ANNUAL REPORT 2009

New Members

1. On 1 January 2009, France's Agency for Veterinary Medicinal Products (AFSSA – ANMV) and Israel's Institute for Standardization and Control of Pharmaceuticals (ISCP) became the 35th and 36th Participating Authorities of PIC/S, respectively.

2. On 1 July 2009, the State Medicines Control Agency (SMCA) of Lithuania joined PIC/S as the 37th Participating Authority.

Pharmaceutical Inspection Co-operation Scheme

The Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) is an informal and flexible arrangement between GMP inspectorates. It entered into force in November 1995. It is run in parallel with the Pharmaceutical Inspection Convention (see Annex II). The common logo for both is PIC/S.

The Scheme retains and improves the Convention's main features, i.e. the networking and confidence building between the national inspection authorities, the development of quality systems, the training of inspectors and other related experts and its work towards global harmonisation of GMP. It is open to the participation of the inspectorates of other countries.

The main decision-making body is the PIC/S Committee in which all Members are represented and which meets at least once a year. The Committee is assisted in its task by an Executive Bureau and a Secretariat.

The PIC/S Executive Bureau's task is to prepare meetings of the Committee, implement the latter's decisions and recommendations, monitor the Scheme's activities and prepare the annual budget. The Bureau is composed of the Chairperson, two Deputies as well as two Members of the Committee. The Composition was amended at the PIC/S Committee meeting of Uppsala (2-3 November 2009) in order to better reflect the regional representation of PIC/S.

Operation of the Scheme

3. In 2009, the PIC/S Committee met twice under the chairmanship of Mr. Jacques Morénas (France / French Health Products Safety Agency) first in Geneva (Switzerland) on 5-6 May 2009 and then in Uppsala (Sweden) on 2-3 November 2009.

4. During these meetings, the Committee:

- continued to discuss the ways to improve the operation of PIC/S and to reshape the organisation in order to remain efficient and to better co-operate with non-Members;
- created a Sub-Committee on Strategic Development aiming at defining PIC/S' strategy and future policy;
- decided to organise a consultation on Participating Authorities' competences in terms of regulation, classification and inspection of sub-categories of medicinal products;
- initiated a survey on the celebration of PIC/S' 40-years jubilee in 2011.

5. In line with its mandate, the Committee reviewed the assessment of new Applicants and the reassessment of older Participating Authorities (see "Membership Applications", below). It also monitored the activities of the Working Group on Training (WGT), the Working Group on the Structure and Operation (WGSO) and the Executive Bureau (EB).

6. The Committee also approved the 2008 accounts, discharged the Chairman for the financial year 2008 and approved the 2009 budget. It also adopted several guidance documents and revised the PIC/S GMP Guide (see "Harmonisation of Guidance documents" below).

7. The Executive Bureau met twice in Geneva (on 26 March and 4 May 2009) and twice in Uppsala (on 2 and 3 November 2009). These meetings were mainly dedicated:

- to discuss financial, administrative and staff related issues;
- to assist the Chairman in the execution of his mandate and;
- to prepare the meetings of the Committee.

8. The Working Group on the Training of Inspectors met in Geneva on 5 May 2009. The meeting was chaired by the First Deputy Chairman, Mr. Tor Gråberg (Sweden / MPA). For more information on the activities of the Working Group on Training, see "Training of Inspectors" below.

9. The newly created Working Group on the Structure an Operation of PIC/S held its first meeting in Geneva on 26 March 2009. The meeting focused on i) reviewing the results of the consultation of Participating Authorities on the operation and the structure of PIC/S; and ii) developing different options in order to improve the current system. The following proposals were considered:

- enlarging of the Executive Bureau;
- restructuring of the Secretariat;
- creating of a sub-committee system;
- introducing of a two-tier membership system.

10. In 2009, the PIC/S Secretariat continued to provide secretariat services to the various PIC/S bodies (Committee, Executive Bureau, Working Group on Training, Working Group on Structure and Operation).

The Participating Authorities of the PIC/S
(Convention and Scheme taken together)

By the end of 2009, PIC/S comprised 37 inspectorates from Argentina, Australia, Austria, Belgium, Canada, Cyprus, Czech Republic (human & veterinary), Denmark, Estonia, Finland, France (human & 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 (see also Annex I).

Membership Applications: Iran and the Philippines apply

11. The membership applications of Iran's Ministry of Health and the Philippines' Bureau of Food and Drugs (BFAD) were lodged on 28 April and 1 June 2009, respectively. After an initial pre-assessment of the application files, the Committee appointed a Rapporteur and a Co-Rapporteur for assessing each application.

