



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

17 November 2010

PRESS RELEASE

**PIC/S MEETINGS
KUALA LUMPUR, MALAYSIA**

From 7 to 12 November 2010 the National Pharmaceutical Control Bureau (NPCB) of Malaysia hosted the following events in Kuala Lumpur: PIC/S Sub-Committee on Training, PIC/S Executive Bureau, PIC/S Committee, annual PIC/S Seminar and PIC/S – ASEAN forum.

1. PIC/S COMMITTEE MEETING (8-9 November 2010)

The PIC/S Committee met on 8-9 November 2010 under the chairmanship of Mr. Tor Gråberg (Swedish Medical Products Agency / MPA). The meeting was attended by 26 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

US FDA AND UKRAINIAN SIQCM JOIN PIC/S

The Committee invited the US Food and Drug Administration (FDA) and the Ukraine's State Inspectorate for Quality Control of Medicines (SIQCM) to join the Scheme as from 1 January 2011. The FDA will become PIC/S' 38th Participating Authority while SIQCM will become PIC/S' 39th Participating Authority.

The US FDA applied for membership back in September 2005. A first on-site assessment visit took place in August 2009. A follow-up visit to the USA was performed on 9-13 August 2010 in order to review the remaining outstanding issues. Following this visit, the audit team recommended to the Committee to accept the membership application of the US FDA.

The FDA Delegation to the PIC/S Committee, headed by Ms. Brenda Holman (Office of Regulatory Affairs) and Mr. Carmelo Rosa (Center for Drug Evaluation & Research), expressed its satisfaction that the 5-year long process came to a successful conclusion and highlighted that the accession to PIC/S was an important objective for the FDA in terms of

international co-operation. It would open a new chapter in its relations with PIC/S Participating Authorities.

The PIC/S Chairman thanked both US FDA and the PIC/S Audit Team for all their efforts.

The Ukraine's State Inspectorate for Quality Control of Medicines (SIQCM) applied to PIC/S back in April 2004. The first on-site visit in the Ukraine took place in March 2010. Following a complementary visit to the Ukraine on 4-6 October 2010, the Rapporteur recommended to the Committee to accept the PIC/S membership of SIQCM.

The Head of SIQCM, Mr. Oleksii Soloviov, thanked the Audit Team for its work and offered to host one of the future PIC/S training events in the Ukraine.

NEW MEMBERSHIP APPLICATIONS

The past months have been very prolific in terms of applications for PIC/S membership, increasing the total number of Applicants from 8 to 11. The following Competent Authorities have lodged their application file since the last Committee meeting:

- United Kingdom's Veterinary Medicines Directorate (VMD), 7 June 2010;
- Taiwan Food and Drug Administration (TFDA), 14 June 2010;
- Brazilian Agência Nacional de Vigilância Sanitária (ANVISA), 30 July 2010

The Committee nominated the Rapporteurs and Co-Rapporteurs for the assessment of these applications. Members also noted that ANVISA had been invited to provide additional information before the assessment could be launched.

40TH ANNIVERSARY

The Committee reviewed the draft programme of the symposium organised in order to celebrate PIC/S' 40th anniversary in Geneva (Switzerland) on 31 May 2011. PIC/S will run a symposium on "40 Years of Co-operation & Mutual Confidence: Challenges & Future Perspectives". Around 80 participants from PIC/S and non-PIC/S Authorities have already announced their intention to attend, among which many Heads of Agencies. Dr. Margaret Hamburg, Commissioner of the US FDA, has confirmed her participation and will deliver a key note address to the symposium, which will coincide with the FDA's first attendance as a full Member of a PIC/S meeting.

EXPLANATORY NOTES FOR INDUSTRY ON SITE MASTER FILE

Members adopted a revision of the PIC/S Explanatory Notes for Industry on the Preparation of a Site Master File. The reasons of the revision were i) the simplification of the document and ii) the implementation of requirements related to QRM. The SMF was revised at the request of the EMA, which will adopt the document in identical terms (to be possibly included in Part 3 of the EU GMP Guide).

