



## PHARMACEUTICAL INSPECTION CONVENTION PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

3 December 2007

### PRESS RELEASE PIC/S MEETINGS IN SINGAPORE

From 18 to 23 November 2007, the following events took place in Singapore: PIC/S Executive Bureau, PIC/S Committee, annual PIC/S Seminar, PIC/S – ASEAN forum and PIC/S – ISPE joint workshop. It is the first time that PIC/S meetings (including the annual PIC/S Seminar) have taken place in Asia!

#### 1. PIC/S COMMITTEE MEETING (19 November 2007)

A joint Committee meeting of the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) was held in Singapore on 19 November 2007 under the chairmanship of Mr. Jacques Morénas (France / French Agency for the Safety of Health Products). With the exception of Austria, Belgium, Iceland and Liechtenstein, all PIC/S Participating Authorities were represented. The competent authorities from Argentina, Israel, Malta and USA, as well as EMEA and WHO 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 31 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, South Africa, Spain, Sweden#, Switzerland#, and the United Kingdom#.

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

##### Argentina and Malta to join in 2008

The Committee invited Argentina's National Institute of Medicaments (INAME) and Malta's Medicines Authority (MMA) to join PIC/S as new Participating Authorities as of 1 January 2008. INAME applied for PIC/S Membership on 26 January 2005 and has been admitted following an assessment of its GMP system (notably the GMP inspectorate, the manufacturer

licensing system and the assessment of quality defects of API and medicinal products) including an on-site assessment visit carried out by a delegation of PIC/S from 25 November to 1 December 2006. A follow-up report on outstanding issues was presented at the Singapore meeting. MMA applied on 2 October 2006 and has been assessed based on assessment reports from Canada and the European Union which both evaluated Malta in the framework of their MRA.

The Committee reviewed the progress made in the assessment of applications submitted by France's Agency for Veterinary Medicinal Products, Israel's Ministry of Health, Lithuania's Department of Pharmacy, the Thai FDA and the US FDA. On-site assessment visits to France, Israel and Thailand are scheduled to take place in 2008.

The Committee also noted that Cyprus' Pharmaceutical Services had applied for PIC/S membership on 2 November 2007 and nominated a Rapporteur and a Co-Rapporteur. The competent authorities of Indonesia and New Zealand also announced their intention to apply for PIC/S membership by 2008. The Committee was informed that the merger between Australia's TGA and New Zealand's MedSafe had been put on hold.

The Committee reviewed the reassessment of Switzerland's Agency for Therapeutic Products (Swissmedic) and Liechtenstein's "Kontrollstelle für Arzneimittel" (KA). Since Swissmedic met all PIC/S requirements, the Committee decided that the reassessment could be closed. Due to the reorganisation of the "Kontrollstelle für Arzneimittel" (KA), now "Amt Für Gesundheit" (AG), Liechtenstein was invited to make a follow-up at the next meeting. The Committee took note that the reassessment of Austria's Medicines and Medical Devices Agency (AGES PharmMed) had started.

The Committee discussed future audits of GMP inspectorates. It decided to develop a roster to enable a better sharing of duties among PIC/S Participating Authorities. The Committee also discussed different possibilities to cover auditors' expenses to allow Participating Authorities with limited resources to take part in audits.

### **Training for inspectors**

The Committee reviewed the programme of the 2008 Seminar which would be held in Krakow (Poland) on Good Distribution Practices for both API and medicinal products. It also noted that the 2009 Seminar would be organised in Uppsala (Sweden) on Sterile Aseptic Manufacturing for both API & medicinal products and that the 2010 Seminar on Herbal Medicines would be hosted by Malaysia.

The Committee also reviewed the outcome of last meetings organised by PIC/S Expert Circles:

- Expert Circle on Hospital Pharmacy (Oslo, Norway, 25-27 June 2007);
- Expert Circle on Quality Risk Management (Paris, France, 2-3 July 2007);
- Expert Circle on Active Pharmaceutical Ingredients (Drafting Group meeting, Paris, France, 12-14 September 2007);
- Expert Circle on Computerised Systems (Dublin, Ireland, 1-3 October 2007);
- Expert Circle on Human Blood and Tissue (Dublin, Ireland, 1-5 October 2007).

The Committee decided to review the composition of Steering Committees of Expert Circles and invited three Expert Circles to review their mandate.

## **Guidance Documents**

The Committee adopted the final draft of the PIC/S Guide to Good Practices for the Preparation of Medicinal Products\* (PE 010-1 (Draft 3)). This guide will present the basic requirements for the preparation of medicinal products by healthcare establishments for direct supply to patients. It will be published on the PIC/S website ([www.picscheme.org](http://www.picscheme.org)) after final editing. The Committee also approved the revision of two guidance documents regarding the drafting of PIC/S documents (PI 001-5 and PI 029-1).

## **Relations with other Organisations**

### European Union

The Committee noted that a co-operation agreement in the form of a Memorandum of Understanding (regarding the training of GMP inspectors, the exchange of information on guidance documents and audits of GMP inspectorates) had been negotiated with the European Medicines Agency (EMA) and was expected to be signed by the end of 2007. A similar agreement (regarding the sharing of information, consultation on guidance documents and training in the field of APIs) was concluded in July 2007 between PIC/S and the European Directorate for the Quality of Medicines & HealthCare (EDQM).

### WHO

PIC/S and WHO's Department of Immunization, Vaccines and Biologicals (IVB) are in the process to negotiate a co-operation agreement (regarding the exchange of information, training and harmonisation of audit tools).

