PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

A N N U A L R E P O R T 2 0 0 1

Summary of Activities

1. The PIC/S Joint Committee met in Prague (Czech Republic) on 22 May 2001 and in Geneva (Switzerland) on 27-28 November 2001 under the chairmanship of Mr. Robert Tribe of TGA, Australia. At the Geneva meeting, the Committee elected Ms. Lilian Hamilton of Sweden's Medical Products Agency (MPA) as Chairperson for the period 2002-2003.

2. At its Prague meeting, the PIC/S Committee decided to accept Greece's National Organization for Medicines (NOM) and Malaysia's National Pharmaceutical Control Bureau (NPCB) as new Members as from 1 January 2002. It also decided to accept both Estonia and Latvia as Observers. It eventually agreed to embark on an ambitious Joint Reassessment Programme.

3. The annual PIC/S seminar was organised by the Czech State Institute for Drug Control (SUKL). It took place in Prague from 23 - 25 May 2001 and dealt with the Inspection of "Utilities Used by the Manufacturer of Pharmaceuticals". 110 participants attended the seminar.

4. The other main PIC/S events during the year 2001 were:

* The application by Poland, Lithuania and Bulgaria to join the Scheme;
* The nomination of a Rapporteur and a Co-rapporteur to assess the application made by Poland's Main Pharmaceutical Inspectorate;
* The PIC/S visits to Greece and Malaysia aiming at fostering contacts and assessing the local GMP inspection system, respectively;
* Increased co-operation with both the EMEA and WHO;
* The annual meeting of the Working Group on the Training of Inspectors (Prague, 21 May 2001);
* The 8th meeting of the Expert Circle on Blood in Sweden, the 3rd meeting of the Expert Circle on Medicinal Gases in Germany, the 3rd and 4 meetings of the Expert Circle on Hospital Pharmacy in the Netherlands and Belgium, respectively;
* The continued monitoring of the PIC/S Joint Visits Groups Programme involving over 70 inspectors;
* The entry into force of the revised PIC/S GMP Guide, the new PIC/S GMP Guide for Blood Establishments and the new PIC/S GMP Guide on Active Pharmaceutical Ingredients.

5. In short: 2001 was a very busy year!

The PIC/S Joint Committee meets twice in 2001

6. The PIC/S Joint Committee (hereafter referred to as "the Committee") met twice in the year 2001: first, in Prague (Czech Republic) on 22 May 2001 and then in Geneva (Switzerland) on 27 and 28 November 2001. Both meetings were chaired by Mr. Robert Tribe (TGA/Australia).

7. At its November meeting, the Committee elected Ms. Lilian Hamilton of Sweden's Medical Products Agency (MPA) as Chairperson for 2002-2003. Mr. Hans Smallenbroek from the Netherlands' Inspectorate of Health Care was elected First Deputy Chairman while Ms. France Dansereau of Canada's Health Products and Food Branch Inspectorate (HPFBI) was elected Second Deputy Chairperson for the same period.

Pharmaceutical Inspection Co-operation Scheme

The Pharmaceutical Inspection Co-operation Scheme (PIC Scheme), which entered into force in November 1995, is an informal and flexible arrangement between the inspectorates of the PIC Contracting States. It is run in parallel with the Pharmaceutical Inspection Convention (see Annex II). It is open to the participation of the inspectorates of other countries.

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.

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.

To ensure greater public security with regard to pharmaceutical products marketed in the PIC/S countries, the Scheme provides that if a participating authority learns of particular circumstances due to which a pharmaceutical product could be of imminent and serious danger, its findings have to be communicated to the other competent authorities under the Scheme.

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

By the end of 2001, PIC/S comprised 24 inspectorates from Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Liechtenstein, Netherlands, Norway, Portugal, Romania, Singapore, Slovak Republic, Spain, Sweden, Switzerland and the United Kingdom (see also Annex I).

