PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

14 November 2011

PRESS RELEASE

PIC/S MEETINGS
CAPE TOWN, SOUTH AFRICA

From 6 to 11 November 2011 the Medicines Control Council (MCC) of South Africa hosted the following events in Cape Town, South Africa: PIC/S Sub-Committee on Training, PIC/S Executive Bureau, PIC/S Committee and annual PIC/S Seminar.

1. PIC/S COMMITTEE MEETING (7-8 November 2011)

The PIC/S Committee met on 7-8 November 2011 under the chairmanship of Mr. Tor Gråberg (Swedish Medical Products Agency / MPA). The meeting was attended by 31 out of 39 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

PIC/S REACHES MEMBERSHIP MILESTONE 40 YEARS AND 40 MEMBERS WITH THE ACCESSION OF SLOVENIAN JAZMP

The Committee invited the Slovenian Agency For Medicinal Products And Medical Devices (JAZMP) to join the Scheme as from 1 January 2012. JAZMP will become PIC/S' 40th Participating Authority the very same year marking the 40th anniversary of PIC/S.

JAZMP applied for membership back in September 2008. An assessment was conducted in view of its accession to PIC/S. A first report was prepared on 29 April 2010, followed by an on-site visit on 19-23 September 2011 to complete the assessment. The audit team recommended to the Committee to accept the membership application of JAZMP.

The admission of JAZMP was welcomed by the JAZMP Delegation led by the Head of Agency Dr. Martina Cvelbar. The PIC/S Chairman thanked both JAZMP and the PIC/S Audit Team.

REVISION OF THE PIC/S SCHEME

The PIC/S Scheme was revised by the Committee in order to reflect several novelties concerning in particular the inclusion of a reference to Good Distribution Practices (GDP), the new PIC/S pre-accession process, the better sharing of information and of confidentiality as well as structural changes.

NEW PIC/S CHAIRPERSON

The PIC/S Committee elected Ms. Helena Baião (Portugal / INFARMED) as Chairperson for the period 2012-2013. This is the first time PIC/S has a Chairperson representing a Participating Authority from Portugal.

NEW MEMBERSHIP APPLICATIONS
JAPAN AND SOUTH KOREA TO JOIN PIC/S IN THE NEAR FUTURE

The PIC/S Chairman informed the Committee that the Competent Authorities of Japan had confirmed their intention to apply for PIC/S membership in the upcoming year.

Mr. Jacques Morénas (French Agency for the Safety of Health Products / AFSSAPS) informed the Committee of his visit in October 2011 to South Korea and underlined the strong commitment expressed at all levels by the Korean Food and Drug Administration (KFDA) in acceding to PIC/S as well as their very good knowledge of PIC/S (notably the assessment process for National Regulatory Authorities) and its requirements. He concluded it was only a matter of time before an application was lodged by KFDA.

NEW PRE-ACCESSION PROCESS

As from July 2011, PIC/S has reviewed its accession guidelines and introduced a new pre-accession process with the advantage of offering a gap-analysis to Competent Authorities which may not be able to comply immediately with all PIC/S requirements.

Armenia's Scientific Centre of Drugs and Medical Technology Expertise (SCDMTE) was the first to take advantage of this new procedure and to submit a pre-accession application request at the occasion of the Committee Meeting on 8 November 2011. Members nominated the Rapporteur and Co-Rapporteur for this first pre-accession.

A pre-accession request was also submitted during the PIC/S seminar on 9 November by Nigeria / NAFDAC.

40TH ANNIVERSARY

The Committee reviewed the symposium organised in order to celebrate PIC/S' 40th anniversary, which took place in Geneva (Switzerland) on 31 May 2011, titled "40 Years of Co-operation & Mutual Confidence: Challenges & Future Perspectives". The anniversary symposium, preceded by an official dinner cruise the evening before, proved to be a great success with more than 160 participants, including the involvement of numerous Heads of Agencies and several non-Members with whom PIC/S was able to establish contact. Several of these non-Members which included Bulgaria, China, Croatia, Georgia, Hong Kong SAR, Hungary (Vet), Japan, Nigeria, Russia, Saudi Arabia, South Korea, Turkey, and Uganda have

since expressed interest in joining PIC/S. The event allowed not only for the celebration of 40 years of PIC/S but also for the promotion of PIC/S and of its contributions to international issues, in particular through the keynote address by US FDA Commissioner Dr. Margaret Hamburg on "The importance of PIC/S in our globalized world". The Chairman commended the Organising Committee and expressed his appreciation to speakers and session chairs for a most well organised and professional event on which PIC/S could capitalize for the development of its new future projects.

