



ANNUAL REPORT 2000

Summary of Activities

1. The PIC/S Joint Committee met twice in the course of the year 2000: first, in Geneva (Switzerland) on 17-18 February 2000 and then in Colmar (France) on 24 October 2000. Both meetings were chaired by Mr. Robert Tribe of TGA, Australia.
2. In 2000 Singapore's National Pharmaceutical Administration became the first Asian agency to join PIC/S while the Italian Department for Drug Evaluation and Pharmacovigilance and the German Ministry of Health ("Zentrale Koordinierungsstelle der Länder") became respectively the 23rd and 24th authority participating in the Scheme.
3. The annual PIC/S seminar was organised by the French Agency for the Safety of Health Products (AFSSAPS). It took place in Colmar from 25 to 27 October 2000 and dealt with "The Inspection of the Manufacture of Biotech Products". The seminar was attended by 109 participants from 34 Inspectorates and 4 agencies.
4. The other main PIC/S events during the year 2000 were:
 - * The application by Greece to join the Scheme (26 May 2000);
 - * The nomination of Rapporteurs to process the applications of Greece, Malaysia and Chinese Taipei;
 - * The PIC/S visits to Estonia and Latvia to assess the local GMP inspection system on 13-17 November and 4-8 December 2000, respectively;
 - * The annual meeting of the Working Group on the Training of Inspectors (Colmar, 23 October 2000);
 - * The 7th meeting of the Expert Circle on Blood, which took place from 30 August to 1 September 2000 in Saariselkä (Finland) and which was attended by 42 Delegates from 25 countries;
 - * The 2nd meeting of the Expert Circle on Hospital Pharmacy, which took place in Heathrow (UK) on 13 October 2000;
 - * The setting up of six new Joint Visits Groups bringing the number of active inspectors involved in the Joint Visits Programme to over 50;
 - * The adoption of the PIC/S recommendation on "Quality System Requirements for Pharmaceutical Inspectorates" (PI 002-1) and of a new GMP Annex on the "Manufacture of Products Derived from Human Blood and Human Plasma".
5. In short: 2000 was a very productive year for PIC/S and the increasing number of authorities having applied to PIC/S or participated in PIC/S events underline the very dynamic expansion of the Scheme since its entry into force in 1995.

The PIC/S Joint Committee meets in Geneva and Colmar

6. The PIC/S Joint Committee met twice in the year 2000: first, in Geneva (Switzerland) on 17 and 18 February 2000 and then in Colmar (France) on 24 October 2000. Both meetings were chaired by Mr. Robert Tribe (TGA/Australia). Ms. Lilian Hamilton (MPA/Sweden) served as first Deputy Chairperson and Mr. Hans Smallenbroek (IHC/Netherlands) as second Deputy Chairman. The PIC/S Joint Committee meeting in Colmar was followed by a seminar on “The Inspection of the Manufacture of Biotech Products” (see below).

7. The main items discussed during the two PIC/S Joint Committee meetings were the relations with other countries and their inspectorates, the proposal on a joint reassessment of PIC/S members, the continuous training of inspectors, the tenure of expert circle meetings in special areas (blood products, medicinal gases and hospital pharmacies), the elaboration of new Recommendations on GMP, and other aspects related to the good functioning of the PIC Scheme.

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.

Singapore becomes the Scheme's youngest and first Asian member

8. On 1st January 2000 **Singapore's** National Pharmaceutical Administration became the first Asian agency to join PIC/S. Singapore applied back in 1997 to join PIC/S. In April 1999 a PIC/S delegation paid a visit to Singapore in order to assess whether the Singaporean system of GMP inspection and licensing was comparable to that referred to in Article 8 of the Pharmaceutical Inspection Cooperation Scheme (PIC/S 1/95). In December 1999 a successful follow-up visit led to the admittance of Singapore to the PIC Scheme as from 1 January 2000.

