PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

23 October 2012

PRESS RELEASE

PIC/S MEETINGS
KIEV, UKRAINE

From 30 September to 5 October 2012 the State Administration of Ukraine on Medicinal Products (SAUMP) hosted the following events in Kiev, Ukraine: PIC/S Sub-Committee on Training, PIC/S Executive Bureau, PIC/S Committee meeting and annual PIC/S Seminar.

1. PIC/S COMMITTEE MEETING (1-2 October 2012)

The PIC/S Committee met on 1-2 October 2012 under the chairmanship of Ms. Helena Baião (Portuguese National Authority of Medicines and Health Products / INFARMED IP). The meeting was attended by 32 out of 41 PIC/S Participating Authorities (PA) as well as by a number of Applicants and Associated Partners. For the list of participants, see Annex.

MAIN NEWS

NEW ZEALAND / MEDSAFE AND CHINESE TAIPEI / TFDA JOIN PIC/S

The Committee invited New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) as well as Chinese Taipei / Taiwan Food and Drug Administration (TFDA) to join the Scheme as from 1 January 2013. Medsafe will become PIC/S' 42nd Participating Authority and TFDA its 43rd Participating Authority.

Medsafe applied for membership back in April 2010. A documentation assessment was conducted in view of its accession to PIC/S, followed by an on-site visit on 7-17 February 2012. The Audit team recommended to the Committee to accept the membership application of Medsafe.

TFDA applied for membership back in June 2010 and is competent for modern medicines. A documentation assessment was conducted in view of its accession to PIC/S, followed by an on-site visit on 4-8 June 2012. The Audit team recommended to the Committee to accept the membership application of TFDA.

Both delegations welcomed their accession by thanking PIC/S and the Audit teams for the help and support provided. The PIC/S Chairperson congratulated both Medsafe and TFDA on their new status.

NEW PRE-ACCESSION MEMBERSHIP APPLICATIONS UGANDA AND BELARUS TO JOIN PIC/S IN THE FUTURE

Further to the submission on 16 July 2012 of a pre-accession application request by Uganda's National Drug Authority (NDA), Members nominated the Rapporteur and Co-Rapporteurs in charge of pre-assessment.

In the margins of the PIC/S Seminar in Kiev, a PIC/S Delegation met with Mr. Godovalnikov, Deputy Minister of Health of Belarus, as well as Mr. Sychev, Executive Director of the Association of International Pharmaceutical Manufacturers of Belarus, in connection with the interest expressed by Belarus in joining PIC/S. On 17 October 2012, a pre-accession membership application was received by PIC/S.

NEW PIC/S EXECUTIVE BUREAU MEMBER AND PIC/S-EU/EMA LIAISON OFFICER

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. Members thanked and paid tribute to him for his active role and strategic vision within the PIC/S Executive Bureau. In view of his replacement for the remaining period of his mandate, Mrs. 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 elected as new Liaison Officer with the EU and EMA, for the same period.

PIC/S INTERNATIONAL API TRAINING PROGRAMME

The PIC/S International API Inspector Training Programme which was instituted at the request of a number of National Drug Regulatory Authorities in response to the challenges posed by the globalisation of the manufacture of Active Pharmaceutical Ingredients (APIs) reached a major breakthrough in its development.

In response to the need to urgently and actively train API inspectors worldwide and further to the successful holding of API training activities during its previous PIC/S Expert Circle on APIs meetings in Singapore (October 2011) and Washington DC (September 2012), PIC/S has developed a threefold PIC/S International API Inspector Training Programme.

The PIC/S International API Inspector Training Programme covers:

- Q7 training, focused on familiarisation with ICH Q7, for 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.

With respect to Q7 training, a new global training course programme, which is not limited to basic training as it will cover the whole of Q7 and will be open to both inspectors and industry, is about to be launched in co-operation with PDA (Parenteral Drug Association).

This first **Q7 Training Course on APIs**, organised jointly by PDA and the Expert Circle on APIs, with the support of China's SFDA, will be held in Beijing (China), on **29-30 October 2012** (https://europe.pda.org). A second course is scheduled in 2012 Lisbon (Portugal); with a repeat in India and the United States for 2013.

