



**PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME**

4 November 2013

PRESS RELEASE

**PIC/S MEETINGS
OTTAWA, CANADA**

From 7 October to 11 October 2013 the Health Products and Food Branch Inspectorate of Health Canada (HPFBI) hosted the following events in Ottawa, Canada: PIC/S Executive Bureau meeting, PIC/S Committee meeting, PIC/S annual Seminar and PIC/S Sub-Committee on Training meeting.

1. PIC/S COMMITTEE MEETING (7-8 October 2013)

The PIC/S Committee met on 7-8 October 2013 under the chairmanship of Ms Helena Paula Baião (Portuguese National Authority of Medicines and Health Products / INFARMED IP). The meeting was attended by 35 out of 43 PIC/S Participating Authorities (PA) as well as by a number of Applicants, Pre-Applicants and Associated Partners. For the list of participants, see Annex.

MAIN NEWS

NEW PIC/S CHAIRPERSON

The PIC/S Committee elected Dr Joey Gouws (South Africa / MCC) as Chairperson for the period 2014-2015. This is the first time PIC/S will have a Chairperson representing a Participating Authority from Africa.

The incoming Chairperson thanked the Committee and paid tribute to the outgoing Chairperson Ms Helena Paula Baião (Portugal / INFARMED IP) for her inspiring and charismatic leadership, marked by a significant increase in PIC/S activities and membership during her term (2012-2013).

NEW PIC/S SUB-COMMITTEE STRUCTURE

Further to the adoption earlier this year of the new Sub-Committee structure of PIC/S, which will allow for a more participative and efficient organisation of PIC/S, the Committee elected the Members, Deputy Chairs and Chairs of this new organisational structure, which will enter into force on 1 January 2014.

Office holders were elected for a period of two years for the following seven Sub-Committees: Training (SCT); Expert Circles (SCEC); Strategic Development (SCSD); Compliance (SCC); GM(D)P Harmonisation (SCH); Budget, Risk and Audit (SCB) and Communication (SC COM). All Sub-Committee Chairs will be Members of the PIC/S Executive Bureau.

NEW PIC/S EXECUTIVE BUREAU

A new PIC/S Executive Bureau was elected as from 1 January 2014 in accordance with the new PIC/S organisational structure. The Executive Bureau Members for the period 2014-2015 are:

- Dr Joey Gouws (South Africa / MCC), PIC/S Chairperson;
- Mr Paul Hargreaves (United Kingdom / MHRA), PIC/S Deputy Chairman and Chair of the Sub-Committee on Budget, Risk and Audit (SCB);
- Ms Helena Paula Baião (Portugal / INFARMED IP), immediate former Chairperson;
- Mr Boon Meow Hoe (Singapore / HSA), Chair of the Sub-Committee on Training (SCT);
- Dr Alexander Hönel (Austria / AGES), Chair of the Sub-Committee on Expert Circles (SCEC);
- Mr Jacques Morénas (France / ANSM), Chair of the Sub-Committee on Strategic Development (SCSD);
- Ms Anne Hayes (Ireland / IMB), Chair of the Sub-Committee on Compliance (SCC);
- Mr Paul Gustafson (Canada / HPFBI), Chair of the Sub-Committee on GM(D)P Harmonisation (SCH);
- Mr Tor Gråberg (Sweden / MPA), Chair of the Sub-Committee on Communication (SC COM).

UNITED KINGDOM'S VETERINARY AGENCY (VMD) JOINS PIC/S

The Committee invited the United Kingdom's **Veterinary Medicines Directorate** (VMD) to join the Scheme from 1 January 2014. VMD will become PIC/S' 44th Participating Authority.

VMD applied for membership in June 2010. A paper assessment was conducted in view of its accession to PIC/S, followed by an on-site visit on 8-12 October 2012. The assessment of VMD, to which Health Canada took part, was the first occasion for a PIC/S assessment to be carried out jointly with an assessment by Health Canada made under the EU-Canada Mutual Recognition Agreement (MRA).

The Audit team recommended to the Committee to accept the PIC/S membership application of VMD. The representative of VMD welcomed their accession by thanking PIC/S and the Audit team for the help and support provided.