9. In February 2000, **Italy**, which was already a member of the Convention since 1990, joined the Scheme. The Italian Department for Drug Evaluation and Pharmacovigilance thus became the 23rd authority participating in the Scheme. In December 2000, **Germany**, which had been the last Convention Member not being a party to the Scheme, eventually joined to become the 24th authority participating in the Scheme.

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

By the end of 2000, 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).

PIC/S Delegations visit Estonia and Latvia

10. Two PIC/S delegations carried out assessment visits in Estonia and Latvia from 13 to 17 November 2000 and from 4 to 8 December 2000, respectively. The purpose of these visits was to evaluate whether the GMP inspection system in these two Baltic countries was comparable to that of the PIC/S Participating Authorities.

11. The Estonian State Agency of Medicines (SAM) and the Latvian State Pharmaceutical Inspection (SPI) applied to join PIC/S in 1996. The reports on the visits will be submitted to the PIC/S Joint Committee for consideration in 2001.

More applications for membership are being processed

12. In 2000 the PIC/S Joint Committee reviewed the applications for membership made by:

- the Greek National Organisation for Medicines (NOM);
- the National Laboratories of Foods and Drugs (NLFD) of Chinese Taipei; and
- the Malaysian National Pharmaceutical Control Bureau (NPCB).

13. It appointed a rapporteur for the application for membership made by Malaysia's NPCB as well as a new rapporteur to continue the assessment of the application made by the NFLD of Chinese Taipei. It also decided to send a PIC/S Delegation to Malaysia in March 2001 to assess the local GMP inspection and licensing system.

14. The Committee was also informed that Lithuania and Poland had expressed an interest in joining the PIC Scheme while the UK-based Veterinary Medicine Directorate (VMD) was also considering a possible participation in the PIC Scheme. A number of other agencies have also shown an interest in the Scheme (Slovenia, Russia, South Africa, etc.).

PIC/S and the EU/EMEA harmonise their co-operation

15. The Joint Committee adopted a document regarding the harmonisation of PIC/S and EU consultation procedures and agreed to a Swiss proposal aiming at the harmonisation of the PIC/S and the EU/MRAs Rapid Alert Procedures. During its two meetings in 2000, the Joint Committee also discussed a proposal by the First Deputy Chairperson on the re-assessment of PIC/S participating authorities. Since the EU Heads of Inspection Agencies had more recently expressed to adopt a similar system, it was decided to aim for a co-operation with the EU joint visit procedure, which could be adopted in 2001, as this approach would save time and resources for both parties.

16. 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.

The 2000 PIC/S seminar focuses on the inspection of biotech products

17. The 2000 seminar, which was organised by the French Agency for the Safety of Health Products (AFSSAPS), was held in Colmar on 25 - 27 October 2000. It dealt with "The Inspection of the Manufacture of Biotech Products".

18. The seminar was attended by 109 participants from 34 Inspectorates and 4 agencies including invited inspectors and speakers from a number of non PIC/S countries or agencies such as Chinese Taipei, the EMEA, Estonia, Japan, Latvia, Lithuania, Malaysia, New Zealand, Poland, Slovenia, Turkey, UNICEF, the USA and WHO. The PIC/S Secretariat will publish the collected papers presented on that occasion in booklet form.

19. The Seminar concentrated on technical and regulatory aspects of biotechnology products as well as on the inspection of biotechnology manufacturing sites. It also included a visit to a local insulin-producing manufacturer and to the European Directorate for the Quality of Medicines (EDQM / European Pharmacopoeia). The Seminar resulted in the establishment of a PIC/S Working Group whose main tasks will be to draft an Aide-Memoire on the inspection of biotechnology plants and to establish a scope and work plan for an Expert Circle on Biotechnology that is to be convened later in 2001.

Annual Meeting of the Working Group on the Training of Inspectors

20. The Working Group on the Training of Inspectors met in Colmar on 23 October 2000 under the chairmanship of Ms. Lilian Hamilton (MPA/Sweden). The Working Group reviewed the operation of the PIC/S joint visits programme (see para. 22) and supervised the activities of the various Expert Circles (see para. 23 – 27). It also prepared the ground for future PIC/S Seminars (see para. 21).

