



ANNUAL REPORT 2006

1. 2006 was another year of successful expansion with two additional pharmaceutical inspectorates accepted as PIC/S Participating Authorities.
2. Poland's Main Pharmaceutical Inspectorate (MPI) became PIC/S' 29th Participating Authority on 1 January 2006. MPI has been admitted following a successful evaluation of the Polish GMP system (including an assessment visit by a PIC/S Delegation in Poland).
3. Estonia's State Agency of Medicines (SAM) was admitted at the autumn meeting of the PIC/S Committee to become PIC/S' 30th Participating Authority with effect from 1 January 2007. SAM, which has been an Observer in PIC/S since 2001, has been admitted after a long but successful evaluation, which also included an on-site assessment visit.

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.

Operation of the Scheme

4. The PIC/S Committee, the PIC/S Executive Bureau and the PIC/S Working Group on the Training of Inspectors met twice in the course of 2006.

5. The PIC/S Committee met under the chairmanship of Mr. Jacques Moréas (France / French Health Products Safety Agency) in Düsseldorf (Germany) on 29-30 May 2006 and in Geneva (Switzerland) on 21-22 November 2006.

6. During these two meetings, the Committee approved the 2005 accounts; it discharged the Chairman for the financial year 2005; and it adopted a budget for 2007. It also reviewed the operation of the Scheme, the assessment of new Applicants and the reassessment of older Members. It noted that Latvia's State Agency of Medicines (ZVA) had succeeded to the State Pharmaceutical Inspection (SPI) and that Austria's AGES PharmMed would take over the PIC/S membership of the Federal Ministry for Health and Women (BMGF) on 1 January 2007.

7. The Committee discussed and adopted a number of guidance documents and monitored the activities carried out by the Working on Training and the Executive Bureau. It re-elected Ms. Eija Pelkonen (Finland / National Agency for Medicines) as Member of the Executive Bureau for the period 2007-2008.

8. The Executive Bureau met in Düsseldorf (28 May 2006) and Geneva (20 November 2006): during the first meeting, the Bureau adopted Rules of Procedures; at the second meeting, it carried out a salary review and performance evaluation of the Secretariat staff.

9. The Working Group on the Training of Inspectors met under the chairmanship of the PIC/S First Deputy Chairman, Dr. Johann Kurz (Austria / BMGF), in Düsseldorf on 29 May 2006 (morning) and in Geneva (Switzerland) on 21 November 2006 (morning). During these two meetings it discussed various training events for PIC/S inspectors (see "Training of Inspectors").

10. As in the past, the PIC/S Secretariat continued to provide secretariat services to the various PIC/S bodies (Committee, Bureau, Working Group on Training.). On 6 February 2006, the Secretariat moved to new offices located in the centre of Geneva (Switzerland).

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

By the end of 2006, PIC/S comprised 29 inspectorates from Australia, Austria, Belgium, Canada, Czech Republic (human & veterinary), Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Malaysia, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Spain, Sweden, Switzerland and the United Kingdom (see also Annex I).

Membership Applications: Thailand, Malta and French Veterinary Agency apply

11. Three Agencies applied for PIC/S membership in 2006.
12. A first membership application was received from Thailand's Food and Drug Administration (Thai FDA) on 24 February 2006. At its spring meeting in Düsseldorf, the Committee reviewed the evaluation report (based on documentation) made by the Rapporteur and Co-Rapporteurs. At the same meeting, representatives from the Thai FDA made a presentation on the Thai GMP system. At its autumn meeting, the Committee mandated the PIC/S Chairman to visit – in connection with a WHO assessment on vaccines – the Thai FDA in order to discuss the membership application. This visit took place on 2 December 2006.
13. The second application was from Malta's Medicines Authority, which officially applied for PIC/S Membership on 2 October 2006. At its autumn meeting the Committee appointed a Rapporteur in order to assess the application.
14. The third membership application was lodged on 11 December 2006 by the French Agency for Veterinary Medicinal Products (AFSSA - ANMV). The French Health Products Safety Agency (AFSSAPS), responsible for medicinal products for human use, is already a PIC/S Participating Authority.
15. The following progress was made with regard to other membership applications:
 - ◆ Assessment visits took place in both South Africa and Argentina: the visit to the South African Medicines Control Council was from 3 to 9 September 2006 while the visit to Argentina's "Instituto Nacional de Medicamentos" (INAME) took place from 27 November to 1 December 2006. Both visits aimed at assessing the local GMP inspection system.
 - ◆ Presentations were made on the GMP inspection systems of the Lithuania's State Medicines Control Agency (SMCA) and the USA's Food and Drug Administration (US FDA). A list of questions in connection with the US FDA's application, prepared by the Rapporteur, was also discussed.
 - ◆ The membership application by Israel's Ministry of Health was reviewed and an on-site assessment was agreed in principle but only once a licensing system has been introduced in Israel.
16. No progress at all was reported on the membership application of Ukraine's Ministry of Health.