OTHER NEWS

Assessment of Applicants and contacts with interested Competent Authorities

An inspection team conducted an on-site assessment visit to the Indonesian National Agency for Drug and Food Control (NADFC) from 1 to 5 November 2010. According to the Audit Team, NADFC is meeting most PIC/S membership requirements. A follow-up visit is scheduled for next year.

The Committee reviewed the membership applications of the Slovenian Agency for Medicinal Products and Medical Devices (JAZMP), the Philippine Bureau of Food and Drugs (BFAD) and New Zealand's Medicines and Medical Devices Safety Authority (Medsafe). An on-site inspection visit to both Slovenia and New Zealand is scheduled to take place in the course of 2011.

Members noted that the completion date for the corrective action plan by the Thai Food and Drug Administration (Thai FDA) had been postponed from 2012 to 2015, i.e. beyond the 6-year timeframe for acceding to PIC/S, which expires in 2012. They decided to conduct a follow-up visit to Thai FDA in the course of 2011, subject to Thai FDA confirming the timeframe for the completion of its action plan by 2012.

Members also reviewed the application of the Iranian Ministry of Health (MoH): the Rapporteur, in charge of the assessment of the application, was still waiting for documents, requested one year ago, and unable to make progress.

Members were informed on the revision of the PIC/S – EEA JAP Audit Checklist jointly conducted by the PIC/S Compliance Group and the EEA Joint Audit Programme's (JAP) Compliance Group in order to introduce – inter alia – indicators for APIs. Members also noted that the PIC/S Compliance Group had started to revise the PIC/S accession guidelines and the membership application form & questionnaire.

The Committee noted that the current and past Chairmen both promoted PIC/S in Japan in September while the Chairman would visit Hong Kong SAR in December in order to make a gap assessment at the request of Hong Kong's Department of Health.

Extension of PIC/S mandate to GDP

The Committee discussed a joint Note by the PIC/S Working Group on Good Distribution Practices (GDP) and the PIC/S Secretariat on the possible extension of PIC/S' mandate to GDP. The Committee decided awaiting the comparison between the EU and WHO GDP Guidelines, to be performed by the Working Group, before deciding which guideline to use as a basis for the PIC/S GDP Guide. Committee Members also discussed whether the future PIC/S GDP Guide should be introduced on a voluntary or compulsory basis.

Exchange of information

The Committee agreed to revise several PIC/S procedures, in order to strengthen confidentiality within PIC/S and to facilitate the exchange of information between PAs and with Partners.

Training of inspectors

The PIC/S Sub-Committee on Training (SCT) met on 7 November 2010 in the afternoon under the chairpersonship of the First Deputy Chairperson, Ms. Helena Baião (Portugal / INFARMED). The SCT reviewed:

- the first PIC/S training seminar for new inspectors to be organised by the Irish Medicines Board (IMB) in Dublin (Ireland) on 24-28 January 2011;
- the international training course on APIs developed by the PIC/S Expert Circle on APIs;
- recent meetings by other PIC/S Expert Circles such as the Expert Circles on APIs, QRM and Human Blood & Tissues;
- the programme of the 2011 Seminar¹.

The SCT also discussed on how to better involve all PAs in PIC/S' training activities and on possible ways to select the organiser of future training seminars. A number of recently admitted PAs were only marginally involved in training activities while some of the older PAs only attended events in Europe.

Harmonisation of guidance documents

The Committee discussed the following draft revisions of the PIC/S GMP Guide:

- Part II (Basic Requirements for APIs);
- Annex 6 (Medicinal Gases) and
- Annex 13 (Investigational Medicinal Products)

Members agreed to postpone the adoption of these revisions until the next Committee meeting in order to await the outcome of the consultation by non-EEA Members of their respective national industry.

The Committee adopted the revisions of:

- the PIC/S Recommendation on the validation of aseptic processes and
- the PIC/S Procedure for handling rapid alerts and recalls arising from quality defects

It also endorsed in principle the following two PIC/S guidelines on Quality Risk Management (QRM) developed by the PIC/S Expert Circle on QRM:

- Recommendation for Risk-based Inspection Planning in the GMP Environment
- Aide-Memoire on the Assessment of Quality Risk Management Implementation

The first guideline is intended for assisting inspectorates in the planning of their inspections following the QRM principles while the second guideline aims at inspecting the implementation of QRM by industry. Both documents will be tested by GMP inspectors during a 4-month validation phase before being formally adopted by the Committee.