Greece and Malaysia are invited to join the Scheme as from 2002

8. At its Prague meeting, the PIC/S Committee decided to accept Greece and Malaysia as new Members as from 1 January 2002.

9. The Greek National Organization for Medicines (NOM) was admitted on the basis of a simplified accession procedure for EU Member States. A PIC/S Delegation visited Greece from 24 to 28 September 2001 in order to foster mutual contacts.

10. The Malaysian National Pharmaceutical Control Bureau (NPCB) was admitted following an evaluation of its GMP system and a visit in March 2001 to assess the local GMP inspection and licensing system. A follow-up visit took place on 29-31 October 2001 to ensure that the NPCB has implemented all recommendations in relation with its rapid and successful accession to the Scheme. Malaysia applied to join PIC/S only as recently as in February 2000.

Latvia and Estonia become Observers

11. The Committee decided to accept both Estonia and Latvia as Observers. Assessment visits to both Estonia and Latvia were carried out in November / December 2000. The Estonian State Agency of Medicines and the Latvian State Pharmaceutical Inspection will be admitted once the local GMP legislation has entered into force and successful follow-up visits in these two Baltic countries, planned to take place in 2002 / 2003, have been completed.

More applications for membership are being processed

12. In 2001 the Committee reviewed the application for membership made by the National Laboratories of Foods and Drugs (NLFD) of Chinese Taipei. It decided to send a PIC/S Delegation to Chinese Taipei by early 2002 in order to assess the local GMP inspection and licensing system. It also expressed concerns on the new rules on the registration of foreign medicinal products introduced by the Bureau of Pharmaceutical Affairs (BOPA), the other branch of Department of Health of Chinese Taipei.

13. The Committee appointed a rapporteur and co-rapporteur to evaluate the recent membership application submitted by Poland's Main Pharmaceutical Inspectorate and the Lithuanian State Medicines Control Agency. It took note of the membership application made by the Bulgarian Drug Agency.

14. A number of other agencies also showed an interest in the Scheme in the course of 2001: Oman's Directorate General of Pharmaceutical Affairs and Drug Control; the Drug Control Division of Thailand's FDA; the Directorate of Drug Control of the United Arab Emirates and UNICEF.

PIC/S embarks on a Joint Reassessment Programme

15. The Committee endorsed a proposal by the First Deputy Chairperson on the reassessment of PIC/S participating authorities. The reassessment aims to ensure that all current Members fulfil their obligations under the Scheme. The Committee decided to work closely with the EU Heads of Inspection Agencies, who adopted a similar programme, and to aim for a joint PIC/S-EU reassessment system in order to avoid unnecessary duplications. The Committee also decided to launch a pilot phase in the second half of 2002 with the participation of Inspectorates from Australia, Greece, Romania and Sweden. In order to guarantee impartiality during the evaluation, it was proposed that assessors should be selected from a pool of experienced inspectors, appointed by PIC/S Member Agencies.

Co-operation with EMEA & WHO is increasing

16. Co-operation with the EMEA continued to be very fruitful. The First Deputy Chairperson, who is also the PIC/S-EU Liaison Officer, attended a total of five meetings of the Ad Hoc Working Group of Inspectors at the EMEA in London. PIC/S was also invited by WHO to participate in the "Global Alliance for the Quality of Pharmaceuticals", which aims at improving the quality of medicines worldwide and harmonising pre-qualification procedures of procured medicines. A decision on a possible PIC/S participation in the Global Alliance will be taken in 2002.

The 2001 PIC/S seminar focuses on the inspection of utilities

17. The 2001 seminar on the inspection of "Utilities Used by the Manufacturer of Pharmaceuticals" was organised by the Czech State Institute for Drug Control (SUKL) in Prague on 23 - 25 May 2001.

18. The seminar was attended by 110 participants from 33 Inspectorates and 7 agencies including invited inspectors and speakers from industry and non PIC/S

countries or agencies such as Chinese Taipei, the EMEA, Estonia, FDA, (Greece)*, Latvia, Lithuania, (Malaysia)*, New Zealand, Poland, Slovenia, UNICEF, and WHO. The collected papers presented on that occasion were published in booklet form.