For information on co-operation with ASEAN and ISPE see page 5.

## **In brief**

The Committee ...

- re-elected Mr. Paul Hargreaves (United Kingdom / MHRA) as Member of the Executive Bureau for the period 2008-2009;
- adopted a revision of the PIC Scheme (new chapter on the reorganisation of Participating Authorities and revised chapter on the sharing of information);
- revised the PIC/S Audit Checklist which was harmonised with the EU JAP Audit Checklist;
- adopted the revised PIC/S Accession Guidelines (new facilitated procedure for Authorities having been assessed by two PIC/S Participating Authorities);
- approved the 2008 budget and adopted the revised Financial Rules;
- adopted a template for Participating Authorities to share information on inspections in non-PIC/S countries;
- noted an oral report by the Chairman on the last meeting of the Executive Bureau (Sunday 18 November);
- confirmed that next meetings would take place in Krakow (Poland) on 26-27 May 2008 and in Geneva (Switzerland) on 11-12 November 2008.

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\* The title of the document may be subject to modification.

## 2. PIC/S SEMINAR – SINGAPORE (20-22 November)

A Seminar on the “Inspection of Manufacturers of Solid Dosage Forms” was held in Singapore from 20 to 22 November 2007. **It was the first time that a PIC/S Seminar was held in Asia.**

The PIC/S Seminar was organised by Singapore’s Health Science Authority (HSA). It was attended by almost 130 participants from 45 agencies from all continents (among which 13 from Asia). **The number of participants and the number of agencies represented both constitute a record in PIC/S Seminar history.** Inspectors from a number of non-Member agencies coming from Brunei Darussalam, China, Cyprus, the European Medicines Agency (EMA), Georgia, Hong-Kong SAR<sup>1</sup>, Indonesia, Israel, Japan, Macau SAR<sup>1</sup>, NIS<sup>2</sup>, South Korea, New Zealand, Philippines, Taipei, Thailand, USA, Vietnam and WHO also participated in the seminar.

PIC/S Seminar was attended for the first time by representatives from Brunei Darussalam, Georgia, Hong-Kong SAR, Macau SAR, the Philippines, South Korea and Vietnam.

Among the seminar participants were also a number of speakers, session chairpersons and workshop leaders. Speakers were mainly provided by PIC/S Participating Authorities, academia and industry.

The Seminar focused on the following topics in the field of GMP inspection of manufacturers of solid dosage forms:

- (i) challenges and issues (e.g. the interface between GMP inspection and drug evaluation);
- (ii) technological advances and new initiatives (e.g. Process Analytical Technology and process understanding);
- (iii) production and quality control (e.g. control of starting materials, in-process & packaging controls, cleaning validation for multi-product manufacturing facilities);
- (iv) environmental control and segregation requirements (e.g. air cleanliness classification for manufacturing facilities).

An entire day was dedicated to parallel workshops. One workshop consisted in case studies on deficiencies and their classification during GMP inspection of solid dosage form manufacturers. Two other workshops were dedicated to the inspection of solid dosage form manufacturing facilities (air cleanliness, microbial & environmental monitoring) and to the need for dedicated equipment or segregated facilities for highly active and/or sensitising agents.

The presentations made at the Seminar will be made available on a CD-ROM (contact the PIC/S Secretariat ([info@picscheme.org](mailto:info@picscheme.org))).

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<sup>1</sup> Special Administrative Region

<sup>2</sup> New Independent States’ Interstate Commission on Standardisation, Registration and Quality Control of Medicines and Medical Devices

### **3. PIC/S - ASEAN FORUM (22 November)**

A half-day meeting between PIC/S and representatives from Regulatory Authorities of the Association of South East Asian Nations (ASEAN) took place in Singapore on 22 November 2007. Representatives from Brunei Darussalam, Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam attended the meeting. PIC/S was represented by the Executive Bureau.

This was the first meeting between PIC/S Participating Authorities and ASEAN. It gave the occasion for both PIC/S and ASEAN to present their respective organisation and to explore possible ways of co-operation on GMP training and GMP Guides and Guidance documents. For PIC/S, it is of particular interest to note that ASEAN countries are in the process of harmonising their GMP inspection systems through the negotiation of an MRA taking PIC/S as a reference. A draft MRA is expected by the end of 2007.

Participants agreed to co-operate in the following fields of GMP: training for inspectors (e.g. joint visits or coached inspections), preparation of application for PIC/S membership, sharing of information (e.g. Rapid Alert System, import for export-only products) and sharing of knowledge on the inspection of herbal medicines.

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### **4. PIC/S – ISPE JOINT WORKSHOP (23 November)**

PIC/S and the International Society for Pharmaceutical Engineering (ISPE) organised in Singapore on 23 November 2007 an interactive joint workshop on “Systems Approach to Quality Risk Management”. It was the first time that PIC/S organised such a joint event with an industry association.

The meeting was open to both regulators and industry. It was attended by more than 226 participants (among which, 65 participants from Regulatory Authorities) representing 34 countries.

Participants attended plenary sessions with presentations from industry and regulatory authority representatives (respectively “Risk Management in Production System, Two Examples” and “Manufacturing of Risky Molecules in Non Dedicated Facilities”). GMP inspectors and industry representatives also participated in practical workshops on different aspects of Quality Risk Management.

The workshop was a success and it is expected that more joint workshops will be organised with professional and industry associations in the future.

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