PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

17 June 2013

PRESS RELEASE

PIC/S MEETINGS
GENEVA, SWITZERLAND

From 28 to 30 May 2013 the following events took place in Geneva (Switzerland): PIC/S Committee Meeting, PIC/S Executive Bureau Meeting and PIC/S Sub-Committee on Training Meeting.

PIC/S COMMITTEE MEETING (28-29 May 2013)

The PIC/S Committee met on 28-29 May 2013 under the chairpersonship of Ms. Helena Baião (Portugal's National Authority of Medicines and Health Products / INFARMED IP). The meeting was attended by 35 out of 43 PIC/S Participating Authorities (PA) as well as by a number of Applicants, Pre-Applicants and Associated Partners. For the list of participants, see Annex.

MAIN NEWS

NEW PIC/S SUB-COMMITTEE STRUCTURE

The PIC/S Committee adopted all documents pertaining to the new Sub-Committee structure of PIC/S. This new organisational structure, which will enter into force on 1 January 2014, aims at favouring the participation of all PIC/S Participating Authorities and is a concrete reply to PIC/S' growing membership. It 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.

The new structure includes seven Sub-Committees, which will be open to Members of the PIC/S Committee as well as to inspectors from PIC/S Participating Authorities, in the following fields: Training (SCT); Expert Circles (SCEC); Strategic Development (SCSD); Compliance (SCC); GM(D)P Harmonisation (SCH); Budget, Risk and Audit (SCB) and Communication (SC COM). The process of nominations to the various Sub-Committees has been initiated and will be finalised during the second half of 2013.

TURKEY APPLIES FOR ACCESSION TO PIC/S

On 3 May 2013, Turkey's Medicines and Medical Devices Agency (TMMDA) officially submitted an application for PIC/S membership. The PIC/S Committee has nominated a Rapporteur and three Co-Rapporteurs, for which two are still subject to confirmation, in charge of the assessment of the accession application.

MEXICO APPLIES FOR PRE-ACCESSION TO PIC/S

On 7 May 2013, Mexico's Federal Commission for the Protection from Sanitary Risks – Ministry of Health (COFEPRIS) officially submitted an application for PIC/S pre-accession membership. The PIC/S Committee has nominated a Rapporteur and three Co-Rapporteurs in charge of the assessment of the pre-accession application.

CLASSIFICATION OF DEFICIENCIES BY PIC/S

Following discussions on the classification of GMP deficiencies at the 2011 PIC/S Seminar in Cape Town (South Africa) and the PIC/S-PDA Europe Workshop in Geneva (Switzerland) in May 2012, the Committee has agreed to further discuss the classification of deficiencies. In this perspective, PIC/S Committee Members discussed possible approaches in view of harmonising the international classification of deficiencies and the common identification of top GMP deficiencies. Several PIC/S Participating Authorities expressed a strong interest in such an endeavour. Consequently, the PIC/S Committee established a Working Group, co-ordinated by Australia / TGA, in order to further explore possible international collaboration in this field.

PIC/S TRAINING ACTIVITIES

The Committee welcomed the following upcoming PIC/S training activities for 2013 and early 2014:

- **PIC/S 2013 Seminar** on "Global Supply Chains and GMP Compliance" (for both API and solid dosage forms) which will be held in Ottawa (Canada), on 9-11 October 2013, hosted by Canada / HPFBI (http://www.picscheme.org/annual-seminar.php);
- the 2nd meeting of the **2nd Expert Circle on Quality Risk Management** which was held in Budapest (Hungary), on 23-24 May 2013, hosted by Hungary / NIP-GYEMSZI (http://www.picscheme.org/expert-circles.php);
- the 1st meeting of the **Expert Circle on Good Distribution Practices** which will be held in Helsinki (Finland), on 11-13 June 2013, hosted by Finland / FIMEA (http://www.picscheme.org/expert-circles.php);
- the 20th meeting of the **Expert Circle on Human Blood, Tissues and Cells**, which will be held in Taipei (Chinese Taipei), on 9-14 September 2013, hosted by Chinese Taipei / TFDA (http://www.picscheme.org/expert-circles.php);
- the 6th meeting of the **Expert Circle on APIs**, which will take place on 19-21 May 2014 in Rome (Italy), hosted by Italy / AIFA.

OTHER NEWS

Development of new projects for PIC/S

While reaffirming that GMP remains PIC/S' main core area of competence, the Committee discussed the progress made in the development of the following new projects for PIC/S since the last Committee Meeting in Kiev (Ukraine).

