PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PS/W 6/2012
11 September 2012

ANNUAL REPORT 2011

Prepared by the Secretariat

Please find attached the annual report of PIC/S for 2011.

ANNUAL REPORT 2011

FOREWORD BY THE PIC/S CHAIRMAN

2011 was a remarkable year for the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and an occasion for celebration and reflection, as it marked the PIC/S's 40th anniversary. We celebrated the occasion with a full day symposium which was held in Geneva (Switzerland) on 31 May 2011 in conjunction with the first PIC/S Committee meeting of the year. The symposium, with the theme "40 Years of Co-operation & Mutual Confidence: Challenges & Future Perspectives", included a retrospective of major milestones in PIC/S history and highlighted the growth of the organisation, both in terms of membership and activities, as well as its important role as a forum for co-operation. 160 participants from 55 countries attended the event, including Competent Authorities from Argentina, Australia, Brazil, Canada, China, Chinese Taipei, Croatia, most EU/EEA Member States, Georgia, Hong Kong SAR, Indonesia, Iran, Israel, Japan, Malaysia, New Zealand, Nigeria, Russia, Singapore, Saudi Arabia, South Africa, South Korea, Switzerland, Thailand, Turkey, Uganda, Ukraine, and USA. This notable participation demonstrated the growing commitment by Regulatory Authorities around the world to co-operation and harmonisation in Good Manufacturing Practices (GMP). During her key note address at the PIC/S 40th anniversary symposium, Dr. Margaret Hamburg, the US FDA Commissioner, noted that the globalisation of supply chains had led to growing cross-border trade in finished medicinal products and Active Pharmaceutical Products (APIs), and called upon all Regulatory Authorities to co-operate more closely and share more information on GMP inspections.

Beyond the celebration of its 40th anniversary, the year 2011 also saw a number of achievements for PIC/S. We were able to welcome two new members with the PIC/S accession on 1 January 2011 of the US Food and Drug Administration (FDA) and the State Administration of Ukraine on Medicinal Products (SAUMP), formerly known as the State Inspectorate for Quality Control of Medicines (SIQCM). In addition, the accession process for Slovenia's Agency for Medicinal Products and Medical Devices (JAZMP) was completed, allowing the Agency to join the Scheme as of 1 January 2012.

PIC/S training activities continued to draw a large number of participants from PIC/S Participating Authorities, Applicants and non-Member Agencies. Due to overwhelming demand, the first PIC/S training course for new inspectors had to be carried out in two sessions, which took place in Dublin (Ireland) in January and August 2011. The PIC/S Annual Seminar, hosted by the South African Medicines Control Council in Cape Town, was also a great success with the participation of over 120 attendees from 46 countries. As the first PIC/S Seminar to be held on the African continent, it allowed three countries from the region to participate in a PIC/S event for the first time, namely Botswana, Zambia and Zimbabwe. For 2012, Ukraine / SAUMP generously offered to host the Annual Seminar in Kiev. The initial preparations for the event got underway and the topic selected was "Qualification and Validation".

In 2011 co-operation with Associated Partners, EDQM, EMA, UNICEF and WHO, continued, our work to reinforce the confidentiality agreements between Participating

Authorities and Partners made good progress and the revision of the respective documents begun. We also examined throughout the year different joint training opportunities with professional organisations such as PDA and ISPE. Furthermore all Partners and several professional and industry associations (APIC, EFPIA, ISPE, IFPMA) attended PIC/S' 40th anniversary celebration.

At its meeting in Cape Town, the Committee elected the First Deputy Chairperson as Chairperson for the period 2012-2013 and elected/re-elected for the same period the other Members of the Executive Bureau. The composition of the Executive Bureau was enlarged to integrate a regional representative for the Americas in order to better reflect PIC/S membership. During its meeting, the Committee also approved the revision of the PIC Scheme and the Rules of Procedure in order to reflect certain structural changes and new developments. The amended Scheme, which will enter into force at the beginning of 2012, includes a reference to Good Distribution Practices (GDP), the new PIC/S pre-accession process and strengthened terms of confidentiality. This restructuring represents new growth opportunities for PIC/S, which remain in line with our philosophy based on co-operation, communication and trust.

