PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PS/W 13/2013
23 August 2013

ANNUAL REPORT 2012

Prepared by the Secretariat

Please find attached the draft annual report of PIC/S for 2012.

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

New Members

1. In 2012, PIC/S welcomed two new Members: Slovenia's Agency for Medicinal Products and Medical Devices (JAZMP) became the 40th PIC/S Participating Authority on 1 January 2012 and the Indonesian National Agency of Drug and Food Control (NADFC) became the 41st PIC/S Participating Authorities on 1 July 2012.

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 Participating Authorities 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 five Members of the Committee.

Operation of the Scheme

2. In 2012, the PIC/S Committee met twice under the chairmanship of Ms. Helena Baião (Portugal's National Authority of Medicines and Health Products / INFARMED I.P.): first in Geneva (Switzerland) on 7-8 May 2012 and then in Kiev (Ukraine) on 1-2 October 2012.

3. During these meetings, the Committee:

- continued to improve the operation of PIC/S and to reshape the organisation in order to remain efficient;
- endorsed in principle a new PIC/S Sub-Committee Structure, which will become operational in 2014;

- reviewed the proposed Terms of References of future Sub-Committees as well as the impact of the Sub-Committee structure on the PIC/S Committee and the Executive Bureau;
- adopted the revised PIC/S Audit Checklist, which now covers APIs, and the PIC/S Audit Report template (both documents are used for the evaluation and re-evaluation of PIC/S Participating Authorities);
- agreed to run a new "train the trainers" course to enable Participating Authorities to run training courses for new inspectors;
- endorsed the revised mandate of the Expert Circle on APIs and the mandate of the Expert Circle on Good Distribution Practices;
- endorsed the Sub-Committee on Training's recommendation to permanently open the Joint Visits Programme (JVP) to Good Clinical Practices (GCP) inspectors;
- discussed project proposals for PIC/S' future development (e.g. extension of PIC/S mandate to Good Clinical Practices (GCP) and Good Pharmacovigiliance (GVP), PIC/S Inspectorates' Academy, biosafety and biosecurity)
- adopted several guidance documents and discussed proposals to revise the PIC/S GMP Guide (see "Harmonisation of Guidance documents" below).

4. 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 Sub-Committee on Training (SCT), the Sub-Committee on Strategic Development (SCSD) and the Executive Bureau (EB).

5. The Committee also approved the 2011 Statement of Accounts, discharged the Secretary of his responsibility for the financial year 2011, reviewed the status of income and expenditures in 2012 and approved the 2013 budget.

6. The Committee took note of the resignation of Mr. Jiří Holý (Czech Republic / ISCVBM), Member of the PIC/S Executive Bureau and Liaison Officer with the EU and EMA. In replacement, Dr Zofia Ulz (Poland / MPI) was elected as Member of the Bureau for the period 1 November 2012 - 31 December 2013. Dr. Manuel Ibarra (Spain / AEMPS) was also elected as new Liaison Officer with the EU and EMA, for the same period.

7. The Executive Bureau met twice, first in Geneva (Switzerland) on 7 May 2012 and then in Kiev (Ukraine) on 1 October 2012. These meetings were mainly dedicated:

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

8. The Sub-Committee on Training met twice, first in Geneva (Switzerland) on 10-11 May 2012 and then in Kiev (Ukraine) on 30 September 2012. The meetings were chaired by the First Deputy Chairperson, Dr. Joey Gouws (South Africa / MCC).

For more information on the activities of the Sub-Committee on Training, see "Training of Inspectors" below.

9. The Sub-Committee on Strategic Development (SCSD) met in London (United Kingdom) on 2 March 2013 under the chairmanship of Mr Jacques Morénas (France / ANSM). The SCSD discussed and finalised its proposal for a new PIC/S Sub-Committee Structure. This new structure, which will be operational in 2014, provides for a more participative and efficient organisation of PIC/S, where each Sub-Committee will be responsible for its respective core areas and will take the lead in developing policies.

10. As in the past, the PIC/S Secretariat continued to provide secretariat services to the various PIC/S bodies, in particular the Committee, the Executive Bureau, the Sub-Committee on Training, and the Sub-Committee on Strategic Development.