The Committee looks forward to these new developments and discussed resources and support necessary to successfully carry forward this global programme. All interest expressed by third parties in supporting the PIC/S International API Inspector Training Programme would be most welcome.

OTHER UPCOMING PIC/S TRAINING ACTIVITIES

The Committee welcomed the other following upcoming PIC/S training activities for 2012:

- the 19th meeting of the **Expert Circle on Human Blood, Tissues and Cells**, which will be held in Singapore (Singapore), on **15-19 October 2012**, which will be hosted by Singapore / HSA (http://www.picscheme.org/expert-circles.php);

- the **Training course on Rapid Microbiological Methods (RMM)** organised by PDA Europe in co-operation with PIC/S, which will be held in Barcelona (Spain), on **8-9 November 2012**. The course is not only for inspectors but also for assessors and aims to offer learning about new technologies by using the most relevant Rapid Microbiological Methods (registration by invitation);

- the 1st meeting of the 2nd **Expert Circle on Quality Risk Management (QRM)**, which will be held in Vienna (Austria), on **3-4 December 2012**, hosted by Austria / AGES (http://www.picscheme.org/expert-circles.php). This meeting is limited in terms of participation as it is primarily intended for QRM experts for the purpose of developing training material.

NEW REVISED PIC/S AUDIT CHECKLIST AND AUDIT REPORT TEMPLATE

The PIC/S Committee reached an important step for evaluation and re-evaluation of PIC/S Participating Authorities and future new Applicant Authorities by formally adopting the Revised PIC/S Audit Checklist in connection with the PIC/S Assessment & Joint Reassessment Programme. This document[1], which covers APIs and for which several indicators (78 instead of the previous 89) have been revised and updated, is set to come into force on 1 January 2013.

At the same time, the PIC/S Audit Report template was successfully revised and is presently available. This report must be used to document any audit conducted within (i) the assessment of new Applicant Authorities; and (ii) the Joint Reassessment Programme. It aims at defining how the audit report (documented evidence of the audit process) has to be filled out by the Audit team until completion of the audit.

OTHER NEWS

Development of new projects for PIC/S

The Committee reviewed the most recent replies received from Heads of Agencies from PIC/S Participating Authorities in connection with the survey carried out earlier this year on PIC/S new projects. The Working Groups established at the last Committee Meeting on 7-8 May 2012 in Geneva (Switzerland) to ensure the successful development of these projects reported the following progress.

With respect to the project of extending PIC/S' mandate to new activities such as Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP), discussions had been carried out with the EMA Ad Hoc Working Groups on GCP and Pharmacovigilance. EMA informed the Committee of the outcome of these discussions as well as the proposals resulting therefrom.

With regards 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.

Finally, with respect to other needs expressed by Heads of Agencies, the Committee agreed to the proposal following which Concept Notes would be developed on such other proposals e.g. addressing biosafety and biosecurity issues, setting up Expert Circles for veterinary issues as well as for medical devices, among others.

[1] The PIC/S – EMA / HMA – MRA Audit Checklist is based on the previous Canadian checklist for MRA audits and used for JAP (Joint Audit Programme) working on behalf of the European Heads of Medicines Agency (HMA) network

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

Re-assessment of Members

The Rapporteur in charge of the re-assessment of the Latvian State Agency of Medicine (ZVA) reported on the successful re-assessment which took place between 26 March and 6 April 2012. The Rapporteur in charge of the re-assessment of Lithuania informed the Committee that the partial-reassessment of the Lithuanian State Medicines Control Agency (SMCA) regarding its participation in PIC/S meetings and training activities, which was launched in February 2012, had been postponed to December 2012.

Assessment of Applicants

Members were informed that Brazil's Agência Nacional de Vigilância Sanitária (ANVISA) would be able to provide the requested translated documents in view of its paper assessment by the end of this year. The Committee nominated a new Rapporteur in charge of the assessment in the person of Mr Mark Birse (UK / MHRA).