Joint Reassessment Programme

17. The Joint Reassessment Programme (JRP) aims at ensuring that older Members of PIC/S still comply with the PIC/S requirements, as demanded from new Applicants. It is run in parallel with the EU's Joint Audit Programme (JAP) and uses basically the same tools.

18. In the course of 2006, the reassessment of the Greece's National Organization for Medicines (EOF) was successfully closed while a reassessment visit took place at the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) from 24 to 28 April 2006. The report was still pending by the end of the year.

19. The reassessments of Iceland's Medicines Control Agency (IMCA), Switzerland's Agency for Therapeutic Products (Swissmedic) and Liechtenstein's "Kontrollstelle für Arzneimittel" (KA), based on already existing Canadian assessment reports, were successfully launched in 2006.

20. The Committee decided to reassess Austria's AGES PharmMed and established a team composed of German, Italian and Swiss inspectors. It also agreed to reassess Australia's Therapeutic Goods Administration (TGA) once its merger with New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) will become effective (1 July 2007).

Training of Inspectors

21. In 2006 the Working Group on the Training of Inspectors reviewed (i) the operation of the Joint Visits Programme; (ii) past and future Expert Circles meetings (notably objectives for 2007); (iii) the preparations for the 2006 Seminar (see below) and the 2007 Seminar on "The Inspection of the Manufacture of Solid Dosage Forms"; and (iv) the evaluations of the 2005 and 2006 Seminars.

22. It decided to revise the PIC/S Guideline for Expert Circles (PI 022-1) and discussed the organisation of the 2008 Seminar on "Good Distribution Practices", which Poland's Main Pharmaceutical Inspectorate (MPI) has generously offered to organise in Krakow. It also agreed that the 2009 Seminar would be on Herbal Medicines (venue to be decided).

23. Based on a proposal made by the Working Group on Training, the Committee decided to create a Working Group on Good Distribution Practices (GDP). Based on another proposal made by the PIC/S Chairman, the Committee agreed to set up a new Expert Circle on Quality Risk Management in order to train Inspectorates. It also decided to open up the Joint Visits Programme to GCP inspectors on a trial basis following a request by EU GCP inspectors to benefit from this training tool.

Joint Visits Programme

24. At the end of 2006, there were 23 joint visit groups under the Joint Visits Programme representing around 70 inspectors from 27 different nationalities.

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.

2006 PIC/S seminar in Düsseldorf

25. The topic of the 2006 PIC/S Seminar was “Quality Risk Management and related ICH topics”. The Seminar took place in Düsseldorf (Germany) from 31 May to 2 June 2006. It was organised by the German Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices (ZLG).

26. The Seminar was attended by around 110 participants from 39 countries. This number includes inspectors from a number of non-Member agencies coming from Argentina, Cyprus, Croatia, the European Medicines Agency (EMA*), Israel, Japan, Lithuania, New Zealand, NIS**, Taipei, Thailand, Serbia, South Africa, and USA.

27. Among the 110 seminar participants were also a number of speakers, session chairpersons and workshop leaders. Speakers were provided by PIC/S Participating Authorities, the EMA, the European Commission, the German Federal Institute for Drugs and Medical Devices (BfArM) and industry.

28. The Seminar focused on:

- (i) the presentation of the ICH process;
- (ii) ICH Q8 “Pharmaceutical Development” from both regulators’ and industry’s perspective;
- (iii) ICH Q9 “Quality Risk Management” from both regulators’ and industry’s perspective;
- (iv) the progress made in the development of ICH Q10 “Quality Systems” and its future use by industry;

* Observer to PIC/S Committee

** New Independent States’ Interstate Commission on Standardisation, Registration and Quality Control of Medicines and Medical Devices

- (v) the interaction and the complementarity of these 3 topics as a common framework.

