PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PS/W 3/2011
25 July 2011

ANNUAL REPORT 2010

FOREWORD BY THE PIC/S CHAIRMAN

As I reflect back on the past 12 months, I am proud to see how the Pharmaceutical Inspection Co-operation Scheme (PIC/S) has continued to develop and strengthen. It has been a great privilege for me to serve my first year as PIC/S Chairman in what has been an exciting and productive year for the organisation. This past year has been particularly prolific in terms of applications for PIC/S membership. The number of applicants increased from 7 to 11, emphasising the growing importance Regulatory Authorities around the world are beginning to place in the need for co-operation and harmonisation. We have seen a record of 4 new applications within one year: in April New Zealand's Medicines and Medical Devices Safety Authority (Medsafe), in June the United Kingdom's Veterinary Medicines Directorate (VMD) and Chinese Taipei's Taiwan Food and Drug Administration (TFDA), and in July Brazil's Agência Nacional de Vigilância Sanitária (ANVISA). The growth in the volume of applications is both a notable challenge but also an outstanding opportunity for PIC/S.

2010 also saw a number of significant achievements for PIC/S not least of which the invitation to the US Food and Drug Administration (FDA) and the Ukraine's State Inspectorate for Quality Control of Medicines (SIQCM) to join the Scheme as from 1 January 2011.

PIC/S continued to provide multiple training opportunities for inspectors from PIC/S and Applicant Authorities. This year the PIC/S Annual Seminar was organised by the Malaysian National Pharmaceutical Control Bureau in Kuala Lumpur. It was a great honour for PIC/S to have the Malaysian Minister of Health and the Senior Director of Pharmaceutical Services at the Ministry of Health for the official opening of the meeting.

The development of relations with our ASEAN colleagues in 2010 was further enhanced with the second PIC/S – ASEAN forum held in Kuala Lumpur (Malaysia) in November. At the meeting, PIC/S was informed that all ASEAN countries had now signed the ASEAN Sectoral Mutual Recognition Arrangement on GMP which would

enter into force on 1 January 2011. To continue to develop co-operation with our ASEAN partner, PIC/S proposed to consider running future PIC/S training courses in Asia.

In Europe PIC/S further consolidated relations with partners with the tacit renewal on 30 July 2010, for a period of three years, of the co-operation agreement between PIC/S and the European Directorate for the Quality of Medicines & HealthCare (EDQM). Furthermore, in December PIC/S and the European Medicines Agency (EMA) approved and signed a revised co-operation agreement. The building blocks to further strengthen and improve confidentiality agreements between Participating Authorities and Partners are being worked on, in order to facilitate the exchange of information. Improving collaboration and trust with Partners is key for PIC/S to achieve a harmonised framework.

Another highlight of 2010 was being able to partake in the preliminary preparations for the PIC/S 40th Anniversary to be celebrated in May 2011. A significant milestone such as this naturally encouraged us to further consider the future of PIC/S and the need to push forward. In this vein PIC/S continued to explore the possibilities to officially extend our mandate to Good Distribution Practices (GDP). Preliminary discussion and preparations were also undertaken for the 2011 Annual Seminar on Good Pharmaceutical Inspection Practices which will take place in Cape Town (South Africa), the first PIC/S Seminar to be held on the African continent.

All of this could only be achieved through the hard work and dedication of members and colleagues who gave significant amount of their time and effort to PIC/S, which is particularly admirable given that it is all done on a voluntary basis. I take this opportunity to thank them all for their unrelenting support. I am confident that with their continuing engagement PIC/S can take on the challenges and opportunities of 2011 and "lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice Standards and quality systems of inspectorates in the field of medicinal products".

Tor Gråberg
(Sweden / MPA)
PIC/S Chairman

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

New Members

1. In 2010, PIC/S comprised 37 inspectorates from Argentina, Australia, Austria, Belgium, Canada, Cyprus, Czech Republic (human & veterinary), Denmark, Estonia, Finland, France (human & veterinary), Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Liechtenstein, Lithuania, Malaysia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, South Africa, Spain, Sweden, Switzerland and the United Kingdom (see also Annex I).

Pharmaceutical Inspection Co-operation Scheme

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

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

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

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

Operation of the Scheme

2. In 2010, the PIC/S Committee met twice under the chairmanship of Mr. Tor Gråberg (Swedish Medical Products Agency / MPA) first in Geneva (Switzerland) on 19-20 May 2010 and then in Kuala Lumpur (Malaysia) 7-12 November 2010.