Membership Applications

11. The on-site assessment visit to New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) took place on 7-17 February 2012. At the Kiev meeting in October 2012 and in line with the recommendation of the Audit Team, the Committee invited New Zealand's Medsafe to join PIC/S as the 42th Participating Authority as from 1 January 2013.

12. The on-site assessment visit to the Taiwan Food and Drug Administration (TFDA) of Chinese Taipei took place on 4-8 June 2012. The Committee reviewed the on-site assessment report during its meeting in in Kiev and agreed to invite Chinese Taipei / TFDA to become the 43rd PIC/S Participating Authority as from 1 January 2013.

13. The Rapporteur on the membership application of the Philippines Food and Drug Administration (PFDA) gave a report to the Committee on the outcome of the on-site assessment visit performed by the Audit Team, which took place on 10-14 September 2012. The Committee decided that a follow-up visit was necessary to verify the implementation of corrective action.

14. The United Kingdom's Veterinary Medicines Directorate (VMD) was subject to a joint assessment by PIC/S and the European Commission under its Mutual Recognition Agreement (MRA) with Canada. It is the first time in PIC/S' history that a PIC/S assessment and a MRA evaluation have been conducted jointly. After a challenging paper assessment under both processes, the joint Audit Team performed an on-site visit assessment on 8-12 October 2012.

15. The Rapporteur for the membership application by the Iranian Ministry of Health (MoH) presented to the Committee an updated evaluation report during the Kiev meeting. The clarifications provided Iran's MoH were considered satisfactory. As the paper assessment was now complete, the Committee decided that an on-site assessment visit could take place in 2013.

16. Members were informed that Brazil's Agência Nacional de Vigilância Sanitária (ANVISA) would provide the requested translation of documents supporting its membership application by the end of 2012. The Committee nominated a new Rapporteur in charge of the assessment on the application of Brazil / ANVISA.

17. On 9 March 2012, Japan's Ministry of Labour and Welfare (MHLW) officially submitted a PIC/S membership application in its name as well as on behalf of the Pharmaceuticals and Medical Devices Agency (PMDA) and the Japanese Prefectures. The PIC/S Committee nominated a Rapporteur and five Co-Rapporteurs for the assessment of the application.

18. On 10 April 2012, the Korea Food and Drug Administration (KFDA) officially submitted an application for PIC/S membership. The PIC/S Committee has nominated a Rapporteur and two Co-Rapporteurs for the assessment of the application.

19. On 2 May 2012 Armenia's Scientific Centre of Drug and Medical Technology Expertise (SCDMTE) submitted the completed Questionnaire and Audit Checklist further to the pre-accession application request which was lodged on 8 November 2011. At the Committee meeting in Kiev in October 2012, the Rapporteur reported on the gap analysis performed as part of the pre-accession procedure.

20. During the second part of 2012, two complete pre-accession applications were received: first by Uganda's National Drug Authority (NDA) on 16 July 2012 and then by Belarus's Ministry of Health (MoH) on 30 September 2012.

21. The PIC/S Committee took note of the interest and willingness expressed by Mexico Federal Commission for the Protection against Sanitary Risk (COFEPRIS) to apply for pre-accession in the near future. It also noted that during a side-meeting at the Second GMP Summit held in Washington DC (United States) on 12-14 September 2012, China State Food and Drug Administration / SFDA indicated that accession to PIC/S was a priority.

Reassessment of Participating Authorities

22. An Audit team performed an on-site assessment visit of the Lithuanian State Medicines Control Agency (SMCA) on 10-12 December 2012. SMCA is partially reassessed regarding its participation in PIC/S, in particular the attendance of meetings and training activities.

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 to 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