MEMBERSHIP APPLICATION BY HONG KONG SAR

Further to the submission on 30 August 2013 of an accession application request by **Hong Kong SAR**'s Pharmacy and Poisons Board (PPBHK), Members nominated the Rapporteur and Co-Rapporteurs in charge of the assessment.

50th ANNIVERSARY OF GMP

This year marks the 50th anniversary of Good Manufacturing Practice (GMP). In 1963, the very first GMP regulations were issued by US FDA. Since then, GMP has come a long way, developing into worldwide recognised standards.

The mission of PIC/S consisting in leading the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products, the PIC/S Chairperson as well as Dr Robin Chiponski, Director General of Health Products and Food Branch Inspectorate (HPFBI) / Canada, were proud to mark this important milestone.

UPCOMING PIC/S TRAINING ACTIVITIES

The Committee welcomed the following upcoming PIC/S training activities for the first half of 2014:

- the next **PIC/S – PDA** (Parenteral Drug Association) Q7 Training Course, part of the PIC/S International API Training Programme, which regularly delivers general API training in several locations around the world. This training course, open to inspectors and industry, will be held in Johannesburg (South Africa), on **18-19 March 2014**, in co-operation with South Africa / MCC and the Pharmaceutical Society of South Africa (<http://www.picscheme.org/various.php>)
- the 2nd meeting of the **Expert Circle on Good Distribution Practices (GDP)**, which will be held in Warsaw (Poland), on **25-27 March 2014**, hosted by Poland / MPI. This meeting will include a Basic GDP Training Course open to interested inspectors (<http://www.picscheme.org/expert-circles.php>);
- the 6th meeting of the **Expert Circle on API**, which will be held in Rome (Italy), on **19-21 May 2014**, hosted by Italy / AIFA. The meeting will include the delivery of advanced training for interested inspectors (<http://www.picscheme.org/expert-circles.php>);

OTHER NEWS

Harmonisation of guidance documents

Harmonisation of the classification of deficiencies

Members were updated on the progress made by the Working Group on the international harmonisation of the classification of deficiencies established in May 2013 under the leadership of Australia / TGA.

Harmonisation of GM(D)P with the European Union

The PIC/S-EMA Liaison Officer provided Members with an update on the involvement of non-EEA experts of PIC/S in the European Medicines Agency (EMA) drafting groups, namely for Annex 15 (Qualification & Validation) and Annex 17 (Parametric Release). Members commented on the implementation of the procedure on the harmonisation of PIC/S and EU consultation procedures between PIC/S and EMA.

The status of current revisions of the PIC/S and EU GMP Guides were reviewed by the Committee and a proposal for the revision of Annex 1 on sterile products discussed. This proposed revision of Annex 1 led the Committee to consider the establishment of a Working Group dedicated to issues in relation with sterile products as well as a possible revision of the PIC/S Recommendation on the technical interpretation of revised Annex 1.

PIC/S Guidance Documents

Members noted the status of the following PIC/S Guidance documents:

- Annex 3 to the PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments would be adopted after review by the competent Working Group of all comments to the final draft;
- A PIC/S GDP Guide has been prepared by the PIC/S Expert Circle on GDP, based on the EU GDP Guide, and was currently under consultation within PIC/S. Members noted that this Guide would be only a voluntary guidance document for non-EEA Participating Authorities of PIC/S, which are competent for GDP.

The sharing of guidance documents developed by individual Members and Partners within PIC/S was discussed.

Development of new projects for PIC/S

The Committee reviewed the progress made on new projects launched after the success of PIC/S 40th anniversary and the subsequent survey carried out in 2012 with all Heads of Agencies from PIC/S Participating Authorities. These new projects aimed at exploring the possibility of extending PIC/S activities to other fields directly or indirectly related to GMP.

The nomination of Members of the PIC/S Working Group on Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP), under the leadership of Austria / AGES, was welcomed by the Committee. This Working Group will have the task of developing in particular possibilities for **training and joint inspections in the field of GCP and GVP**,

in co-operation with the European Medicines Agency (EMA). Members also decided on the establishment of a small Working Group on biosafety, under the leadership of France / ANSES, which will focus on specific issues relevant to **GMP in connection with biosafety containment**.

