



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

PS/W 3/2014
2 June 2014

ANNUAL REPORT 2013

Prepared by the Secretariat

Please find attached the draft Annual Report of PIC/S for 2013.

ANNUAL REPORT 2013

New Members, new applications

1. In 2013, PIC/S welcomed two new Members: on 1 January 2013 New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) became the 42nd PIC/S Participating Authority and the Taiwan Food and Drug Administration (TFDA) of Chinese Taipei became the 43rd PIC/S Participating Authority.
2. Two new membership applications, from Turkey's Medicines and Medical Devices Agency (TMMDA) and Hong Kong's Pharmacy and Poisons Board (PPBHK), as well as three pre-accession applications from Chile's "Instituto de Salud Pública" (Public Health Institute), Kazakhstan's Committee for the Control of Medical and Pharmaceutical Activities (CCMPA), Ministry of Health, and Mexico's Federal Commission for the Protection from Sanitary Risks – Ministry of Health (COFEPRIS) were received during the year.
3. The continuous expansion of PIC/S shows that the organisation is dynamic and attractive. At the end of 2013, a record number of 13 membership applications were in the process of being assessed.

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.

New PIC/S Sub-Committee Structure

4. A new Sub-Committee structure of PIC/S, which will enter into force on 1 January 2014, was adopted as a concrete reply to PIC/S's growing membership and which will allow for more participative and efficient organisation. The new organisational structure will be based 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. The Committee adopted a set of documents to manage the new Sub-Committees. These documents include mandates and terms of references of future Sub-Committees.

Development of new projects for PIC/S

5. While reaffirming that GMP remains PIC/S' main core area of competence, 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.

Extending PIC/S' mandate

6. With respect to the project of extending PIC/S' mandate from GMP to new fields such as Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP), Members reviewed the outcome of the consultation of non-EEA PIC/S Members with respect to the proposals made by the EMA Ad Hoc GCP and Pharmacovigilance Working Groups.

7. 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) and also to further review all feedback received and explore the scope, needs and resources involved in this project, while avoiding any duplication of activities with EMA.

Creating a PIC/S Inspectorates' Academy

8. With regards to the project of creating a PIC/S Inspectorates' Academy to provide cost-efficient, primarily web-based, high quality harmonised GMP training for Inspectorates on a global scale, the Ad-hoc Working Group established for the development of this project, co-ordinated by HSA / Singapore, informed the Committee of the near completion of the detailed survey on training needs which was currently underway with all PIC/S Participating Authorities, Applicants, Partners and selected non-Member National Drug Regulatory Authorities.

Exploring the link between GMP and biosafety issues

9. 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. A Concept Paper was prepared by ANSES / France, proposing that PIC/S further explore the link between GMP and biosafety issues, in particular the development of guidance for biological hazards assessment and appropriate safety measures (biosafety). Participating Authorities interested by this issue were invited to comment on this proposal.

Other specific projects

10. Finally, the Committee was updated on other specific projects as well as follow-ups to preliminary contacts established with selected external donors in view of ensuring the development of these future projects. Members also discussed the appropriate follow-ups to be given to the replies by Heads of Medicines Agencies further to the survey carried out with them last year, which initiated these new projects after the PIC/S 40th anniversary in 2011.

Operation of the Scheme

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

12. During these meetings, the Committee:

- continued to improve the operation of PIC/S and to reshape the organisation in order to remain efficient;
- endorsed in principle a new PIC/S Sub-Committee Structure, which will become operational in 2014 (see paragraph 4 above);
- adopted the revised PIC/S Audit Checklist, which now covers APIs, and the PIC/S Audit Report template (both documents are used for the evaluation and re-evaluation of PIC/S Participating Authorities);
- endorsed the Sub-Committee on Training's recommendation to permanently open the Joint Visits Programme (JVP) to Good Clinical Practices (GCP) inspectors;
- discussed project proposals for PIC/S' future development (see paragraphs 5-10 above);
- adopted several guidance documents and discussed proposals to revise the PIC/S GMP Guide (see "Harmonisation of Guidance documents" below);
- reviewed the assessment of new Applicants and the reassessment of older Participating Authorities (see "Membership Applications" below);
- monitored the activities of the Sub-Committee on Training (SCT) and the Executive Bureau (EB);
- endorsed a Note confirming that English should remain the sole working language of PIC/S;
- reviewed and endorsed the revision of the PIC/S Aide-Memoire on the Organisation of Seminars; the revision of the PIC/S Guidelines on Expert

