PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

21 May 2012

PRESS RELEASE

PIC/S MEETINGS
GENEVA, SWITZERLAND

From 7 to 11 May 2012 the following events took place in Geneva, Switzerland: PIC/S Committee Meeting, PIC/S Executive Bureau, PIC/S Sub-Committee on Training and the PIC/S-PDA Europe Workshop, with the latter bringing together regulators and industry.

PIC/S COMMITTEE MEETING (7-8 May 2012)

The PIC/S Committee met on 7-8 May 2012 under the chairpersonship of Ms. Helena Baião (Portugal's National Authority of Medicines and Health Products / INFARMED IP) who became Chair of PIC/S on 1 January 2012. The meeting was attended by 37 out of 40 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

INDONESIA JOINS PIC/S

The Committee invited the Indonesian National Agency of Drug and Food Control (NADFC) to join the Scheme as from 1 July 2012. NADFC will become PIC/S' 41st Participating Authority.

NADFC applied for membership back in April 2008. An assessment was conducted in view of its accession to PIC/S followed by an on-site visit in November 2010. A follow-up visit, in particular with respect to traditional herbal medicines issues, took place in December 2011. Further to this visit, actions and corrective measures were undertaken by NADFC which led the PIC/S Audit team to recommend to the Committee to accept the membership application of NADFC.

JAPAN APPLIES TO PIC/S

On 9 March 2012, Japan's Ministry of Health, Labour and Welfare (MHLW) officially submitted an application in its name as well as on behalf of the Pharmaceuticals and Medical Devices Agency (PMDA) and the Japanese Prefectures for PIC/S membership. The PIC/S Committee has nominated a Rapporteur and five Co-Rapporteurs for the assessment of the application.

SOUTH KOREA APPLIES TO PIC/S

On 10 April 2012, the Korea Food and Drug Administration (KFDA) officially submitted an application for PIC/S membership. The PIC/S Committee has nominated a Rapporteur and two Co-Rapporteurs for the assessment of the application.

NEW ORGANISATIONAL STRUCTURE FOR PIC/S

The PIC/S Committee endorsed in principle the new Sub-Committee Structure of PIC/S which was finalised by the PIC/S Sub-Committee on Strategic Development (SCSD) at its last meeting in March 2012 in London under the SCSD chairmanship of Mr Jacques Morénas (France / ANSM). This new structure, which will be operational as of 1 January 2014, foresees a more participative and efficient organisation of PIC/S, where each Sub-Committee will be responsible for its respective core areas and will take the lead in developing policies. This new structure will include Sub-Committees in the following fields: Training (SCT); Expert Circles (SCEC); Strategic Development (SCSD); (Re-)Assessment (SC on Compliance – SCC); GM(D)P Harmonisation (GMDP SC); Risk, Audit and Budget (RA&B SC) and Communication (COM SC).

NEW PROJECTS FOR PIC/S

Further to the outcome of a consultation carried out among Heads of Agencies of PIC/S Participating Authorities in connection with new projects under development, the Committee established new Working Groups in order to explore how to develop some of these new projects with the following objectives:

- extending PIC/S' mandate to new activities such as Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GPP);
- creating a PIC/S Inspectorate Academy to provide cost-efficient, primarily web-based, high quality harmonised training for Inspectorates.

Other projects as well as possible sources of external support and funding were discussed by the Committee and will be explored further in view of ensuring the development of these future activities.

PIC/S - PDA EUROPE WORKSHOP

In conjunction with the PIC/S Committee, PDA Europe in co-operation with PIC/S hosted a one and half day Workshop on 9-10 May 2012 in Geneva on "GMP Inspection Practices and Trends" (https://europe.pda.org/userfiles/downloads/2012_PICS_Brochure.pdf).

This event, drawing 180 participants from 45 countries, was a first of its kind bringing together regulators and industry to enable them to share experiences on GMP inspection practices, particularly through interactive discussions on concrete case studies.

Workshop topics included: Driver for success of a Pharmaceutical Quality Management System; Documentation on manufacturing and batch release procedure; Personnel issues – training; Sterility assurance including filter integrity test, process simulation of isolators - new technologies; Design and maintenance of facility/equipment (including dedicated facilities); Root cause analysis and corrective actions.

The Workshop provided participants from industry as well as regulators with the unique opportunity to discuss such essential perspectives as continual improvement, management of discrepancies and achievement of harmonisation of practices. Outcomes of this event will be consolidated in order to issue useful material for both regulators and industry.

OTHER NEWS

Re-assessment of Members, Assessment of Applicants and contacts with interested Competent Authorities

On behalf of the EMA Compliance Group, Mr. Jacques Morénas (France / ANSM) updated Members on the revision of the PIC/S – EMA / HMA – MRA Audit Checklist[1] and Audit Report. This Checklist which now covers APIs and in which several indicators (amounting to 78 in lieu of the previous 89) have been revised and updated, will facilitate the way Regulatory Authorities are assessed.