Finally, I wish to acknowledge once again the commitment and efforts of PIC/S Members and colleagues, whose continued invaluable support has helped PIC/S become a pioneer organisation in the field of pharmaceutical inspections and GMP. It has been an honour to serve as Chairman of PIC/S for the past two years and I am pleased to be succeeded by Ms. Helena Baião (Portugal / INFARMED IP), whose guidance and charisma will further strengthen PIC/S in its mission to enhance global co-operation and harmonisation of Good Manufacturing Practices.

Tor Gråberg
(Sweden / MPA)
PIC/S Chairman

Helena Baião, elected PIC/S Chairperson 2012-13, with Mr. Tor Gråberg, PIC/S Chairman 2010-2011.

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

New Members

1. On 1 January 2011, USA's Food and Drug Administration (FDA) and the State Administration of Ukraine on Medicinal Products (SAUMP), formerly the Ukraine's State Inspectorate for Quality Control of Medicines (SIQCM), became the 38th and 39th Participating Authorities of PIC/S, respectively.

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 2011, the PIC/S Committee met twice under the chairmanship of Mr. Tor Gråberg (Swedish Medical Products Agency / MPA): first in Geneva (Switzerland) on 30 May 2011 and then in Cape Town (South Africa) 7-8 November 2011.

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;
- amended the Accession Guidelines to introduce a pre-accession procedure to avoid premature membership applications; and included the

possiblity for Applicants to pay 50% of the annual membership fee to enable them to attend PIC/S Committee meetings as Observers.

- revised the PIC/S Application Form and Questionnaire in order to align the questionnaire with the 89 criteria of the PIC/S audit check-list, which is used for both the assessment of Applicants Authorities and the re-assessment of PIC/S Participating Authorities;
- revised the PIC Scheme to include a reference to Good Distribution Practices (GDP), the new PIC/S pre-accession process, the reinforcement of the confidentiality of shared information as well as certain structural changes;
- revised the Committee's Rules of Procedure to reflect the reinforcement of the confidentiality of information exchanged under the PIC Scheme;
- attended the symposium on "40 Years of Co-operation & Mutual Confidence: Challenges & Future Perspectives", organised to celebrate PIC/S' 40th anniversary, which took place in Geneva (Switzerland) on 31 May 2011;
- discussed project proposals for PIC/S' future development and the letters requesting for support from PIC/S Heads of Agencies.

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 2010 accounts, discharged the Secretary of this responsibility for the financial year 2010 and approved the 2011 budget. It also adopted several guidance documents and discussed proposals to revise the PIC/S GMP Guide (see "Harmonisation of Guidance documents" below).

6. The Executive Bureau met twice, first in Geneva (Switzerland) on 1 June 2011 and then in Cape Town (South Africa) on 7 November 2011. 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.

7. The Sub-Committee on Training met twice, first in Geneva (Switzerland) on 1 June 2011 and then in Cape Town (South Africa) on 6 November 2011. The meetings were chaired by the First Deputy Chairperson, Ms. Helena Baião (Portugal / INFARMED IP). 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 Chaired by Mr Jacques Morénas (France / AFSSAPS) postponed its third meeting to the first quarter of 2012.

9. In 2011, 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

10. An on-site assessment visit to Slovenia's Agency for Medicinal Products and Medical Devices (JAZMP) was performed by the Assessment Team on 19-23 September 2011, during which no significant deviations were found. Satisfied with the submitted corrective/preventive actions (CAPA) plan, which addressed some issues identified during the visit, the Committee invited JAZMP to accede to PIC/S as from 1 January 2012.

11. Following the on-site assessment visit to Indonesia's National Agency for Drug and Food Control (NADFC), in November 2010, NADFC provided the Assessment Team with 2 CAPA reports and its new GMP Guide for Traditional Medicines. A follow-up visit to NADFC was performed on 5-9 December 2011 following which, the Assessment Team requested NADFC to provide a number of documents in English and an updated CAPA by 8 March 2012.