Circles; and a draft PIC/S Guideline on co-operation with Professional Associations;

- adopted the PIC/S Annual Report for 2012;
- approved the statement of the 2012 accounts and endorsed the related Financial Audit Report;
- re-appointed the external auditor for the financial audit of the 2013 accounts;
- approved the 2014 Budget;
- paid tribute to a long standing Member of the Committee and of the Executive Bureau in the person of Dr Vassiliki Revithi, further to her retirement from Greece / EOF.

13. The Executive Bureau met twice, first in Geneva (Switzerland) on 28 May 2013 and then in Ottawa (Canada) 7-8 October 2013. These meetings were mainly dedicated:

- to discussing financial, administrative and staff related issues;
- to assisting the Chairperson in the execution of his/her mandate and;
- to preparing the meetings of the Committee.

14. The Sub-Committee on Training met twice, first in Geneva (Switzerland) on 30 May 2013 and then in Ottawa (Canada) on 11 October 2013. The meetings were chaired by the First Deputy Chairperson, Dr Joey Gouws (South Africa / MCC). For more information on the activities of the Sub-Committee on Training, see “PIC/S Training Activities” below.

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

Assessment of Applicants

16. The Rapporteur in charge of the assessment of **Brazil's** Agência Nacional de Vigilância Sanitária (ANVISA) met with ANVISA representatives in Sao Paulo on 26-27 June 2013 to discuss the paper assessment of ANVISA, which was planned to start next year, once ANVISA had translated all supporting documents.

17. The Committee nominated a new Rapporteur and three new additional Audit team members to deal with the membership application by **Iran's** Ministry of Health (MoH). Due to changes in the assessment team, the date for the on-site inspection visit was postponed.

18. On 30 August 2013 a membership application was submitted by **Hong Kong SAR's** Pharmacy and Poisons Board (PPBHK). Members nominated the Rapporteur and Co-Rapporteurs in charge of the assessment.

19. The Rapporteur in charge of the membership application of **Japan's** Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) & Japanese 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. The Rapporteur also reported on the evaluation of API, carried out on behalf of the European Commission, at the request of the Japanese authorities, in connection with the implementation of the EU Directive applicable to the manufacturing of API intended for export to the European Union. A specific on-site visit for this purpose had taken place on 15-22 April 2013. The Rapporteur highlighted the advantage of combining both the PIC/S application and the European Commission's API assessment and reported on the positive outcome of the latter which had resulted in Japan being added to the white list. The Japanese delegation expressed its gratitude for the co-ordination between both assessments, thereby minimizing duplication.

20. The Committee approved the draft evaluation report of the paper assessment presented by the Rapporteur for **Korea's** Food & Drug Administration (KFDA). Since 23 March 2013, the KFDA has been raised to the status of Ministry of Food and Drug Safety (MFDS). The Members accepted the Rapporteur's proposal to enlarge the Audit team presently composed of himself and two Co-Rapporteurs and nominated two new Co-Rapporteurs and one new Audit team member. They also endorsed the proposal by the Rapporteur to schedule an on-site inspection visit in January 2014.

21. Members were updated on the outcome of the report on the on-site assessment visit of **the Philippines'** Food and Drug Administration (PFDA) which took place on 10-14 September 2012, and the subsequent decision to carry out a follow-up visit to verify the implementation of corrective action, and discussed the opportunity of a clock-stop further to a request made by Philippines' FDA. The Philippines / PFDA submitted a corrective action plan shortly before the PIC/S Committee Meeting in October in Ottawa.

