PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

8 June 2011

PRESS RELEASE

PIC/S 40th ANNIVERSARY SYMPOSIUM & PIC/S COMMITTEE MEETING

On 31 May 2011, PIC/S hosted an international symposium to commemorate the 40th Anniversary of the Organisation. The symposium was preceded by a PIC/S Committee meeting (on 30 May 2011), which was exceptionally opened to non-Members, and followed by a meeting of the PIC/S Sub-Committee on Training and the PIC/S Executive Bureau (both on 1 June 2011). The symposium also coincided with the first attendance as full Members of PIC/S by the Ukrainian State Inspectorate for Quality Control of Medicines (SIQCM) and the US Food and Drug Administration (FDA). All meetings took place in Geneva (Switzerland).

PIC/S 40th ANNIVERSARY SYMPOSIUM (31 May 2011)

The symposium, entitled "40 Years of Co-operation & Mutual Confidence: Challenges & Future Perspectives", aimed at celebrating 40 years of PIC/S and highlighting PIC/S' contributions to international issues. It was opened by PIC/S Chairman, Mr. Tor Gråberg (Sweden / MPA), who delivered an introductory presentation on "PIC – The Velvet Revolution", during which he underlined the need for PIC/S to further promote co-operation based on communication, mutual trust and harmonisation.

The Chairman's introductory presentation was followed by three sessions on (i) Key considerations for becoming a PIC/S Participating Authority; (ii) Management of risk; and (iii) Challenges ahead and the future of PIC/S. Through a mix of presentations, panel discussions and "Questions & Answers", participants were confronted with a variety of issues such as "Common challenging areas prior to being assessed for PIC/S membership", "Risk to the quality of the medicine, risk to the patient, what has changed since the heparin crisis", "Quality Risk Management: the risks and advantages of the approach for inspections", "How can we balance value, effort and risk in foreign GMP inspections?", "Working with industry and professional organisations: the challenges of remaining independent", and "Managing resources: can inspections be self-sustaining?"

US FDA Commissioner, Dr. Margaret Hamburg, delivered a key note address on "The importance of PIC/S in our globalized world". She called upon all Regulatory Authorities to co-operate more closely and share information on GMP inspections. Due to the globalisation

of the supply chain, a growing part of finished products and Active Pharmaceutical Ingredients (APIs) were imported. Globalisation represented not only new opportunities for manufacturers but also considerable challenges for Regulatory Authorities. No one country was capable of inspecting the world on its own. All PIC/S Members, including the US FDA, needed to think how to best pool resources and work together to protect public health. For the FDA, PIC/S represented the best way to avoid the duplication of efforts and to allocate resources based on risk. FDA considered PIC/S as a "global leader in helping to ensure the quality of drugs". The Commissioner's speech is available for downloading at the following link: http://www.fda.gov/NewsEvents/Speeches/ucm257974.htm (it is also available on the PIC/S web site).

The symposium ended with a closing key note presentation by First Deputy Chairperson, Ms. Helena Baião (Portugal / INFARMED) on "What future for PIC/S?" The presentation included perspectives on PIC/S' future role in various fields such as the harmonisation of GMP or inspector's training. Considering PIC/S' well-established role in the training of inspectors, Ms. Baião suggested that PIC/S creates a professional "Inspectors' Academy" delivering a variety of courses ranging from basic training to highly specialised training for inspectors. Trained inspectors were an asset for all PIC/S Participating Authorities and the most effective way to protect public health and the patient.

160 participants from 55 countries participated in the event, including Competent Authorities from Argentina, Australia, Brazil, China, Chinese Taipei, Croatia, most EU/EEA Member States, Georgia, Hong Kong SAR, Indonesia, Iran, Israel, Japan, Malaysia, New Zealand, Nigeria, Russia, Singapore, Saudi Arabia, South Africa, South Korea, Switzerland, Thailand, Turkey, Uganda, Ukraine, and USA. All PIC/S partners: EMA, EDQM, UNICEF and WHO were equally present as well as professional and industry associations such as APIC, EFPIA, ISPE, IFPMA, PDA. For the list of Participating Agencies and Organisations, see Annex.

PIC/S COMMITTEE MEETING (30 May 2011)

The PIC/S Committee met on 30 May under the chairmanship of Mr. Tor Gråberg (Sweden / MPA). The meeting was attended by 101 participants including representative of 38 out of 39[1] PIC/S Participating Authorities (PA), 7 Applicants, and 4 Associated Partners. As the meeting was exceptionally opened to Non-Members participating in PIC/S' 40th anniversary, representatives from 12 Non-PIC/S Regulatory Authorities took also part in the meeting.

