PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

6 December 2006
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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 **21 and 22 November 2006** under the chairmanship of Mr. Jacques Morénas (France / AFSSAPS). All PIC/S Participating Authorities were represented. The EMEA* and WHO* as well as the competent authorities of Estonia*, Lithuania, 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#.

Assessment and Reassessment of Authorities:

Malta applies, Estonia to join as of 2007

The Committee noted that Malta's Medicines Authority has officially applied for PIC/S Membership in October 2006. A Rapporteur was nominated in order to assess the application.

It discussed the situation of Estonia's State Agency of Medicines (SAM) and decided to invite SAM to become a full Member of PIC/S as from 1 January 2007. SAM will be PIC/S' 30th Participating Authority.

The representatives of Lithuania's State Medicines Control Agency (SMCA) and of the USA's Food and Drug Administration (US FDA) made a presentation of their GMP

* Observer to PIC/S Committee

inspection system. The Committee took note that the Rapporteur for the US FDA had prepared a list of questions to be addressed by the US FDA.

The membership applications of Argentina's National Institute of Medicaments (INAME) and South Africa's Medicines Control Council (MCC) were also reviewed, the latter in presence of South African representatives. The assessment visit in South Africa took place in September 2006 and the report is on its way. The assessment visit in Argentina is scheduled from 27 November to 1 December 2006.

The Committee was informed on the progress in the application made by Israel's Ministry of Health and on the visit by the PIC/S Chairman to Thailand's Food and Drug Administration scheduled on 2 December 2006.

The Committee decided that the reassessment of Greece's National Organization for Medicines (EOF) could be closed. It noted that the report on the reassessment of United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) was still pending and that the reassessments of Iceland's Medicines Control Agency (IMCA), Switzerland's Agency for Therapeutic Products (Swissmedic) and Liechtenstein's "Kontrollstelle für Arzneimittel" (KA) had been launched.

New Competent Authorities in Austria and Latvia

The Committee noted that in Austria AGES PharmMed would succeed to the Federal Ministry for Health and Women (BMGF) as the new PIC/S Competent Authority as from 1 January 2007. The Committee appointed a team, composed by German, Italian and Swiss inspectors, for the reassessment of Austria. In Latvia, the State Agency of Medicines (ZVA) succeeded to the State Pharmaceutical Inspection (SPI) as Competent Authority in January 2006.

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

The Committee adopted new Guidelines on Partnership replacing the Guidelines on PIC/S Observer Status. The Guidelines introduce the status of "Associated Partner" (replacing the current status of "Observer") and the concept of "Non-Binding Partnership", which aims at defining areas of co-operation between PIC/S and the Associated Partner.

The PIC/S Chairman updated the Committee on his visits to the EMEA, DG SANCO**, DG Enterprise** and EDQM**. It was the first time that a PIC/S Chairman initiated such visits to these European Institutions. Generally, the outcome of these visits was positive, especially in terms of coordination of training activities with the EMEA and EDQM. The Committee decided to initiate an informal exchange of letters with all these organisations on the development of future co-operation.

The Committee discussed the project developed by DG SANCO on "European Standards and Training for the Inspection of Tissue Establishments" (EUSTITE) as well as a new training and standards programme on human blood. It noted that both projects were led by tissue and blood banks, respectively, and agreed to involve PIC/S in these programmes as an associated partner.

** 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

It also decided to exchange letters with WHO's Immunization, Vaccines & Biologicals (IVB) Department in order to co-operate in the fields of training, assessment of Drug Regulatory Authorities, etc.

Training for inspectors

The Committee noted that the PIC/S Working Group on the Training of Inspectors had met in Geneva on 21 November in the morning. The Working Group…

- reviewed the activities of the PIC/S Joint Visit Programme (JVP): 25 groups are active and 7 have completed their cycle;
- discussed on PIC/S guidelines on coached inspections;
- reviewed the evaluation of the 2006 Seminar in Düsseldorf on Quality Risk Management and related ICH Topics;
- 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) and the 2009 Seminar on Herbal Medicines (venue to be decided);
- reviewed the objectives of all PIC/S Expert Circles for 2007.