12. Thailand's Food and Drug Administration (Thai FDA) provided two CAPA plans which both exceeded its 6 year timeframe for acceding to PIC/S (February 2012). Thai FDA requested to submit a final CAPA by the end of February 2012.

13. The Committee reviewed the reports on the paper assessment of the United Kingdom's Veterinary Medicines Directorate (VMD), which was carried out jointly between PIC/S and Canada (the latter in the framework of the EU – Canada MRA) and noted that the on-site assessment visit to VMD was postponed to the first half of 2012.

14. The Committee reviewed the application of New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) and noted that the on-site assessment visit to Medsafe would take place in the first quarter of 2012.

15. The Philippines' Agency officially informed PIC/S of a change in name from Bureau of Food and Drugs (BFAD) to Food and Drug Administration (FDA). A second report on the paper assessment of the Philippines' FDA was presented to the Committee.

16. On 14 February 2011 the Committee nominated, by written procedure, the Co-Rapporteurs for the assessment of the Taiwan Food and Drug Administration (TFDA) of Chinese Taipei. At its meeting in Cape Town the Committee reviewed the paper assessment report and agreed that an on-site assessment visit would take place in the course of 2012.

17. Iran's Ministry of Health (MoH) provided the missing documents requested for the paper assessment; unfortunately, many of the documents were in Farsi. The Committee reviewed the preliminary paper assessment report and agreed that the on-site assessment visit should only take place once the requested documents were submitted in English and MoH complied with PIC/S requirements.

18. At its meeting in May the Committee reviewed the application of Brazil's Agência Nacional de Vigilância Sanitária (ANVISA) and nominated 2 additional Co-Rapporteurs. ANVISA application was still considered as incomplete as the assessment documentation had still not been provided in English.

19. The Chairman informed the Committee that Japan's Ministry of Labour and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency (PMDA) and the Japanese Prefectures had confirmed their intention to apply for PIC/S membership in the first quarter of 2012.

20. In Cape Town, the Committee noted the strong commitment expressed by the Korean Food and Drug Administration (KFDA) to accede to PIC/S. It was only a matter of time before an application was lodged by KFDA

21. Armenia's Scientific Centre of Drug and Medical Technology Expertise (SCDMTE) submitted a pre-accession request on 8 November 2011 and the Committee nominated a Rapporteur and Co-Rapporteur. After a preliminary assessment, the application was considered as incomplete and SCDMTE was requested to provide a completed questionnaire and audit checklist.

22. Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) submitted a pre-accession request on 9 November 2011. The application, however, was considered incomplete.

23. Several non-Member National Drug Regulatory Authorities attended PIC/S' 40th anniversary symposium, during which Agencies from Bulgaria, China, Croatia, Georgia, Hong Kong SAR, Hungary (Vet), Japan, Nigeria, Russia, Saudi Arabia, South Korea, Turkey and Uganda expressed interest in joining PIC/S.

Reassessment of Participating Authorities

24. The reassessment of Latvia / ZVA was postponed until 2012, at the request of the head of ZVA's GMP Inspection Department.

25. The Committee agreed to the partial re-assessment of Lithuania / SMCA 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

26. In 2011, the Sub-Committee on Training reviewed:

- the reports on the first and second PIC/S training courses for new inspectors organised by the Irish Medicines Board (IMB) in Dublin (Ireland) on 24-28 January 2011 and 16-22 August 2011, respectively; and the "train the trainers" proposal by IMB, which would allow for further dissemination of the course;
- meeting programmes by PIC/S Expert Circles such as the Expert Circles on APIs and Human Blood, Tissues and Cells;
- the international training course on APIs developed by the PIC/S Expert Circle on APIs;
- the assessment report of closed Joint Visits Groups and statistics of the Joint Visit Programme;
- the first two reports of the Coached Inspection Programme;
- the possibility to develop web-based training for inspectors;
- the new mandate proposal from the GDP and QRM Expert Circles as well as the written proposal by the Expert Circle on Computerised Systems on the revision of the PIC/S Guide on Good Practices for Computerised Systems in Regulated GxP Environments (PI 011-3);
- the PIC/S Pluriannual Training Schedule, which identified training objectives for PIC/S between 2009 and 2012;
- the evaluation report from the 2010 PIC/S Seminar; the draft programme of the 2011 Seminar on "Good Pharmaceutical Inspection Practices" (South Africa, 9-11 November 2011); and the draft programme for the 2012 Seminar on "Qualification and Validation".

