



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

15 May 2009

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 **5-6 May 2009** under the chairmanship of Mr. Jacques Morénas (France / French Agency for the Safety of Health Products). 32 out of 36 PIC/S Participating Authorities (PAs) were represented; apologies were received from Argentina's INAME, the French Veterinary Agency, Iceland's IMCA and Singapore's HSA. Representatives from EDQM, EMEA, UNICEF and WHO as well as from Lithuania's State Medicines Control Agency, Ukraine's State Inspectorate for Quality Control of Medicines 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 36 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 (both Human# and Veterinary), Germany#, Greece, Hungary#, Iceland#, Ireland#, Israel, Italy#, Latvia, Liechtenstein#, Malaysia, Malta, Netherlands, Norway#, Poland, Portugal#, Romania#, Singapore, Slovak Republic, South Africa, Spain, Sweden#, Switzerland#, and the United Kingdom#.

Assessment and Reassessment of Authorities

Lithuania joins PIC/S

Based on the follow-up report by the Rapporteur, the Committee agreed on the accession to PIC/S of Lithuania's State Medicines Control Agency (SMCA) as from 1 July 2009. Lithuania will become PIC/S' 37th Participating Authority.

Assessment and Reassessment of other Authorities

The Committee reviewed the membership applications of Ukraine's State Inspectorate for Quality Control of Medicines (SIQCM) and of USA's Food and Drug Administration (US FDA) in the presence of their representatives. It discussed the details of the on-site assessment visit in the USA, which will take place in the course of 2009. It also discussed the impact of the reorganisation of the Competent Authority in the Ukraine – the second full reorganisation since the application was submitted in 2004.

The Committee noted the preliminary assessment report on the application by Slovenia's Agency for Medicinal Products and Medical Devices (JAZMP). The Chairman updated Members on the implementation process of corrective actions by Thailand's FDA. He also informed the Committee on the progress made in the assessment of Indonesia's National Agency for Food and Drug Control (NADFC).

The Committee noted that the Secretariat had received the application form for PIC/S membership from the Ministry of Health of Iran the week before.

Members were also informed on the interest of the Competent Authorities from Brazil, Japan, New Zealand and Russia regarding PIC/S membership.

The Committee noted that the on-site reassessment visit to Austria's Medicines and Medical Devices Agency (AGES PharmMed) would take place the week after the Committee meeting.

Improvement & Restructuring of PIC/S

The Committee discussed the following two options (minimum & maximum) proposed by the Working Group on the Operation & Structure of PIC/S based on suggestions made by PAs:

- Minimum option: to keep the system basically unchanged with a greater involvement of PAs;
- Maximum option: to reorganise the structure of PIC/S, either by introducing a system of sub-committees which would assist the Committee, or by creating a larger and more powerful Executive Bureau ("Executive Committee").

The Committee requested the Working Group to explore the maximum option and to come up with a consolidated proposal in time for the next meeting.

It also considered the advantages and disadvantages of possibly introducing in the future a two-tier membership in order to involve non-PIC/S Competent Authorities (such as India and China) and to facilitate their possible accession to PIC/S.

Training for inspectors

The Committee adopted the Procedure for Coached Inspection (PS/W 2/2008). This new training programme will enable inexperienced inspectors to team up with experienced inspectors during routine inspections in order to improve their inspection techniques.

The Committee also adopted the new mandate of the Expert Circle on Computerised Systems with a view to develop and to deliver a training course on the inspection of computerised systems for GxP inspections.

The First Deputy Chairman, Mr. Tor Gråberg (Sweden / MPA), made an oral report on the meeting of the PIC/S Working Group on the Training of Inspectors (WGT), which was held on 5 May 2009 in the morning. The WGT reviewed the yearly objectives of all PIC/S Expert Circles and Working Groups. It discussed the programme of the 2009 Seminar which will take place in Uppsala (Sweden) on 4-6 November 2009 on “Aseptic and Sterile Manufacturing from APIs to Finished Dosage Forms”. Members also commented on the draft programme of the 2010 Seminar on the “Inspection of Traditional Medicines”, which will be held in Kuala Lumpur (Malaysia) in November 2010. The WGT reviewed PIC/S’ pluriannual training schedule summarising the organisation’s present and future training activities and agreed that the latter should be posted on the PIC/S website once endorsed by the PIC/S Committee.

The WGT also:

- noted an update on the operation of the Joint Visit Programme since the last meeting: there are currently 25 active groups, representing around 75 inspectors from 23 countries;
- welcomed the offer by South Africa’s Medicines Control Council to host the 2011 PIC/S Seminar;
- discussed the possibility to develop web-based training for inspectors.

