PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

17 November 2009

PRESS RELEASE

PIC/S COMMITTEE MEETING
UPPSALA, SWEDEN

The PIC/S Committee met in Uppsala (Sweden) on **2-3 November 2009** in conjunction with the 2009 Annual Seminar. The meeting was attended by 36 out of 37 PIC/S Participating Authorities (PA) as well as by a number of Applicants and Associated Partners. For the list of participants, see Annex I.

MAIN NEWS

JACQUES MORÉNAS HANDS OVER TO TOR GRÅBERG

This was the last meeting chaired by Mr. Jacques Morénas (French Agency for the Safety of Health Products) after a mandate of 4 years – the longest ever in PIC/S' history. During these years, PIC/S expanded from 28 to 37 Participating Authorities and signed co-operation agreements with UNICEF, EMEA, EDQM and WHO. Co-operation with professional associations such as ISPE and PDA was also stepped up by Mr. Morénas, who will be replaced by Mr. Tor Gråberg (Sweden / MPA) as from 1 January 2010. After the chairmanship of Ms. Lilian Hamilton (2002-2003), this is the second time in less than 10 years that MPA has provided a Chairperson to PIC/S. It underlines MPA's pre-eminent role in providing leadership in European (EMEA) and international public health organisations.

US FDA: A GIANT LEAP FORWARD

The US FDA has made a giant leap forward in the PIC/S accession process. A PIC/S Delegation, headed by Mr. Paul Hargreaves (United Kingdom / MHRA), made a 2-week on-site assessment visit in the USA in August 2009: more progress was achieved during these two weeks than during the previous three years of assessment! The team assessed the US GMP inspection system and also observed inspections carried out by FDA inspectors. It also met with FDA Commissioner, Dr. Margaret Hamburg, who stated that PIC/S membership was a top priority for the FDA. The PIC/S assessment report has been forwarded to the FDA for comments. The latter are now awaited. The FDA sent a small but highly competent

Delegation to Uppsala comprising Ms. Brenda Holman (ORA) and Mr. Carmelo Rosa (CDER).

NEW, ENLARGED EXECUTIVE BUREAU

The PIC/S Committee has elected a new Executive Bureau for the period 2010-2011, which has been enlarged on a trial basis in order to better reach out to all continents, in particular Asia, where PIC/S is rapidly expanding – notably among ASEAN nations. Africa, Southern and Eastern Europe as well as veterinary Agencies are now also better represented, as reflected in the new composition of the Bureau: Mr. Tor Gråberg (Sweden / MPA), Chairman; Ms. Helena Baião (Portugal / INFARMED), First Deputy Chairperson; Dr. Joey Gouws (South Africa / MCC), Second Deputy Chairperson; Mr. Paul Hargreaves (United Kingdom / MHRA), Member; Dr. Vassiliki Revithi (Greece / EOF), Member; Mr. Boon Meow Hoe (Singapore / HSA), Alternate Member; and Mr. Jirí Holy (Czech Republic / ISCVBM), Alternate Member.

INTERPRETATION OF ANNEX I

The Committee has adopted a long-awaited technical interpretation of the revised Annex 1 to the PIC/S GMP Guide, which had been prepared by Swissmedic. The interpretation will be soon available on the PIC/S web site. Annex 1 of the PIC/S GMP Guide is identical to Annex 1 of the EU GMP Guide (both Guides are equivalent in terms of GMP requirements).

OTHER NEWS

Improving PIC/S' structure and operation

The Committee has continued its discussions on how to best reshape PIC/S in order to remain efficient and better involve both Members and non-Members. It has decided to create a Sub-Committee on Strategic Development which will be in charge of defining PIC/S' strategy and future policy as well as considering whether to increase the number of Sub-Committees.

The Committee has also discussed a consolidated proposal on a two-tier membership system, prepared by TGA / Australia. The proposal aims at better integrating non-Members, which do not fulfil PIC/S requirements. The proposal will be further discussed at the next meeting – in particular with regard to scope, requirements and procedure.

Members have also decided to identify possible differences between Participating Authorities in terms of regulation, classification and inspection regarding specific sub-categories of medicinal products (e.g. herbal, veterinary, medicinal gases, radiopharmaceuticals, etc.).