Joint Visits Programme and Coached Inspections Programme

27. A call for new candidates for the Joint Visits Programme was made on 13 October 2011 and 5 new applications were received. At the end of 2011, there were 13 applications pending, 15 active Joint Visit Groups under the Joint Visits Programme representing 51 inspectors from around 20 different nationalities.

28. The first four PIC/S Coached Inspections took place during 2011. Three of the four inspections took place during a third-country inspection. Several new applications were received from both junior and senior 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.

2011 PIC/S Seminar in Cape Town

29. The 2011 PIC/S Seminar was organised by the South African Medicines Control Council (MCC). It was held in Cape Town (South Africa) on 9-11 November 2011. It was officially opened by Ms. Mandisa Hela, Registrar of Medicines, Medicines Control Council of South Africa, who took pride in South Africa being the first African country to join PIC/S and the first to hold a PIC/S seminar on the African continent.

30. The Seminar was attended by around 120 participants, including participants from 6 African countries namely Botswana, Nigeria, Uganda, Zambia, Zimbabwe and South Africa. This number includes inspectors from the following non-Member agencies / organisations: Armenian Scientific Centre of Drugs and Medical Technology Expertise SCDMTE, Botswana's Ministry Of Health Drugs Regulatory Unit, Bulgarian Drug Agency BDA, Chinese SFDA, European Directorate for the Quality of Medicines & HealthCare (EDQM*), Hong Kong SAR / Department of Health, Indonesian NADFC, Hungarian Central Agricultural Office, Directorate Of Veterinary Medicinal Products, Iranian Ministry of Health, Japanese PMDA and MHLW, New Zealand's Medsafe, Nigerian National Agency For Food and Drug Administration And Control (NAFDAC), Philippines Food and Drug Administration

(PFDA), South Korean FDA, Taiwan FDA, Uganda National Drug Authority, the United Nations International Children's Emergency Fund (UNICEF*), the World Health Organization (WHO*) the Zambian Pharmaceutical Regulatory Authority and the Zimbabwe's Medicines Control Authority

31. Among the 120 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*) and academia.

32. The Seminar focused on the following objectives:

1) to address practical aspects relating to the inspection process;
2) to equip the inspector with non-technical skills to perform inspections;
3) to share amongst inspectors experiences and lessons learned from performing GMP inspections.

33. The 2.5 day seminar started with a series of lectures, presentations, panel discussions and was followed by four workshops on the 2nd day of the seminar dealing with:

- What to look for regarding company systems and past inspection observations;
- Review similarities and differences for the top 10 deficiencies cited by PIC/S members;
- Identifying "red flags" during inspections – what inspectors must avoid;
- Classification of non-compliance / deficiencies with GMP.

34. During the last day of the seminar, two presentations followed by a panel discussion as well as a summary of the workshops were presented.

Expert Circles & Working Groups

Expert Circle on APIs

35. The 4th meeting of the Expert Circle on API, jointly organised by the Australian Therapeutic Goods Administration (TGA) and Singapore Health Sciences Authority (HSA), took place in Singapore on 12-14 October 2011. A total of 63 participants attended the meeting on Advanced Training in API Inspections

* PIC/S Partners

Expert Circle on Computerised Systems

36. The Expert Circle on Computerised Systems did not meet during the year 2011. The 8th meeting of Expert Circle, which was to take place in 2011 in Austria, was postponed to the first half of 2012.