19. The Seminar concentrated on technical and regulatory aspects of utilities used in the manufacturing of sterile and non-sterile pharmaceutical products such as pharmaceutical water and steam, heating, ventilation and air conditioning (HVAC), compressed air and gases.

Annual Meeting of the Working Group on the Training of Inspectors

20. The Working Group on the Training of Inspectors met in Prague on 21 May 2001 under the chairmanship of Ms. Lilian Hamilton (MPA/Sweden). The Working Group reviewed the operation of the PIC/S joint visits programme (see para. 23) and supervised the activities of the various Expert Circles (see para. 24 – 28). It also prepared the ground for future PIC/S Seminars (see para. 21 – 22).

Seminars in 2002 and 2003 will deal with good clinical practices and quality control laboratories

21. The Committee took note of the good preparations for the 2002 PIC/S Seminar on "The Interface Between Good Clinical Practice (GCP) and GMP in the Manufacture and Audit of Clinical Trial Products", which will take place at Château Montebello (Quebec, Canada) on 9-11 October 2002. It also reviewed the preliminary programme presented by the Slovak State Institute for Drug Control (SIDC) on the 2003 seminar on the Inspection of Quality Control Laboratories (Bratislava, 4-6 June 2003).

22. Spain, Romania and Germany offered to host the 2004, 2005 and 2006 seminars, respectively.

Nineteen PIC/S Joint Visits groups are operational

23. At its annual meeting in Prague, the Working Group on the Training of Inspectors set up three new groups were while modifying the composition of three other groups. In 2001 there are nineteen groups participating in the programme representing 70 inspectors from 25 different nationalities.

---

* Greece and Malaysia have been invited to join PIC/S by 1 January 2002.

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.

All Expert Circles meet in 2001 – A new Expert Circle on Computerised Systems is created

24. All the three already established Expert Circles (human blood and tissue, medicinal gases and hospital pharmacy) met in the course of 2001. A new Expert Circle on Computerised Systems was established at the Prague Committee meeting. The first meeting of this new Expert Circle will be held on 12-13 June 2002 in the United Kingdom.

Expert Circle on Human Blood and Tissue

25. The name of the Expert Circle on Blood was changed to "Expert Circle on Human Blood and Tissue". The 8th meeting of the "Expert Circle on Human Blood and Tissue" was held in Stockholm (Sweden) from 25 to 27 June 2001. It was attended by 50 participants from 22 countries. The next meeting will be organised by the French AFSSAPS in Paris on 19-21 June 2002.

Expert Circle on Medicinal Gases

26. 32 inspectors from 20 countries participated in the 3rd meeting of the Expert Circle on Medicinal Gases took place in Düsseldorf (Germany) from 4 to 6 September 2001. The next meeting will be hosted by Finland in 2003.

Expert Circle on Hospital Pharmacy

27. Two meetings were organised under the hospices of the Expert Circle on Hospital Pharmacy: the first took place in Leiden (Netherlands) on 12-13 March 2001 and was attended by 14 participants representing 11 countries (it was the Expert Circle's 3rd meeting); the second was held in Brussels (Belgium) and attended by 13 countries (4th Expert Circle meeting). The next meeting will be organised in Iceland on 15 April 2002.

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, medicinal gases, hospital pharmacy and computerised systems. Expert Circles meet regularly to develop draft guidance, recommendations, etc. in their respective fields of specialisation.

New or revised PIC/S guidance documents are adopted

28. On 1 January 2001 the PIC/S internal recommendation on "Quality System Requirements for Pharmaceutical Inspectorates" (PI 002-1) and the new Annex 14 to the PIC/S GMP Guide on the "Manufacture of Products Derived from Human Blood and Human Plasma" entered into force.

