PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

2 June 2010

PRESS RELEASE

PIC/S COMMITTEE MEETING
GENEVA, SWITZERLAND

The PIC/S Committee met in Geneva (Switzerland) on 19-20 May 2010 under the chairmanship of Mr. Tor Gråberg (Swedish Medical Products Agency / MPA) who became Chairman of PIC/S on 1 January 2010. The meeting was attended by 32 out of 37 PIC/S Participating Authorities (PA) as well as by a number of Applicants and Associated Partners. For the list of participants, see Annex.

MAIN NEWS

INTERNATIONAL COLLABORATION FOR THE QUALITY OF APIs

The Committee has discussed a Concept Paper by the European Commission for enhanced co-operation in the field of APIs, in which PIC/S is identified as one of the main stakeholders. Members of the Committee believe that the proposal is a recognition of PIC/S and also a great opportunity to play an important role in the field of APIs, regarding:

i) the assessment of Competent Authorities;
ii) training (through the Expert Circle on APIs) and;
iii) sharing of information related to APIs inspections.

In relation with the Commission's proposal, the Committee has also considered a project developed by the PIC/S Expert Circle on APIs in co-operation with other partners (e.g. EDQM, EMA, ICH, US FDA, WHO, etc.) for organising an international training for inspectors on APIs. The training will focus on i) an introduction to ICH Q7 (basic course) and ii) on how to inspect APIs (advanced course).

PIC/S' 40th ANNIVERSARY

PIC/S' 40th anniversary will be celebrated in Geneva on 31 May 2011 and will include a discussion forum divided into two sessions dedicated to past achievements (i.e. the lessons gained from the first 40 years of existence) and future challenges.

FOLLOW-UP VISIT TO US FDA

Following discussions with an FDA delegation, composed of representatives of CDER and ORA[1], the Committee has agreed to make a follow-up visit to the USA in August 2010 in order to review the outstanding issues. The assessment team will come up with a recommendation regarding FDA's accession to PIC/S in time for the next Committee meeting.

MEMORANDUM OF UNDERSTANDING WITH RUSSIA

Members have endorsed a Memorandum of Understanding (MoU) between PIC/S and the Russian Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor) with a view to encourage the latter's application for PIC/S membership. The MoU was signed by the PIC/S Chairman and the Head of Roszdravnadzor during a visit in Moscow in February 2010.

NEW ZEALAND' MEDSAFE APPLIES

On 16 April 2010, New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) officially submitted an application for PIC/S membership. The Committee has nominated a Rapporteur and two Co-Rapporteurs for the assessment of Medsafe's application.

MEETING WITH DEPARTMENT OF HEALTH OF HONG KONG SAR

On 18 May 2010, in the margin of the Committee meeting, the PIC/S Chairman together with several Executive Bureau Members met with a Delegation from Hong Kong SAR led by Dr. P. Y. Lam, Director of Hong Kong's Department of Health. The meeting focused on the Department of Health's intention to submit an application for PIC/S membership.

OTHER NEWS

Assessment of Applicants and contacts with interested Competent Authorities

The Committee has discussed the assessment report on the Ukrainian State Inspectorate for Quality Control of Medicines (SIQCM), following the on-site assessment visit in Kiev from 22 to 26 March 2010. Members have agreed that a follow-up visit to the Ukraine would be useful in order to verify the implementation of corrective actions.

Members have nominated a visiting team to conduct an on-site assessment visit to the Indonesian National Agency for Drug and Food Control (NADFC) during the first week of November 2010. The Committee noted that no progress has been achieved in the assessment of the Iranian Ministry of Health, due to the lack of response from the latter. It has also reviewed the status of the membership applications of the Philippines' Bureau of Food and Drugs (BFAD) and the Slovenian Agency for Medicinal Products and Medical Devices (JAZMP).

[1] CDER: Center for Drug Evaluation & Research; ORA: Office of Regional Operations

The Committee agreed to initiate the revision of the joint PIC/S – EEA JAP Audit Checklist in order to revise several indicators and introduce APIs in the audit checklist[2]. Members also agreed in principle that the PIC/S membership application form and questionnaire should be revised, accordingly.

Extension of PIC/S mandate to GDP

The Committee has discussed the possibility for PIC/S to officially extend its mandate to Good Distribution Practices (GDP). In order to avoid duplication, Members also considered the possibility to take over the revised EU or WHO GDP Guidelines rather than developing PIC/S GDP guidelines. The Committee has decided to invite the Working Group on GDP to draft a Note in time for the next meeting of the Committee on how to extend PIC/S' mandate to GDP.

Exchange of information

On the basis of a Note by the Secretariat, the Committee has discussed several possibilities for strengthening confidentiality between PAs and with Partners in order to facilitate the exchange of information.

Members have agreed on a questionnaire to be submitted to PAs in order to establish a complete overview of their respective competences regarding the inspection of medicinal products and other practices (e.g. GDP).

Training of inspectors

The PIC/S Sub-Committee on Training (SCT) met on 18 May 2010 under the chairpersonship of the First Deputy Chairperson, Ms. Helena Baião (Portuguese National Institute of Pharmacy and Drugs / INFARMED). The SCT:

- welcomed a proposal made by the Irish Medicine Board (IMB) to organise and host a basic training seminar for new inspectors;
- reviewed the yearly objectives and activities of all PIC/S Expert Circles;
- commented on the programmes of the 2010 Seminar [3] and 2011 Seminar [4];
- considered the possible use of web-based training.