3. During these meetings, the Committee:

- continued to improve the operation of PIC/S and to reshape the organisation in order to remain efficient and to better co-operate with non-Members;

- discussed several possibilities for strengthening confidentiality between PAs and with Partners in order to facilitate the exchange of information;
- discussed the possibility for PIC/S to officially extend its mandate to Good Distribution Practices (GDP) and considered the possibility to take over the revised EU or WHO GDP Guidelines;
- discussed a Concept Paper by the European Commission for enhanced co-operation in the field of APIs, in which PIC/S is identified as one of the main stakeholders;
- adopted a revision of the PIC/S Explanatory Notes for Industry on the Preparation of a Site Master File (SMF). The EMA requested the revision because they will adopt the document in identical terms in Part 3 of the EU GMP Guide;
- reviewed the draft programme of the PIC/S' 40th anniversary in Geneva (Switzerland) on 31 May 2011. PIC/S will run a symposium on "40 Years of Co-operation & Mutual Confidence: Challenges & Future Perspectives".

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

5. The Committee also approved the 2009 accounts, discharged the Chairman for the financial year 2009 and approved the 2010 budget. It also adopted several guidance documents and revised the PIC/S GMP Guide (see "Harmonisation of Guidance documents" below).

6. The Executive Bureau met twice, first in Geneva (Switzerland) on 17 May 2010 and then in Kuala Lumpur (Malaysia) 8 November 2010. These meetings were mainly dedicated:

- to discuss financial, administrative and staff related issues;
- to assist the Chairman in the execution of his mandate and;
- to prepare the meetings of the Committee and the 40th anniversary.

7. The Sub-Committee on Training met twice, first in Geneva (Switzerland) on 18 May 2010 and then in Kuala Lumpur (Malaysia) 7 November 2010. The meetings were chaired by the First Deputy Chairperson, Ms. Helena Baião (Portugal / INFARMED). For more information on the activities of the Sub-Committee on Training, see "Training of Inspectors" below.

8. The Sub-Committee on Strategic Development of PIC/S held its second meeting in Geneva on 13 July 2010. Under the Chairmanship of Mr. Jacques Morénas (France / AFSSAPS), the meeting focused its discussions on the following issues:

- the possibility of introducing a two-tier membership system;
- the better representation of non-EU PAs in PIC/S;
- the increasing number of membership applications and the necessity to revise the accession process;
- how to improve co-operation with WHO;
- the introduction of a regionalised training system.

9. In 2010, the PIC/S Secretariat continued to provide secretariat services to the various PIC/S bodies (Committee, Executive Bureau, Sub-Committee on Training and Sub-Committee on Strategic Development).

Membership Applications: New Zealand, UK Vet, Chinese Taipei and Brazil apply

10. The Committee reviewed the update provided by the US's Food and Drug Administration (FDA) on the progress made by the FDA to meet PIC/S' 89 indicators and discussed the report on the PIC/S follow up visit in Washington DC on 9-12 August 2010. It noted that the US FDA had demonstrated remarkable commitment to comply with all PIC/S requirements and agreed with the Audit Team's recommendation. It thus invited the US FDA to accede to PIC/S on 1 January 2011 as PIC/S' 38th Participating Authority.

11. Following two on-site assessment visits in Kiev, on 22-26 March 2010 and on 4-6 October 2010, the Committee discussed the assessment report on the Ukraine's State Inspectorate for Quality Control of Medicines (SIQCM). Satisfied that SIQCM had made impressive efforts to address all outstanding issues and deficiencies identified during the first on-site visit in March 2010, the Committee invited Ukraine's SIQCM to accede to PIC/S as from 1 January 2011 as the 39th PIC/S Participating Authority.

12. The Committee noted that the completion date for the corrective action plan by the Thai Food and Drug Administration (Thai FDA) had been postponed from 2012 to 2015, i.e. beyond the 6-year timeframe for acceding to PIC/S, which expires in 2012. The Committee decided to conduct a follow-up visit to Thai FDA in the course of 2011, subject to Thai FDA confirming the timeframe for the completion of its action plan by 2012.

13. An on-site assessment visit to Indonesia's National Agency for Drug and Food Control (NADFC) took place from 1-5 November 2010. According to the Audit Team, NADFC was meeting most PIC/S membership requirements and a follow-up visit would be scheduled in the course of 2011.

14. Missing translations and supporting documents from Slovenia's Agency for Medicinal Products and Medical Devices (JAZMP) slowed down the assessment process during 2010.