Furthermore, Members noted with satisfaction the near completion of the survey assessing the respective training needs of PIC/S Participating Authorities, Applicants, Partners and non-Member National Drug Regulatory Authorities, which was carried out by the Working Group in charge of initiating a **PIC/S Inspectorates' Academy**, under the leadership of Singapore / HSA. The objective of this Academy will be to provide cost-efficient, primarily web-based, high quality harmonized GMP training for Inspectorates at a global scale.

Re-assessment of Members, Assessment of Applicants & Pre-Applicants and contacts with interested Competent Authorities

Re-assessment and Assessment Procedure

The European Medicines Agency (EMA) updated the Committee on the setting up of a Drafting Group by the Joint Assessment Programme (JAP) Compliance Group, in which PIC/S would be represented. This Drafting Group would be entrusted to draft a guideline on the interpretation of the Audit Checklist which is used by PIC/S, the EMA and Canada.

Assessment of Applicants

The Rapporteur in charge of the assessment of **Brazil / ANVISA** reported on his visit to Sao Paulo on 26-27 June 2013. He informed the Committee that the paper assessment of ANVISA was planned to start next year.

The Committee was informed of a re-organisation affecting **Iran / MoH**.

The Rapporteur in charge of the membership application of **Japan / MHLW & PMDA & Prefectures** provided the Committee with an oral update on the successful outcome of the on-site inspection visit performed by the Audit team, which took place on 9-13 September 2013.

Members approved the report on the paper assessment of **Korea / MFDS** and endorsed the proposal by the Rapporteur to schedule an on-site inspection visit in January 2014.

Members were updated that **Philippines / PFDA** had submitted a corrective action plan shortly before the meeting.

The Rapporteur in charge of the application of **Turkey / TMMDA**, which submitted an application on 3 May 2013, informed Members that the paper assessment was about to start.

Assessment of Pre-Applicants

The Committee endorsed the report of the Rapporteur in charge of the pre-accession application of **Armenia / SCDMTE**. Members welcomed the outcome of this pre-accession application which had proven the utility of this new procedure in helping identify some of the changes to be implemented prior to the filing of a PIC/S membership accession request.

SCDMTE proposed to address the recommendations made by providing a corrective action plan.

Members took note of the current status of the paper evaluation of the pre-accession application by **Belarus / MoH**.

With regards to the evaluation of the pre-accession application lodged by **Mexico / COFEPRIS** on 7 May 2013, the Rapporteur provided an oral update to the Committee on the gap-analysis which was currently underway. He highlighted the fact that at this stage no major gaps had been identified by the Assessment team.

Members were updated on the status of the pre-accession application of **Uganda / NDA** for which the representative introduced the proposed corrective action plan, in reply to the gap-analysis carried out by the Assessment team. The Rapporteur and Co-Rapporteur will assess this corrective action plan.

Contacts with China's Food and Drug Administration (CFDA)

A side-meeting between the PIC/S Executive Bureau and **China's** Food and Drug Administration (CFDA) took place in order to provide any necessary clarifications with regards to a possible future accession or pre-accession, further to a previous indication that accession to PIC/S was a priority for CFDA.

Exchange of information

In light of the results of a consultation carried out with WHO, Members discussed the possibility of sharing Rapid Alerts with non-PIC/S Members, such as ASEAN Members. The Committee considered also extending the sharing of Rapid Alerts to PIC/S Applicants.

Members also took note of several re-organisations and changes affecting Participating Authorities, in particular Austria / AGES, Belgium / AFMPS, Canada / HPFBI, Chinese Taipei / TFDA, Ireland / IMB, Italy / AIFA, Poland / MPI and South Africa / MCC.

Training of inspectors

The PIC/S Sub-Committee on Training (SCT) met on 11 October 2013 in the afternoon.

The SCT:

- discussed a new proposal by the Irish Medicines Board (IMB) on a “train the trainers” course to enable other Participating Authorities to run training seminars for new inspectors;
- discussed various proposals of co-operation in the field of training received from Professional and Industry Organisations including ISPE, PDA and IFPMA;
- discussed the outcome of the **PIC/S 2013 Seminar** on “Global Supply Chains and GMP Compliance” which was hosted by Canada / HPFBI in Ottawa (Canada) on 9-11 October 2013;
- reviewed and discussed the tentative programme and organisation of the **PIC/S 2014 Seminar** on “Dedicated facilities or not?” which will be hosted by France / ANSM in Paris (France) in October 2014;