OTHER NEWS

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

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

Due to the lack of attendance of the Lithuanian State Medicines Control Agency (SMCA) to PIC/S activities, members decided to conduct a partial re-assessment and appointed a re-assessment team.

The Committee reviewed the membership application of the Indonesian National Agency for Drug and Food Control (NADFC) for which an on-site assessment was performed in November 2010. A follow-up visit, in particular with respect to traditional herbal medicines issues, is scheduled to take place in December 2011 by the audit team.

The Committee reviewed the membership applications of the Taiwan Food and Drug Administration (TFDA) of Chinese Taipei, the United Kingdom's Veterinary Medicines Directorate (VMD), the Philippines Food and Drug Administration (PFDA) and New Zealand's Medicines and Medical Devices Safety Authority (Medsafe), all for which an on-site inspection visit is to be scheduled for the upcoming year.

Members were updated on the membership application of Brazil's Agência Nacional de Vigilância Sanitária (ANVISA) and took note of the recent changes as well as of the commitments undertaken for 2012.

Members noted with concern that the Thai Food and Drug Administration (Thai FDA) might not be able to pass as well as to implement the requested corrective/ preventive actions in time to meet the 6-year timeframe for acceding to PIC/S which will expire in February 2012. Thai FDA requested to allow them to address and complete all the requested corrective/ preventive actions by February 2012. Members endorsed the proposal to wait till end of February to see if sufficient objective evidence would be provided.

Members also reviewed the application of the Iranian Ministry of Health (MoH): the Rapporteur, in charge of the assessment of the application, had finally received documents which were difficult to evaluate as many of these documents were in Farsi. Members decided to postpone the decision about the on-site inspection until the next meeting in Geneva. The on-site visit will be decided after the documents required will be submitted in English to facilitate the assessment.

Finally members took note of the positive outcome of the recent visit by Mr. Jacques Morénas (French Agency for the Safety of Health Products / AFSSAPS) to China SFDA as well as of other follow-ups to contacts for future potential applications from Croatia / MoH & HALMED, Georgia / MoH, Hong-Kong SAR / DoH, Hungary (Vet) / MgSzH, Mexico / COFEPRIS, Nigeria / NAFDAC, Russia / Minpromtorg, Saudi Arabia / SFDA, Serbia / MoH, Turkey / MoH, Uganda / NDA, Zambia / PRA and Zimbabwe / MCAZ.

Exchange of information

Several instruments have successfully been developed, respectively revised to ensure better exchange of information, these include:

- A mapping of the respective competences of PIC/S Participating Authorities;
- A revised list of third countries inspections carried out by PIC/S Participating Authorities;
- A revised list of inspectors from PIC/S.

Training of inspectors

The PIC/S Sub-Committee on Training (SCT) met on 6 November 2011 in the afternoon under the chairpersonship of the First Deputy Chairperson, Ms. Helena Baião (Portugal / INFARMED). The SCT reviewed:

- the statistics for the Joint Visits Programme (JVP) and the reports for the six closed joint visits cycles;
- the first and second Coached Inspections which took place in July and August 2011;
- the report on the second PIC/S training seminar for new inspectors organised by the Irish Medicines Board (IMB) in Dublin (Ireland) in August 2011;
- the proposal by Irish Medicines Board (IMB) on a "train the trainers" initiative to enable other Participating Authorities to run the training seminars for new inspectors;
- the oral report on the advanced training course on APIs developed by the PIC/S Expert Circle on APIs which took place in Singapore on 12-14 October 2011;
- the PIC/S Pluriannual Training Schedule (2009-2012);
- the proposed mandate by the PIC/S Expert Circle on GDP, the proposal by the Expert Circle on Computerised Systems on the revision of the PIC/S Guide on Good Practices for Computerised Systems in Regulated GxP Environments and the new QRM Expert Circle mandate.
- the programme of the 2012 Seminar on "Qualification and Process Validation: Today and Tomorrow" to take place on 3-5 October, hosted in Kyiv, Ukraine, by the Ukrainian State Administration on Medicinal Products (SAUMP).

