



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

21 November 2008

**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) took place in Geneva (Switzerland) on **11-12 November 2008** under the chairmanship of Mr. Jacques Morénas (France / French Agency for the Safety of Health Products). With the exception of Iceland / IMCA and Spain / AEMPS, all PIC/S Participating Authorities were represented. Representatives from EMEA, UNICEF and WHO as well as from France's Veterinary Agency, Israel's Institute for Standardization and Control of Pharmaceuticals, Lithuania's Department of Pharmacy, Ukraine's State Service for Medicine and Medical use Products and the US Food and Drug Administration 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 34 Participating Authorities in the PIC/S (Convention (#) and Scheme taken together). The PIC/S Participating Authorities are coming from Argentina, Australia#, Austria#, Belgium#, Canada, Cyprus, Czech Republic (both Human and Veterinary), Denmark#, Estonia, Finland#, France#, Germany#, Greece, Hungary#, Iceland#, Ireland#, Italy#, Latvia, Liechtenstein#, Malaysia, Malta, Netherlands, Norway#, Poland, Portugal#, Romania#, Singapore, Slovak Republic, South Africa, Spain, Sweden#, Switzerland#, and the United Kingdom#.

**Slovenia applies for membership**

The Committee noted that Slovenia's Agency for Medicinal Products and Medical Devices (JAZMP) applied for PIC/S membership on 28 October 2008. The Committee nominated a Rapporteur and a Co-Rapporteur for the assessment of the Slovenian application.

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

The membership applications of France's Veterinary Agency (ANMV), Israel's Institute for Standardization and Control of Pharmaceuticals (ISCP), Lithuania's Department of Pharmacy (SMCA) and Ukraine's State Service for Medicine and Medical use Products (SMMP) were reviewed in the presence of their representatives. The Committee reviewed the evaluation reports prepared by the Rapporteurs (FUP report on ANMV and interim progress report on SMMP) and agreed on the accession to PIC/S of ANMV and ISCP as from 1 January 2009. It also accepted in principle the accession of SMCA as from 1 July 2009, provided that outstanding issues identified by the Rapporteur are implemented before the next Committee meeting. Members agreed to evaluate the progress made in the Ukrainian application at their next meeting, prior to decide on an on-site assessment visit in the Ukraine.

The Committee also reviewed the work-plan to implement corrective actions submitted by Thailand's FDA. It discussed the details of the on-site assessment visit of the US Food and Drug Administration (US FDA) which will take place in January 2009. The Chairman updated Members on the progress made in the assessment of Indonesia's National Agency for Food and Drug Control (NADFC) which applied in April 2008.

The Committee reviewed the follow-up report on the reassessment of Liechtenstein's "Amt für Gesundheit" (AG). As all outstanding issues resulting from the reorganisation of the Competent Authority in Liechtenstein have been addressed, Members agreed to close the reassessment. They also noted an interim status report on the reassessment of Austria's Medicines and Medical Devices Agency (AGES PharmMed).

In addition, the Committee agreed to await the report by Canada on its audit in Latvia (in the scope of the EU-Canada MRA) before launching the reassessment of Latvia's State Agency of Medicine (ZVA).

## **Questionnaire**

The Committee reviewed the results of an internal questionnaire on Participating Authorities' (PAs) satisfaction with the current structure and operation of PIC/S. The overall satisfaction of PAs was good. In order to further improve the current system in place within PIC/S for facing new challenges (e.g. increasing of membership, management of PAs' resources, etc.), the Committee nominated a Working Group in charge of reviewing suggestions made by PAs and providing proposals for the next meeting of the Committee.

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

The PIC/S Working Group on the Training of Inspectors (WGT) met in Geneva on 11 November 2008 in the morning. The WGT discussed the improvement of PAs' participation and inspectors' involvement in the PIC/S Joint Visit Programme (JVP). It also discussed the way to report upon joint visits.

Members of the WGT reviewed the draft revision of the Guideline for Expert Circles (PI 022-2 (Draft 3)) as well as the draft Standard Operating Procedure on Coached Inspections (PS/W 2/2008 (Draft 2)) and decided that both documents could be submitted to the Committee for adoption. They also approved the terms of reference (PS/W 20/2008) of the Working Group on Annex 3 (radiopharmaceuticals) to the revised PIC/S Guide to Good Practices for the

Preparation of Medicinal Products in Healthcare Establishments. They made some comments to the new mandate of the Expert Circle on Computerised Systems (PS/W 19/2008).

The WGT also noted:

- the evaluation report on the 2008 Seminar (PS/INF 43/2008) on “Good Distribution Practices” (Krakow (Poland), 28-30 May 2008), showing the great satisfaction of participants;
- the revised draft programme of the 2009 Seminar (PS/INF 44/2008 (Rev.)) on “Aseptic and Sterile Manufacturing from APIs to Finished Dosage Forms” which will take place in Uppsala (Sweden) on 4-6 November 2009;
- the provisional programme of the 2010 Seminar (PS/INF 45/2008) on the “Inspection of Traditional Medicines” which will be organised in Malaysia in November 2010.