¹ Cape Town (South Africa) on 9-11 November 2011 on "Good Inspection Practices"

Co-operation with Associated Partners and other Organisations

The Committee adopted a revision of the co-operation agreement between PIC/S and EMA. It also noted that the co-operation agreement signed by PIC/S with EDQM was tacitly renewed on 30 July 2010 for a period of three years. Members decided to organise a meeting with WHO in order to discuss the ways to strengthen co-operation between the two organisations.

IN BRIEF...

The Committee ...

- adopted the 2011 budget;
- discussed the future of the Pharmaceutical Inspection Convention (PIC);
- was given a report on the Executive Bureau meeting on 8 November 2010 in Kuala Lumpur as well as a report on the meeting of the Sub-Committee on Strategic Development (SCSD) on 13 July 2010 in Geneva;
- confirmed that the next meeting will take place in Geneva (Switzerland) on 30 May 2011 in conjunction with the celebration of PIC/S' 40th anniversary on 31 May 2011.

2. PIC/S ANNUAL SEMINAR

The PIC/S Committee meeting was followed by a Seminar on the “**Inspection of traditional / herbal medicines**”, which was held in Kuala Lumpur (Malaysia) on 10-12 November 2010.

The PIC/S Seminar was organised by the Malaysian National Pharmaceutical Control Bureau (NPCB) and was opened by Dato' Sri Liow Tiong Lai, Minister of Health, Malaysia, who delivered a speech on the importance of traditional / herbal medicines in Malaysia for both patients and manufacturers. Speeches were also given by Dato' Eisah Abdul Rahman, Senior Director of Pharmaceutical Services at the Ministry of Health of Malaysia and Mr. Tor Gråberg, PIC/S Chairman. Dato' Eisah Abdul Rahman was the Chief Inspector in charge of the membership application of NPCB to PIC/S back in 2000-2001 (the first by a developing country) and greatly contributed to NPCB's rapid accession to PIC/S in 2002 in a record time of less than 2 years. She has also been the driving force behind the organisation of the 2010 Seminar in Malaysia.

The Seminar was attended by 93 participants from 36 countries. This number includes inspectors from the following non-Member agencies / organisations: Brunei / DPS, Chinese SFDA, the European Directorate for the Quality of Medicines (EDQM*), Hong Kong SAR / Department of Health, Indonesian NADFC, Iranian Ministry of Health, Japanese PMDA, Laos FDA, New Zealand's Medsafe, Oman's DGPA, Slovenian JAZMP, South Korean FDA, Taiwan FDA, Thai FDA, Ukrainian SIQCM, the United Nations International Children's Emergency Fund (UNICEF*) and US FDA.

* PIC/S Partners

Among the 93 seminar participants were also a number of speakers, session chairpersons and workshop leaders. Speakers were provided by PIC/S Participating Authorities, the World Health Organization (WHO*), Chinese SFDA, academia and industry associations.

The Seminar's objectives were:

- to learn about traditional / herbal medicinal products from experienced Asian countries;
- to bridge the gap of interpretation of PIC/S Annex 7 (manufacturing of herbal medicinal products) in order to achieve consistence and similar interpretation of GMP for traditional / herbal medicinal products;
- to harmonise the inspection approaches for PIC/S PAs;
- to identify necessary improvements of Annex 7 and to establish an Aide-Memoire on the inspection of traditional / herbal medicinal products with the aim of facilitation of the planning and conduct of inspections

The 2.5 day seminar started with a series of lectures and presentations and was followed by four workshops on the 2nd day of the seminar dealing with:

- Requirements on manufacturing facilities and utilities for the manufacturing of traditional / herbal medicinal products;
- Quality control on traditional / herbal medicinal products;
- Risk management of traditional / herbal medicinal products manufacturing facilities;
- Necessity for modifying PIC/S Annex 7 and proposal for the development of an Aide-Memoire for the inspection of traditional / herbal medicinal products

In addition, seminar participants have also attended two on-site visits at the Forest Research Institute of Malaysia. During the last day of the seminar, a summary of the workshops as well as future trends were presented.