23. In 2012, the Sub-Committee on Training:

- reviewed all on-going and future training activities of PIC/S, in particular the Joint Visits Programme, the Coached Inspections Programme, the training course for new inspectors as well as training provided by PIC/S Expert Circles;
- decided that in the last quarter of each year a PIC/S Training Schedule covering a period of 18 months would be issued in order to facilitate planning and budgeting of PIC/S training activities;
- reviewed the meeting programmes of the Expert Circle on Computerised Systems, the Expert Circle on APIs and the Expert Circle on Human Blood, Tissues and Cells;
- reviewed the evaluation report on the 2011 PIC/S Seminar in Cape Town (South Africa, 9-11 November 2011); the draft programme of the 2012 Seminar on "Qualification and Validation" (Ukraine, 3-5 October 2012 – see also below); and the draft programme for the 2013 Seminar on "GMP Impacts on Global Supply Chains" in Canada (9-11 October 2013);
- reviewed the conclusions of the Workshop on "GMP Inspection Practices and Trends" organised jointly by PIC/S and PDA Europe, which was held in Geneva (Switzerland) on 9-10 May 2012;
- discussed a proposal by the Irish Medicines Board (IMB) on a "train the trainers" course to enable Participating Authorities to run a training seminar for new inspectors;
- noted that following the Seminar in Kiev the IMB would also conduct a training course for new GMP inspectors from Commonwealth of Independent States;
- discussed the possibility to develop joint webinars with professional organisations such as ISPE or PDA;
- reviewed the potential in offering video training on the PIC/S website based on the recordings of PIC/S training events.

Joint Visits Programme

24. At the end of 2012, there were 15 active Joint Visit Groups under the Joint Visits Programme representing 51 inspectors from around 20 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.

2012 PIC/S Seminar in Kiev

25. The 2012 PIC/S Seminar on "**Qualification and Validation: Today and Tomorrow**" was organised by the State Administration of Ukraine on Medicinal Products (SAUMP) with the support of the State Training Center for Good Manufacturing / Distribution Practice. It was held in Kiev (Ukraine) on 3-5 October 2012. The Seminar was opened by an official welcome address by Ms. Raisa Bohatyriova, Vice Prime Minister and Minister of Health of Ukraine, who took pride in Ukraine being the first former Soviet Union State to accede to PIC/S membership, successfully harmonising its legislation to international standards and implementing a quality system ensuring the safety of medicines.

26. The Seminar was attended by around 100 participants from 44 countries. This number includes inspectors from the following non-PIC/S Member agencies / organisations: Armenian Scientific Centre of Drugs and Medical Technology Expertise SCDMTE, Belarus Ministry of Health, Bulgarian Drug Agency BDA, Croatia Ministry of Health, China State Food and Drug Administration SFDA, European Directorate for the Quality of Medicines & HealthCare (EDQM*), Hong Kong SAR / Department of Health, Japanese PMDA and MHLW, New Zealand's Medsafe, South Korean FDA, Chinese Taipei TFDA, Turkey Ministry of Health, Uganda National Drug Authority, the United Nations International Children's Emergency Fund (UNICEF*), the World Health Organisation (WHO*).

27. Among the seminar participants were also a number of speakers, session chairpersons and workshop facilitators. Speakers were provided by PIC/S Participating Authorities, the *International Society for Pharmaceutical Engineering* (ISPE**) and the Parenteral Drug Association (PDA**).

28. The Seminar's objectives were to give to GMP inspectors theoretical and practical knowledge of new approaches to qualification and validation (Q&V), the theory and practice of Process Analytical Technology (PAT), control strategy of Real Time Release Testing (RTRT) and other important issues.

29. The 2.5 day seminar started with a series of lectures and presentations, which was followed in the second day by four parallel workshops on:

- QRM application for classification of deficiencies in production equipment qualification;
- Risk Based Aseptic Processes Validation – view of inspector;

* PIC/S Partners

** Professional Organisations with whom PIC/S liaises

- Main points for inspecting PAT and RTRT;
- Implementing New Validation Approaches.

30. During the last day of the Seminar, a summary of the outcome of the workshops was presented followed by a presentation on "Q&V – harmonised PIC/S approach, new expectations from ICH level".

Expert Circles & Working Groups

Expert Circle on APIs

31. The Expert Circle on APIs held its 5th meeting in Washington DC (USA) on 17-19 September 2012. Organised by the US Food and Drug Administration, the meeting was on Sterile APIs and Biotechnology Inspections. There were 120 participants from 39 different countries.

32. In 2012, the Expert Circle on APIs continued to develop and implement the 'PIC/S International API Training Programme' which comprises three segments:

- Q7 training, focused on familiarisation with ICH Q7, for both industry and regulators;
- Q&A on ICH Q7 on the interpretation of the requirements of ICH Q7, for industry and regulators;
- advanced training on API inspection, focusing on improving the skills and sharing approaches for addressing contemporary issues, for regulators only.