Assessing (or re-assessing) Austria, Indonesia, Iran, Latvia, Philippines, Slovenia, Thailand, and Ukraine

The Committee has agreed to conduct an on-site assessment visit in the Ukraine in March 2010 and nominated the visiting team. It has also nominated the Rapporteurs and Co-Rapporteurs for the assessment of the membership applications of the Ministry of Health of Iran and the Bureau of Food and Drugs of the Philippines, respectively (both applied in 2009).

The Committee has reviewed the membership applications of Indonesia / NADFC, Slovenia / JAZMP, and Thailand's FDA. It has closed the reassessment of Austria's Medicines and Medical Devices Agency (AGES PharmMed) following the successful on-site visit in Austria in May 2009. The next reassessment will be that of Latvia's State Agency of Medicines (ZVA).

On 5 November 2009, in the margin of the meetings in Uppsala, Mr. Jacques Morénas (PIC/S Chair), Mr. Daniel Brunner (PIC/S Secretary), and Mr. André Kovacs (PIC/S Assistant Secretary) met with a Delegation from the Federation of Russia led by Prof. Sergey Maksimov, Head of the Division of Licensing at the Federal Agency for the Supervision of Healthcare and Social Development (Roszdravnadzor). The meeting was very positive and highlighted Roszdravnadzor's intention to submit a membership application, once an action plan, designed to meet PIC/S requirements, had been completed. The PIC/S Chair was invited to Moscow in order to explain PIC/S to Roszdravnadzor and Russian industry.

Planning ahead the training for inspectors

The Committee has adopted a pluriannual training schedule listing all PIC/S training activities for the period 2009-2012 in order to better plan and summarise its training activities (Seminars, Expert Circle meetings, Joint Visits, Coached Inspections, etc.). The schedule will be made available on the PIC/S web page dedicated to training in the near future.

Members have also reviewed the programme of the 2010 Seminar on the "Inspection of Traditional Medicines", which will take place in Kuala Lumpur (Malaysia) on 10-12 November 2010. They have also taken note that the 2011 Seminar, hosted by South Africa, will be on "Good Inspection Practices".

New or revised Guidance Documents

The Committee has adopted a revised PIC/S SOP for Handling Rapid Alerts (PI 010-4) in parallel with the revision of the EU Rapid Alert Procedure. It has decided to launch a public consultation of national and international industry associations on the revision of the Site Master File (PE 008-4 (Draft 6)). It has agreed to consult PIC/S PAs by written procedure regarding the revision of Annex 7 to the PIC/S GMP Guide in the light of some concerns expressed by TGA/Australia. It has finally endorsed an illustrative example of methodology for the implementation of QRM in pharmaceutical industry (to be published on the PIC/S web site).

Co-operation with Associated Partners and other Organisations

The Committee has been given an update on recent GMP activities undertaken by its Partners (EDQM, EMEA, UNICEF & WHO) and other bodies (ASEAN, ICH, ISPE & PDA).

Members have noted that the ASEAN sectoral MRA for GMP Inspections, signed in April 2009 by ASEAN Member States and using the PIC/S GMP system as benchmarking, should be fully implemented by 1 January 2011.

The Committee has expressed its satisfaction that both the European Directorate for the Quality of Medicines & Healthcare (EDQM) and UNICEF are now sharing their scheduled inspections with PIC/S and that a co-operation arrangement with WHO was signed on 27 May 2009. Co-operation with the WHO Department on the Quality & Safety of Medicines, in particular the pre-qualification programme, has substantially progressed over the past few months.

Members have noted that the ICH Quality Implementation Working Group is developing a training program for workshops to be held in the three ICH regions in 2010.

IN BRIEF…

The Committee has…

- noted an oral report by the Chairman on the Executive Bureau meeting in Uppsala on 2 November 2009;
- adopted a Note describing the services provided by the PIC/S Secretariat, which will be published – together with a Compilation of PIC/S Documents – on a web page accessible to Members only;
- approved the 2009 accounts and discharged the Chairman for the financial year 2009;
- adopted the budget for 2010 for CHF 525,400;
- adopted a revision of the PIC/S Financial Rules, which will transfer financial responsibilities from the Chair to the Secretary as from 2010;
- confirmed that the next meetings would take place in Geneva (Switzerland) on 19-20 May 2010 and in Kuala Lumpur (Malaysia) on 8-9 November 2010.