Expert Circles & Working Groups

Expert Circle on Human Blood and Tissue

29. The 13th meeting of the Expert Circle on Human Blood and Tissue was held in Utrecht (Netherlands) on 19-22 September 2006. It was organised by the Dutch Inspectorate of Health Care (IGZ) and attended by 50 participants from 25 countries (of which 5 non-Members). The meeting mainly focused on the inspection of tissue. It included an overview on legislative changes and projects in PIC/S and non-PIC/S countries as well as presentations on the practical aspects of procurement (donation of tissues), risk management and future developments. Practical workshops were organised on procurement, donor testing, processing, bacterial contamination and documentation. There was also a visit of a cell therapy products manufacturer. A number of recommendations were addressed to the PIC/S Committee for consideration.

Expert Circle on Hospital Pharmacy

30. The 9th meeting of the Expert Circle on Hospital Pharmacy was held in Lisbon (Portugal) on 6-7 June 2006. It was organised by Portugal's "Instituto Nacional da Farmácia e do Medicamento" (INFARMED) and attended by 17 participants from 16 countries. The meeting focused on discussing comments from PIC/S Participating Authorities on the draft guide on "Good Manufacturing Practices for Medicinal Products in Pharmacies".

Expert Circle on Computerised Systems

31. The 5th meeting of the Expert Circle on Computerised Systems, organised by ZLG, took place in Düsseldorf (Germany) from 29-30 May 2006. It was attended by 25 inspectors from 18 countries (including Cyprus, Israel, Japan, and South Africa). The meeting was split up into two parts: a one-day experts meeting focusing on an update to inspecting computer validation followed by one-day basic course on "how to inspect Computerised Systems during GxP-inspections".

Expert Circle on Medicinal Gases

Following the completion of its work plan, the Expert Circle on Medicinal Gases was suspended until further notice.

Expert Circle on Active Pharmaceutical Ingredients

32. The second meeting of the Expert Circle on Active Pharmaceutical Ingredients (APIs), which was originally scheduled to take place in the United Kingdom in the last quarter 2006, was postponed to 2007.

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, hospital pharmacy, computerised systems, active pharmaceutical ingredients, etc. Expert Circles meet regularly to develop draft guidance, recommendations, etc. and offer training in their respective fields of specialisation.

Harmonisation of guidance documents

33. The following PIC/S documents were adopted in the course of 2006:
- the PIC/S Aide-Memoire on Medicinal Gases (PI 025-1);
 - the revised PIC/S GMP Guide (PE 009-5) including additions to Chapters 1, 6 and 8.
34. The Committee also agreed to revise the format of the PIC/S GMP Guide (PE 009-5) in line with the EU GMP Guide: Chapter 1 to 9 will become Part I while the Guide on APIs (PE 007-2) will become Part II of the revised PIC/S GMP Guide.
35. It further agreed to release the second draft of the PIC/S Guide to Good Practices for Preparation of Medicinal Products in Pharmacies (PE 010-1, Draft 2) for consultation to national and international hospital and pharmacy associations.
36. The list of PIC/S publications is available on the PIC/S web site: <http://www.picscheme.org>

Relations with other organisations

37. The Committee adopted new Guidelines on Partnership replacing the Guidelines on PIC/S Observer Status. The Guidelines introduce the status of “Associated Partner” (replacing the current status of “Observer”) and the concept of “Non-Binding Partnership”, which aims at defining areas of co-operation between PIC/S and the Associated Partner.
38. In September and October 2006, the PIC/S Chairman, accompanied by the Secretary, visited the European Medicines Agency (EMA), the European Commission’s Health and Consumer Protection Directorate-General (DG SANCO), the European Commission’s Enterprise and Industry Directorate-General (DG Enterprise) and the European Directorate for Quality Medicines EDQM (PIC/S Chairman only).
39. It was the first time that a PIC/S Chairman initiated such visits to these European Institutions. The outcome of these visits was generally positive, especially in terms of co-ordination of training activities with the EMA and EDQM. The Committee decided to initiate an informal exchange of letters with all these organisations on the development of future co-operation. It also decided to exchange

letters with WHO's Immunization, Vaccines & Biologicals (IVB) Department in order to co-operate in the fields of training, assessment of Drug Regulatory Authorities, etc.