15. The Committee reviewed the application of Iran's Ministry of Health (MoH). The Rapporteur, in charge of the assessment of the application, was still waiting for documents and unable to make progress.

16. A preliminary report on the assessment of the Philippines' Bureau of Food and Drugs (BFAD) was presented to the Committee. The latter agreed that the on-site assessment visit to the Philippines should take place once BFAD had replied to the report.

17. New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) officially submitted an application for PIC/S membership on 16 April 2010. The Committee nominated a Rapporteur and two Co-Rapporteurs for the assessment of Medsafe's application and agreed that an on-site assessment visit could take place in the course of 2011.

18. On 7 June 2010, the United Kingdom's Veterinary Medicines Directorate (VMD) officially submitted an application for PIC/S membership. The Committee nominated a Rapporteur and Co-Rapporteur for the assessment and agreed that the on-site assessment visit would take place during the second half of 2011, possibly jointly with Health Canada.

19. The Committee nominated a Rapporteur for the assessment of the application submitted, on 14 June 2010, by the Taiwan Food and Drug Administration (TFDA) of Chinese Taipei.

20. Brazil's Agência Nacional de Vigilância Sanitária (ANVISA) officially submitted an application for PIC/S membership on 30 July 2010. The Committee nominated two Rapporteurs and a Co-Rapporteur. After a pre-assessment, the application was considered incomplete as most of the documentation had been submitted in Portuguese.

21. Members endorsed a Memorandum of Understanding (MoU) signed by the PIC/S Chairman and the Head of Russia's Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor), in Moscow in February 2010, with a view to encourage the latter's application for PIC/S membership.

22. The PIC/S Chairman together with several Executive Bureau Members met, on 18 May 2010, with a Delegation from Hong Kong SAR led by the Director of Hong Kong's Department of Health. The meeting focused on the Department of Health's intention to submit an application for PIC/S membership. Subsequently the Chairman visited Hong Kong SAR in December 2010 in order to make a gap assessment at the request of Hong Kong's Department of Health.

23. The current and past Chairmen both promoted PIC/S in Japan in September 2010 and met with officials from the Japanese Ministry of Health, Labour and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency (PMDA) and also representatives from the Japanese Pharmaceutical Manufacturers Association (JPMA).

Reassessment of Participating Authorities

24. The reassessment of Latvia / ZVA was postponed until the return of the head of the GMP Inspection Department in 2011. Considering the large number of applications (10 in 2010), the reassessments were reduced due to limited resources.

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

25. In 2010, the Sub-Committee on Training reviewed:

- the first PIC/S training seminar for new inspectors to be organised by the Irish Medicines Board (IMB) in Dublin (Ireland) on 24-28 January 2011;
- meetings by PIC/S Expert Circles such as the Expert Circles on APIs, Quality Risk Management and Human Blood, Tissues and Cells;
- the international training course on APIs developed by the PIC/S Expert Circle on APIs;
- the operation of the Joint Visit Programme and discussed the active encouragement of participation from new Participating Authorities;
- the progress of the newly implemented Coached Inspection Programme;
- the possibility to develop web-based training for inspectors;
- the draft programme of the 2011 Seminar on "Good Inspection Practices" (South Africa, 9-11 November 2011).

<u>Joint Visits Programme and Coached Inspections Programme</u>

26. At the end of 2010, there were 20 active joint visit groups under the Joint Visits Programme, representing more than 80 inspectors from around 20 different nationalities.

27. In order to provide training to new inspectors or inspectors wishing to improve their inspection skills in a specific field, PIC/S introduced in 2009 a programme on coached inspections. In 2010, the majority of application emanated from Junior Inspectors.

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.

2010 PIC/S Seminar in Kuala Lumpur

28. The 2010 Seminar was organised by the Malaysian National Pharmaceutical Control Bureau (NPCB). It was held in Kuala Lumpur (Malaysia) from 10-12 November 2010 on the "GMP inspection of herbal / traditional medicine manufacturers". It was officially opened by Dato' Sri Liow Tiong Lai, Minister of Health, Malaysia, and Dato' Eisah Abdul Rahman, Senior Director of Pharmaceutical Services at the Ministry of Health of Malaysia.