Harmonisation of guidance documents

The Committee has discussed the draft revision of Annex 7 (Herbal Medicinal Products) to the PIC/S GMP Guide in particular the requirement of GACP[5] compliance of herbal medicinal products' suppliers. It has agreed to consult non-EEA PIC/S PAs by written

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2 The revision will be performed jointly by the PIC/S Compliance Group and the EEA Joint Audit Programme's (JAP) Compliance Group.

3 Kuala Lumpur (Malaysia) on 10-12 November 2010 on the "Inspection of Traditional Medicines"

4 Cape Town (South Africa) on 9-11 November 2011 on "Good Inspection Practices"

5 Good Agricultural and Collection Practices

procedure and to invite inspectors to consider the issue at the 2010 Seminar on the "Inspection of Traditional Medicines".

Co-operation with Associated Partners and other Organisations

The Committee has discussed with PIC/S Associated Partners [6] on possible ways to improve co-operation with PIC/S. In particular, the Committee has:

- discussed the need to revise and to renew the co-operation agreement between PIC/S and EMA, which expired on 29 January 2010;
- considered the proposals made by the representatives of WHO regarding the possible ways to improve co-operation in terms of training and sharing of information (e.g. inspection schedules and results);
- noted that the co-operation agreements signed by PIC/S with EDQM and UNICEF, respectively, were working well.

Members have been informed that a second PIC/S – ASEAN forum will be organised in Kuala Lumpur (Malaysia) on 12 November 2010, in conjunction with the annual PIC/S Seminar.

Members have noted that the ICH Quality Implementation Working Group will deliver an integrated implementation training workshop on 2-4 June 2010 in Tallinn (Estonia).

IN BRIEF…

The Committee has…

- noted that the Executive Bureau met in Geneva on 17 May 2010;
- agreed to officially terminate the International Medicinal Inspectorate Database (IMID) project, which was frozen since 2005;
- adopted the 2009 Annual Report with an amendment;
- approved the audit report on the 2009 accounts and discharged the past Chairman of his responsibilities for the financial year 2009;
- been given a presentation on the Pharmaceutical Inspection Convention (PIC) by Dr. Andreas Ziegler (University of Lausanne);
- noted that the Working Group on the Structure and Operation of PIC/S (WGSO) and the Sub-Committee on Strategic Development (SCSD), met on 22 February 2010 in Geneva;
- confirmed that the next meeting will take place in Kuala Lumpur (Malaysia) on 8-9 November 2010.

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[6] EDQM, EMA, UNICEF and WHO

Annex

List of Authorities having participated in the PIC/S Committee Meeting

MEMBERS	**ACRONYM**
Argentinian National Institute of Drugs *Instituto Nacional de Medicamentos*	INAME
Australian Therapeutic Goods Administration	TGA
Austrian Agency for Health and Food Safety *Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH*	AGES PharmMed
Belgian Federal Agency for Medicines and Health Products *Agence Fédérale des Médicaments et des Produits de Santé*	AFMPS
Canadian Health Products and Food Branch Inspectorate	HPFBI
Cypriot Pharmaceutical Services	CyPHS
Czech State Institute for Drug Control *Státní Ústav pro Kontrolu Léčiv*	SÚKL
Czech Institute for State Control of Veterinary Biologicals and Medicines	ISCVBM
Danish Medicines Agency	DKMA
Estonian State Agency of Medicines	SAM
Finnish Medicines Agency	FIMEA
French Agency for the Safety of Health Products *Agence Française de Sécurité Sanitaire des Produits de Santé*	AFSSAPS
French Agency for Veterinary Medicinal Products *Agence Nationale du Médicament Vétérinaire*	ANMV
German Central Authority of the Länder for Health Protection regarding Medicinal Products and Medical Devices *Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten*	ZLG
Greek National Organisation for Medicines *Εθνικός Οργανισμός Φαρμάκων*	EOF
Irish Medicines Board	IMB
Israeli Institute for the Standardization and Control of Pharmaceuticals	ISCP
Italian Medicines Agency *Agenzia Italiana del Farmaco*	AIFA
Liechtenstein's Office of Healthcare A*mt für* G*esundheit*	AG
Malaysian National Pharmaceutical Control Bureau	NPCB
Maltese Medicines Authority	MAM
Netherlands' Inspectorate of Health Care *Inspectie voor de Gezondheidszorg*	IGZ
Norwegian Medicines Agency	NOMA
Polish Main Pharmaceutical Inspectorate	MPI
Portuguese National Institute of Pharmacy and Drugs *Instituto Nacional da Farmácia e do Medicamento*	INFARMED
Romanian National Medicines Agency	NMA
Singapore's Health Sciences Authority	HSA

List of Authorities having participated in the PIC/S Committee Meeting (cont'd)

South African Medicines Control Council	MCC
Spanish Agency of Drugs and Health Products *Agencia Española del Medicamento y Productos Sanitarios*	AEMPS
Swedish Medical Products Agency	MPA
Swiss Agency for Therapeutic Products	Swissmedic
United Kingdom's Medicines and Healthcare Products Regulatory Agency	MHRA

APPLICANTS	**ACRONYM**
Ukrainian State Inspectorate for Quality Control of Medicines	SIQCM
US Food and Drug Administration	FDA

PARTNERS	**ACRONYM**
European Directorate for the Quality of Medicines & HealthCare	EDQM
European Medicines Agency	EMA
United Nations International Children's Emergency Fund	UNICEF
World Health Organization	WHO

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 37 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#, Lithuania, Malaysia, Malta, Netherlands, Norway#, Poland, Portugal#, Romania#, Singapore, Slovak Republic, South Africa, Spain, Sweden#, Switzerland#, and the United Kingdom#.

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