PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

10 June 2008

PRESS RELEASE

PIC/S COMMITTEE MEETING
KRAKOW, POLAND

A joint Committee meeting of the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) took place in Krakow (Poland) on **26-27 May 2008** under the chairmanship of Mr. Jacques Morénas (France / French Agency for the Safety of Health Products). All PIC/S Participating Authorities were represented. Representatives from EDQM, EMEA, UNICEF and WHO as well as from Cyprus' Pharmaceutical Services, France's Veterinary Agency 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 33 Participating Authorities in the PIC/S (Convention (#) and Scheme taken together). The PIC/S Participating Authorities are coming from Argentina, Australia#, Austria#, Belgium#, Canada, 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#.

Indonesia applies for membership

The Committee noted that Indonesia's National Agency for Food and Drug Control (NADFC), applied for PIC/S membership on 29 April 2008.

Assessment and Reassessment of other Authorities

The membership applications of Cyprus' Pharmaceutical Services (CPS) and France's Veterinary Agency (AFSSA-ANMV) were reviewed in the presence of their representatives. The latter made a short presentation on their respective GMP systems. The Committee

reviewed the evaluation reports prepared by the Rapporteurs and agreed on the accession to PIC/S of CPS as from 1 July 2008 and of AFFSA-ANMV as from 1 January 2009 (provided that outstanding issues are addressed before the next Committee meeting).

The Committee reviewed the assessment report on Thailand's FDA's application and noted that the latter had been invited to submit an action plan for corrective actions by mid-August 2008.

It also discussed the application by the US Food and Drug Administration (US FDA) and agreed on an on-site assessment visit before the next Committee meeting. Members noted that an on-site assessment visit would also take place in Israel in August 2008 as well as a follow-up visit in Lithuania before the next Committee meeting. They were also informed that, at the occasion of the 2008 annual seminar in Krakow (see annex), the PIC/S Chairman would meet with a delegation from the Ukraine to discuss the reactivation of the Ukrainian Ministry of Health's application to PIC/S.

The Committee reviewed the report on the successful reassessment of United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) and agreed to close the reassessment. It also noted that the reassessment of Austria's Medicines and Medical Devices Agency (AGES PharmMed) and of Liechtenstein's "Amt für Gesundheit" (AG) were on-going.

In addition, the Committee agreed in principle to reassess the Participating Authority from Latvia following the merger in 2006 of the State Pharmaceutical Inspection (SPI) with the State Agency of Medicine (ZVA).

Training for inspectors: meeting of the Working Group

The PIC/S Working Group on the Training of Inspectors met in Krakow on 26 May 2008 in the morning. The meeting mainly focused on reviewing the mandates and objectives for 2008 of PIC/S Expert Circles. The Working Group also reviewed the draft revision of the Guideline for Expert Circles (PI 022-2 (Draft)) regarding the role and the composition of Expert Circles' Steering Committees. Members also discussed the use of password-protected webpages dedicated to each Expert Circle on the PIC/S website.

Members noted the creation of a Drafting Group responsible for developing an Annex 3 on radiopharmaceuticals to the revised PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments.

The Working Group also noted:

- the Evaluation Report on the 2007 Seminar (PS/INF 13/2008) on the "Inspection of Manufacturers of Solid Dosage Forms", held in Singapore on 20-22 November 2007;
- the final programme (PS/INF 10/2007) of the 2008 PIC/S Seminar on "Good Distribution Practices" (Krakow, 28-30 May 2008);
- the provisional programme of the 2009 Seminar on "Aseptic and Sterile Manufacturing from APIs to Finished Dosage Forms" which would take place in Uppsala (Sweden) on 5-7 November 2009.

Exchange of Information

The Committee reviewed the draft PIC/S Standard Operating Procedures on Team Inspections (PI 031-1 (Draft)) describing the way to initiate, plan, conduct, report upon and follow-up inspections to be performed jointly by PIC/S Participating Authorities in non-PIC/S countries. Members also noted a list of third-country inspections (PS/W 13/2007 (Rev.)) to be performed by PIC/S Participating Authorities in 2008 and beyond. The list will be updated regularly with a view to avoid duplication of inspections.

Guidance Documents

The Committee agreed to adopt the revision of Chapter I (Part I) and Annex 1 as well as a new Annex 20 to the PIC/S GMP Guide by written procedure.

It adopted the mandate of the Working Group on Good Distribution Practices (GDP). The mandate will consist in the drafting of several Recommendations and an Aide-Memoire related to different aspects of GDP inspection. These documents will, then, serve as a basis for a PIC/S GDP Guide.

The committee also:

- noted that the revised PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE 010-2) had entered into force on 1 April 2008;
- noted that the deadline to comment the draft Aide Memoires on Packaging (PI 028-1 (Draft 3)) and on the Inspection of APIs (PI 030-1 (Draft 1)) was 30 June 2008;

Relations with other Organisations

ASEAN

The Committee discussed the outcome of the first PIC/S-ASEAN forum (Singapore, 22 November 2007). It noted that the ASEAN Task Force on GMP decided to take the PIC/S GMP system and the PIC/S Quality System requirements for Pharmaceutical Inspectorates as a benchmark for ASEAN integration in the field of GMP. The Committee was also informed that a Sectoral MRA in the field of GMP could be signed by the ten ASEAN countries by the end of 2008. The MRA will however, exclude active pharmaceutical ingredients, biopharmaceuticals, radiopharmaceuticals, herbal medicines and investigational medicinal products.