29. The Seminar was attended by 93 participants from 36 countries. This number includes inspectors from the following non-Member agencies / organisations: Brunei / DPS, China / SFDA, Chinese Taipei / TFDA, the European Directorate for the Quality of Medicines (EDQM[1]), Hong Kong SAR / DoH, Indonesia / NADFC, Iran / MoH, Japan / PMDA, Korea FDA, Laos FDA, New Zealand / Medsafe, Oman / DGPA, Slovenia / JAZMP, Thai FDA, Ukraine / SIQCM[2], the United Nations International Children's Emergency Fund (UNICEF[*]) and US FDA[**].

30. Among the 93 seminar participants were also a number of speakers, session chairpersons and workshop leaders. Speakers were provided by PIC/S Participating Authorities, the World Health Organization (WHO[*]), China's SFDA, academia and industry associations.

31. The Seminar focused on the following objectives:

1) to learn about traditional / herbal medicinal products from experienced Asian countries;

[1] PIC/S Partners

[2] PIC/S Participating Authority as from 01.01.2011

2) to bridge the gap of interpretation of PIC/S Annex 7 (manufacturing of herbal medicinal products) in order to achieve consistence and similar interpretation of GMP for traditional / herbal medicinal products;
3) to harmonise the inspection approaches for PIC/S PAs;
4) to identify necessary improvements of Annex 7 and to establish an Aide-Memoire on the inspection of traditional / herbal medicinal products with the aim of facilitation of the planning and conduct of inspections.

32. The 2.5 day seminar was composed of a series of lectures and presentations. They were completed on the 2nd day by four workshops on:

- Requirements on manufacturing facilities and utilities for the manufacturing of traditional / herbal medicinal products;
- Quality control on traditional / herbal medicinal products;
- Risk management of traditional / herbal medicinal products manufacturing facilities;
- Necessity for modifying PIC/S Annex 7 and proposal for the development of an Aide-Memoire for the inspection of traditional / herbal medicinal products.

Expert Circles & Working Groups

Expert Circle on APIs

33. The 3rd meeting of the Expert Circle on API took place in Dublin (Ireland) on 26-28 May 2010. A total of 68 participants from 27 different organisations attended the meeting on Supply Chain Management and Quality Risk Management for Inspection Planning. The Steering Committee also elaborated a training programme for new and experienced API inspectors.

Expert Circle on Computerised Systems

34. The Expert Circle on Computerised Systems did not meet during the year 2010. The 8th meeting of the Expert Circle will take place in 2011 in Austria.

Expert Circle on Human Blood, Tissues and Cells

35. The Expert Circle on Human Blood, Tissues and Cells held their 17th meeting in Saint-Denis (France) from 28 September - 1 October 2010. A total of 73 participants attended the meeting. The focus was on international activities, training courses and workshops on blood, tissues, cells and advanced therapies in the form of role plays. The next meetings are set to be held in Estonia in 2011 and in Singapore in 2012.

Expert Circle on Quality Risk Management (QRM)

36. The 5th meeting of the Expert Circle on QRM took place in Warsaw (Poland) on 9 September 2010. The Expert Circle decided to finalise both draft guidelines on

the Risk-based Inspection Model and an Aide Memoire. The 5th meeting took place directly after the QRM training held on 7-8 September 2010 in Warsaw (Poland). An assessment of the training was carried out enabling the Expert Circle to conclude that the immediate objectives for training on QRMs were attained.

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

37. The 2nd meeting of the Working Group on Annex 3 to the PIC/S Guide on Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE 010) took place in Lisbon (Portugal) on 23-25 June 2010. A total of 17 participants attended the meeting, which included presentations on radiopharmaceuticals and discussions on the revision of Annex 3 on radiopharmaceuticals.

Working Group on Good Distribution Practices (GDP)

38. The Working Group on GDP met for the third time in Oslo (Norway) on 18-21 May 2010. At the meeting the extension of PIC/S' mandate to GDP was reviewed. The WG on GDP proposed, in a joint Note, to turn into an Expert Circle with the primary aim to train inspectors in the field of GDP. A first meeting of the Expert Circle on GDP will take place in Finland in April 2012.

Harmonisation of guidance documents

39. In 2010, PIC/S adopted the revision of:

- the PIC/S Recommendation on the validation of aseptic processes (PI 007-6), and
- the PIC/S Procedure for handling rapid alerts and recalls arising from quality defects (PI 010-4).

40. PIC/S endorsed in principle the following two PIC/S guidelines on Quality Risk Management (QRM) developed by the PIC/S Expert Circle on QRM:

- Recommendation for Risk-based Inspection Planning in the GMP Environment (PI 037-1 (Draft));
- Aide-Memoire on the Assessment of Quality Risk Management Implementation (PI 038-1 (Draft)).