29. In the course of 2001, the PIC/S GMP Guide was revised twice:

- The amended paragraph 42 of Annex I (dealing with the validation of aseptic processes , the revised Annex 6 on the Manufacture of Medicinal Gases (PE 003-1), the new Annex 15 on Qualification and Validation and the new Annex 17 on Parametric Release all entered into force on 1 September 2001;

- The new Annex 4 on the Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products and the new Annex 5 on the Manufacture of Immunological Veterinary Medicinal Products were both adopted at the Geneva Committee meeting and will enter into force on 1 January 2002.

30. The above revisions have been made in parallel with those undertaken by the EU under the PIC/S-EU consultation procedure. With the exception of specific references to the EU legislation, the EU and the PIC/S GMP Guides are identical in substance.

31. In addition, the Committee adopted the following guides, which all entered into force on 1 September 2001:

- It adopted the PIC/S GMP Guide for Blood Establishments (PE 005-1);

- It adopted the ICH Q7A Guideline as a stand-alone PIC/S GMP Guide on Active Pharmaceutical Ingredients. The new guide replaces the previous PIC/S guideline for the manufacture of active pharmaceutical ingredients (PH 2/87);

- It adopted the Guidance on Parametric Release (PI 005-1) as a PIC/S-internal recommendation for the use of inspectors.

32. It also agreed to submit the following draft recommendations to industry comment:

- the draft Recommendation on Isolators Used for Aseptic Processing and Sterility Testing (PE 004-1, draft 3) was sent for industry comments on 1 June 2001 for a period of three months;

- the draft PIC/S Guidance on Best Practices for Computerised Systems in Regulated "GxP" Environments will be released for industry comments by early 2002 for a period of six months.

33. The Committee also agreed on a revision of the Standard Operation Procedure on the Editing of PIC/S Documents (PI 001-1)

34. Furthermore, the PIC/S Joint Committee discussed the following draft / revised documents:

- Annexes 1 and 13 to the PIC/S GMP Guide (revision in parallel with the EU);

- Draft Aide-Memoire on the inspection of utilities (for the use of inspectors);

- Explanatory Notes for Industry on the Preparation of a Site Master File (revision of the introduction).

35. The list of PIC/S publications is attached at Annex III.

PIC/S on line

36. The Web Site Editorial Committee, which met in Prague on 21 May 2001, discussed several projects under way (hyperlinks to French, German and Spanish translations of PIC/S documents, password protected "chat room" for inspectors, extranet, etc.) as well as the hand-over of the web site (http://www.picscheme.org) from TGA to the PIC/S Secretariat by 2003. The PIC/S web site has attracted a growing number of visitors.

LIST OF PIC/S PARTICIPATING AUTHORITIES
(in 2001)

AUSTRALIA	GMP Audit and Licensing Section Therapeutic Goods Administration Department of Health and Age Care GPO Box 100 AU-Woden Act 2606
AUSTRIA	Federal Ministry of Social Security and Generations Radetzkystrasse 2 AT-1030 Vienna
BELGIUM	Ministère des Affaires sociales, Santé publique et Environnement Inspection Générale Pharmacie Cité Administrative de l'Etat Quartier Vésale BE-1010 Bruxelles
CANADA	Health Products and Food Branch Inspectorate (HPFBI) Health Canada 11, Holland Ave., 2nd Floor Holland Cross, Locator 3002C CA-Ottawa, Ontario K1A OK9
CZECH REPUBLIC	State Institute for Drug Control Srobárova 48 CZ-100 41 Prague 10
DENMARK	Danish Medicines Agency 378 Frederikssundsvej DK-2700 Brønshøj
FINLAND	National Agency for Medicines Mannerheimintie 166 P.O. Box 55 FI-00301 Helsinki
FRANCE	French Agency for the Safety of Health Products (AFSSAPS) 143-145 Boulevard Anatole France FR-93285 Saint Denis