Seminars in 2001 and 2002 will deal with utilities and good clinical practices

21. The Joint Committee decided that the next PIC/S Seminar would take place in Prague and be hosted by the Czech “State Institute for Drug Control” on 23-25 May 2001. It agreed with the proposed topic on “Utilities used by the Manufacturer of Pharmaceuticals”. The Joint Committee also welcomed the proposal by the Therapeutic Products Programme of Health Canada to host the 2002 Seminar and agreed with the proposed topic on “The Interface between GCP and GMP in the Manufacture and Audit of Clinical Trial Products”.

Six new PIC/S Joint Visits groups are set up for the training of inspectors

22. At its annual meeting in Colmar, the Working Group on the Training of Inspectors set up six new groups while modifying the composition of three other groups. In 2000 there are seventeen groups participating in the programme representing 51 inspectors from 22 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.

A new Expert Circle on biotechnology is established

23. The PIC/S Joint Committee endorsed the decision by the Working Group on the Training of Inspectors to monitor the work carried out by the Expert Circles. It also

decided to establish a new Expert Circle on Biotechnology. The Committee also endorsed a policy, proposed by Working Group on the Training of Inspectors, regarding PIC/S' involvement in conferences.

24. Two of three already established Expert Circles (blood and hospital pharmacy) met in the course of 2000. However, there was no meeting of the Expert Circle on medicinal gases.

Expert Circle on Blood

25. The 7th meeting of the Expert Circle on Blood took place in Saariselkä (Finland). 42 Delegates from 25 countries took part in the 3-day seminar (30 August - 1 September 2000). The Expert Circle decided to extend its scope to encompass tissues, including stem cells, and to establish working groups, whose task would be to draft guidelines on "Stem cells", "Tissues" and the "Inspection of Plasmapheresis Establishments". The next Expert Circle would be held in Sweden from 25 to 27 June 2001.

Expert Circle on Hospital Pharmacy

26. The 2nd meeting of the Expert Circle on Hospital Pharmacy took place in Heathrow (UK) on 13 October 2000. It finalised a list of terms used to describe hospital pharmacy activities and their definitions. It decided that in the future it would concentrate discussions on aseptic manipulations carried out within hospital pharmacies. The next meeting would take place in Amsterdam on 12-13 March 2001.

Expert Circle on Medicinal Gases

27. As the Expert circle on medicinal gases meets once every other year, no meeting took place in 2000. The next meeting of the Expert Circle on Medicinal Gases will be held in Düsseldorf (Germany) from 4 to 6 September 2001.

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 biotech products. Expert Circles meet regularly to develop draft guidance, recommendations, etc. in their respective fields of specialisation.

PIC/S guidance documents have been or are in the process of being finalised

28. On 1 January 2000 the recommendations on Sterility Testing (PE 001-1) and on the Validation of Aseptic Processes (PE 002-1) entered into force.

29. In the course of the year, the PIC/S Joint Committee adopted the following two documents, which will enter into force on 1 January 2001:

- A PIC/S internal recommendation on "Quality System Requirements for Pharmaceutical Inspectorates" (PI 002-1);
- A new Annex 14 to the PIC/S GMP Guide on the "Manufacture of Products Derived from Human Blood and Human Plasma". This new Annex is in line with Annex 14 of the EU GMP Guide.

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

- Draft Guidance on Parametric Release (PR 2/99-1 DRAFT 7)
- Draft Revised Annex on Medicinal Gases (PE 003-1 DRAFT 3)
- Draft Recommendations on Isolator Technology (PE 004-1 DRAFT);
- Draft GMP Guide for Blood Centres (PE 005-1 DRAFT 4)
- Draft Guide on Best Practices for Computerised Systems in Regulated "GxP" Environments (PE 006-1 DRAFT 1)

31. The Committee also agreed on a copyright licensing policy of PIC/S publications for commercial distribution.

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

PIC/S now on line

33. The PIC/S Joint Committee commended TGA Australia for designing the excellent PIC/S web site (<http://www.picscheme.org>), successfully launched on 12 May 2000. The web site had attracted over 30,000 visitors from July to September 2000. It further agreed that PIC/S draft documents, which had been released for industry comments, should be placed on the web site.

