was held in Düsseldorf (Germany) from 31 May to 2 June 2006.

The PIC/S Seminar was organised by the German Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices (ZLG). It was attended by around 110 participants from 39 countries. This number includes inspectors from a number of non-Member agencies coming from Argentina, Cyprus, Croatia, the European Medicines Agency (EMA<sup>\*</sup>), Estonia<sup>\*</sup>, Israel, Japan, Lithuania, New Zealand, NIS<sup>1</sup>, Taipei, Thailand, Serbia, South Africa, and USA.

It was the first time that a PIC/S Seminar was attended by representatives from Croatia’s Agency for Medicinal Products and Medical Devices.

Among the 110 seminar participants were also a number of speakers, session chairpersons and workshop leaders. Speakers were provided by PIC/S Participating Authorities, the EMA, the European Commission, the German Federal Institute for Drugs and Medical Devices (BfArM) and industry.

The Seminar focused on:

- (i) the presentation of the ICH process;
- (ii) ICH Q8 “Pharmaceutical Development” from both regulators’ and industry’s perspective;
- (iii) ICH Q9 “Quality Risk Management” from both regulators’ and industry’s perspective;
- (iv) the progress made in the development of ICH Q10 “Quality Systems” and its future use by industry;
- (v) the interaction and the complementarity of these 3 topics as a common framework.

The presentations made at the Seminar will be made available on a CD-ROM.

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\* Observer to PIC/S Committee

<sup>1</sup> New Independent States’ Interstate Commission on Standardisation, Registration and Quality Control of Medicines and Medical Devices