US FDA AND UKRAINE'S SIQCM ATTEND MEETING AS FULL MEMBERS FOR THE FIRST TIME

The Committee welcomed the US Food and Drug Administration (FDA) and the Ukraine's State Inspectorate for Quality Control of Medicines (SIQCM), which joined the PIC Scheme on 1 January 2011 and which attended for the first time a PIC/S Committee as full Members.

PIC/S INTRODUCES A PRE-ACCESSION PROCEDURE

The Committee amended the Accession Guidelines and introduced a pre-accession procedure in order to avoid premature membership applications and to ensure that Applicant Authorities meet basic PIC/S requirements. The amended Guidelines also provide for the possibility for an Applicant to request a "clock stop" during the application process. They also foresee the

[1] Only Lithuania's State Medicines Control Agency did not attend.

right for Applicants to attend PIC/S Committee meetings as Observers during the accession process and the related obligation to pay 50% of the annual membership fee.

The Committee also revised the PIC/S Application Form and Questionnaire in order to align the questionnaire with the 89 criteria of the PIC/S audit check-list, which is used for both the assessment of Applicant Authorities and the re-assessment of PIC/S Participating Authorities.

PIC/S REINFORCES CONFIDENTIALITY WHILE CONSIDERING WHETHER TO EXTEND ITS MANDATE TO GDP

The Committee discussed a proposal to revise the PIC Scheme, which is the Organisation's constitution, as well as the Rules of Procedure in order to reinforce the confidentiality of information exchanged by Participating Authorities (PA) as well as to avoid conflict of interests. The proposals will be officially adopted at the next meeting in Cape Town (7-8 November 2011) following a written consultation during the summer. Among the information exchanged between PA are e.g. scheduled "third country inspections". The information is exchanged in order to avoid that the same product / manufacturing sites is inspected by several PIC/S PA for the same reason. Information on such planned inspections has increased from 295 in 2010 to 735 in 2011.

Members also discussed the possibility of extending PIC/S' mandate to GDP, which is largely supported, as there is a growing number of serious problems encountered during the inspection of the supply chain. The European Medicines Agency (EMA), together with experts from EU Member States, is currently working on a draft GDP Guide. It will soon be released for public consultation by the European Commission and could serve as a basis for the PIC/S GDP Guide. A comparison between the WHO GDP Guide and the draft EU GDP Guide was given at the meeting. The extension of PIC/S' mandate to GDP will be further discussed at the next meeting where a survey on the exact competences of all PIC/S PA in the field of GMDP (Good Manufacturing and Distribution Practice) will be available.

A RECORD NUMBER OF APPLICATIONS…

9 Authorities are in the process of acceding to the Scheme, of which 4 applied in 2010. They are (in alphabetical order):

- Agência Nacional de Vigilância Sanitária (ANVISA), Brazil;
- Agency for Medicinal Products and Medical Devices (JAZMP), Slovenia;
- Bureau of Food and Drugs (BFAD), Philippines;
- Medicines and Medical Devices Safety Authority (Medsafe), New Zealand;
- Ministry of Health (MoH), Iran;
- National Agency for Drug and Food Control (NADFC), Indonesia;
- Taiwan Food and Drug Administration (TFDA), Chinese Taipei;
- Thai Food and Drug Administration (Thai FDA), Thailand;
- Veterinary Medicines Directorate (VMD), United Kingdom.

The membership application by Brazil's ANVISA is still incomplete, as a number of supporting documents, submitted in Portuguese, must first be translated. The applications of TFDA and the Iranian MoH are still at an early stage (so-called "paper evaluation"). On-site assessment visits are scheduled to take place in the next 12 months for Slovenia's JAZMP, the UK's VMD, New Zealand's Medsafe and the Philippines' BFAD (the latter provided that

GMP requirements for traditional medicines are applied). A follow-up visit to Indonesia's NADFC will take place before the end of the year. A decision on the membership application by the Thai FDA will be taken at the next meeting in Cape Town.

