PIC/S
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

www.picscheme.org May 2015

Leading the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products

PRESS RELEASE: PIC/S MEETINGS IN GENEVA (SWITZERLAND)

From 11 to 13 May 2015, the following meetings took place in Geneva (Switzerland) at the "IATA Conference Centre": PIC/S Committee, PIC/S Executive Bureau and bilateral meeting between PIC/S Executive Bureau and China Food and Drug Administration (CFDA).

Hong Kong SAR / PPBHK joins PIC/S

The PIC/S Committee met on 11-12 May 2015 under the chairpersonship of Dr Joey Gouws (South Africa's Medicines Control Council / MCC). At the meeting, the PIC/S Committee invited the Pharmacy and Poisons Board of Hong Kong (PPBHK), Hong Kong SAR, to join the Scheme as from 1 January 2016. PPBHK will become PIC/S' 47th Participating Authority.

PIC/S Committee Meeting, Geneva, Switzerland

PPBHK applied for membership on 30 August 2013. A paper assessment was conducted in view of its accession to PIC/S, followed by an on-site visit on 19-23 January 2015. The Audit team recommended to the Committee to accept the PIC/S membership application of PPBHK.

Interview of Mr Lot Chan, Chief Pharmacist, Drug Office of Department of Health (Hong Kong SAR / PPBHK)

Q: PIC/S is proud to welcome PPBHK as new Member. What would you say are the expected benefits and impact of your accession to PIC/S, in particular for your Agency (PPBHK) and the manufacturing industry of Hong Kong SAR?

A: Accession to PIC/S raises the standard and widens the exposure of both PPBHK and the manufacturing industry of Hong Kong SAR. Inspectors of the Hong Kong Department of Health, i.e. inspectors who conduct GMP inspections for PPBHK, have gained much experience and knowledge in the past years through the enhancement of our quality system, participation in PIC/S meetings and training, and exchanging ideas and experience with inspectors around the globe. The manufacturing industry of Hong Kong also took this opportunity to upgrade their manufacturing standards and strengthen their training. We believe the biggest impact is that we now have a more robust system to ensure the quality of drugs available in the market, which directly benefits the Hong Kong community.

The representatives of Hong Kong SAR / PPBHK, Mr Lot Chan and Ms Linda Woo, with the Rapporteur, Mr Tor Gråberg (Sweden / MPA) and the PIC/S Chairperson, Dr Joey Gouws (South Africa / MCC).

Q: What were the most significant challenges encountered in the frame of the PIC/S membership application?

A: Hong Kong SAR has a drug regulatory framework comparable to that in other countries and the GMP Inspectorate has established a quality system since 2009. The manufacturing industry of Hong Kong has also been very supportive to our accession to PIC/S. Probably the biggest challenge is capacity building, in both the GMP Inspectorate and the manufacturing industry.

cont'd

Q: You have adopted the current version of the PIC/S GMP Guide as new GMP Guide to come into force on 1 October 2015. Could you tell us how this new Guide will be implemented?

A: Since the end of 2014, all licensed manufacturers were required to fully comply with the PIC/S GMP Guide as one of their licensing conditions with effect from 1 October 2015. The Inspectorate also started to inspect manufacturers based on the PIC/S GMP Guide since the end of 2014. After the amendment of the laws early this year, PPBHK is also empowered to adopt and issue GMP Guide for manufacturers. Such GMP Guide issued by the PPBHK, i.e. the PIC/S GMP Guide, will come into force on 1 October 2015 by notice to be published in gazette.

China Food and Drug Administration Delegation with PIC/S Executive Bureau Members

China / CFDA set to join PIC/S in near future

A meeting between the PIC/S Executive Bureau and a Delegation from the China Food and Drug Administration (CFDA) took place on 13 May 2015. Discussions focused on the planning of a roadmap for a future accession of CFDA to PIC/S as well as opportunities for co-operation between CFDA and PIC/S prior to accession, in particular in the field of training and gap analysis. The CFDA Delegation was invited to attend as Special Guest the PIC/S Committee meeting on 11-12 May 2015.