The application of the Iranian Ministry of Health (MoH) for which the Rapporteur presented her updated evaluation report was reviewed by the Committee. The clarifications provided were considered satisfactory. The paper assessment now complete, the scheduling of on-site inspection visit was decided as well as the issuance of a call in view of the composition of the PIC/S Audit team.

Members were informed by the Rapporteur in charge of the application of Japan's Ministry of Health, Labour and Welfare (MHLW), who submitted an application on 9 March 2012, in its name as well as on behalf of the Pharmaceuticals and Medical Devices Agency (PMDA) and the Japanese Prefectures, that the paper assessment had started.

Members were equally updated by the Rapporteur in charge of the application of Korea Food and Drug Administration (KFDA), who submitted an application on 10 April 2012, that the paper assessment had started.

The Rapporteur on the membership application of the Philippines Food and Drug Administration (PFDA) reported to the Committee on the outcome of the on-site inspection visit performed by the Audit team, which took place on 10-14 September 2012.

With regards to the United Kingdom's Veterinary Medicines Directorate (VMD), the Committee took note of the on-site inspection visit scheduled on 8-12 October 2012.

Assessment of Pre-Applicants

The Rapporteur in charge of the pre-accession application of the Armenia's Scientific Centre of Drugs and Medical Technology Expertise (SCDMTE) reported on the gap analysis performed within the pre-accession procedure.

Contacts with interested Competent Authorities

The PIC/S Committee acknowledged the interest and willingness expressed by Mexico Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in applying for

pre-accession in the near future. Members were also updated on the fact 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.

Finally, Members took note of other new updates with regards to contacts for future potential applications such as from Hong-Kong SAR / DoH; Turkey / MoH; Nigeria / NAFDAC; Bhutan / Drug Regulatory Authority; Kazakhstan / National Center for Expertise of Drugs, among others.

Exchange of information

Members were informed of the outcome of the 2nd International GMP Summit for Regulators organised by the United States Food and Drug Administration (US FDA) on 12-14 September 2012 in Washington DC (USA). Ms. Stephanie Reid (Canada / HPFBI), Member of the PIC/S Executive Bureau, gave two presentations at this event on behalf of PIC/S. She also attended two side meetings: one with representatives of China / SFDA, the other with senior officials of US FDA.

US FDA highlighted some of the main outcomes of this second Summit further to which the Committee decided, on proposal of the PIC/S Executive Bureau, to establish a new Working Group to examine how PIC/S could address some of the issues resulting therefrom.

The advantages and disadvantages of sharing Rapid Alerts with non-PIC/S Members were discussed by the Committee. Due to the complexity of the issue and the numerous consequences to be taken into account, it was decided to consult the World Health Organisation (WHO).

The merits of the use of electronic signatures as a means to facilitate document management were discussed and Members agreed to share experiences in this field.

The Committee took note of several reorganisations affecting Participating Authorities, in particular the French National Drug and Health Products Safety Agency (France / ANSM). Legislative changes were communicated by the Canadian Health Products and Food Branch Inspectorate (HPFBI) and the South African Medicines Control Council (MCC). The United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) updated the Committee on the development of a new software for Quality Risk Management (QRM), a new Good Clinical Practices (GCP) Guide and informed Members on a survey being carried out by McKinsey consultants.

Training of inspectors

The PIC/S Sub-Committee on Training (SCT) met on 30 September 2012 in the afternoon under the chairpersonship of the First Deputy Chairperson, Dr. Joey Gouws (South Africa / MCC). The SCT:

- reviewed all training activities and 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 and discussed the proposal by the Irish Medicines Board (IMB) on a "train the trainers" course to enable other Participating Authorities to run the training seminars for new inspectors;
- noted that following the Seminar in Kiev, the IMB would conduct a training course for new GMP inspectors from the region (Commonwealth of Independent States) to be organised by the State Administration of Ukraine on Medicinal Products (SAUMP);
- reviewed the proposed development of webinars with Professional Organisations;
- 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;
- welcomed the potential in offering video training on the PIC/S website based on the recordings of PIC/S training events;
- discussed the programme and organisation of the **PIC/S 2013 Seminar** on "Global Supply Chains and GMP Compliance", which will be hosted by Canada / HPFBI in Ottawa (Canada) on 7-11 October 2013;
- reviewed the 8th meeting of the **Expert Circle on Computerised Systems** which was held in Vienna (Austria), on 22-24 May 2012, hosted by Austria / AGES;
- noted that the mandate of the PIC/S Expert Circle on Good Distribution Practices (GDP) had been adopted and that the Expert Circle would be planning a first meeting as well as electing a Chair.