… AND MORE AUTHORITIES ARE CONSIDERING APPLYING

The PIC/S Chairman carried out a visit to the Department of Health of Hong Kong SAR in December 2010. The purpose of the visit was to ensure that there was no significant gap between the local GMP requirements and those requested from PIC/S. The visit was very positive and the Department has shown a keen interest in applying for membership. Other Non-Members, who attended the PIC/S Committee meeting, expressed a similar interest. In the margins of the 40th Anniversary, PIC/S Members of the Executive Bureau also met with representatives of the Turkish Ministry of Health, the Competent Authorities of the Russian Federation and Japan's Pharmaceutical and Medical Devices Agency.

FIRST TRAINING COURSE FOR NEW INSPECTORS

For the first time ever, a PIC/S training course for new inspectors has been organised. On 24-28 January 2011 the Irish Medicines Board (IMB) hosted the event in Dublin (Ireland). This first course has been a great success and a second and possibly third course will be organised by IMB this year in Dublin. The course is to a large extent funded by PIC/S while IMB is responsible for elaborating the training module and the practical organisation of the course.

ADVANCED TRAINING COURSE ON APIs

The PIC/S Expert Circle on APIs is in the process of elaborating a training module for an advanced training course for API inspectors. The course is jointly organised by Australia's TGA and Singapore's HSA and will take place in Singapore on 12-14 October 2011. For more information, see http://www.picscheme.org/expert-circles.php

2011 SEMINAR ON "GOOD PHARMACEUTICAL INSPECTION PRACTICES"

On 9-11 November 2011, South Africa / MCC will host a PIC/S Seminar on "Good Pharmaceutical Inspection Practices" in Cape Town. This is the first time ever that a PIC/S Seminar will be held on the African continent. The Seminar will consist in a mix of presentations and workshops. Presentations will be on strengthening and enhancing the skills of an inspector in relation to non technical aspects of the inspection process, which will include the practical aspects of the inspection phases as well as communication, negotiation and reading body language. Workshops will be on issues such as:

- What to look for regarding past inspection observations and quality systems;
- Review similarities and differences for the top 10 deficiencies cited by PIC/S members;
- Identifying "red flags" during inspections – what inspectors should avoid;
- Security and data integrity considerations on record keeping.

The seminar is open to the participation of GMP inspectors from PIC/S and National Drug Regulatory Authorities around the world. For more information, see http://www.picscheme.org/annual-seminar.php

2012 SEMINAR IN THE UKRAINE

Ukraine / SIQCM has generously offered to host the 2012 Seminar in Kiev (1-5 October 2012, subject to confirmation). The Seminar topic is "Qualification and Validation".

OTHER TRAINING EVENTS

The 18th meeting of the Expert Circle on Human Blood, Tissues and Cells will be organised by Estonia / SAM and take place in Tallinn on 26-30 September 2011. For more information, see http://www.picsestonia2011.com/

CO-OPERATION WITH PARTNERS AND OTHER ORGANISATIONS

PIC/S continues to actively co-operate with its Associated Partners (EDQM, EMA, UNICEF and WHO) while co-operating on training issues with professional organisations such as PDA and ISPE. Since the last PIC/S Committee meeting in Kuala Lumpur in November 2010,

- the revised PIC/S – EMA co-operation agreement was signed by the PIC/S Chairman and the outgoing EMA Executive Director, Thomas Lönngren, on 28 December 2010;
- an informal meeting took place on 29 May 2011 between a PIC/S Delegation led by Second Deputy Chairperson, Dr. Joey Gouws (South Africa / MCC), and representatives of WHO / QSM (Medicines) and WHO / IVB (Vaccines). The meeting aimed at strengthening relations in the field of training and avoiding unnecessary duplications, in particular in the field of the assessment of National Drug Regulatory Authorities.

NEXT MEETING

The next PIC/S Committee meetings will take place in Cape Town (South Africa) on 7-8 November 2011.

* * * * * * *

For more information on PIC/S, visit the PIC/S web site at the following link: http://www.picscheme.org/index.php

Annex

List of Authorities and Organisations having participated in the PIC/S 40th Anniversary Symposium