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

	MEMBERS	ACRONYM
Argentina	Instituto Nacional de Medicamentos	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	AFMPS
Canada	Health Products and Food Branch Inspectorate	HPFBI
Cyprus	Pharmaceutical Services	CyPHS
Czech Republic	Státní Ústav pro Kontrolu Léčiv	SÚKL
	Ústav pro Státní Kontrolu Veterinárních Biopreparátů a Léčiv	ISCVBM
Denmark	Danish Medicines Agency	DMA
Estonia	State Agency of Medicines	SAM
Finland	National Agency for Medicines	NAM
France	Agence Française de Sécurité Sanitaire des Produits de Santé	AFSSAPS
	Agence Nationale du Médicament Vétérinaire	ANMV
Germany	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten	ZLG
Greece	Εθνικός Οργανισμός Φαρμάκων	EOF
Hungary	National Institute of Pharmacy	NIP
Iceland	The Icelandic Medicines Control Agency	IMCA
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	ZVA
Lithuania	State Medicines Control Agency	SMCA
Malaysia	National Pharmaceutical Control Bureau	NPCB
Malta	Medicines Authority Malta	MAM
Netherlands	Inspectie voor de Gezondheidszorg	IGZ
Norway	Norwegian Medicines Agency	NOMA
Poland	Main Pharmaceutical Inspectorate	MPI
Portugal	Instituto Nacional da Farmácia e do Medicamento	INFARMED
Romania	National Medicines Agency	NMA
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	AEMPS
Sweden	Medical Products Agency	MPA
Switzerland	Swiss Agency for Therapeutic Products	Swissmedic
United Kingdom	Medicines and Healthcare Products Regulatory Agency	MHRA

List of Authorities having participated in the PIC/S Committee Meeting (cont'd)

	APPLICANTS	ACRONYM
Indonesia	National Agency of Drug and Food Control	NADFC
Slovenia	Agency for Medicinal Products and Medical Devices	JAZMP
Ukraine	State Inspectorate for Quality Control of Medicines	SIQCM
USA	Food and Drug Administration	FDA

	PARTNERS	ACRONYM
	European Directorate for the Quality of Medicines & HealthCare	EDQM
	European Medicines Agency	EMEA
	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 37 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#, and the United Kingdom#.

2009 PIC/S SEMINAR –UPPSALA

The PIC/S Committee meeting was followed by a Seminar on "**Aseptic & Sterile manufacturing from API to finished dosage forms**", which was held in Uppsala (Sweden) on 4-6 November 2009.

The PIC/S Seminar was organised by the Swedish Medical Products Agency (MPA). It was attended by 103 participants from 44 countries. This number includes inspectors from a number of non-Member agencies coming from Croatia, the European Medicines Agency (EMEA*), Indonesia, the European Directorate for the Quality of Medicines (EDQM*), Hong Kong SAR, Indonesia, Japan, New Zealand, South Korea, Thailand, Taipei, the Ukraine, UNICEF*, US FDA and WHO*.

Among the 103 seminar participants were also a number of speakers, session chairpersons and workshop leaders. Speakers were provided by PIC/S Participating Authorities, academia and industry.

The Seminar's objectives were:

1) To create an understanding for the rapid development within aseptic / sterile manufacturing. To explain some technical challenges that inspectors will face.

2) To harmonise specific topics correlated to aseptic and sterile manufacturing in order to facilitate the interpretation of GMP and the conduct of inspections.

3) To highlight future trends for industry and regulators.

The 2.5 day seminar started with a series of lectures and presentations given by academia, inspectors, etc. and was followed by four workshops on the 2nd day of the seminar dealing with:

- How to inspect aseptic/sterile manufacturing?
- Microbiological Rapid Methods
- Interpretation of revised Annex 1
- How is Annex 1 applicable during API manufacturing?

During the last day of the seminar, a summary of the workshops as well as future trends were presented.

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* PIC/S Partners