The Committee approved the setting-up of a new Expert Circle on Quality Risk Management in order to train Inspectorates in this particular field starting with ICH Q9. The Expert Circle will be open to experts form the EU, Japan and the USA.

Guidance Documents

The Committee noted that the second draft of the PIC/S Guide to Good Practices for Preparation of Medicinal Products in Pharmacies had been released for consultation to national and international hospital and pharmacy associations.

In brief

The Committee…

- adopted the 2007 Budget and selected an external financial auditor to audit the 2006 accounts;
- re-elected Ms. Eija Pelkonen (Finland / National Agency for Medicines) as Member of the Executive Bureau for the period 2007-2008;
- agreed on the principle to have a joint PIC/S – ISPE Workshop in Singapore on Quality Risk Management, in conjunction with the 2007 PIC/S Seminar (20-22 November 2007);
- revised the first version of an Information Brochure on PIC/S;
- decided that the next meeting would take place in Geneva (Switzerland) on 15-16 May 2007.

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Annex

FIRST PIC/S – INDUSTRY FORUM

On 23 November 2006 PIC/S met for the first time with representatives of international industry and professional associations, i.e. EFPIA, FIP, IFPMA, ISPE and PDA[***]. PIC/S was led by a Delegation involving the Chairman (Mr. Jacques Morénas, France / AFSSAPS), the representatives of the Netherlands / IGZ, Sweden / MPA and the United Kingdom / MHRA. The following PIC/S Participating Authorities also attended the meeting: Australia / TGA, Austria / BMGF, Canada / HPFBI, Latvia / ZVA, Singapore / HSA, Slovak Republic / SIDC and Switzerland / Swissmedic.

The meeting aimed at exchanging information and identifying possible areas of co-operation in terms of GMP (e.g. training).

The main operational conclusions from the meeting are:

1. On GMP Training:

1.1 PIC/S and Industry to exchange information on training programmes in advance (6 months at least).

1.2 Industry associations to encourage manufacturers to provide training material to PIC/S in the form of short videos or photos on a particular stage (e.g. granulation) of the manufacturing process of solid dosage forms, which is the topic of the 2007 PIC/S Seminar in Singapore.

1.3 Industry associations to encourage manufacturers to provide concrete cases / good examples on the implementation by industry of Quality Risk Management (QRM).

1.4 PIC/S and industry associations to explore the possibility to develop training based on one scenario (e.g. on QRM) to be looked at by inspectors and industry in separate sessions with common feed-back/discussion at the end.

1.5 Industry to facilitate visits ("walk around") of manufacturing sites by PIC/S Inspectorates e.g. to present positive and negative aspects of a new technology, to familiarise (junior) GMP inspectors with a particular manufacturing process, etc.

1.6 Industry associations to make it possible for PIC/S inspectors to "anonymously" take part in professional training without being "pinned down" with questions.

1.7 PIC/S to discuss to organise back-to-back meetings with industry & professional associations.

*** EFPIA: European Federation of Pharmaceutical Industry Associations
FIP: International Pharmaceutical Federation
IFPMA: International Federation of Pharmaceutical Manufacturers & Associations
ISPE: International Society of Pharmaceutical Engineers
PDA: Parenteral Drug Association

2. On GMP Inspections:

2.1 Industry associations to encourage companies to be more pro-active:

2.1.1 by informing PIC/S Inspectorates on the last / forthcoming inspection by another Inspectorate;

2.1.2 by spontaneously submitting the last inspection report;

2.1.3 by fixing across the board (in the entire manufacturing site / in other sites) deficiencies noted by an Inspector in one particular spot;

2.1.4 by ensuring the commitment of the company's top management to GMP;

2.1.5 by encouraging non-PIC/S Authorities to join PIC/S.

2.2 PIC/S to consider better ways to share / use information on inspections.

2.3 PIC/S to discuss the possibility of "team inspections" by several PIC/S Participating Authorities.

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