Harmonisation of batch certificates

34. Although PIC/S has not been directly involved in the harmonisation of batch certificates, the opportunity was taken at the end of the PIC/S Seminar in Colmar for the GMP regulators of Australia, Canada, EU, New Zealand, Switzerland and the USA to meet and to discuss the possibility of having a harmonised batch certificate for the various MRAs (mutual recognition agreements) between these countries.

**LIST OF PIC/S
PARTICIPATING AUTHORITIES**
(in 2000)

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	Ministerie van Sociale Zaken Volksgezondheid en Leefmilieu Algemene Farmaceutische Inspectie Rijksadministratief Centrum Vesaliusgebouw BE-1010 Brussels
CANADA	Therapeutic Products Programme Health Canada 11, Holland Ave., 2 nd Floor Holland Cross, Locator 3002C CA-Ottawa, Ontario K1A 1B6
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-93200 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 Pavilhão 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 Farmacéutico C/Huertas 75 ES-28014 MADRID
SWEDEN	Medical Products Agency Box 26 SE-751 03 Uppsala
SWITZERLAND	
<i>For sera and vaccines</i>	Division of Biologicals Federal Office of Public Health CH-3003 Berne
<i>For all other medicinal products</i>	Intercantonal Office for the Control of Medicines 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

- **Guide to Good Manufacturing Practice for Medicinal Products** (PH 1/97 (Rev.))
 - Ann 1 ➤ Manufacture of sterile medicinal products
 - Ann 2 ➤ Manufacture of biological medicinal products for human use
 - Ann 3 ➤ Manufacture of radiopharmaceuticals
 - Ann 4 ➤ Not yet adopted by the PIC/S. See Guideline PH 6/92
 - Ann 5 ➤ Not yet adopted by the PIC/S. See Guideline PH 6/92
 - 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

Guidelines:

- - for the Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products and for the Manufacture of Immunological Veterinary Medicinal Products (PH 6/92)
- - for the Manufacture of Active Pharmaceutical Ingredients (PH 2/87)

Explanatory Notes:

- - 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)*
- - 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)

Recommendations:

- - on a Quality System for Official Medicines Control Laboratories (PH 2/95)
- - on Validation Master Plan, Installation and Operational Qualification, Non-Sterile Process Validation and Cleaning Validation (PR 1/99-2)
- - on Sterility Testing (PE 001-2)
- - on the Validation of Aseptic Processes (PE 002-2)
- - on Quality System Requirements for Pharmaceutical Inspectorates (PI 002-1)**

Aide-Memoire:

- For the Inspection of Blood Donation and Plasmaspheresis (PH 5/97)
- PIC/s Expert Circle on Medicinal Gases (Sigtuna, November 1997) (PH 1/98)
- NEW** ○ PIC/s Expert Circle on Blood (Saariselkä (Finland) 30 August – 1 September 2000)

* Replacing PH 6/91
** Replacing PH 7/94

Booklets on Seminars organized under the auspices of the Pharmaceutical Inspection Convention
(in English only)

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

Prices

The Guide to Good Manufacturing Practice for Medicinal Products (PH 1/97)	
is invoiced at	S.Frs. 40.- per copy
All seminar booklets are invoiced at	S.Frs. 40.- per copy
The Guidelines, Supplementary Guidelines, Explanatory Notes, Recommendations and Aide-Memoire are invoiced at	S.Frs. 25.- per copy
Documents with this sign are available on the web " www.picscheme.org "	

These publications can be obtained from the

Secretariat to the Pharmaceutical Inspection Convention
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