



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

23 June 2004

PRESS RELEASE

**PIC/S COMMITTEE MEETING
EL VENDRELL, SPAIN**

A joint Committee meeting of the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) took place in El Vendrell (Catalonia, Spain) on **14 and 15 June 2004** under the chairmanship of Mr. Hans Smallegenbroek (Netherlands / Inspectorate of Health Care). All PIC/S Participating Authorities were represented. The Czech Veterinary Institute, the EMEA*, Estonia*, Poland, South Africa, Chinese Taipei and WHO* also participated in the meeting.

First meeting as an independent organisation

The meeting in El Vendrell was the first since PIC/S became an independent organisation on 1 January 2004 with an autonomous Secretariat based in Geneva, Switzerland. PIC/S' legal status is that of an Association under the Swiss law. Its official registration at the Geneva "Registre du Commerce" is almost completed. To ensure the good functioning of the organisation, the Committee adopted its own financial regulations. It also appointed a financial auditor to review the 2003 financial accounts. The question of whether to turn PIC/S into a truly international organisation was deferred to a Working Group.

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international agreements 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 27 Participating Authorities in the PIC/S (Convention and Scheme taken together). All countries, which are parties to the Convention (#), are members of the Scheme. The PIC/S Participating Authorities are Australia#, Austria#, Belgium#, Canada, Czech Republic, Denmark#, Finland#, France#, Germany#, Greece, Hungary#, Iceland#, Ireland#, Italy#, Latvia, Liechtenstein#, Malaysia, Netherlands, Norway#, Portugal#, Romania#, Singapore, Slovak Republic, Spain, Sweden#, Switzerland#, and the United Kingdom#.

* Observer to PIC/S Committee

Israel, South Africa and Ukraine apply for membership

The Committee appointed Rapporteurs to evaluate the membership applications received by Israel's Ministry of Health, South Africa's Medicines Control Council and Ukraine's Ministry of Health. It also adopted new Guidelines for Accession, which include a timeframe of maximum six years, during which the Applicant must complete the application process. Applications exceeding six years will be rejected.

The Committee took note that the European Commission had agreed that the pre-MRA¹ inspections to the ten new EU Member States, which acceded to the Union on 1 May 2004, could be combined with PIC/S for the evaluation and review of its own membership applications, provided that both the European Commission and the assessed country had given their consent.

Regarding Estonia's State Agency of Medicines, the Committee agreed that the Commission's pre-MRA inspection in September 2004 could be used to determine whether Estonia now complied with all PIC/S requirements.

The Committee decided that on the basis of its own assessment and in close co-operation with Germany, which had been involved in a comprehensive twinning project with Poland, notably in the field of GMP inspections, a PIC/S Delegation would be sent to Poland in September 2004.

Following a pre-MRA inspection by the Commission to the Czech Institute for State Control of Veterinary Biologicals and Medicaments (ISCVBM), the Committee invited the Rapporteur to draw conclusions from the Commission's report and determine whether the PIC/S membership application by the ISCVBM could be accepted.

The Committee invited the Bureau of Food and Drug Analysis (BFDA) of Chinese Taipei to re-apply once all PIC/S recommendations, made during the visit to Taipei in May 2002, had been implemented. The BFDA applied for PIC/S membership back in May 1998.

The Committee agreed to wait for the Commission's pre-MRA inspection before considering further steps with the membership application made by Lithuania's Department of Pharmacy.

The Committee appointed a Co-Rapporteur to assist the Rapporteur in evaluating the application made by UNICEF to become an Observer to PIC/S.

The Committee decided to return the incomplete membership application to the Bulgarian Drug Agency (BDA). The incomplete application was received in May 2001.

¹ Mutual Recognition Agreement (MRA)

Joint Reassessment Programme (JRP)

The Committee was informed on the recently completed reassessment of the Norwegian Medicines Agency (NOMA) and updated on measures taken by Greece's National Organization for Medicines (EOF) following its recent reassessment.

The Committee was also given an update on the current reassessment of Italy's Dipartimento per la Valutazione dei Medicinali e la Farmacovigilanza (DVMF); preparations for the reassessment of the Slovak State Institute for Drug Control (in conjunction with the Commission's pre-MRA inspection); the planned reassessment of Germany (subject to the mutual acceptance of result between the EU's Joint Audits Programme and the PIC/S Joint Reassessment Programme); and the follow-up visit to Romania's National Medicines Agency (NMA) in spring 2005 (following NMA's reassessment in 2003).