### **Exchange of Information**

The Committee commented the second draft of the Standard Operating Procedure (PI 031-1 (Draft 2)) on Team Inspections by PIC/S PAs in non-PIC/S countries and asked the coordinator to include additional comments in a new draft. Once finalised, the SOP will be a very useful tool for performing joint inspections. Members also noted the revised list of inspections in non-PIC/S countries (PS/W 13/2007 (Rev. 2)) performed by PAs in 2008 and already scheduled for the period 2009-2011.

### **Guidance Documents**

The Committee adopted the revisions of Chapter I (Part I) and Annex 1 as well as a new Annex 20 (ICH Q9) to the PIC/S GMP Guide. It also noted the draft revision of Annex 3 and decided to adopt it by written procedure.

The Committee also:

- noted that the Aide-Memoire on Packaging (PI 028-1) was adopted by written procedure on 31 October 2008;
- adopted the Aide-Memoire on the Inspection of APIs (PI 030-1);
- reviewed the second draft of the revised Explanatory Notes for Industry on the Preparation of a Site Master File (PE 008-4 (Draft 2)) and agreed to adopt the revised document by written procedure.

### **Relations with other Organisations**

#### ASEAN

The ASEAN Liaison Authority (Malaysia / NPCB) informed the Committee that the Sectoral MRA in the field of GMP will likely be signed by the ten ASEAN countries by the end of the year. The Committee also noted that the duty of ASEAN Liaison Authority will be taken over by Singapore / HSA for the period 2009-2011.

#### Europe

The Committee noted an update on the recent inspection activities of the European Directorate for the Quality of Medicines & Healthcare (EDQM). Members also agreed that the CEP

suspension letters issued by EDQM would be circulated to all Committee Members in the scope of the implementation of the co-operation agreement between PIC/S and EDQM.

The representative of EMEA summarised the activities of the EMEA GMDP Inspectors' Working Group since the last Committee meeting. She also informed the Committee on EMEA's audit schedule for 2009 in the scope of the EU Joint Audit Programme (JAP).

### UNICEF

The representative of UNICEF's Supply Division made a short update on his organisation's inspection activities in 2008. The Committee also discussed the draft co-operation agreement between PIC/S and UNICEF and authorised the Chairman to sign the finalised agreement on behalf of PIC/S.

### WHO

The representative of WHO's Department for Quality Assurance and Safety of Medicines (QSM) summarised the department's recent inspection and training activities. Members also noted that the two years transitional period for WHO to negotiate a partnership agreement with PIC/S will end in 2009. The Chairman invited QSM to make a proposal on possible co-operation between the two organisations as soon as possible.

### Industry associations

The Committee discussed the second joint workshop with PDA and ISPE on the "Manufacture of Sterile Medicinal Products (EU-PIC/S GMP revised Annex 1)" which would take place in Geneva (Switzerland) on 13-14 November 2008 (see also Annex).

It also discussed the proposal by the European Compliance Academy to possibly develop co-operation with PIC/S. Due to resource constraints, the Committee decided to limit its joint activities with industry and professional associations to PDA and ISPE without developing new co-operations for the years to come.

### **In brief**

The Committee ...

- elected Ms. Joey Gouws (South Africa / MCC) as Executive Bureau Member for the period 2009-2010;
- noted an oral report by the Chairman on the last meeting of the Executive Bureau (Monday, 10 November);
- approved the 2009 budget;
- agreed on the creation of a training fund;
- adopted the revised Guideline for Expert Circles (PI 022-2);
- adopted the revised Procedure for Observing Inspections (PS/W 10/2002 (Rev. 2));
- decided to ask the Expert Circle on Computerised Systems to clarify its new mandate;
- noted the updated version of the PIC/S information brochure;
- confirmed that the next meetings would take place in Geneva (Switzerland) on 5-6 May 2009 and in Uppsala (Sweden) on 2-3 November 2009.

### **PIC/S – PDA/ISPE JOINT WORKSHOP (13-14 November)**

In conjunction with the Committee meeting, PIC/S in partnership with the Parenteral Drug Association (PDA) and the International Society for Pharmaceutical Engineering (ISPE) organised an interactive joint workshop on the “Manufacture of Sterile Medicinal Products (EU-PIC/S GMP revised Annex 1)” in Geneva on 13-14 November. It was the second time that PIC/S co-organised such a joint event with professional and industry associations.

The meeting was open to both regulators and industry. It was attended by more than 80 participants (among which, 50% came from Regulatory Authorities) representing around 30 countries.

The workshop started with a plenary session including presentations on the interpretation of the revised Annex 1 and on inspection experiences from both regulators’ and industry’s perspectives. GMP inspectors and industry representatives also participated in practical workshops (case studies) on the capping of vials, media fills (process simulations), the continuous monitoring, the clean area classification and ISO norms as well as on the sterilisation and depyrogenation of contact parts and containers.

The workshop was unanimously considered as a success by both inspectors and industry representatives. More joint workshops will likely be organised with these professional and industry associations in the future.

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