12. An on-site assessment visit to USA's Food and Drug Administration (US FDA) took place from 10-14 August and 17-21 August 2009. The team assessed the US GMP inspection system (US FDA headquarters and regional offices) and observed inspections carried out by US FDA inspectors. It also met with US FDA Commissioner, Dr. Margaret Hamburg, who ensured that US FDA's accession to PIC/S was a priority. Considerable progress was achieved during the visit, while the team considered that the remaining outstanding issues could be easily rectified by the Applicant.

13. The membership application by the Ukraine's Competent Authority was discussed in the light of the latter's new reorganisation – the second full reorganisation since the application was submitted in 2004[1]. The Committee decided to continue with the assessment process initiated in 2004 and nominated an audit team to conduct an on-site assessment visit in the Ukraine in March 2010.

14. The Committee noted the preliminary assessment report on the application by Slovenia's Agency for Medicinal Products and Medical Devices (JAZMP) and was given a presentation on the Slovenian GMP inspection system. It also agreed to possibly waive the on-site assessment visit to Slovenia, provided that the Canadian MRA visit in Slovenia was conducted before the end of 2010.

15. The Committee reviewed the membership application of Indonesia's National Agency of Drug and Food Control (NADFC) in the light of the Rapporteur's preliminary report. It also discussed with an Indonesian delegation the exact scope of NADFC's application, notably with regard to the inspection of herbal medicines.

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[1] In March 2009, the State Inspection on Medical Drugs Quality Control was replaced by the State Inspectorate for Quality Control of Medicines (SIQCM).

16. The Rapporteur in charge of the assessment of Thailand's Food and Drug Administration (Thai FDA) continued to follow-up the implementation process of corrective actions.

Reassessment of Participating Authorities

17. Following the successful on-site visit in Austria in May 2009, the reassessment of Austria's Medicines and Medical Devices Agency (AGES PharmMed) was closed. The Committee thus decided to launch the reassessment of Latvia's State Agency of Medicines (ZVA).

Joint Reassessment Programme (JRP)

For many years, only Applicants to the Convention or the Scheme were subject to assessment. Founding Members were, however, never assessed. In order ensure that both new applicants and older members fulfil the same requirements, a Joint Reassessment Programme (JRP) was launched in 2000 under which existing PIC/S members are now also reassessed for equivalence on a regular basis. It is run in parallel with the EU's Joint Audit Programme (JAP) and uses basically the same tools.

Training of Inspectors

18. In 2009, the Working Group on the Training of Inspectors:

- prepared PIC/S' pluriannual training schedule summarising the organisation's present and future training activities;
- discussed the organisation of a training seminar for new inspectors;
- reviewed the yearly objectives of all PIC/S Expert Circles and Working Groups;
- monitored the operation of the Joint Visit Programme;
- discussed the possibility to develop web-based training for inspectors;
- monitored the preparation for the 2009 Seminar (see below);
- made comments on the draft programme of the 2010 Seminar on the "Inspection of Traditional Medicines" (Kuala Lumpur, 10-12 November 2010);
- noted that South Africa would host the 2011 PIC/S Seminar on "Good Inspection Practices".

Joint Visits Programme and Coached Inspections Programme

19. At the end of 2009, there were 28 active joint visit groups under the Joint Visits Programme, representing more than 80 inspectors from around 20 different nationalities.

20. In order to provide training to new inspectors or inspectors wishing to improve their inspection skills in a specific field, PIC/S introduced in 2009 a programme on coached inspections. The programme consists in teaming up a junior inspector with an experimented inspector during a routine inspection. The programme is open to inspectors from Participating Authorities and Applicants.

PIC/S Joint Visit Groups

Another means of training inspectors of the PIC/S countries has been devised in the form of joint visits to manufacturers by inspectors of different countries. Groups of three inspectors are set up on the basis of applications sent to the PIC/S Secretariat. Each inspector is assigned within his/her group to act in turn as host for one year and guest for the other two years.

Visits are carried out in English or in a language commonly agreed by inspectors. Joint reports are drafted after each visit and sent to the Committee for evaluation.

The organisation of the joint visits has proved an excellent means for the further training of inspectors through mutual exchange of experience and a useful contribution to the maintenance of mutual confidence between competent authorities. Participants have also the possibility to discuss and compare their inspection methods and their interpretation of GMP rules.

2009 PIC/S Seminar in Uppsala

21. The 2009 Seminar was organised by the Swedish Medical Products Agency (MPA). It was held in Uppsala (Sweden) from 4 to 6 November 2009 on "Aseptic and Sterile Manufacturing from APIs to Finished Dosage Forms".