- reviewed the latest developments regarding the PIC/S International API Training Programme, in particular the schedule of the Q7 Training Courses planned in several different locations around the world in 2014 organised by the **Expert Circle on APIs and PDA**;
- noted that the 6th meeting of the **Expert Circle on APIs** would be held in Rome (Italy), on 19-21 May 2014, hosted by Italy / AIFA;
- noted that the 20th meeting of the **Expert Circle on Human Blood, Tissues and Cells** was held in Taipei (Chinese Taipei), on 9-14 September 2013, hosted by Chinese Taipei / TFDA;
- reviewed the 2nd meeting of the 2nd **Expert Circle on Quality Risk Management** which was held in Budapest (Hungary), on 23-24 May 2013, hosted by Hungary / GYEMSZI-NIP and noted that another meeting of the full Expert Circle or a sub-set of it will be held in December 2013 or in early 2014 for advancing the development of training modules;
- reviewed the 1st meeting of the **Expert Circle on Good Distribution Practices** which was held in Helsinki (Finland), on 11-13 June 2013, hosted by Finland / FIMEA and noted the planning of the second meeting as well as a **Basic GDP Training Course** for Inspectors in Warsaw (Poland) on 25-27 March 2014, hosted by Poland / MPI;
- was updated on the planned activities of the **Expert Circle on Computerized Systems** for 2014;
- discussed the potential of development and the access rights to the video-recorded training available on the PIC/S password-protected website.

Co-operation with Associated Partners and other Organisations

PIC/S Associated Partners, namely **EDQM, EMA, UNICEF** and **WHO** gave an update on their current inspection activities.

The Committee took note of the respective current status of the revision of partnership agreements with EDQM, UNICEF and WHO, with regards to the inclusion of a clause on confidentiality.

An update on **ASEAN activities** was given by the PIC/S – ASEAN Liaison Officer, followed by the nomination of Indonesia / NADFC as PIC/S ASEAN Liaison Authority for the period 2014-2015.

Members took note of a proposal by **EMA** on a harmonised programme for maintenance of equivalency in supervision of manufacturers and were updated by the PIC/S Secretariat on the status of the procedure in view of the signing of a Memorandum of Understanding between PIC/S and the **Heads of EEA Medicines' Agencies ("HMA")** for the recognition of audits between Joint Assessment Programme and PIC/S' Assessment and Re-Assessment.

The transfer to **ICH** of the PIC/S Q&A document on Q7, limited to the application of the ICH criteria, was approved by the Committee, which looked forward to strengthening its co-operation with ICH in the future.

Finally, the Committee adopted a Guideline on Co-operation with Professional Associations such as **ISPE, PDA, IFPMA**, inasmuch as such co-operation can broaden the scope of PIC/S activities, provide valuable support and resources, and lead to the undertaking of joint projects, particularly in the field of training.

IN BRIEF...

The Committee ...

- was given an oral report on the Executive Bureau meeting in the morning of 7 October 2013 in Ottawa during which Executive Bureau Members discussed the Organisation of the Bureau during the transitional period until the entry into force of the new Executive Bureau as from 1 January 2014, participation and representation of PIC/S in past and future international conferences, policy matters including the planning of new projects and the enhancing of the status of PIC/S, relations with media as well as financial and staff issues;
- re-appointed the external auditor for the financial audit of the 2013 accounts, approved the 2014 Budget;
- noted that a proposal, endorsed by the Sub-Committee on Training, to amend the PIC/S Aide-Memoire on Organising Seminars will be submitted for adoption by written procedure;
- approved minor amendments to the PIC/S Accession Guidelines relating to the covering of expenses;
- agreed to reconvene in May 2014.

2. PIC/S ANNUAL SEMINAR

The PIC/S Committee meeting was followed by a Seminar on "**Global Supply Chains and GMP Compliance**", which was held in Ottawa (Canada), on 9-11 October 2013.

The PIC/S Seminar was organised by the Health Products and Food Branch Inspectorate (HPFBI) at Health Canada.

The Seminar was opened by an official welcome address by Ms Robin Chiponski, Director General of HPFBI, who admired the international co-operation within PIC/S. She said that such international co-operation was essential in addressing the complex and emerging challenges facing regulators globally. She underlined some of the initiatives taken by HPFBI and looked forward to hearing and discussing the perspectives of other regulators as well as invited industry speakers in view of promoting new forms of collaboration and new mechanisms to improve compliance with respect to global supply chains.