PIC/S strenghtens international regulatory co-operation in the field of GMP

A number of initiatives aiming at strengthening international regulatory co-operation in the field of GMP are currently being undertaken by PIC/S, under the impulse of the PIC/S Sub-Committee on Strategic Development (SCSD). The objective is to improve the sharing and to facilitate the mutual acceptance/ reliance of GMP information. Since its inception, PIC/S has offered a proactive frame for inspection sharing and has encouraged its Members to accept inspection findings on a voluntary basis, by relying on mutual trust and confidence building, based on the PIC/S accession process.

In the context of increased foreign inspections and multiple initiatives in the field of co-operation between drug regulatory authorities, these efforts need to be enhanced and are presently being notably directed at reducing the number of “same scope inspections”. Same scope inspections, which are to be distinguished from multiple inspections for which industry is responsible, are GMP inspections, which have exactly the same scope and which are consequently redundant and unnecessary.

PIC/S Chairperson, Dr Joey Gouws (South Africa / MCC) and PIC/S Chair of Sub-Committee on Strategic Development, Mr Jacques Morénas (France / ANSM).

At its meeting of 11-12 May 2015, the Committee reviewed the preliminary outcome of a survey carried out among PIC/S Participating Authorities on the mutual acceptance / reliance of same scope inspection results for domestic as well as foreign inspections. The Committee also adopted a new procedure for informing foreign regulatory authorities of inspections to be conducted in their jurisdiction. Such a procedure will help facilitate promotion of co-operation and effective exchange of information between PIC/S Participating Authorities and increase opportunities to observe inspections or perform joint inspections, among other advantages.

These initiatives are set to further strengthen existing measures by PIC/S such as the maintenance of a list of planned foreign inspections - which in 2014 included more than 2,300 planned inspections globally – as well as the PIC/S procedure for team inspections. These measures already contribute in the avoidance of duplicate inspections as PIC/S Members are encouraged to either perform a joint inspection or rely on the inspection report from a PIC/S Participating Authority (or PIC/S Partner Organisation).

In this perspective, the Committee also agreed to further strengthen its co-operation with other international initiatives such as the **ICMRA** (International Coalition of Medicines Regulatory Authorities). ICMRA is also involved in exploring the better sharing and reliance of GMP information between its Members. Through closer co-operation with ICMRA, some PIC/S goals and initiatives could be further advanced such as facilitating the acceptance of same scope inspection results. By joining efforts, leveraging resources and sharing co-ordination around issues resulting from complex supply chains, international co-operation could be greatly strengthened in order to lead towards the global provision of safe and effective, quality medicines by rationalising inspections and allowing for more efficient deployment of global inspection resources, while avoiding duplication.

The **OECD** (Organisation for Economic Co-operation and Development) also recently invited PIC/S to participate in a survey on international regulatory co-operation, in which some PIC/S accomplishments, in particular in the field of training, were highlighted. A proposal by **WHO** (World Health Organisation) aiming at upscaling co-operation with PIC/S in view of strengthening regulatory systems, was equally discussed by the Committee. The Sub-Committee on Strategic Development (SCSD) and the Sub-Committee on Compliance (SCC) will work on this proposal. PIC/S welcomes these new developments which will further enhance international co-operation alike the excellent co-operation already established with the **EMA** (European Medicines Agency) in this field, in order to strengthen the evaluation process and the training of auditors in charge of the assessment of Drug Regulatory Authorities.

PIC/S Inspectors Academy

The Committee welcomed progress achieved in the establishment of the PIC/S Inspectors' Academy (PIA). The Academy is a PIC/S initiative to set up a web-based educational centre under the PIC/S umbrella which aims at harmonising and standardising GMP training at an international level through an accredited qualification system. The PIA will not only offer general or advanced training for inspectors but will also serve as a platform for discussion and sharing among regulators thus contributing to global harmonisation and interpretation of GMP. The first stage of the PIA consisting in the launch of the web platform will be operational as of Q3 2015. Further developments will be implemented step by step until full completion of the project by 2019. A number of external stakeholders such as ISPE, PDA, IFPMA and WHO have expressed interest in this landmark project.