22. The Seminar was attended by 103 participants from 44 countries including inspectors from a number of non-Member agencies coming from Croatia, the European Medicines Agency (EMA*), 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*.

23. The Seminar focused on the following objectives:

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.

24. The 2.5 day seminar was composed of lectures and presentations given by academia, inspectors and industry. They were completed by four workshops on:

- How to inspect aseptic/sterile manufacturing?;
- Microbiological rapid methods;
- Interpretation of revised Annex 1;
- How is Annex 1 applicable during API manufacturing?

* PIC/S Partners

25. The Seminar had been very successful and participants were generally satisfied with the overall organisation but also with the scientific content of presentation and workshops.

Expert Circles & Working Groups

Expert Circle on APIs

26. The Expert Circle on APIs did not meet during the year 2009. The 3rd meeting of the Expert Circle will take place in Dublin (Ireland) in May 2010.

Expert Circle on Computerised Systems

27. The 7th meeting of the Expert Circle on Computerised Systems took place in Melbourne (Australia) on 23-26 November 2009. During the meeting a new training module on computerised systems' inspection was delivered. Around 25 inspectors participated in the training, among which almost 50% came from Asian Competent Authorities.

Expert Circle on Human Blood and Tissue

28. Denmark / DMA organised the 16th meeting of the Expert Circle on Human Blood, Tissue and Cells in Copenhagen (Denmark) on 22-24 September 2009. The meeting was attended by 51 participants from 26 countries. The programme comprised eleven technical sessions, including three workshops. Presentations were given by inspectors, representatives from the WHO and industry.

Expert Circle on Quality Risk Management (QRM)

29. The 4th meeting of the Expert Circle on QRM took place in Saint-Denis (France) on 27-28 April 2009. During the meeting, hosted by France / AFSSAPS, a working group worked on the finalisation of a training programme for inspectors on the inspection of quality risk management systems. Two other working groups further developed i) models for quality risk management systems for inspectorates and ii) guidance on the assessment of quality risk management implementation in industry.

Why Expert Circles?

PIC/S Expert Circles have been set up by the PIC/S Joint Committee to facilitate the discussions and the exchange of information among inspectors specialised in a specific area of GMP such as blood, computerised systems, active pharmaceutical ingredients, quality risk management, etc. Expert Circles meet regularly to develop draft guidance, recommendations, etc. and offer training in their respective fields of specialisation.

Working Group on Annex 3 to PE 010

30. The 1st meeting of the Working Group on Annex 3 to the PIC/S Guide on Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE 010), took place in London (United Kingdom) on 18-19 June 2009. The meeting was organised by United Kingdom / MHRA and included presentations (on e.g. small-

scale production of radiopharmaceuticals, PET, etc.) and discussions on the way to initiate the drafting of the new Annex 3 to PE 010.

Working Group on Good Distribution Practices (GDP)

31. The Working Group on GDP met for the second time in Dublin (Ireland) on 31 March – 2 April 2009. The aim of the meeting was to review the draft guidance documents on GDP, developed by the WG. The meeting also included several presentations and case studies (on e.g. suspension of a wholesaler's license and interruption of the cold chain during transport).

Harmonisation of guidance documents

32. In 2009, PIC/S adopted a Recommendation (PI 032-2) for the technical interpretation of Annex 1 to the PIC/S GMP Guide, which has been prepared by Switzerland / Swissmedic. The Recommendation is the outcome of joint consultations of EEA and PIC/S Competent Authorities. It summarises the interpretations which an inspector should adopt when performing an inspection of a manufacturer of sterile medicinal products and reflects the most important changes introduced in the revised Annex 1.

33. A revised PIC/S GMP Guide (PE 009-9) entered into force on 1 September 2009, following the revision of Annex 3 on the manufacture of radiopharmaceuticals.

34. The following PIC/S documents were also adopted / revised in the course of 2009:

- Standard Operating Procedure (SOP) on Team Inspections (PI 031-1);
- Recommendation on Aseptic Processes (PI 007-5)

35. The list of PIC/S publications is available on the PIC/S web site: http://www.picscheme.org

Relations with other organisations

ASEAN

36. The PIC/S Committee noted with satisfaction that the ASEAN Sectoral Mutual Recognition Arrangement (MRA) on the GMP inspection of manufacturers of medicinal products was signed in 2009. The latter takes the PIC/S GMP system and the PIC/S Quality System Requirements for Pharmaceutical Inspectorates as a benchmark for ASEAN integration in the field of GMP. ASEAN Nations wishing to join the MRA should either be a PIC/S Participating Authority or demonstrate that they operate a PIC/S-equivalent GMP inspection system.