Exchange of Information

The Committee adopted the Standard Operating Procedure (SOP) on Team Inspections (PI 031-1) enabling PIC/S PAs to perform joint inspections and thus to save resources. It also decided to extend the scope of the list of inspections carried out by PIC/S PAs – initially only intended for third country inspections – to include APIs inspections performed in other PIC/S countries.

Guidance Documents

The Committee:

- discussed a technical interpretation of the revised Annex 1 to the PIC/S GMP Guide prepared by Switzerland / Swissmedic and requested PAs to send their additional comments / suggestions to Swissmedic;
- confirmed that the revised Annex 3 to the PIC/S GMP Guide (PE 009-8) will enter into force on 1 September 2009;
- extended the deadline for non-EEA PAs to comment the draft revision of Annex 7 to the PIC/S GMP Guide;
- noted a Concept Paper issued by EMEA on the incorporation of ICH Q 10 in the EU GMP Guide;
- reviewed the fourth draft of the revised Explanatory Notes for Industry on the Preparation of a Site Master File (PE 008-4 (Draft 4)) and agreed to have a common

final draft with EMEA prior to consult national and international industry and professional associations;

- discussed the draft revision of the PIC/S SOP for Handling Rapid Alerts (PI 010-4 (Draft)), initiated upon the revision of the EU Rapid Alert Procedure;
- adopted the revision of the PIC/S Recommendation on Aseptic Processes (PI 007-5) in order to align the interpretation of data with the revised Annex 1 of the PIC/S GMP Guide.

Relations with other Organisations

ASEAN

The Committee noted that the ASEAN Sectoral Mutual Recognition Arrangement (MRA) on the GMP inspection of manufacturers of medicinal products was signed by the ASEAN Economic Ministers at the 14th ASEAN Summit and Related Summits on 10 April 2009 in Pattaya (Thailand). The MRA calls for the recognition of GMP certifications and/or inspection reports issued by ASEAN Inspection Services - i.e. ASEAN GMP Inspectorates which are members of PIC/S or which have demonstrated a PIC/S-equivalent system of inspection.

Europe

The Representative of the European Directorate for the Quality of Medicines & Healthcare (EDQM) updated the Committee on its inspection activities since the last meeting. Members also discussed the possibility to develop a co-operation with EDQM's Department of Biological Standardisation, OMCL Network and HealthCare

The representative of EMEA summarised the recent activities of the EMEA GMDP Inspectors' Working Group and updated the Committee on the status of public access to the EudraGMP database as well as on the current and future revisions of the EU GMP Guide.

UNICEF

The Committee noted that a co-operation agreement between PIC/S and UNICEF's Supply Division was signed on 15 January 2009.

WHO

The Committee discussed a proposal by WHO to sign a co-operation arrangement with PIC/S. The co-operation would be implemented between PIC/S and WHO's team of Quality Assurance and Safety and WHO's team of Immunization, Vaccines and Biologicals. It would focus on the training of inspectors and on the sharing of documents. The Committee authorised the PIC/S Chairman to sign the co-operation arrangement.

The representative of WHO's Department for Quality Assurance and Safety of Medicines (QSM) summarised his department's recent inspection and training activities.

Industry associations

The Committee noted the positive feedback from the joint workshop with PDA and ISPE, held in Geneva (Switzerland) in November 2008 on the “Revised Annex 1 to EU-PIC/S GMP Guide: new and possible uses of Quality risk Management”. The Committee also discussed the possible organisation of future joint workshops in connection with PIC/S Expert Circle meetings.

A representative from PDA made a presentation on *Paradigm Change in Manufacturing Operations*. Members also accepted an offer by ISPE to provide inspectors from PIC/S PAs with full access to ISPE’s website, including to ISPE’s “Community of Practices”.

In brief

The Committee ...

- noted that the Executive Bureau had met in Geneva on 10 November 2008 as well as on 26 March and 4 May 2009;
- adopted the 2008 Annual Report;
- approved the audit report on the 2008 accounts and discharged the Chairman of his responsibilities for the financial year 2008;
- agreed on a Secretariat proposal to post a compilation of PIC/S documents on the password-restricted area of the PIC/S website;
- agreed in principle to create a “PIC/S award” to be given each year to the most active Member of the PIC/S community and to the most supportive PA;
- nominated a task force for the organisation of PIC/S’ 40-years jubilee in conjunction with the May 2010 Committee meeting;
- confirmed that the next meetings would take place in Uppsala (Sweden) on 2-3 November 2009 and in Geneva (Switzerland) on 19-20 May 2010.

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