In short

Current PIC/S Working Groups

The Committee was updated on the work being carried out by :

- the PIC/S Working Group on Harmonisation of Classification of Deficiencies ;
- the PIC/S Working Group on Advance Therapy Medicinal Products (ATMPs) ;
- the EMA-PIC/S Joint Drafting Group on the revision of Annex 1 (sterile manufacturing) of the PIC/S-EU GMP Guide ;
- the PIC/S Project Management Steering Committee in charge of the PIC/S Inspectors' Academy (PIA) ;
- the PIC/S Working Group on Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP).

New PIC/S Working Groups

The Committee decided to establish :

- a new PIC/S Working Group on Data Integrity ;
- a new PIC/S Working Group on Veterinary Medicinal Products ;
- a new PIC/S Working Group on Controlling Cross-Contamination in Shared Facilities.

In short (cont'd)

Ongoing activities

The Committee

- was updated on revisions currently underway for Chapters 1, 2, 6 and 7 of the PIC/S GMP Guide as well as for Annexes 13, 15 and 17 ;
- approved training and qualification requirements for PIC/S Rapporteurs and Audit teams ;
- endorsed the development of a new PIC/S risk-based re-assessment procedure and discussed the planning of future re-assessments ;
- discussed opportunities for future joint training with Professional and Other Organisations such as ISPE in the field of QRM and PDA in the field of API.

PIC/S Applications Updates

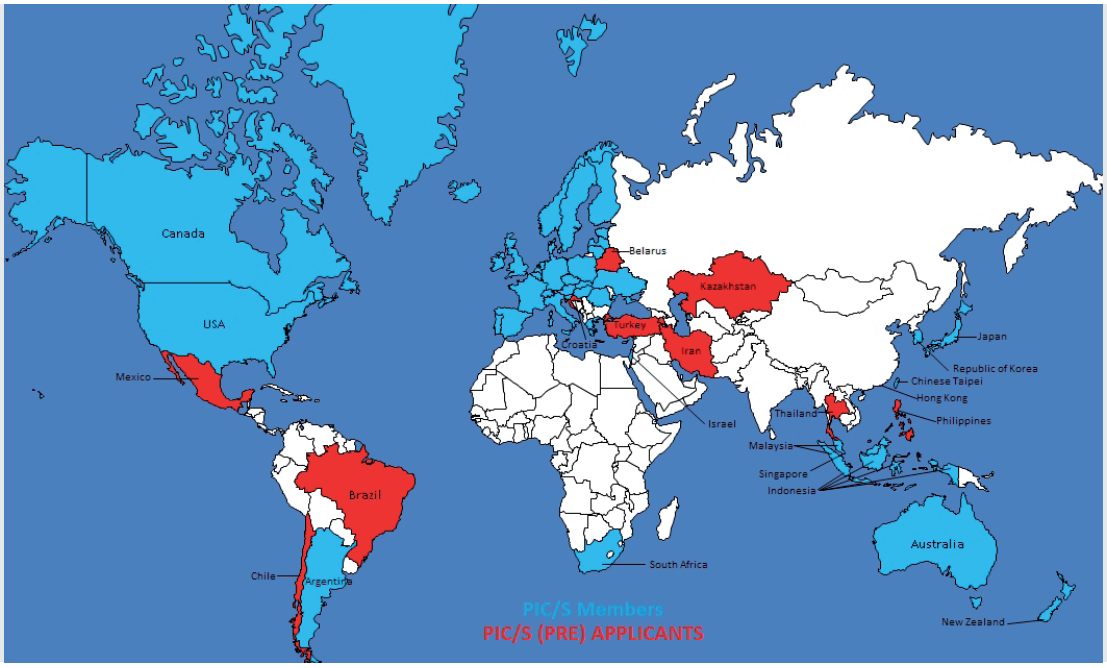
- Thailand / Thai FDA applied for membership on 20 March 2015 ;
- Audit Teams for Brazil / ANVISA and Thailand / Thai FDA were appointed ;
- The paper assessment of Turkey / TMMDA has been completed ;
- On-site assessment visits were scheduled for Croatia / HALMED and Iran / MoH in 2015 ;
- The pre-accession gap analysis has been completed for Belarus / MoH.