Europe

37. Throughout 2009, PIC/S continued to maintain a fruitful co-operation with the European Directorate for the Quality of Medicines & Healthcare (EDQM) and with the European Medicines Agency (EMA).

UNICEF

On 15 January 2009, PIC/S signed a co-operation agreement with UNICEF's Supply Division, notably on the sharing of information (e.g. third-country inspection schedules).

WHO

38. A co-operation arrangement between PIC/S and WHO was signed on 27 May 2009. Co-operation with WHO's Department on the Quality & Safety of Medicines, in particular the pre-qualification programme, made substantial progresses during the year.

PIC/S website

39. In the course of 2009, the following upgrades were performed on the PIC/S website (www.picscheme.org):

- the page "Publications" was reorganised in order to facilitate the overview on the different categories of documents dedicated to inspectorates and industry;
- the "Training" page was developed in order to better describe and "advertise" PIC/S training activities (as well as some non-PIC/S training events);
- a new page "Accession" was created describing PIC/S membership requirements and the accession procedure;
- the password-restricted "Members Area" was upgraded in order to create different sub-areas (e.g. Committee, Expert Circles, etc.).

Elections

40. In Uppsala, the Committee elected Mr. Tor Gråberg (Sweden / MPA) as PIC/S Chairman for the period 2010 – 2011. It also elected Ms. Helena Baião (Portugal / INFARMED) as First Deputy Chairperson and Dr. Joey Gouws (South Africa / MCC) as Second Deputy Chairperson, for the same period. The composition of the Executive Bureau was completed by the (re-)election of Dr. Vassiliki Revithi (Greece / EOF), Member; Mr. Paul Hargreaves (United Kingdom / MHRA), Member; Mr. Boon Meow Hoe (Singapore / HSA), Alternate Member representing the Australasian region; and Mr. Jirí Holy (Czech Republic / ISCVBM), Alternate Member representing the veterinary sector.

LIST OF PIC/S
PARTICIPATING AUTHORITIES & PARTNERS
(as of 31 December 2009)

I - PARTICIPATING AUTHORITIES

(in the alphabetical order of the country in which they are located)

	PARTICIPATING AUTHORITY	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 *(Institute for State Control of Veterinary Biologicals and Medicaments)*	ISCVBM
Denmark	Danish Medicines Agency	DMA
Estonia	State Agency of Medicines	SAM
Finland	Finnish Medical Agency	FIMEA
France	Agence Française de Sécurité Sanitaire des Produits de Santé *(French Health Products Safety Agency)*	AFSSAPS
	Agence Nationale du Medicament Veterinaire *(French Agency for Veterinary Medicinal Products)*	ANMV
Germany	Bundesministerium für Gesundheit *(Federal Ministry for Health)*	BMG
	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 Control Agency	IMCA
Ireland	Irish Medicines Board	IMB
Israel	Institute for the Standardization and Control of Pharmaceuticals	ISCP

Italy	Agenzia Italiana del Fármaco	AIFA
Latvia	Zāļu Valsts Aģentūra *(State Agency of Medicines)*	ZVA
Liechtenstein	Amt für Gesundheit	AG
Lithuania	State Medicines Control Agency	SMCA
Malaysia	National Pharmaceutical Control Bureau	NPCB
Malta	Medicines Authority	MAM
Netherlands	Inspectie voor de Gezondheidszorg *(Inspectorate of Health Care)*	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

II – PARTNERS

(in the alphabetical order of their acronyms)

	PARTNER	**ACRONYM**
	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

From the Pharmaceutical Inspection Convention

to the Pharmaceutical Inspection Co-operation Scheme

The Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products (Pharmaceutical Inspection Convention) entered into force in 1971.

The Convention applies to inspection of the manufacture of medicinal and related products intended for human use, which are subject to control under health legislation. It provides that the Contracting States will exchange, on the basis of inspections, such information as is necessary for the health authorities in an importing Contracting State to be able to recognise inspections carried out in the Contracting State of the manufacturer.

In 2000 the Convention was operating between eighteen countries, namely, Australia, Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Liechtenstein, Norway, Portugal, Romania, Sweden, Switzerland and the United Kingdom

Due to some incompatibility for the Member States of the European Union (and for the States parties to the European Economic Area) between their obligations under the Convention and under the EU, the conclusion of another type of agreement than the Convention was agreed upon. This is an arrangement between the inspectorates of the present Contracting States to the Convention but also open to the participation of the inspectorates of other countries. The new arrangement called "Pharmaceutical Inspection Co-operation Scheme" (or PIC Scheme) was put into force in November 1995.

The Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Co-operation Scheme are run concurrently by one joint Committee and one Secretariat. The common logo for both is PIC/S.