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3. SECOND PIC/S – ASEAN FORUM (12 November 2010)

A PIC/S delegation, conducted by the PIC/S Chairman, met with a delegation from ASEAN² comprising a Representative of the ASEAN Secretariat as well as ASEAN Competent Authorities (CAs) from Brunei, Indonesia, Laos, Malaysia, Singapore and Thailand during a half-day meeting, which took place in Kuala Lumpur on 12 November. The purpose of this second forum was to discuss the way to initiate co-operation between the two organisations (e.g. in terms of training).

The PIC/S delegation recalled that most PIC/S training activities were open to inspectors from ASEAN CAs and proposed to consider periodically running future PIC/S training courses in the Australasian region in order to facilitate the participation of ASEAN inspectors.

² Association of South East Asian Nations (ASEAN)

The Representative of the ASEAN Secretariat informed the PIC/S delegation that the ASEAN sectoral MRA³ on GMP had been signed by all ASEAN countries and would enter into force on 1 January 2011. The ASEAN Secretariat will maintain a list of inspection services fulfilling the MRA's requirements (i.e. either being a PIC/S Participating Authority or operating a PIC/S-equivalent GMP inspection system). The PIC/S delegation offered to provide advice to ASEAN CAs on how to reach PIC/S membership requirements.

The PIC/S delegation invited all ASEAN CAs as well as the ASEAN Secretariat to the 40th anniversary of PIC/S, which would be held in Geneva on 31 May 2011 (see "Main News" of the Committee meeting above).

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

MEMBERS	ACRONYM
Argentinean National Institute of Drugs <i>Instituto Nacional de Medicamentos</i>	INAME
Australian Therapeutic Goods Administration	TGA
Austrian Agency for Health and Food Safety <i>Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH</i>	AGES PharmMed
Canadian Health Products and Food Branch Inspectorate	HPFBI
Cypriot Pharmaceutical Services	CyPHS
Czech State Institute for Drug Control <i>Státní Ústav pro Kontrolu Léčiv</i>	SÚKL
Czech Institute for State Control of Veterinary Biologicals and Medicines	ISCVBM
Danish Medicines Agency	DKMA
Finnish Medicines Agency	FIMEA
French Agency for the Safety of Health Products <i>Agence Française de Sécurité Sanitaire des Produits de Santé</i>	AFSSAPS
French Agency for Food, Environmental & Occupational Health Safety <i>Agence nationale de la sécurité sanitaire de l'alimentation, de l'environnement et du travail</i>	ANSES
German Central Authority of the Länder for Health Protection regarding Medicinal Products and Medical Devices <i>Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten</i>	ZLG
Greek National Organisation for Medicines <i>Εθνικός Οργανισμός Φαρμάκων</i>	EOF
Irish Medicines Board	IMB
Italian Medicines Agency <i>Agenzia Italiana del Farmaco</i>	AIFA
Malaysian National Pharmaceutical Control Bureau	NPCB
Netherlands' Inspectorate of Health Care <i>Inspectie voor de Gezondheidszorg</i>	IGZ
Norwegian Medicines Agency	NOMA
Polish Main Pharmaceutical Inspectorate	MPI
Portuguese National Institute of Pharmacy and Drugs <i>Instituto Nacional da Farmácia e do Medicamento</i>	INFARMED
Singapore's Health Sciences Authority	HSA
South African Medicines Control Council	MCC
Spanish Agency of Drugs and Health Products <i>Agencia Española del Medicamento y Productos Sanitarios</i>	AEMPS
Swedish Medical Products Agency	MPA
Swiss Agency for Therapeutic Products	Swissmedic
United Kingdom's Medicines and Healthcare Products Regulatory Agency	MHRA

APPLICANTS	ACRONYM
New Zealand's Medicines and Medical Devices Safety Authority	Medsafe
Slovenian Agency for Medicinal Products and Medical Devices	JAZMP
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
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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