APPLICANTS (8)

Brazil / ANVISA
Croatia / HALMED
Hong-Kong SAR / PPBHK
(Member as of 1 Jan. 2016)
Iran / MoH
Mexico / COFEPRIS
Philippines / PFDA
Thailand / Thai FDA
Turkey / TMMDA

PRE-APPLICANTS (3)

Belarus / MoH
Chile / ISP
Kazakhstan / CCMPA



Overview of current PIC/S 46 Members (blue) and 11 (Pre-) Applicants (red)

Recent PIC/S Training

• Advanced Training Course by PIC/S Expert Circle on QRM, hosted by PMDA, in Tokyo (Japan) on 8-10 December 2014 ;

• PIC/S-PDA ICH Q7 Training by Expert Circle on API and PDA, in co-operation with MFDS, with the support of the EU Commission, in Seoul (Republic of Korea) on 22-23 January 2015 ;

• PIC/S-PDA ICH Q7 Training by Expert Circle on API and PDA, in co-operation with ANVISA with the support of the EU Commission, in Brasilia (Brazil) on 10-12 February 2015 ;

• PIC/S Expert Circle on GDP, hosted by TFDA, in Taipei (Chinese Taipei) on 24-26 March 2015.

Advanced Training Course by Expert Circle on QRM, hosted by PMDA, in Tokyo (Japan) on 8-10 December 2014. Dr Shingou Sakurai, Director Office of Manufacturing/Quality and Compliance (Japan / PMDA), Dr Kevin O'Donnell, Chair of the PIC/S Expert Circle on QRM (Ireland / HPRA), Dr Tawaragi, Safety Officer (Japan / PMDA), Dr Tatsuya Kondo, Chief Executive (Japan / PMDA)

Coming up…

• **23-24 June 2015:** PDA Conference on Quality and Regulations, in co-operation with PIC/S, in Brussels (Belgium) http://www.picscheme.org/various.php ;

• **14-18 September 2015:** PIC/S-PDA ICH Q7 Training in Hyderabad and Ahmedabad (India) by PIC/S Expert Circle on API jointly with PDA, with the support of the EU Commission and in co-operation with DIA and APIC http://www.picscheme.org/various.php ;

• **5-7 October 2015:** Advanced QRM Training Courses in Los Angeles (USA) by PIC/S Expert Circle on QRM, hosted by US FDA http://www.picscheme.org/expert-circles.php ;

• **7-9 October 2015:** Annual PIC/S Seminar on Biopharmaceuticals in Nusa Dua (Indonesia), hosted by Indonesia / NADFC http://www.picscheme.org/annual-seminar.php ;

• **20-22 October 2015:** PIC/S Expert Circle and Advanced Training on API in Strasbourg (France), hosted by EDQM http://www.picscheme.org/expert-circles.php and https://www.edqm.eu/en/PICS-Meeting-2015-1676.html ;

• **26-30 October 2015:** PIC/S Expert Circle on Human Blood, Tissues, Cells and ATMPs in Rome (Italy), hosted by AIFA http://www.picscheme.org/expert-circles.php ;

• **November 2015:** PIC/S-PDA ICH Q7 Training in China by PIC/S Expert Circle on API jointly with PDA, with the support of the EU Commission ;

• **30 June-5 July 2016:** PIC/S New Inspector Training Course in Dublin (Ireland), hosted by HPRA (tbc) ;

• **6-8 July 2016:** Annual PIC/S Seminar on Inspectorates of the Future in Manchester (UK), hosted by MHRA.