GERMANY	Federal Ministry for Health Am Probsthof 78a DE-53108 Bonn
HUNGARY	National Institute of Pharmacy P.O. Box 450 HU-1372 Budapest 5
ICELAND	The Icelandic Medicines Control Agency (IMCA) Eiðistorg 13-15 P.O. Box 180 IS-170 Seltjarnarnes
IRELAND	Irish Medicines Board Block A Earlsfort Centre Earlsfort Terrace IE-Dublin 2
ITALY	Ministero della Sanità Dipartimento per la Valutazione dei Medicinali e la Farmacovigilanza Viale della Civiltà Romana 7 IT-00144 Rome
LIECHTENSTEIN	ALKVW / Kontrollstelle für Arzneimittel Postplatz 2 LI-9494 Schaan
NETHERLANDS	Inspectorate of Health Care P.O. Box 16119 NL-2500 BC Den Haag
NORWAY	Inspection Services Norwegian Medicines Agency Sven Oftedals Vei, 6 NO-0950 Oslo 1
PORTUGAL	Instituto Nacional da Farmácia e do Medicamento (INFARMED) Avenida do Brasil, no 53 Pavilhaõ 21-A PT-1700 Lisbon

ROMANIA	National Medicines Agency Strada Maior Aviator Stefan Sanatescu 48 Sectorul I RO-Bucharest
SINGAPORE	Manufacturing and Quality Audit Division Centre for Pharmaceutical Administration Health Sciences Authority Singapore 2 Jalan Bukit Merah SG - Singapore 169547
SLOVAK REPUBLIC	State Institute for Drug Control Kvetná 11 SK-825 08 Bratislava 2
SPAIN	Agencia Española del Medicamento Subdirección General de Seguridade de Medicamentos Division de Inspección y Control Farmaceútico C/Huertas 75 ES-28014 Madrid
SWEDEN	Medical Products Agency Box 26 SE-751 03 Uppsala
SWITZERLAND	Swissmedic Swiss Agency for Therapeutic Products Erlachstrasse 8 CH-3000 Berne 9
UNITED KINGDOM	Medicines Control Agency Market Towers 1 Nine Elms Lane GB-London SW8 5NQ

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.

LIST OF PIC/S PUBLICATIONS

Revised 25 March 2002

PIC/S Guides

- Guide to Good Manufacturing Practice for Medicinal Products (PH 1/97 (Rev.3))
  - Ann 1 ➢ Manufacture of sterile medicinal products
  - Ann 2 ➢ Manufacture of biological medicinal products for human use
  - Ann 3 ➢ Manufacture of radiopharmaceuticals
  - Ann 4 ➢ Manufacture of veterinary medicinal products other than immunologicals
  - Ann 5 ➢ Manufacture of immunological veterinary medicinal products
  - Ann 6 ➢ Manufacture of medicinal gases
  - Ann 7 ➢ Manufacture of herbal medicinal products
  - Ann 8 ➢ Sampling of starting and packaging materials
  - Ann 9 ➢ Manufacture of liquids, creams and ointments
  - Ann 10 ➢ Manufacture of pressurised metered dose Aerosol preparations for inhalation
  - Ann 11 ➢ Computerised systems
  - Ann 12 ➢ Use of ionising radiation in the manufacture of medicinal products
  - Ann 13 ➢ Manufacture of investigational medicinal products
  - Ann 14 ➢ Manufacture of products derived from human blood or human plasma
  - Ann 15 ➢ Qualification and validation
  - *Ann 16* ➢ *Not adopted by PIC/S*
  - Ann 17 ➢ Parametric release
- GMP Guide for Blood Establishments (PE 005-1)
- GMP Guide for Active Pharmaceutical Ingredients (PE 007-1)