Ms. Helena Paula Baião, PIC/S Chairperson, then delivered her opening comments thanking HPFBI for hosting this year's Seminar and emphasising the importance of this year's topic with respect to PIC/S' role as a global leader in ensuring the quality of drugs. She drew attention to some of the key issues such as drug shortages and how risks may be mitigated through GMP/GDP inspections. She recalled that co-operation and mutual trust is a key value to PIC/S and cited PIC/S seminars as a unique opportunity for high quality training by regulators for regulators.

The Seminar, which is the second one in the history of PIC/S organised in Canada, was attended by more than 100 participants from 42 countries. This number includes inspectors from the following non-PIC/S Member agencies / organisations: Armenian Scientific Centre of Drugs and Medical Technology Expertise / SCDMTE, Brazilian Agência Nacional de Vigilância Sanitária / ANVISA, Chinese Food and Drug Administration / CFDA, European Directorate for the Quality of Medicines & HealthCare (EDQM^{*}), European Medicines Agency (EMA^{*}), Hong Kong SAR's Pharmacy and Poisons Board / PPBHK, Japanese Ministry of Health, Labour and Welfare / MHLW & Pharmaceuticals and Medical Devices Agency / PMDA, Kenyan Pharmacy and Poisons Board, Mexican Federal Commission for the Protection from Sanitary Risks, Ministry of Health / COFEPRIS, Nigerian National Agency for Food and Drug Administration and Control / NAFDAC, Philippines' Food and Drug Administration / PFDA, Korean Ministry of Food and Drug Safety / MFDS, Tanzanian East African Community Medicines and Food Safety, Turkish Medicines and Medical Devices Agency / TMMDA, Uganda's National Drug Authority / NDA, the United Nations International Children's Emergency Fund (UNICEF^{*}) and the World Health Organisation (WHO^{*}).

Among the Seminar participants were also a number of speakers, session chairpersons and workshop facilitators. Speakers were provided by PIC/S Participating Authorities and Partners, the International Society for Pharmaceutical Engineering (ISPE^{**}) and the Canadian Pharmacists Association.

* PIC/S Partners

** Professional Organisations with whom PIC/S liaises

The Seminar's objectives were to discuss the ongoing issues that regulatory authorities across the globe have been facing in regards to compliance with GMP standards as well as provide an opportunity to promote new collaborations within the international community and explore mechanisms which could be established to improve compliance with GM(D)P standards and reduce the occurrence of events that adversely impact continued supply of safe and effective medicines of high quality.

The 2.5 day Seminar started with a series of lectures and presentations, followed by five parallel workshops on the 2nd day of the Seminar dealing with:

- Managing GMP Compliance while Minimizing Supply Interruptions;
- GMP / GDP Inspection – Counterfeits and Diversion;
- Regulatory Oversight of Imported Medicines;
- Storage Conditions Excursions and Storage / Shipping Validation Assessments during GMP Inspections;
- Assessment of API Supply Chain Integrity during GMP Inspection.

During the last day of the Seminar, a summary of the outcome of the workshops was presented followed by a presentation on “Package/Shipping Solutions for Global Product Distribution”.

The Canadian Health Products and Food Branch Inspectorate (HPFBI) concluded the Seminar by thanking all parties involved in its organisation and by welcoming this occasion for regulators to resolve their global issues together, share key information as well as reflect on the informative results of the workshops.

The organiser of next year's seminar, the French National Drug and Health Products Safety Agency (ANSM) thanked Canada / HPFBI on behalf of PIC/S for the excellent organisation and for the hosting of this year's Seminar further to which it invited participants to the 2014 PIC/S Seminar on “Dedicated facilities or not?”, which will take place in October 2014 in Paris, France.