The Rapporteur in charge of the re-assessment of the Latvian State Agency of Medicine (ZVA) updated Members on the re-assessment which took place between 26 March and 6 April 2012.

The Rapporteur in charge of the partial re-assessment of the Lithuanian State Medicines Control Agency (SMCA) updated members on the partial re-assessment which has not yet taken place.

The Committee was given an update by the PIC/S Liaison Officer for membership applications on all current membership applications, pre-accession applications as well as contacts with interested Competent Authorities.

[1] This Checklist is based on the previous Canadian checklist for MRA audits and used for JAP (Joint Audit Programme) working on behalf of the European Heads of Medicines Agency (HMA) network

In particular, the Committee noted the status of Brazil's Agência Nacional de Vigilância Sanitária (ANVISA) and United Kingdom's Veterinary Medicines Directorate (VMD) applications and reviewed the application of the Iranian Ministry of Health (MoH) for which the Rapporteur, in charge of the assessment of the application, had received the requested application documentation in English. She provided the Committee with her second evaluation report of the paper assessment to which the Iranian Ministry of Health, unable to attend the Committee Meeting, would be invited to respond.

An oral update by the Rapporteur in charge of the application of New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) was given to the Committee on the on-site inspection visit which took place in February 2012. Members also noted the upcoming on-site inspection visits scheduled for Chinese Taipei's Taiwan Food and Drug Administration (TFDA) on 4-8 June 2012 and Philippines' Food and Drug Administration (PFDA) on 10-14 September 2012.

The Committee discussed the final report on corrective and preventive actions provided by the Thai Food and Drug Administration (Thai FDA).

In connection with the new pre-accession process, Members acknowledged that on 2 May 2012 Armenia's Scientific Centre of Drugs and Medical Technology Expertise (SCDMTE) had submitted the completed Questionnaire and Audit Checklist further to the pre-accession application request which was lodged on 8 November 2011.

Exchange of information

The Committee took note of several reorganisations affecting Participating Authorities, in particular the Danish Health and Medicines Authority (Denmark / DMA), the French National Drug and Health Products Safety Agency (France / ANSM) and the Hungarian National Institute for Quality- and Organizational Development in Healthcare and Medicines, National Institute of Pharmacy (Hungary / GYEMSZI NIP).

Training of inspectors

The PIC/S Sub-Committee on Training (SCT) met in the afternoon of 10 May and in the morning of 11 May 2012 under the chairpersonship of the First Deputy Chairperson, Dr. Joey Gouws (South Africa / MCC). The SCT:

- reviewed the immediate positive outcome of the PIC/S-PDA Europe Workshop on "GMP Inspection Practices and Trends" and discussed possible future training events with PDA and with ISPE;
- reviewed the objectives and activities of the Joint Visits Programme, Coached Inspections Programme, training courses for new inspectors as well as all PIC/S Expert Circles;
- welcomed the following upcoming training events :

    - the 8th meeting of the **Expert Circle on Computerised Systems** which will be held in Vienna (Austria), on 22-24 May 2012, hosted by Austria / AGES

- the 5th meeting of the **Expert Circle on APIs**, which will take place on 17-19 September 2012 in Washington DC (USA), hosted by USA / US FDA, (http://www.picscheme.org/expert-circles.php);
  preceded by the 2nd **International GMP Summit for Regulators** organised by USA / US FDA which will take place on 12-14 September 2012 in Washington DC (USA)

- the 19th meeting of the **Expert Circle on Human Blood, Tissues and Cells**, which will be held in Singapore (Singapore), on 15-19 October 2012, hosted by Singapore / HSA (http://www.picscheme.org/expert-circles.php);

- discussed the programme and organisation of the upcoming **PIC/S 2012 Seminar** on "Qualification and Validation: Today and Tomorrow" which will be held in Kiev (Ukraine), on 3-5 October 2012, hosted by Ukraine / SAUMP (http://picseminar2012.org);
- discussed the programme and organisation of the **PIC/S 2013 Seminar** on "GMP Impacts on Global Supply Chains", which will be held in Ottawa (Canada), in the fall of 2013 (dates to be determined), hosted by Canada / HPFBI;
- commented on the report of the PIC/S 2011 Seminar on "Good Pharmaceutical Inspection Practices" hosted in November 2011 by South Africa / MCC;
- discussed the possibility of a training course for new inspectors to be organised by Ukraine / SAUMP;
- reviewed the mandate of the PIC/S GDP Expert Circle.

Furthermore, the PIC/S Committee:

- endorsed the new "train the trainers" course to enable other Participating Authorities to run training courses for new inspectors;
- endorsed the revised mandate of the Expert Circle on APIs;
- endorsed the SCT recommendation to permanently open the Joint Visits Programme (JVP) to Good Clinical Practices (GCP) inspectors.