41. The first guideline is intended to assist inspectorates in the planning of their inspections following the QRM principles while the second guideline aims at inspecting the implementation of QRM by industry. Both documents will be tested by GMP inspectors during a 4-month validation phase before being formally adopted by the Committee.

42. PIC/S discussed the revision of Annex 7 (Herbal Medicinal Products) to the PIC/S GMP Guide, in particular the requirement of GACP[3] compliance of herbal medicinal products' suppliers. The revision has not been adopted.

43. PIC/S also discussed the following draft revisions of the PIC/S GMP Guide:

- Part II (PS/W 16/2010);
- Annex 6 (Medicinal Gases);
- Annex 13 (Investigational Medicinal Products).

44. Members agreed to postpone the adoption of these revisions until 2011 in order to await the outcome of the consultation by non-EEA Members of their respective national industry.

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

Relations with other organisations

ASEAN

46. The second PIC/S – ASEAN forum was held in Kuala Lumpur (Malaysia) on 12 November 2010 following the annual PIC/S Seminar. ASEAN Competent Authorities (CAs) from Brunei, Indonesia, Laos, Malaysia, Singapore and Thailand as well as the ASEAN Secretariat were represented.

47. The PIC/S delegation was conducted by the PIC/S Chairman and comprised some Members of the Executive Bureau and the Secretariat. The delegation recalled that most PIC/S training activities were open to ASEAN CAs and proposed to consider running future PIC/S training courses in Asia in order to facilitate the participation of ASEAN inspectors.

48. During the meeting PIC/S was informed that in 2010 the ASEAN Sectoral Mutual Recognition Arrangement on GMP was signed by all ASEAN countries and would enter into force on 1 January 2011.

49. The Committee also nominated Malaysia / NPCB as the PIC/S - ASEAN Liaison Authority for the period 2011-2012.

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3 Good Agricultural and Collection Practices

EDQM

50. PIC/S and EDQM tacitly renewed their co-operation agreement on 30 July 2010 for a period of three years.

EMA

51. In December 2010 a revised co-operation agreement between PIC/S and EMA was approved and signed by both parties. The proposed changes concerned the inclusion of Good Distribution Practices in the scope of the co-operation as well as the strengthening of confidentiality and the improvement of the sharing of information.

WHO

52. The First Deputy Chairperson represented PIC/S at the 45th meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, which took place in Geneva on 18-22 October 2010.

53. PIC/S and WHO also discussed possible ways to improve co-operation in terms of training and sharing of information.

PIC/S website

54. In the course of 2010, upgrades were performed on the PIC/S website (www.picscheme.org) to facilitate browsing and usage of the site.

LIST OF PIC/S
PARTICIPATING AUTHORITIES & PARTNERS
(as of 31 December 2010)

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[4]	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 Medicines Agency	DMA
Estonia	State Agency of Medicines	SAM
Finland	Finnish Medicines Agency	FIMEA
France [5]	Agence Française de Sécurité Sanitaire des Produits de Santé *(French Health Products Safety Agency)*	AFSSAPS
	Agence Nationale du Médicament Vétérinaire *(French Agency for Veterinary Medicinal Products)*	ANMV
Germany [6]	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

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

[5] AFSSAPS and ANMV count as two distinct Participating Authorities.

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

Hungary	National Institute of Pharmacy	NIP
Iceland	The Icelandic Medicines Agency	IMA
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	Instituto Nacional da Farmácia e do Medicamento	INFARMED
Romania	National Agency for Medicines and Medical Devices	NAMMD
Singapore	Health Sciences Authority	HSA
Slovak Republic	State Institute for Drug Control	SIDC
South Africa	Medicines Control Council	MCC
Spain	Agencia Española del Medicamento y Productos Sanitarios *(Spanish Agency of Drugs and Health Products)*	AEMPS
Sweden	Medical Products Agency	MPA
Switzerland	Swiss Agency for Therapeutic Products	Swissmedic
United Kingdom	Medicines and Healthcare Products Regulatory Agency	MHRA

II – PARTNERS

(in the alphabetical order of their acronyms)

	PARTNER	**ACRONYM**
	European Directorate for the Quality of Medicines & HealthCare	EDQM
	European Medicines Agency	EMA
	United Nations International Children's Emergency Fund	UNICEF
	World Health Organization	WHO

From the Pharmaceutical Inspection Convention

to the Pharmaceutical Inspection Co-operation Scheme

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

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

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

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

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