The SCT recommended to permanently open the JVP to GCP inspectors and discussed how to improve participation of PAs. With regards to Coached Inspections, the SCT noted with satisfaction that the first Coached Inspections had taken place successfully since the programme was established. The SCT welcomed the merits of a "train the trainers" course and discussed relevant topics for this course. Possible options for future annual training seminars were considered.
The Canadian Health Products and Food Branch Inspectorate (HPFPI) confirmed it will host the 2013 seminar in Canada.

Harmonisation of guidance documents

A new consultation procedure between PIC/S and the European Medicines Agency (EMA) had been discussed in order to ensure further improvements in the harmonisation between the EU and the PIC/S GMP Guides and related documents. This new procedure aims at informing each party of ongoing revisions of current documents and endorsement of new documents, including the sharing of early drafts in order to facilitate appropriate involvement in the adoption process.

Members discussed the revision of Annexes 2, 6, 7 and 13 of the PIC/S GMP Guide. Non-EEA Participating Authorities will consult their respective stakeholders shortly.

The Committee discussed and agreed, further to a consultation carried out with non-EEA Participating Authorities, on considering the adoption of a part III to the PIC/S GMP Guide, as a separate document, for guidance documents of a non-legally binding nature.

The Committee also discussed the following two draft PIC/S guidelines on Quality Risk Management (QRM):

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

Both documents were presently ready for formal adoption.

The Committee decided the establishment of two new Working Groups with the following objectives:

- development of a concept paper on whether there is a need to revise the PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments;
- extension of the use of the PIC/S Standard Operating Procedure for handling Rapid Alerts and Recalls arising from Quality Defects to notify serious inspectional issues.

Co-operation with Associated Partners and other Organisations

The Committee discussed amendments to the standing partnership agreements to include a clause to cover the exchange of classified information, in line with PIC/S Note on Confidentiality and on the basis of the recently revised co-operation agreement between PIC/S and EMA. Members instructed the Secretariat to prepare a revision of all partnership agreements.

The strengthening of co-operation with the European Commission, ISPE, PDA and WHO in the field of training and the sharing of training material was encouraged by the Committee.

IN BRIEF…

The Committee …

- elected Ms. Helena Baião (Portugal / INFARMED) as Chairperson for the period 2012-2013;
- elected Dr. Joey Gouws (South Africa / MCC) as First Deputy Chairperson for the period 2012-2013;
- elected Mr. Paul Hargreaves (UK / MHRA) as Second Deputy Chairman for the period 2012-2013;
- re-elected Dr. Vassiliki Revithi (Greece / EOF), as Member of the Bureau for the period 2012-2013;
- re-elected Mr. Boon Meow Hoe (Singapore / HSA) as Member of the Bureau / regional representative for Asia and Australasia for the period 2012-2013;
- re-elected Mr. Jirí Holý (Czech Republic / ISCVBM) as Member of the Bureau / representative for the veterinary Agencies for the period 2012-2013;
- elected Ms. Stephanie Reid (Canada / HPFBI) as Member of the Bureau / regional representative for the Americas for the period 2012-2013;
- elected Ms. Anne Hayes (IMB / Ireland) as Member of the Bureau for the period 2012-2013;
- adopted the 2012 budget;
- adopted the revised Scheme and the Rules of Procedure of PIC/S;
- took note of the PIC/ Blueprint interim report which presents the progress made so far towards achieving the goals outlined by PIC/S in its Blueprint (road map) for the period 2005-2015;
- endorsed the proposal to approach Head of Agencies of Participating Authorities with a letter and proposals of projects for PIC/S future development;
- took note of the amendments of the final draft of the Terms of Reference for PIC/S Subcommittees;
- took note of the holding of a next SCSD meeting in January 2012 in Geneva;
- was given a report on the Executive Bureau meeting on 7 November 2011 in Cape Town during which Executive Bureau members discussed in particular proposals for structural changes to the Bureau, as well as a new funding and communication strategy;
- decided to ask the Expert Circle on Good Distribution Practices (GDP) to clarify its new mandate and proposal for a first meeting in 2012;
- confirmed that the next meeting will take place in Geneva (Switzerland) on 7-8 May 2012;
- thanked Mr. Tor Gråberg (Swedish Medical Products Agency / MPA) for his chairmanship, congratulated him on his successful endeavours as well as for the achievements of PIC/S carried out under his chairmanship and presented him with a gift as token of its recognition.