Harmonisation of guidance documents

The PIC/S Committee adopted the new consultation procedure "Harmonisation of PIC/S and EMA GMDP IWG Consultation Procedures" between PIC/S and the European Medicines Agency (EMA) which will ensure further improvements in the harmonisation between the EU and the PIC/S GMP Guides and related documents. This new procedure will offer the advantage of enabling each party to be informed of ongoing revisions of current documents and of the endorsement of new documents, including the sharing of early drafts in order to facilitate appropriate involvement in the adoption process.

Members took note of the status of current revisions of the PIC/S and EU GMP Guides within the frame developed by the PIC/S – EMA Liaison Officer to ensure harmonisation.

Co-operation with Associated Partners and other Organisations

PIC/S Associated Partners, namely EDQM, EMA, UNICEF and WHO gave an update on their current activities, particularly with respect to inspections.

An update on ASEAN activities including the training of inspectors and the listing process for Inspectorates within ASEAN for the exchange of GMP inspection reports and certificates, was given by the PIC/S – ASEAN Liaison Officer as well as an update on the application of the ASEAN Traditional Medicines and Health Supplements (TMHS) Guide.

The PIC/S Chair reported on her participation in the International Leadership Forum (ILF) Conferences & ISPE associated regulatory affairs forums in April in Japan and China.

IN BRIEF…

The Committee …

- noted the new division of tasks in the Executive Bureau;
- was given an oral report on the Executive Bureau meeting in the morning of 7 May 2012 in Geneva during which Executive Bureau members discussed in particular the future organisation of the Executive Bureau under the new Sub-Committee Structure, PIC/S representation in international conferences, cross-references to official translations of the EU or PIC/S GMP Guide on the PIC/S website as well as financial and staff issues;
- approved the statement of accounts 2011 and noted the Audit Report on the 2011 accounts;
- approved the Annual Report 2011;
- noted that the Sub-Committee on Strategic Development met on 2 March 2012 in London;
- confirmed that English was to remain the sole working language of PIC/S;
- confirmed that the next meeting would take place in Kiev (Ukraine) on 1-2 October 2012.

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Annex

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

MEMBERS	**ACRONYM**
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 Health and Medicines Authority	DMA
Estonian State Agency of Medicines	SAM
Finnish Medicines Agency	FIMEA
French National Drug and Health Products Safety Agency *Agence nationale de sécurité du médicament et des produits de santé*	ANSM
French Agency for Food, Environmental & Occupational Health Safety *Agence nationale de la sécurité sanitaire de l'alimentation, de l'environnement et du travail*	ANSES
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
Hungarian National Institute for Quality- and Organizational Development in Healthcare and Medicines National Institute of Pharmacy	GYEMSZI - NIP
Icelandic Medicines Agency	IMA
Irish Medicines Board	IMB
Israeli Institute for Standardization and Control of Pharmaceuticals	ISCP
Italian Medicines Agency *Agenzia Italiana del Farmaco*	AIFA
Latvian State Agency of Medicine *Zāļu Valsts Aģentūra*	ZVA
Liechtenstein's Office of Healthcare *Amt für Gesundheit*	AG
Lithuanian State Medicines Control Agency	SMCA
Maltese Medicines Authority	MAM
Netherlands' Inspectorate of Health Care *Inspectie voor de Gezondheidszorg*	IGZ
Norwegian Medicines Agency	NOMA
Polish Main Pharmaceutical Inspectorate	MPI

Portugal's INFARMED – National Authority of Medicines and Health Products, IP *Autoridade Nacional do Medicamento e Produtos de Saúde IP*	INFARMED IP
Romanian National Agency for Medicines and Medical Devices	NAMMD
Singapore's Health Sciences Authority	HSA
Slovenian Agency for Medicinal Products and Medical Devices	JAZMP
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
Ukrainian State Administration on Medicinal Products	SAUMP
US Food and Drug Administration	FDA

APPLICANTS	**ACRONYM**
Brazil's Agência Nacional de Vigilância Sanitária	ANVISA
Indonesia's National Agency for Drug and Food Control	NADFC
Japan's Ministry of Health, Labour and Welfare & Pharmaceuticals and Medical Devices Agency & Japanese Prefectures	MHLW / PMDA
Korea Food and Drug Administration	KFDA
New Zealand's Medicines and Medical Devices Safety Authority	Medsafe
Taiwan Food and Drug Administration of Chinese Taipei	TFDA
PRE-APPLICANTS	
Armenia's Scientific Centre of Drugs and Medical Technology Expertise	SCDMTE

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 40 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, Slovenia, South Africa, Spain, Sweden#, Switzerland#, the Ukraine, the United Kingdom# and the United States of America.

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