33. In the framework of the Q7 training for both industry and regulators, PIC/S and the Parenteral Drug Association (PDA) jointly organised two Training Courses on APIs: the first in Beijing (China) on 29-23 October 2012 and the second in Lisbon (Portugal) in 5-6 December 2012.

Expert Circle on Computerised Systems

34. The Expert Circle on Computerised Systems held its 8th meeting in Vienna (Austria) on 22-24 May 2012. There were 58 delegates representing 30 countries. The meeting focused on discussion relating to proposed changes to the "PIC/S Guidance Document on Good Practices for Computerised Systems in regulated GxP environments" (PI 011-3).

Expert Circle on Human Blood, Tissues and Cells

35. The Expert Circle on Human Blood, Tissues and Cells held its 19th meeting in Singapore on 15-17 October 2012. A total of 66 participants (including speakers) attended the meeting representing 26 countries. The meeting was on 'Advancing the Science & Regulations in Human Blood, Tissues and Cells'.

Expert Circle on Quality Risk Management (QRM)

36. The Expert Circle on QRM, which was given a new mandate by the PIC/S Committee, held a meeting in Vienna (Austria) on 3-4 December 2012. This meeting was limited in terms of participation to QRM experts, who met to develop training material.

Expert Circle on Good Distribution Practices (GDP)

37. At its meeting in Kiev in 2012, the PIC/S Committee decided to establish an Expert Circle on Good Distribution Practices which replaces a previously existing Working Group on GDP. The first meeting of the Expert Circle on GDP is planned in Helsinki (Finland) in the first half of 2013.

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

38. The Working Group on Annex 3 to the PIC/S Guide to Good Practices for the Preparation of Radiopharmaceuticals in Healthcare Establishments (PE 010) held its 3rd meeting in London on 25-26 October 2012. A first draft of Annex 3 was submitted to comments to PIC/S Participating Authorities in December 2012.

Harmonisation of guidance documents

39. On 30 May 2012, the new procedure on the harmonisation of PIC/S and EU consultation procedures between PIC/S and the European Medicines Agency (EMA) was signed. The new procedure will ensure better harmonisation between the EU and the PIC/S GMP Guides and other guidance documents.

40. One of the main advantages of the new procedure consists in the involvement of experts from non-EEA Participating Authorities in the revision of the EU GMP Guide and Annexes. As a result, experts from Canada / HPFBI and USA / US FDA will take part in the EU drafting group for the revision of Annex 15 on Qualification and Validation while experts from Australia / TGA, Canada / HPFBI and USA / US FDA will be involved in the revision of Annex 17 on Parametric Release.

41. Members adopted the following revisions to the PIC/S GMP Guide and Annexes:

- Annex 6 on Medicinal Gases;
- Annex 7 on Manufacture of herbal medicinal products;
- Chapter 4 & Annex 11 on Computerised Systems;
- Annex 13 on Investigational Medicinal Products.

42. Regarding the revision of Annex 2 on Biologicals and Annex 14 on Blood & Plasma, the Committee decided to establish a Working Group, which was mandated to transpose the revision of the corresponding EU Annexes for PIC/S purpose.

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

Development of new projects for PIC/S

44. The Committee reviewed replies received from Heads of Agencies from PIC/S Participating Authorities in connection with the survey carried out on PIC/S new projects.

45. With respect to the project of extending PIC/S' mandate to new activities such as Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP), the EMA Ad Hoc Working Groups on GCP and Pharmacovigilance were consulted and the EMA reported on the outcome of the discussions.

46. With regard to the project of creating a PIC/S Inspectorates' Academy to provide cost-efficient, primarily web-based, high quality harmonised training for Inspectorates, the PIC/S Working Group met just after the Committee meeting on 2 October 2012. At this occasion, it decided as a first step to develop Training Questionnaires for National Drug Regulatory Authorities in order to collect information relating to training from all PIC/S Participating Authorities, Applicants, Partners and non-Member National Drug Regulatory Authorities.

47. Finally, with respect to other needs expressed by PIC/S Heads of Agencies, the Committee agreed to first develop concept papers on issues such as biosafety and biosecurity or the setting up of Expert Circles for veterinary issues or medical devices.