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List of Authorities having participated in the PIC/S Committee Meeting

MEMBERS	ACRONYM
Argentinean National Institute of Drugs <i>Instituto Nacional de Medicamentos</i>	INAME
Australian Therapeutic Goods Administration	TGA
Austrian Agency for Health and Food Safety <i>Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH</i>	AGES
Belgian Federal Agency for Medicines and Health Products <i>Agence Fédérale des Médicaments et des Produits de Santé</i>	AFMPS
Canadian Health Products and Food Branch Inspectorate	HPFBI
Chinese Taipei's Taiwan Food and Drug Administration	TFDA
Czech State Institute for Drug Control <i>Státní Ústav pro Kontrolu Léčiv</i>	SÚKL
Czech Institute for State Control of Veterinary Biologicals and Medicines	ISCVBM
Danish Medicines Agency	DMA
Estonian State Agency of Medicines	SAM
Finnish Medicines Agency	FIMEA
French National Drug and Health Products Safety Agency <i>Agence nationale de sécurité du médicament et des produits de santé</i>	ANSM
French Agency for Food, Environmental & Occupational Health Safety <i>Agence nationale de la sécurité sanitaire de l'alimentation, de l'environnement et du travail</i>	ANSES
German Central Authority of the Länder for Health Protection regarding Medicinal Products and Medical Devices <i>Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten</i>	ZLG
Hungarian National Institute for Quality- and Organizational Development in Healthcare and Medicines National Institute of Pharmacy	GYEMSZI - NIP
Indonesia's National Agency for Drug and Food Control	NADFC
Irish Medicines Board	IMB
Italian Medicines Agency <i>Agenzia Italiana del Farmaco</i>	AIFA
Latvian State Agency of Medicine <i>Zāļu Valsts Aģentūra</i>	ZVA
Malaysian National Pharmaceutical Control Bureau	NPCB
Maltese Medicines Authority	MAM
Netherlands' Inspectorate of Health Care <i>Inspectie voor de Gezondheidszorg</i>	IGZ
Norwegian Medicines Agency	NOMA
New Zealand's Medicines and Medical Devices Safety Authority	Medsafe
Polish Main Pharmaceutical Inspectorate	MPI
Portugal's INFARMED – National Authority of Medicines and Health Products, IP <i>Autoridade Nacional do Medicamento e Produtos de Saúde IP</i>	INFARMED IP
Singapore's Health Sciences Authority	HSA

Slovak State Institute for Drug Control	SIDC
Slovenian Agency for Medicinal Products and Medical Devices	JAZMP
South African Medicines Control Council	MCC
Spanish Agency of Drugs and Health Products <i>Agencia Española del Medicamento y Productos Sanitarios</i>	AEMPS
Swedish Medical Products Agency	MPA
Swiss Agency for Therapeutic Products	Swissmedic
United Kingdom's Medicines and Healthcare Products Regulatory Agency	MHRA
Ukrainian State Administration on Medicinal Products	SAUMP

APPLICANTS	ACRONYM
Brazil's Agência Nacional de Vigilância Sanitária	ANVISA
Hong Kong SAR's Pharmacy and Poisons Board	PPBHK
Japan's Ministry of Health, Labour and Welfare & Pharmaceuticals and Medical Devices Agency & Japanese Prefectures	MHLW / PMDA
Korea's Ministry of Food and Drug Safety	MFDS
Turkey's Medicines and Medical Devices Agency	TMMDA
United Kingdom's Veterinary Medicines Directorate	VMD
PRE-APPLICANTS	
Armenia's Scientific Centre of Drugs and Medical Technology Expertise	SCDMTE
Mexico's Federal Commission for the Protection from Sanitary Risks – Ministry of Health (COFEPRIS)	COFEPRIS
Uganda's National Drug Authority	NDA

PARTNERS	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

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities which provide together an active and constructive co-operation in the field of GMP. Their purpose is the networking between competent authorities, the development and maintenance of mutual confidence, the exchange of information and experience in the field of GMP and related areas and the mutual training of inspectors.

There are currently 43 Participating Authorities in the PIC/S (Convention (#) and Scheme taken together). The PIC/S Participating Authorities are coming from Argentina, Australia#, Austria#, Belgium#, Canada, Chinese Taipei, Cyprus, Czech Republic (both Human and Veterinary), Denmark#, Estonia, Finland#, France (both Human# and Veterinary), Germany#, Greece, Hungary#, Iceland#, Indonesia, Ireland#, Israel, Italy#, Latvia, Liechtenstein#, Lithuania, Malaysia, Malta, Netherlands, New Zealand, Norway#, Poland, Portugal#, Romania#, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden#, Switzerland#, the Ukraine, the United Kingdom# and the United States of America.

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