Extending PIC/S' mandate

With respect to the project of extending PIC/S' mandate from GMP to new fields such as Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP), Members reviewed the outcome of the consultation of non-EEA PIC/S Members with respect to the proposals made by the EMA Ad Hoc GCP and Pharmacovigilance Working Groups. The Committee decided to establish a Working Group composed of GCP / GVP inspectors, for which a call would be issued, with a view to further review all feedback received and explore the scope, needs and resources involved in this project, while avoiding any duplication of activities with EMA.

Creating a PIC/S Inspectorates' Academy

With regards to the project of creating a PIC/S Inspectorates' Academy to provide cost-efficient, primarily web-based, high quality harmonised training for Inspectorates, the Ad-hoc Working Group established for the development of this project, co-ordinated by HSA / Singapore, provided the Committee with an update on the progress made with respect to the detailed survey on training needs which was currently underway with all PIC/S Participating Authorities, Applicants, Partners and selected non-Members.

Exploring the link between GMP and biosafety issues

With respect to other needs expressed by Heads of Agencies, the Committee took note of a Concept Paper prepared by ANSES / France, proposing that PIC/S further explore the link between GMP and biosafety issues, in particular the development of guidance for biological hazards assessment and appropriate safety measures (biosafety). Participating Authorities interested by this issue have been invited to comment on this proposal.

Other specific projects

Finally, the Committee was updated on other specific projects as well as follow-ups to preliminary contacts established with selected external donors in view of ensuring the development of these future projects. Members also discussed the appropriate follow-ups to be given to the replies by Heads of Medicines Agencies further to the survey carried out with them last year, which initiated these new projects after the PIC/S 40th anniversary in 2011.

Re-assessment of Members and Assessment of Applicants & Pre-Applicants

Re-assessment of Members

The Rapporteur in charge of the re-assessment of the **Lithuanian State Medicines Control Agency (SMCA)** updated members on the partial re-assessment which took place on 10-11 December 2012. The planning of future re-assessments of other Participating Authorities was also discussed by the Committee.

Assessment of Applicants

Members were informed by the Rapporteur in charge of the membership application of **Brazil's Agência Nacional de Vigilância Sanitária (ANVISA)** that the requested English translation of the membership application would be discussed during a bilateral meeting scheduled with ANVISA on 26-27 June 2013 in Sao Paulo (Brazil).

The Rapporteur in charge of the membership application by the **Iranian Ministry of Health (MoH)** recalled that the Committee had decided at its last meeting to proceed with an on-site inspection visit. The current Audit team, composed of the Rapporteur and two Co-Rapporteurs, had not been able to find a suitable date until now. The Rapporteur informed the Committee that she would be unable to continue in this function as she was due for retirement from her Agency. The Committee nominated a new Rapporteur as well as three new additional Audit team members and it was decided that the on-site visit was to be planned preferably before the end of the year. Otherwise a clock-stop would be granted.

With respect to **Japan's Ministry of Health, Labour and Welfare (MHLW)**, which had submitted an application in its name as well as **on behalf of the Pharmaceuticals and Medical Devices Agency (PMDA) & Japanese Prefectures**, the Rapporteur presented his draft preliminary assessment report. Members noted that an on-site inspection visit was scheduled to take place from 9 to 13 September 2013. The Rapporteur also reported on the evaluation of API, carried out on behalf of the European Commission, at the request of the Japanese authorities, in connection with the implementation of the EU Directive applicable to the manufacturing of API intended for export to the European Union. A specific on-site visit for this purpose had taken place on 15-22 April 2013. The Rapporteur highlighted the advantage of combining both the PIC/S application and the European Commission's API assessment and reported on the positive outcome of the latter which had resulted in Japan being added to the white list. The Japanese delegation expressed its gratitude for the co-ordination between both assessments, thereby minimizing duplication.

The Rapporteur for **Korea's Food & Drug Administration (KFDA)** presented his draft evaluation report of the paper assessment of KFDA, which has since 23 March 2013 been raised to the status of **Ministry of Food and Drug Safety (MFDS)**. He proposed to enlarge the Audit team presently composed of himself and two Co-Rapporteurs. The Committee nominated two new Co-Rapporteurs and one new Audit team member.

Members were updated on the outcome of the report on the on-site assessment visit of **Philippines' Food and Drug Administration (PFDA)** which took place on 10-14 September 2012 and discussed the opportunity of a clock-stop further to a request made by Philippines' FDA.

The Secretariat provided an update on the outcome of the on-site assessment visit of the **United Kingdom's Veterinary Medicines Directorate (VMD)** which took place on 8-12 October 2012. The final report had been sent to VMD for comments.