Relations with other organisations

ASEAN

48. The PIC/S – ASEAN Liaison Officer reported on ASEAN activities including the training of inspectors, the listing process for Inspectorates within ASEAN for the exchange of GMP inspection reports and certificates and the application of the ASEAN Traditional Medicines and Health Supplements (TMHS) Guide.

Associated Partners and Professional Associations

49. PIC/S continued to actively co-operate with its Associated Partners (EDQM, EMA, UNICEF and WHO) while co-operating on training issues with professional organisations such as PDA and ISPE.

50. The Committee took note that the Heads of EEA Medicines' Agencies ("HMA") had discussed the mutual recognition of audits between the HMA's Joint Assessment Programme (JAP) and PIC/S' Assessment and Re-Assessement of pharmaceutical inspectorates.It was hoped that a Memorandum of Understanding between PIC/S and HMA could be signed in the near future.

PIC/S website

51. In the course of 2012, further upgrades were performed on the PIC/S website (www.picscheme.org) including: the publication of an introductory webpage in French and in Spanish, respectively; a more user-friendly new presentation system for the publication of documents in open access; the development of a VOD gallery to allow for the publication of recorded training material; several minor updates to the appearance of certain pages.

****

LIST OF PIC/S
PARTICIPATING AUTHORITIES & PARTNERS
(as of 31 December 2012)

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[1]	Státní Ústav pro Kontrolu Léčiv *(State Institute for Drug Control)*	SÚKL
	Ústav pro Státní Kontrolu Veterinárních Biopreparátů a Léčiv *(Czech Institute for State Control of Veterinary Biologicals and Medicines)*	ISCVBM
Denmark	Danish Health and Medicines Agency	DHMA
Estonia	State Agency of Medicines	SAM
Finland	Finnish Medicines Agency	FIMEA
France [2]	Agence National de Sécurité du Médicament et des Produits de Santé *(National Drug and Health Products Safety Agency)*	ANSM
	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (*French Agency for Food, Environmental & Occupational Health Safety*)	ANSES

[1] SÚKL and ÚSKVBL count as two distinct Participating Authorities.

[2] ANSM and ANMV count as two distinct Participating Authorities.

Germany [3]	Bundesministerium für Gesundheit *(Federal Ministry of 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 for Quality- and Organizational Development in Healthcare and Medicines National Institute of Pharmacy	NIP-GYEMSZI
Iceland	The Icelandic Medicines Agency	IMA
Indonesia	National Agency for Drug and Food Control	NADFC
Ireland	Irish Medicines Board	IMB
Israel	Institute for the Standardization and Control of Pharmaceuticals	ISCP
Italy	Agenzia Italiana del Farmaco	AIFA
Latvia	Zāļu Valsts Aģentūra *(State Agency of Medicines)*	ZVA
Liechtenstein	Amt für Gesundheit *(Office of Healthcare)*	AG
Lithuania	State Medicines Control Agency	SMCA
Malaysia	National Pharmaceutical Control Bureau	NPCB
Malta	Medicines Authority Malta	MAM
Netherlands	Inspectie voor de Gezondheidszorg *(Inspectorate of Health Care)*	IGZ
Norway	Norwegian Medicines Agency	NOMA
Poland	Main Pharmaceutical Inspectorate	MPI
Portugal	Autoridade Nacional do Medicamento e Produtos de Saúde IP	INFARMED IP
Romania	National Agency for Medicines and Medical Devices	NAMMD
Singapore	Health Sciences Authority	HSA
Slovak Republic	State Institute for Drug Control	SIDC
Slovenia	Agency for Medicinal Products and Medical Devices	JAZMP
South Africa	Medicines Control Council	MCC
Spain	Agencia Española del Medicamento y Productos Sanitarios *(Spanish Agency of Drugs and Health Products)*	AEMPS

[3] BMG and ZLG count as one Participating Authority.

Sweden	Medical Products Agency	MPA
Switzerland	Swiss Agency for Therapeutic Products	Swissmedic
Ukraine	State Administration of Ukraine on Medicinal Products	SAUMP
United Kingdom	Medicines and Healthcare Products Regulatory Agency	MHRA
United States of America	United States Food and Drug Administration	US FDA

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.