The Committee agreed that auditors of the EU's Joint Audits Programme and the PIC/S Joint Reassessment Programme should be trained jointly. On the basis of a presentation given by Canada's Health Products and Food Branch Inspectorate (HPFBI) on its new MRA evaluation procedure, the Committee agreed to examine whether the Canadian procedure could be taken over by PIC/S to evaluate Applicants and re-evaluate Participating Authorities.

International Medicinal Inspectorates Database

The Director of the International Medicinal Inspectorates Database (IMID) reported that four PIC/S Authorities had joined the IMID since the last Committee meeting, bringing its total number to 15.

The International Medicinal Inspectorates Database (IMID) aims at establishing - on a voluntary basis - a database containing information on GMP inspections carried out (or to be carried out) by IMID participating Regulatory Authorities. The IMID exclusively targets medicinal products (finished products, active pharmaceutical ingredients (APIs) and investigational medicinal products), which have been manufactured in non-PIC/S countries. The main aim of the IMID is to alleviate the workload of PIC/S Members with regard to third-country inspections. This is to be achieved by sharing information on the GMP compliance status of manufacturing sites. The IMID will result in a reduction in the number of inspections, in particular of duplicative inspections.

There are currently 15 Participating Authorities in the IMID: Australia, Belgium, Canada, Czech Republic, France, Hungary, Iceland, Italy, Latvia, Malaysia, Netherlands, Romania, Singapore, Sweden, and Switzerland. For more information on the IMID, see <http://www.picscheme.org/IMID/imid.htm>

In brief

The Committee...

- adopted a revision of the PIC/S recommendation on Quality System Requirements for Pharmaceutical Inspectorates (PI 002), bringing it in line with the recently adopted EU document on the same subject;
 - bid farewell to Dr. Bernhard Scherz (Switzerland / Swissmedic) and Mr. Robert Tribe (Australia / TGA), who chaired the PIC/S Committee in 1998-1999 and 2000-2001, respectively, as this was their last meeting as Members of the Committee;
 - agreed that the next meeting would take place in Geneva (Switzerland) on 9-10 November 2004.
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2004 PIC/S SEMINAR - EL VENDRELL

The joint meeting of the PIC/S Committee was followed by a Seminar on the Inspection of Active Pharmaceutical Ingredients, which was held in El Vendrell (Catalonia, Spain) from 16 to 18 June 2004.

The PIC/S Seminar was organised by the "Agencia Española de Medicamentos y Productos Sanitarios" (AEM) in co-operation with the "Generalitat de Catalunya, Departament de Salut". It was attended by 94 participants from 40 countries. This number includes inspectors from a number of non-PIC/S countries/entities and agencies such as Brazil, China, Cyprus, European Directorate for the Quality of Medicines (EDQM), European Medicines Agency (EMA*), Estonia*, Israel, Lithuania, New Zealand, Poland, Serbia-Montenegro, South Africa, Chinese Taipei, Ukraine and US FDA.

It was the first time that a PIC/S Seminar was attended by representative from China's State Food and Drug Administration, Israel's Ministry of Health and the European Directorate for the Quality of Medicines (EDQM).

Among the 94 seminar participants were also a number of speakers, session chairpersons and workshop leaders. In addition, five speakers were invited to address the seminar but did not attend the Seminar as such: one speaker came from the European Commission, one from EDQM, one from the World Health Organisation (WHO*) and two from industry.

The Seminar focused on:

- (i) the differences between the GMP Guide on Active Pharmaceutical Ingredients (APIs) and the GMP Guide on Medicinal Products;
- (ii) the difference in the manufacturing process as well as in the way of carrying out inspections of APIs (in comparison with medicinal products); and
- (iii) the drafting of guidance documents, in particular an Aide Memoire on the inspection of APIs and the classification of deficiencies and findings.

The Seminar resulted in the setting up of a PIC/S Expert Circle on the Inspection of APIs, whose first task will be to finalise the guidance documents. The collected papers presented at the Seminar will be made available on a CD-ROM (orders can be addressed to the PIC/S Secretariat).

* Observer to PIC/S Committee