Assessment of Pre-Applicants

The Rapporteur in charge of the pre-accession application of **Armenia's Scientific Centre of Drugs and Medical Technology Expertise (SCDMTE)** gave the Committee an update on the paper evaluation currently in preparation further to the replies received from SCDMTE to the gap-analysis. A new Co-Rapporteur was also nominated by the Committee.

Further to the lodging of a pre-accession application by **Belarus's Ministry of Health (MoH)** on 30 September 2012, the Rapporteur and two Co-Rapporteurs, who were appointed in March 2013 by written procedure, provided an update on the outcome of their paper evaluation.

Members were informed of the outcome of the paper evaluation with respect to **Uganda's National Drug Agency (NDA)** application for pre-accession. A new Rapporteur was appointed, as well as a new Member of the Assessment team.

Exchange of information

The Committee reviewed the outcome of the **mapping of GMP competencies** of all PIC/S Participating Authorities and was updated on the efforts underway to map GDP competencies.

With respect to sharing of information, PIC/S Members and Partners discussed further improvements and benefits in connection with the process of maintaining and updating PIC/S' list of planned foreign inspections, with a view to better facilitate the sharing of inspection findings, avoid any unnecessary duplication, enhance synergies, maintain mutual confidence and offer a reply to the expectations of industry.

Members took note of several reorganisations and changes affecting Participating Authorities, in particular Belgium / AFMPS; Canada / HPFBI; Portugal / INFARMED IP; Ukraine SAUMP; UK / MHRA and the US FDA.

UK / MHRA gave a presentation on the launch of the MHRA Innovative Office, the launch of the new MHRA Risk Based Inspection Programme and on the MHRA-India relationship. US FDA also provided a written report on the Second International GMP Summit which was held in Washington DC (USA) on 12-14 September 2012.

Training of inspectors

The PIC/S Sub-Committee on Training (SCT) met on 30 May 2013 under the chairpersonship of the First Deputy Chairperson, Dr. Joey Gouws (South Africa / MCC). The SCT:

- discussed the programme and organisation of the upcoming **PIC/S 2013 Seminar** on "Global Supply Chains and GMP Compliance" (for both API and solid dosage forms) which will be held in Ottawa (Canada), on 9-11 October 2013, hosted by Canada / HPFBI;
- reviewed the activities of all PIC/S Expert Circles and upcoming Expert Circle meetings and training events;

- discussed the outcome of a side meeting which took place in the margins of the Committee Meeting on 29 May 2013 between a PIC/S Delegation and Representatives of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and WHO on a proposal by IPFMA for a Regional Training Initiative on GMP Implementation. The potential for future co-operation in the field of training was welcomed;
- took note of the developments relating to the PIC/S International API Training Programme, in particular reviewed the Q7 Training Courses organised jointly by PIC/S and PDA in Beijing (China) and Lisbon (Portugal) in 2012 and took note of future Q7 Training Courses for 2013/2014, with the possible involvement of other interested partners, in several locations around the world;
- assessed the PIC/S Pluriannual Training Schedule for the period 2009-2012;
- reviewed the report of the PIC/S 2012 Seminar on "Qualification and Validation: Today and Tomorrow" hosted on 3-5 October 2012 by Ukraine / SAUMP;
- noted the update provided by Ireland / IMB on future plans for the organisation of a "train the trainers" course as well as the outcome of the training course for new inspectors from the Commonwealth of Independent States (CIS), which took place just after the 2012 PIC/S Seminar in Kiev (Ukraine), under the bilateral arrangement between Ukraine / SAUMP and Ireland / IMB;
- discussed and reviewed the revision of the PIC/S Aide-Memoire on the Organisation of Seminars; the revision of the PIC/S Guidelines on Expert Circles; and a draft PIC/S Guideline on co-operation with Professional Associations;
- reviewed the evaluation report of the Course on Rapid Microbiological Methods (RMM) organised by PDA Europe in co-operation with PIC/S, in Barcelona (Spain) on 8-9 November 2012;
- reviewed the activities of the Joint Visits Programme and Coached Inspections Programme and made some recommendations for improvements regarding the operation and participation in these training programmes;
- discussed and welcomed the potential in the development of future web-based training and the posting of video recordings of PIC/S training events on the password-restricted part of the PIC/S website.

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.

The Committee took note of the consultation carried out with EDQM, UNICEF and WHO on the revision of partnership agreements in order to include a clause on confidentiality.