Expert Circle on Human Blood, Tissues and Cells

37. The Expert Circle on Human Blood, Tissues and Cells held its 18th meeting in Tallinn (Estonia) on 26-30 September 2011. A total of 75 participants attended the meeting. The meeting was on "Substances of Human Origin: the Good, the Bad and the Ugly". The next meeting is set to be held in Singapore in 2012.

Expert Circle on Quality Risk Management (QRM)

38. The Expert Circle on QRM completed its mandate in 2011 and submitted to the Sub-Committee on Training a proposal for a new mandate which would focus on offering advanced QRM to GMP inspectors.

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

39. The Working Group on Annex 3 did not meet during the year 2011. The 3rd meeting of the Working Group will be held in 2012.

Working Group on Good Distribution Practices (GDP)

40. The Working Group on GDP elaborated a questionnaire to establish the GDP competence of PIC/S Participating Authorities. The Working Group informed the Committee that 33 out of 39 Members were responsible for GDP. The proposed mandate by the Working Group on GDP was not approved by the Sub-Committee on Training. The proposed 1st meeting, which was planned for April 2012, was thus postponed to autumn 2012.

41. The Committee agreed to establish two new Working Groups with the following objectives:

- the development of a concept paper on whether there is a need to revise the PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments;

- the use of the PIC/S Standard Operating Procedure for handling Rapid Alerts and Recalls arising from Quality Defects to notify serious inspectional issues.

Harmonisation of guidance documents

42. In 2011 PIC/S adopted the revision of the Recommendation for Risk-based Inspection Planning in the GMP Environment (PI 037-1)

43. The Committee discussed the Aide-Memoire on the Assessment of Quality Risk Management Implementation (PI 038-1).

44. Members discussed the revision of Annexes 2, 6, 7 and 13 of the PIC/S GMP Guide. Non-EEA Participating Authorities were asked to consult their respective stakeholders to allow for the adoption of the revisions in 2012.

45. PIC/S also discussed the possible adoption of a part III to the PIC/S GMP Guide, as a separate document, for guidance documents of a non-legally binding nature

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

Relations with other organisations

ASEAN

47. The Committee was informed that the ASEAN Sectoral MRA on GMP came into force on 1 January 2011.

Associated Partners and Professional Associations

48. 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.

49. At its Cape Town meeting the Committee discussed and agreed to amend the partnership agreements to include a clause to cover the exchange of classified information, in line with PIC/S Note on Confidentiality and on the basis of the recently revised co-operation agreement between PIC/S and EMA.

PIC/S website

50. In the course of 2011, further upgrades were performed on the PIC/S website (www.picscheme.org) including: creation of a diaporama to enhance visual communication, special section dedicated to 40th Anniversary, improved accessibility of PIC/S publications as well as improved internal structure to facilitate access to documents in members' area.

Elections

51. In Cape Town, the Committee elected Ms. Helena Baião (Portugal / INFARMED IP) as PIC/S Chairperson for the period 2012 – 2013. It also elected as First Deputy Chairperson Dr. Joey Gouws (South Africa / MCC) and as Second Deputy Chairman, Mr. Paul Hargreaves (United Kingdom / MHRA) for the same period. The composition of the Executive Bureau was completed by the election / re-election of Dr. Vassiliki Revithi (Greece / EOF), Member; Mr. Boon Meow Hoe (Singapore / HSA), Member; Mr. Jirí Holy (Czech Republic / ISCVBM), Member, Ms Stephanie Reid (Canada / HPFBI), Member and Mr. Tor Gråberg (Sweden / MPA), Member.

LIST OF PIC/S
PARTICIPATING AUTHORITIES & PARTNERS
(as of 31 December 2011)

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 Medicines Agency	DMA
Estonia	State Agency of Medicines	SAM
Finland	Finnish Medicines Agency	FIMEA
France [2]	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 [3]	Bundesministerium für Gesundheit *(Federal Ministry of Health)*	BMG

1 SÚKL and ÚSKVBL count as two distinct Participating Authorities.

2 AFSSAPS and ANMV count as two distinct Participating Authorities.

3 BMG and ZLG count as one Participating Authority.

	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 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	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
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
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.