	PIC/S PARTICIPATING AUTHORITIES	ACRONYM
Argentina	Instituto Nacional de Medicamentos *(National Institute of Drugs)*	INAME
Australia	Therapeutic Goods Administration	TGA
Austria	Austrian Agency for Health and Food Safety	AGES
Belgium	Agence Fédérale des Médicaments et des Produits de Santé *(Federal Agency for Medicines and Health Products)*	AFMPS
Canada	Health Products and Food Branch Inspectorate	HPFBI
Cyprus	Pharmaceutical Services	CyPHS
Czech Republic	Státní Ústav pro Kontrolu Léčiv *(State Institute for Drug Control)*	SÚKL
	Ústav pro Státní Kontrolu Veterinárních Biopreparátů a Léčiv *(Czech Institute for State Control of Veterinary Biologicals and Medicines)*	ISCVBM
Denmark	Danish Medicines Agency	DMA
Estonia	State Agency of Medicines	SAM
Finland	Finnish Medicines Agency	FIMEA
France	Agence Française de Sécurité Sanitaire des Produits de Santé *(French Health Products Safety Agency)*	AFSSAPS
	Agence Nationale du Médicament Vétérinaire *(French Agency for Veterinary Medicinal Products)*	ANMV
Germany	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten *(Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices)*	ZLG
Greece	Εθνικός Οργανισμός Φαρμάκων *(National Organization for Medicines)*	EOF
Hungary	National Institute of Pharmacy	NIP
Iceland	The Icelandic Medicines Agency	IMA
Ireland	Irish Medicines Board	IMB
Israel	Institute for the Standardization and Control of Pharmaceuticals	ISCP
Italy	Agenzia Italiana del Farmaco	AIFA
Latvia	Zāļu Valsts Aģentūra *(State Agency of Medicines)*	ZVA
Liechtenstein	Amt für Gesundheit *(Office of Healthcare)*	AG
Malaysia	National Pharmaceutical Control Bureau	NPCB
Malta	Medicines Authority Malta	MAM
Netherlands	Inspectie voor de Gezondheidszorg *(Inspectorate of Health Care)*	IGZ

	PIC/S PARTICIPATING AUTHORITIES (cont'd)	**ACRONYM**
Norway	Norwegian Medicines Agency	NOMA
Poland	Main Pharmaceutical Inspectorate	MPI
Portugal	Instituto Nacional da Farmácia e do Medicamento	INFARMED
Romania	National Agency for Medicines and Medical Devices	NAMMD
Singapore	Health Sciences Authority	HSA
Slovak Republic	State Institute for Drug Control	SIDC
South Africa	Medicines Control Council	MCC
Spain	Agencia Española del Medicamento y Productos Sanitarios *(Spanish Agency of Drugs and Health Products)*	AEMPS
Sweden	Medical Products Agency	MPA
Switzerland	Swiss Agency for Therapeutic Products	Swissmedic
Ukraine	State Inspectorate for Quality Control of Medicines	SIQCM
United Kingdom	Medicines and Healthcare Products Regulatory Agency	MHRA
United States of America	United States Food and Drug Administration	US FDA
	PIC/S APPLICANTS	
Brazil	Agência Nacional de Vigilância Sanitária	ANVISA
Chinese Taipei	Taiwan Food and Drug Administration	TFDA
Indonesia	National Agency for Drug and Food Control	NADFC
Iran	Ministry of Health	MoH
New Zealand	Medicines and Medical Devices Safety Authority	Medsafe
Slovenia	Agency for Medicinal Products and Medical Devices	JAZMP
Thailand	Food and Drug Administration	FDA
United Kingdom	Veterinary Medicines Directorate	VMD
	PIC/S ASSOCIATED PARTNERS	
	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
	NON-MEMBERS	
Bulgaria	Bulgarian Drug Agency	BDA
China	State Food and Drug Administration	SFDA
Hong Kong SAR	Department of Health	DoH
Croatia	Agency for Medicinal Products and Medical Devices	HALMED
Georgia	State Regulation Agency for Medical Activity	MoH
Hungary	Directorate of Veterinary Medicinal Products	MgSzH

	NON-MEMBERS (cont'd)	**ACRONYM**
Japan	Pharmaceuticals and Medical Devices Agency	PMDA
Nigeria	National Agency for Food and Drug Administration and Control	NAFDAC
Russia	Federal Service on Surveillance in Healthcare and Social Development	Roszdravnadzor
	Ministry of Trade and Industry	Minpromtorg
Saudi Arabia	Saudi Food & Drug Authority	SFDA
South Korea	Korea Food & Drug Administration	KFDA
Turkey	Ministry of Health	MoH
Uganda	National Drug Authority	NDA
	PROFESSIONAL AND OTHER ORGANISATIONS	
	Active Pharmaceutical Ingredients Committee	APIC
	European Federation of Pharmaceutical Industries and Associations	EFPIA
	International Federation of Pharmaceutical Manufacturers & Associations	IFPMA
	International Society for Pharmaceutical Engineering	ISPE
	Parenteral Drug Association	PDA

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

* * * * * * *