Harmonisation of guidance documents

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 PIC/S Liaison Officer reported on the first experiences in the implantation of this new procedure which ensures better harmonisation between the EU and the PIC/S GMP Guides and related documents.

One of the main advantages of the new procedure consists in the earlier involvement of PIC/S non-EU countries in the EU revisions as well as helping the EU use resources from non-EU countries where needed. The planned revisions of Annex 15 on Qualification and Validation and Annex 17 on Parametric Release, which are subject to the new procedure, are good examples. Canada / HPFBI and USA / US FDA will take part in the drafting group for Annex 15 and Australia / TGA, Canada / HPFBI and USA / US FDA for Annex 17.

PIC/S and EMA welcomed the successful implementation of this new co-operation. The frame developed by the PIC/S – EMA Liaison Officer to ensure harmonisation has led to the finalisation of a table including the status of current revisions of the PIC/S and EU GMP Guides. The PIC/S Committee reviewed the table, which will be maintained and updated by PIC/S.

Members reviewed the revision of several PIC/S GMP Guides and Annexes based on the revisions of the EU GMP Guides and Annexes.

The following revisions were <u>adopted</u>:

- Annex 6 on Medicinal Gases, for which the Committee also decided on the establishment of an Expert Circle;
- Annex 7 on Herbals;

- Chapter 4 & Annex 11 on Computerised Systems;
- Annex 13 on Investigational Medicinal Products.

The following revisions were discussed;

- Annex 2 on Biologicals and Annex 14 on Blood & Plasma. For these, the Committee decided on the establishment of a Working Group mandated to adapt the revision in accordance with the comments received from Members and take over the issues resulting from the transposition of the EU GMP Guide to the PIC/S GMP Guide.

With regards to Annex 3 on Radiopharmaceuticals, Members took note that the PIC/S Working Group in charge of Annex 3 to the PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments, had planned a meeting in order to finalise the first draft on Annex 3. This meeting will take place in London on 25-26 October 2012 at the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA).

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.

Members discussed how access to EMA's EUDRA GMP Database could be granted to PIC/S Participating Authorities which are non-EEA and non-MRA Partners.

United Kingdom / MHRA reported on the discussions about the recognition of audits between the Heads of EEA Medicines' Agencies ("HMA") Joint Assessment Programme and PIC/S' Assessment and Re-Assessement, for which the next step would consist in the signing of a Memorandum of Understanding between PIC/S and HMA.

IN BRIEF…

The Committee …

- congratulated the Indonesian National Agency for Drug and Food Control (NADFC) for its accession to PIC/S as from 1 July 2012 and its first attendance to a Committee Meeting in its capacity as Participating Authority;
- was given an oral report on the Executive Bureau meeting in the morning of 1 October 2012 in Kyiv during which Executive Bureau Members discussed several aspects of the Organisation of the Bureau, participation and representation of PIC/S in past and future international conferences, meetings with Heads of Agencies as well as financial and staff issues;
- re-appointed the external auditor for the financial audit of the 2012 accounts, approved the 2013 Budget and noted the changes of staff underway at the PIC/S Secretariat;
- discussed a note confirming that English was to remain the sole working language of PIC/S;
- discussed the Terms of References in view of the implementation of the new Sub-Committee Structure of PIC/S;
- agreed to reconvene on 28-29 May 2013 in Geneva (Switzerland).

2. PIC/S ANNUAL SEMINAR

The PIC/S Committee meeting was followed by a Seminar on "**Qualification and Validation: Today and Tomorrow**", which was held in Kiev (Ukraine), on 3-5 October 2012.

The PIC/S Seminar 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.