40. At its autumn meeting in Geneva, the Committee also discussed a project developed by DG SANCO on "European Standards and Training for the Inspection of Tissue Establishments" (EUSTITE) as well as a new training and standards programme on human blood. It noted that both projects were led by tissue and blood banks, respectively, and agreed to involve PIC/S in these programmes. An official representative from PIC/S was nominated as Liaison Officer for EUSTITE.

First PIC/S – Industry Forum

41. On 23 November 2006 PIC/S met for the first time with representatives of international industry and professional associations, i.e.

- EFPIA: European Federation of Pharmaceutical Industry Associations;
- FIP: International Pharmaceutical Federation;
- IFPMA: International Federation of Pharmaceutical Manufacturers & Associations;
- ISPE: International Society of Pharmaceutical Engineers;
- PDA: Parenteral Drug Association.

42. The meeting aimed at exchanging information and identifying possible areas of co-operation in terms of GMP (e.g. training).

43. The main operational conclusions from the meeting were the following:

- ❖ On GMP training, both parties agreed to exchange information on training programmes. Pharmaceutical manufacturers were encouraged to provide training material to PIC/S (e.g. short videos or photos) and facilitate visits ("walk around") of manufacturing sites by PIC/S Inspectorates. Both parties also agreed to explore the possibility to organise back-to-back meetings and develop common training workshops. The first such joint workshop will be organised by PIC/S and ISPE in November 2007. The workshop will be on Quality Risk Management and take place after the 2007 PIC/S Seminar in Singapore.
 - ❖ On GMP inspections, pharmaceutical companies were encouraged to be more pro-active by (i) informing PIC/S Inspectorates on the last / forthcoming inspection by another Inspectorate; (ii) spontaneously submitting the last inspection report; (iii) fixing across the board deficiencies noted by an Inspector in one particular spot; (iv) ensuring the commitment of the company's top management to GMP; and (v) encouraging non-PIC/S Authorities to join PIC/S. PIC/S agreed to consider better ways to share / use information on inspections as well as discuss the possibility of "team inspections".
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**LIST OF PIC/S
PARTICIPATING AUTHORITIES & OBSERVERS**
(as of 31 December 2006)

I - PARTICIPATING AUTHORITIES

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

	PARTICIPATING AUTHORITY	ACRONYM
Australia	Therapeutic Goods Administration	TGA
Austria	Bundesministerium für Gesundheit und Frauen <i>(Federal Ministry for Health and Women)</i>	BMGF
Belgium	Direction Générale de la Protection de la Santé Publique: Médicaments	DGM
Canada	Health Products and Food Branch Inspectorate	HPFBI
Czech Republic	Státní Ústav pro Kontrolu Léčiv <i>(State Institute for Drug Control)</i>	SÚKL
	Ústav pro Státní Kontrolu Veterinárních Biopreparátů a Léčiv <i>(Czech Institute for State Control of Veterinary Medicaments and Biologicals)</i>	ÚSKVBL
Denmark	Danish Medicines Agency	DMA
Finland	National Agency for Medicines	NAM
France	Agence Française de Sécurité Sanitaire des Produits de Santé <i>(French Health Products Safety Agency)</i>	AFSSAPS
Germany	Bundesministerium für Gesundheit <i>(Federal Ministry for Health)</i>	BMG
	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten <i>(Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices)</i>	ZLG
Greece	Εθνικός Οργανισμός Φαρμάκων <i>(National Organization for Medicines)</i>	EOF
Hungary	National Institute of Pharmacy	NIP
Iceland	The Icelandic Medicines Control Agency	IMCA
Ireland	Irish Medicines Board	IMB
Italy	Agenzia Italiana del Fármaco	AIFA
Latvia	Zāļu Valsts Aģentūra <i>(State Agency of Medicines)</i>	ZVA
Liechtenstein	Kontrollstelle für Arzneimittel	KA
Malaysia	National Pharmaceutical Control Bureau	NPCB

Netherlands	Inspectie voor de Gezondheidszorg (<i>Inspectorate of Health Care</i>)	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
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 - OBSERVERS

(in the alphabetical order of their acronyms)

	OBSERVERS	ACRONYM
	European Medicines Agency	EMA
Estonia	State Agency of Medicines	SAM
	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.