The Committee also:

- decided to open the Joint Visit Programme to inspectors from ASEAN countries;
- noted that Malaysia / NPCB had shared with PIC/S its new draft GMP Guide on herbal medicines which is more detailed and stringent than Annex 7 on herbal medicines of the PIC/S GMP Guide);
- noted that PIC/S has sent its SOP on rapid alert system to ASEAN;
- considered the possibility to have a new PIC/S-ASEAN forum in conjunction with the 2010 Seminar in Malaysia.

Commonwealth of Independent States (CIS)

The Chairman informed the Committee that the CIS Interstate Commission on Standardization, Registration and Quality Control of Pharmaceuticals had contacted PIC/S in order to develop co-operation between the two organisations. The Committee requested further information on CIS activities in the field of GMP inspections.

Europe

The representative of the European Directorate for the Quality of Medicines & HealthCare (EDQM) made a presentation on inspection activities related to API certification scheme. Members then discussed how to implement the co-operation agreement signed in 2007 between PIC/S and EDQM. As a first step, PIC/S decided to invite EDQM to the next meeting of the PIC/S Expert Circle on APIs (Basel, 3-5 December 2008) as well as to submit the draft PIC/S Aide-Memoire on APIs to EDQM for comments.

The Committee noted that a co-operation agreement between PIC/S and EMEA was signed in December 2007 by the PIC/S Chairman and the Executive Director of EMEA. The representative of EMEA summarised the activities of the EMEA GMDP Inspectors' Working Group since the last Committee meeting and made a presentation on the EudraGMP database.

The Committee also noted that:

- a reply by DG SANCO* to the Chairman's letter on possible co-operation with PIC/S was still awaited;
- the Chairman had offered PIC/S' support for training purposes to the recently created joint EMEA/HMA** Training Project Team.

UNICEF

The representative of UNICEF made a short update on its organisation's inspection activities in 2007. The Committee also discussed the field of the future co-operation with UNICEF and suggested the latter to consider the possibility to either (i) apply for full PIC/S membership or (ii) to negotiate an associated partnership with 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 discussed future co-operation with WHO.

Industry associations

The Committee discussed the outcome of the first joint PIC/S-Industry Workshop (Singapore, 23 November 2007) on "Systems Approach to Quality Risk Management" and agreed that the experience had been very positive. It also noted that the next joint workshop would take place in Geneva (Switzerland) on 13-14 November 2008 on the "Manufacture of Sterile Medicinal Products (EU-PIC/S GMP Annex 1)".

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* DG SANCO: European Commission's Health and Consumer Protection Directorate-General

** HMA: Heads of EU Medicines Agencies

In brief

The Committee …

- extended by secret ballot the mandate of the Chairman by the end of 2009;
- elected Mr. Tor Gråberg (Sweden / MPA) as First Deputy Chairman for the period 2008-2009;
- elected Ms. Helena Baião (Portugal / INFARMED) as Second Deputy Chairperson for the period 2008-2009;
- approved the 2007 accounts and discharged the Chairman for the financial year 2007;
- adopted the 2007 PIC/S Annual Report;
- adopted the revised version of the Procedure for Observing Inspections (PS/W 10/2002 (Rev.2));
- confirmed that the next meetings would take place in Geneva (Switzerland) on 12-13 November 2008 and on 5-6 May 2009.

It also noted …

- an oral report by the Chairman on the last meeting of the Executive Bureau (Sunday 25 May);
- that the homepage and the structure of the PIC/S website had been changed on 28 April 2008.

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Annex

2008 PIC/S SEMINAR – KRAKOW

The joint meeting of the PIC/S Committee was followed by a Seminar on "Good Distribution Practices as one of the Key Elements for Quality of Medicinal Products" which was held in Krakow (Poland) on 28-30 May 2008.

The PIC/S Seminar was organised by Poland's Main Pharmaceutical Inspectorate (MPI). Around 120 participants from 40 countries attended the seminar including inspectors from a number of non-Member agencies and organisations coming from CIS[1], Cyprus, EDQM, EMEA, France (Veterinary Agency), Indonesia, Israel, Lithuania, Serbia, South Korea, Taipei, Ukraine, UNICEF, USA and WHO. It was also the first time that a PIC/S Seminar was attended by a representative from Egypt.

Among the 120 seminar participants were also a number of speakers, session chairpersons and workshop leaders. Speakers were provided by PIC/S Participating Authorities, EMEA, US FDA and industry.

The Seminar focused on:

- the legal aspects of GDP inspections (existing and future guidelines);
- the application of risk analysis in GDP inspection planning;
- the definition of most frequent deficiencies in wholesaling and the development of suitable strategies for inspectors;
- the risk of counterfeit products in legal distribution channels;
- the definition of problems in the scope of distribution of APIs.

A whole day was also dedicated to workshops on:

- the most frequent deficiencies during GDP inspections;
- quality risk management in the field of wholesale distributors' inspection;
- inspection of GDP for APIs;
- discovering counterfeit during GDP inspections.

The Seminar proceedings will be made available on CD-ROM for purchase at the PIC/S Secretariat (info@picscheme.org).

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[1] Commonwealth of Independent States' Interstate Commission on Standardisation, Registration and Quality Control of Medicines and Medical Devices