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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 Rome (Italy)

From 15 to 21 May 2014, the meetings of the PIC/S Committee, the PIC/S Executive Bureau and the PIC/S Expert Circle on Active Pharmaceutical Ingredients (APIs) took place in Rome (Italy)

Dr Joey Gouws
PIC/S Chairperson

PIC/S Committee Meeting

The PIC/S Committee, preceded by the PIC/S Executive Bureau meeting, met on 15-16 May 2014 under the chairpersonship of Dr Joey Gouws (South Africa's Medicines Control Council / MCC). The Chairperson said that it was a particular honour for Africa to chair PIC/S for the first time in history. The meeting was attended by 35 out of 44 PIC/S Participating Authorities (PA) as well as by a number of Applicants, Pre-Applicants and Associated Partners. For the list of Members and Partners (http://picscheme.org/members.php)

Japan and South Korea to Join PIC/S

The Committee invited the competent authorities of Japan and South Korea to join PIC/S as of 1 July 2014. Japan will become the 45th PIC/S Participating Authority and will be represented by the Pharmaceutical & Food Safety Bureau of the Ministry of Health, Labour & Welfare (MHLW), the Pharmaceutical and Medical Devices Agency (PMDA) and the GMP Inspectorates of Japan's Prefectures. South Korea's Ministry of Food and Drug Safety (MFDS) will become the 46th PIC/S Participating Authority.

Japan's Accession to PIC/S

Japan applied for membership in March 2012. A paper assessment was conducted in view of its accession to PIC/S, followed by an on-site visit on 9-13 September 2013. Due to the size of the assessment and the workload involved, the assessment of Japan implied a larger than usual audit team composed of seven PIC/S experts. At the Committee meeting of 15-16 May 2014, the audit team recommended to the Committee to accept the PIC/S membership application of Japan. The accession of Japan was welcomed by Mr Haruo Akagawa, Director of Compliance and Narcotics Division (MHLW), who thanked PIC/S on behalf of MHLW, PMDA and the Prefectures Inspectorates. He expressed his appreciation for the hard work carried out by the audit team and welcomed the fact that accession to PIC/S had conferred an international recognition to the Japanese GMP regulation system. He reiterated the Japanese authorities' commitment to PIC/S objectives and expressed their willingness to promote and contribute to PIC/S activities.

South Korea's Accession to PIC/S

South Korea applied for membership in April 2012 through the Korean Food & Drug Administration (KFDA). On 23 March 2013, the status of KFDA was elevated to ministerial level and the name was changed to "Ministry of Food and Drug Safety" (MFDS). A paper assessment was conducted in view of the accession of MFDS to PIC/S, followed by a pre-audit visit on 17-18 December 2013 and an on-site visit on 13-17 January 2014. Five PIC/S experts took part in the final audit team. At the Committee meeting of 15-16 May 2014, the audit team recommended to the Committee to accept the PIC/S membership application of South Korea. The Director General of the Pharmaceutical Safety Bureau of MFDS, Mr. MooYoung Yoo, welcomed the accession of MFDS and thanked PIC/S for their accession and the audit team for their help and support. He stated that since the introduction of GMP to Korea nearly 40 years ago, in 1977, Korean GMP had been continuously revised and updated to conform to international GMP standards. The PIC/S accession procedure had provided the opportunity for further revisions which would be completed by June 2014.

PIC/S Adopts GDP Guide

The PIC/S Committee adopted a Guide on Good Distribution Practice (GDP), which will enter into force on 1 June 2014. The PIC/S GDP Guide is based on the EU GDP Guide. While the EU GDP Guide is legally binding in the EU/EEA, the PIC/S GDP Guide is a non-binding guidance document in PIC/S, as not all PIC/S Participating Authorities are competent for GDP inspections.

Today's distribution network for medicinal products is increasingly complex and involves many players. This GDP Guide and its guidelines lay down appropriate tools to assist wholesale distributors in conducting their activities and to prevent falsified medicines from entering the legal supply chain. Compliance with these guidelines will ensure control of the distribution chain and consequently maintain the quality and the integrity of medicinal products.

Thailand to Apply to PIC/S

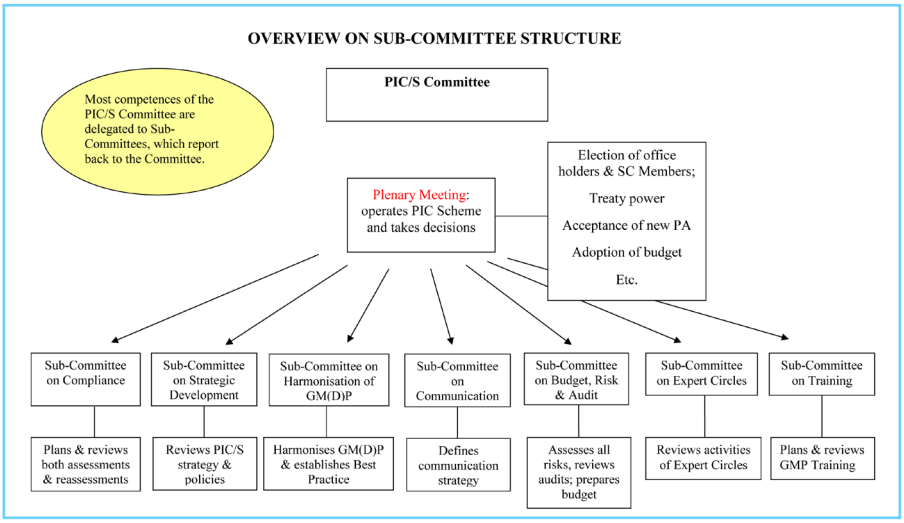
The Secretary General of Thailand's Food and Drug Administration (Thai FDA), Dr Bonchai Somboonsook, officially announced during the Committee meeting of 15-16 May 2014, that Thai FDA would soon submit a membership application to PIC/S.