An update on **ASEAN activities** was given by the PIC/S – ASEAN Liaison Officer, in particular on the 2nd Meeting of the Joint Sectoral Committee (JSC) on GMP Inspection of Manufacturers of Medicinal Products (JSC GMP MRA) which was held on 14 – 15 May 2013 in Bali, Indonesia.

The PIC/S-WHO Liaison Officer reported on her participation in the WHO Expert Committee on Specifications for Pharmaceutical Preparations meeting which took place in Amsterdam (Netherlands) in October 2012. WHO gave a presentation on the WHO programme for strengthening National Regulatory Authorities in the area of vaccines.

The Committee was provided with an update on the progress made at the last meeting of HMA on discussions relating to the recognition of audits between HMA (Joint Assessment Programme) and PIC/S (Assessment and Re-Assessement) as well as an update on the proposal for transferring to ICH the PIC/S Q&A document on Q7 for which the conditions of the transfer would still need to be agreed.

The PIC/S Chair flagged her participation in the IPSE 2012 Annual Meeting in San Francisco (USA) in November 2012 and the PDA-EMA joint conference in Lisbon (Portugal) in December 2012.

IN BRIEF…

The Committee …

- congratulated New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) and Chinese Taipei's Taiwan Food and Drug Administration (TFDA) for their accession to PIC/S as from 1 January 2013 and for their first attendance to a Committee Meeting in their capacity as Participating Authorities;
- paid tribute to a long standing Member of the Committee and of the Executive Bureau in the person of Dr. Vassiliki Revithi, further to her retirement from Greece / EOF;
- was given an oral report by the PIC/S Chairperson on the Executive Bureau meeting which took place in the morning of 28 May in Geneva (Switzerland) during which Executive Bureau Members discussed the review of duties of Bureau Members, the revision of Executive Bureau Rules of Procedure in connection with the new Sub-Committee structure, participation and representation of PIC/S in past and future international conferences, several policy matters including project planning, relations with media and follow-ups to the GMP Summit in Washington DC (USA), as well as financial and staff issues;
- was informed by the Chairperson about her new responsibilities within her Agency;
- welcomed the new PIC/S Assistant Secretary;
- noted the participation and representation of PIC/S in past and future international conferences;
- adopted the PIC/S Annual Report for 2012;
- approved the statement of the 2012 accounts and endorsed the recommendations in connection therewith;
- noted the Audit Report on the 2012 accounts and was given an update by the Secretariat on the 2013 accounts;
- endorsed a Note confirming that English should remain the sole working language of PIC/S;
- agreed to reconvene in Ottawa (Canada) on 7-8 October 2013.

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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	AGES
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
Chinese Taipei's Taiwan Food and Drug Administration	TFDA
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
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
Indonesia's National Agency for Drug and Food Control	NADFC
Irish Medicines Board	IMB
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
Maltese Medicines Authority	MAM
Netherlands' Inspectorate of Health Care *Inspectie voor de Gezondheidszorg*	IGZ
New Zealand's Medicines and Medical Devices Safety Authority	Medsafe
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

Singapore's Health Sciences Authority	HSA
Slovak State Institute for Drug Control	SIDC
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
Ukrainian State Administration on Medicinal Products	SAUMP
United Kingdom's Medicines and Healthcare Products Regulatory Agency	MHRA
US Food and Drug Administration	FDA

APPLICANTS	**ACRONYM**
Iranian Ministry of Health	MoH
Japan's Ministry of Health, Labour and Welfare & Pharmaceuticals and Medical Devices Agency & Japanese Prefectures	MHLW / PMDA
Korea's Ministry of Food and Drug Safety	MFDS
Philippines' Food and Drug Administration	PFDA
Turkey's Medicines and Medical Devices Agency	TMMDA
PRE-APPLICANTS	
Armenia's Scientific Centre of Drugs and Medical Technology Expertise	SCDMTE
Mexico's Federal Commission for the Protection from Sanitary Risks – Ministry of Health (COFEPRIS)	COFEPRIS
Uganda's National Drug Authority	NDA

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 43 Participating Authorities in the PIC/S (Convention (#) and Scheme taken together). The PIC/S Participating Authorities are coming from Argentina, Australia#, Austria#, Belgium#, Canada, Chinese Taipei, Cyprus, Czech Republic (both Human and Veterinary), Denmark#, Estonia, Finland#, France (both Human# and Veterinary), Germany#, Greece, Hungary#, Iceland#, Indonesia, Ireland#, Israel, Italy#, Latvia, Liechtenstein#, Lithuania, Malaysia, Malta, Netherlands, New Zealand, 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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