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. Ms. Helena Baião, PIC/S Chairperson, then delivered her opening comments highlighting the importance of the topic of this year's Seminar. She recalled that Qualification and Validation had long been a priority of PIC/S and underlined the main goals of the Seminar, based on new approaches in this field. Her speech was followed by the opening presentation from the Chairman of the State Administration of Ukraine on Medicinal Products (SAUMP), Mr. Oleksiy Solovyov, who thanked PIC/S for entrusting SAUMP with the honour of hosting this year's Seminar and gave an opening presentation about Ukraine and the importance of its pharmaceutical market including an overview of SAUMP's achievements, strategy and future objectives.

The Seminar, a first in the CIS (Commonwealth of Independent States) region, 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, Chinese 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[*]).

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[**]).

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.

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* PIC/S Partners

** PIC/S Partners Professional Organisations with whom PIC/S liaises

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

- QRM application for classification of deficiencies in production equipment qualification;
- Risk Based Aseptic Processes Validation – view of inspector;
- Main points for inspecting PAT and RTRT;
- Implementing New Validation Approaches.

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".

The PIC/S Chairperson concluded the Seminar and thanked the State Administration of Ukraine on Medicinal Products (SAUMP) and the State Training Center for Good Manufacturing / Distribution Practice for the excellent organisation and for hosting the Seminar.

After which followed a presentation by the Canadian Health Products and Food Branch Inspectorate (HPFBI) who will be hosting the 2013 PIC/S Seminar on "Global Supply Chains and GMP Compliance", which will take place from 7-11 October 2013 in Ottawa, Canada.

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Annex

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

MEMBERS	**ACRONYM**
Australian Therapeutic Goods Administration	TGA
Austrian Agency for Health and Food Safety *Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH*	AGES
Canadian Health Products and Food Branch Inspectorate	HPFBI
Czech State Institute for Drug Control *Státní Ústav pro Kontrolu Léčiv*	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 *Agence nationale de sécurité du médicament et des produits de santé*	ANSM
French Agency for Food, Environmental & Occupational Health Safety *Agence nationale de la sécurité sanitaire de l'alimentation, de l'environnement et du travail*	ANSES
German Central Authority of the Länder for Health Protection regarding Medicinal Products and Medical Devices *Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten*	ZLG
Greek National Organisation for Medicines *Εθνικός Οργανισμός Φαρμάκων*	EOF
Indonesia's National Agency for Drug and Food Control	NADFC
Irish Medicines Board	IMB
Italian Medicines Agency *Agenzia Italiana del Farmaco*	AIFA
Latvian State Agency of Medicine *Zāļu Valsts Aģentūra*	ZVA
Lithuanian State Medicines Control Agency	SMCA
Malaysian National Pharmaceutical Control Bureau	NPCB
Maltese Medicines Authority	MAM
Netherlands' Inspectorate of Health Care *Inspectie voor de Gezondheidszorg*	IGZ
Norwegian Medicines Agency	NOMA
Portugal's INFARMED – National Authority of Medicines and Health Products, IP *Autoridade Nacional do Medicamento e Produtos de Saúde IP*	INFARMED IP
Singapore's Health Sciences Authority	HSA
Slovenian Agency for Medicinal Products and Medical Devices	JAZMP
Slovak State Institute for Drug Control	SIDC
South African Medicines Control Council	MCC
Spanish Agency of Drugs and Health Products *Agencia Española del Medicamento y Productos Sanitarios*	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
US Food and Drug Administration	FDA

APPLICANTS	**ACRONYM**
Japan's Ministry of Health, Labour and Welfare & Pharmaceuticals and Medical Devices Agency & Japanese Prefectures	MHLW / PMDA
Korea Food and Drug Administration	KFDA
New Zealand's Medicines and Medical Devices Safety Authority	Medsafe
Taiwan Food and Drug Administration of Chinese Taipei	TFDA
PRE-APPLICANTS	
Armenia's Scientific Centre of Drugs and Medical Technology Expertise	SCDMTE
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 41 Participating Authorities in the PIC/S (Convention (#) and Scheme taken together). The PIC/S Participating Authorities are coming from Argentina, Australia#, Austria#, Belgium#, Canada, 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, 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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