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2. PIC/S ANNUAL SEMINAR

The PIC/S Committee meeting was followed by a Seminar on "**Good Pharmaceutical Inspection Practices"**, which was held in Cape Town, (South Africa) on 9-11 November 2011.

The PIC/S Seminar was organised by the South African Medicines Control Council (MCC) and was opened by Ms. Mandisa Hela, Registrar of Medicines, Medicines Control Council of South Africa, who took pride in South Africa being the first African country to join PIC/S and the first to hold a PIC/S seminar on the African continent. Her speech was followed by an opening address by Ms. Precious Matsoso, Director General: Health, Department of Health of South Africa, who delivered an address highlighting the growing importance of GMP and of technical co-operation and resource sharing, particularly with respect to the African continent and the role South Africa aspires to play in connection therewith. She concluded her opening address stating that "You [participants to the PIC/S seminar] are the safeguard of public health". Mr. Tor Gråberg, PIC/S Chairman, then delivered an opening presentation on World-Wide GMP (Global Medicines Perfection) trends (principles and philosophy*).*

The Seminar, a first for the African continent, was attended by 128 participants, including participants from 6 African countries namely Botswana, Nigeria, Uganda, Zambia, Zimbabwe and South Africa. This number includes inspectors from the following non-Member agencies / organisations: Armenian Scientific Centre of Drugs and Medical Technology Expertise SCDMTE, Botswana's Ministry Of Health Drugs Regulatory Unit, Bulgarian Drug Agency BDA, Chinese SFDA, European Directorate for the Quality of Medicines & HealthCare (EDQM*), Hong Kong SAR / Department of Health, Indonesian NADFC, Hungarian Central Agricultural Office, Directorate Of Veterinary Medicinal Products, Iranian Ministry of Health, Japanese PMDA and MHLW, New Zealand's Medsafe, Nigerian National Agency For Food and Drug Administration And Control (NAFDAC), Philippines Food and Drug Administration (PFDA), South Korean FDA, Taiwan FDA, Uganda National Drug Authority, the United Nations International Children's Emergency Fund (UNICEF*), the World Health Organisation (WHO*) the Zambian Pharmaceutical Regulatory Authority and the Zimbabwe's Medicines Control Authority.

Among the 128 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*) and academia.

The Seminar's objectives were:

- to address practical aspects relating to the inspection process;
- to equip the inspector with non-technical skills to perform inspections;
- to share amongst inspectors experiences and lessons learned from performing GMP inspections.

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* PIC/S Partners

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

- What to look for regarding company systems and past inspection observations;
- Review similarities and differences for the top 10 deficiencies cited by PIC/S members;
- Identifying "red flags" during inspections – what inspectors must avoid
- Classification of non-compliance / deficiencies with GMP

During the last day of the seminar, two presentations followed by a panel discussion as well as a summary of the workshops were presented.

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Annex

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

MEMBERS	**ACRONYM**
Argentinean National Institute of Drugs *Instituto Nacional de Medicamentos*	INAME
Australian Therapeutic Goods Administration	TGA
Austrian Agency for Health and Food Safety *Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH*	AGES PharmMed
Canadian Health Products and Food Branch Inspectorate	HPFBI
Czech State Institute for Drug Control *Státní Ústav pro Kontrolu Léčiv*	SÚKL
Czech Institute for State Control of Veterinary Biologicals and Medicines	ISCVBM
Danish Medicines Agency	DMA
Estonian State Agency of Medicines	SAM
Finnish Medicines Agency	FIMEA
French Agency for the Safety of Health Products *Agence Française de Sécurité Sanitaire des Produits de Santé*	AFSSAPS
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
Irish Medicines Board	IMB
Italian Medicines Agency *Agenzia Italiana del Farmaco*	AIFA
Malaysian National Pharmaceutical Control Bureau	NPCB
Maltese Medicines Authority	MAM
Netherlands' Inspectorate of Health Care *Inspectie voor de Gezondheidszorg*	IGZ
Norwegian Medicines Agency	NOMA
Polish Main Pharmaceutical Inspectorate	MPI
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**
Taiwan Food and Drug Administration of Chinese Taipei	TFDA
Indonesia's National Agency for Drug and Food Control	NADFC
Iran's Ministry of Health	MoH
New Zealand's Medicines and Medical Devices Safety Authority	Medsafe
Philippines Food and Drug Administration	PFDA

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 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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