PIC/S Recommendations and Explanatory Notes

- Recommendation on a Quality System for Official Medicines Control Laboratories (PH 2/95)
- Recommendation on Sterility Testing (PE 001-2)
- Recommendation on Quality System Requirements for Pharmaceutical Inspectorates (PI 002-1)
- Guidance on Parametric Release (PI 005-1)
- Recommendation on Validation Master Plan, Installation and Operational Qualification, Non-sterile Process Validation, Cleaning Validation (PI 006-1)[1]
- Recommendation on the Validation of Aseptic Processes (PI 007-1)[2]
- Explanatory Note for Industry on the Preparation of a site master file to be part of the information requested under Article 2 of the Pharmaceutical Inspection Convention (PH 4/93)[3]
- Explanatory Note for the National Inspectors of PIC Competent Authorities on the preparation of information requested under Article 2 of the Pharmaceutical Inspection Convention (PH 8/92)

---

1 Replacing PR 1/99-2

2 Replacing PE 002-2

3 Replacing PH 6/91

Booklets on Seminars and Expert Circles organised under the auspices of PIC/S

Seminars booklets

- Manufacture and quality control under contract (Berne, Switzerland, July 1974)
- The manufacturer's quality control department. Structural and functional aspects (Copenhagen, Denmark, June 1975)
- Stability of pharmaceutical products (Salzburg, Austria, June 1976)
- Modern methodology for the isolation, identification and quantification of drugs and related substances (Uppsala, Sweden, June 1977)
- Inspection in tablet manufacture (Copenhagen, Denmark, June 1980)
- Good manufacturing practice in the manufacture of active ingredients (Liestal/Basle, Switzerland, June 1980)
- Application of GMP rules in the control laboratory (Budapest, Hungary, June 1981)
- Safety aspects of the packaging of pharmaceutical products (Lisbon, Portugal, June 1983)
- Requirements of good manufacturing practice and quality control in the production of biological products (Frankfurt a/Main, Germany, May 1984)
- Premises for pharmaceutical manufacture (Oslo, Norway, June 1985)
- Plastics and their pharmaceutical applications (Sigtuna, Sweden, June 1986)
- The business of pharmaceutical inspection (Cambridge, United Kingdom, September 1987)
- Water for pharmaceutical purposes (Jongny, Switzerland, September 1988)
- Contamination risks in the manufacture of parenterals (Baden, Austria, September 1989)
- Blood and blood products (Hillerød, Denmark, September 1990)
- Audit - Pharmaceutical Inspection (Felsötárkány, Hungary, June 1991)
- New aspects of products derived from biotechnology (Montecatini, Italy, May 1992)
- The Role of Inspection and Testing in relation to the Marketing authorization (Louvain, France, September 1993)
- Qualification and validation in Pharmaceutical Manufacture (Dublin, Ireland, July 1994)
- Inspecting the Manufacture of Sterile Products - Current and Future Trends (Hveragerði, Iceland, June 1995)
- Inspection of computer systems (Sydney, Australia, September 1996)
- Manufacture and inspection of Active Pharmaceutical Ingredients (Naantali, Finland, June 1997)
- Quality System for Pharmaceutical Inspectorates (Zeist, Netherlands, June 1998)
- Non-Technical Aspects of Inspection (Oxford, United Kingdom, September 1999)
- The Inspection of Products derived from Biotechnologies (Colmar, France, October 2000)

NEW → - Utilities used by the Manufacturer of Pharmaceuticals (Prague, Czech Republic, May 2001)

Expert circles

- PIC/s Expert Circle on Medicinal Gases (Sigtuna, November 1997) (PH 1/98)
- PIC/s Expert Circle on Blood (Saariselkä (Finland) 30 August – 1 September 2000)

Prices	PIC/S Guide and Seminar/Expert Circles booklets are invoiced at	CHF 40.- per copy postage included
	PIC/S Recommendations and Explanatory Notes are invoiced at	CHF 25.- per copy postage included

\ Documents with this sign are available at http://www.picscheme.org

These publications can be obtained from

Secretariat to the Pharmaceutical
Inspection Co-operation Scheme
c/o EFTA Secretariat
9-11, rue de Varembé
CH - 1211 GENEVA 20

Tel.: +41 22 / 749.12.65
Fax: +41 22 / 740.09.20
e-mail: pics@efta.int
website:http://www.picscheme.org