Current PIC/S Membership Applications

Thai FDA will therefore be joining the 10 Authorities currently under assessment for PIC/S membership, among which 5 for accession (Brazil / ANVISA; Hong-Kong SAR / PPBHK; Iran / MoH; Philippines / PFDA and Turkey / TMMDA) and 5 for pre-accession (Armenia / SCDMTE; Belarus / MoH; Chile / ISP; Kazakhstan / CCMPA and Mexico / COFEPRIS). At the Committee meeting on 15-16 May 2014, Uganda / NDA was the first Authority to complete the pre-accession process since this new procedure was initiated in 2011. The main advantage of the pre-accession procedure is to offer of a gap-analysis on the readiness of an authority to apply to PIC/S. After fulfilling its CAPA, Uganda / NDA will then be invited to file an application to PIC/S.

Implementation of the New PIC/S Sub-Committee Structure

The PIC/S Chairperson reported on the first 5 months of operation of the new Sub-Committee structure of PIC/S which entered into force on 1 January 2014. The new structure composed of seven Sub-Committees, includes Members of the PIC/S Committee as well as inspectors from PIC/S Participating Authorities. Among the Sub-Committee Members, 57% are from non-EU PIC/S Participating Authorities, reflecting the fact that PIC/S has become less of an eurocentric and an ever more global international Organisation.



Each of the 7 Sub-Committee Chairs, members of the PIC/S Executive Bureau, reported to the Committee on the activities covered by their respective Sub-Committees, 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 Chairperson welcomed the implementation of this new structure and the initiatives taken by the Sub-Committees which were allowing for a more participative and efficient organisation of PIC/S. Opportunities for co-operation with other organisations such as the International Coalition of Medicines Regulatory Authorities (ICMRA) and ICH as well as Professional Associations such as ISPE and PDA were being explored by the relevant Sub-Committees.

This new structure is also an adequate and concrete reply to PIC/S' growing membership, which as of 1 July 2014, will count 46 Participating Authorities worldwide.

PIC/S Expert Circle on APIs Meeting

The 6th meeting of the PIC/S Expert Circle on APIs was held back-to-back with the PIC/S Committee meeting in Rome (Italy) from 19-21 May 2014, hosted by the Italian Medicines Agency (AIFA). The Expert Circle meeting, part of the PIC/S International API Training Programme, delivered advanced training for inspectors in APIs. The meeting was attended by more than 120 delegates

from regulatory agencies, including PIC/S Members and non-Members, originating from 45 different countries from Europe, the Americas, Asia and Africa.

This advanced training event was a unique occasion for regulators to discuss and explore technical topics related to the production and control of active pharmaceutical ingredients as well as benefit from training specifically aimed at the inspections of manufacturers of APIs. This event also provided participants with the opportunity to harmonise inspection approaches in this field as the quality of active pharmaceutical ingredients, within the global supply chain, can be ensured only if regulatory agencies work together in the harmonization of standards of inspection.

The overall objective of the meeting was to strengthen international co-operation and share experience in the field of inspections. The topics of the meeting, divided into plenary sessions and workshops, were process validation and cleaning validation as well as «contemporary issues» such as counterfeiting, data integrity and heparin inspections.

Upcoming PIC/S Training Activities

▪ **PIC/S – IMB New Inspector Training Course** which will be hosted and run by Ireland / IMB from 16-19 June 2014 in Dublin (Ireland), followed by a **Train the Trainer** course on 20 June 2014 (http://www.picscheme.org/various.php);

▪ **PIC/S – PDA** (Parenteral Drug Association) **Q7 Training Course**, part of the PIC/S International API Training Programme set up by the PIC/S Expert Circle on API, which regularly delivers general API training in several locations around the world. The next training courses, open to inspectors and industry, will be held in Brussels (Belgium), on 18-19 September 2014 and in Brasilia (Brazil), in October 2014, in co-operation with Brazil / ANVISA (http://www.picscheme.org/various.php)

▪ **PIC/S 2014 Seminar** on "Dedicated Facilities or not" which will be hosted by France / ANSM on 22-24 October 2014 in Paris (France) (http://www.picscheme.org/annual-seminar.php);

▪ **PIC/S Advanced QRM Training Course** for GMP inspectors, which will be hosted by Japan / PMDA in Tokyo (Japan), on 8-10 December 2014, organised by the PIC/S Expert Circle on Quality Risk Management (http://www.picscheme.org/expert-circles.php).