22. On 3 May 2013, **Turkey's** Medicines and Medical Devices Agency (TMMDA) officially submitted an application for PIC/S membership. The PIC/S Committee nominated a Rapporteur and three (?) Co-Rapporteurs in charge of the assessment of the accession application. The paper assessment began in October.

23. The report on the on-site assessment visit of the **United Kingdom's Veterinary Medicines Directorate (VMD)**, which took place on 8-12 October 2012, was discussed and VMD was invited to join the Scheme from 1 January 2014 as PIC/S' 44th Participating Authority.

Assessment of Pre-Applicants

24. The Rapporteur in charge of the pre-accession application of **Armenia's** Scientific Centre of Drugs and Medical Technology Expertise (SCDMTE) gave the Committee an update on the paper evaluation currently in preparation further to the replies received from SCDMTE to the gap-analysis. A new Co-Rapporteur was also nominated by the Committee. The Committee endorsed the report and 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.

25. Further to the lodging of a pre-accession application by **Belarus**'s Ministry of Health (MoH) on 30 September 2012, the Rapporteur and two Co-Rapporteurs, who were appointed in March 2013 by written procedure, provided an update on the outcome of their paper evaluation.

26. **Chile**'s Instituto de Salud Pública (Public Health Institute of Chile) submitted an application for PIC/S pre-accession membership on 30 December 2013. **Kazakhstan**'s Committee for the Control of Medical and Pharmaceutical Activities (CCMPA), Ministry of Health, submitted an application for PIC/S pre-accession on 1 November 2013. A Rapporteur (Ukraine / SAUMP) was nominated by written procedure in November 2013.

27. On 7 May 2013, **Mexico**'s Federal Commission for the Protection from Sanitary Risks – Ministry of Health (COFEPRIS) officially submitted a pre-accession application for PIC/S membership. The PIC/S Committee nominated a Rapporteur and three Co-Rapporteurs in charge of the assessment of the pre-accession application. During the year, the Rapporteur made good progress with the gap-analysis: no major gaps were identified.

28. Members were informed of the outcome of the paper evaluation with respect to **Uganda**'s National Drug Agency (NDA) application for pre-accession. A new Rapporteur was appointed, as well as a new Member of the Assessment team. In response to the gap-analysis carried out by the Assessment team the representative introduced the proposed corrective action plan which will be assessed by the Rapporteur and Co-Rapporteur.

Reassessment of Participating Authorities

29. The Rapporteur in charge of the reassessment of **Lithuania**'s State Medicines Control Agency (SMCA) updated members on the partial reassessment which took place on 10-11 December 2012 regarding SMCA's attendance of meetings and training activities. The planning of future reassessments of other Participating Authorities was also discussed by the Committee.

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.

Exchange of Information

30. The Committee reviewed the outcome of the mapping of GMP competencies of all PIC/S Participating Authorities and was updated on the efforts underway to map GDP competencies.

31. With respect to sharing of information, PIC/S Members and Partners discussed further improvements and benefits in connection with the process of maintaining and updating PIC/S' list of planned foreign inspections, with a view to better facilitate the sharing of inspection findings, avoid any unnecessary duplication, enhance synergies, maintain mutual confidence and offer a reply to the expectations of industry.

32. Members took note of several reorganisation activities and changes affecting Participating Authorities, in particular Austria / AGES; Belgium / AFMPS; Canada / HPFBI; Chinese Taipei / TFDA; Ireland / IMB; Italy / AIFA; Poland / MPI; Portugal / INFARMED IP; Ukraine SAUMP; UK / MHRA; South Africa / MCC and the US FDA.

33. UK / MHRA gave a presentation on the launch of the MHRA Innovative Office, the launch of the new MHRA Risk Based Inspection Programme and on the MHRA-India relationship. US FDA also provided a written report on the Second International GMP Summit which was held in Washington DC (USA) on 12-14 September 2012.

34. 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.

35. 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.

PIC/S Training Activities

36. The following PIC/S training activities were held in 2013:

- the 2nd meeting of the **2nd Expert Circle on Quality Risk Management** held in Budapest (Hungary), on 23-24 May 2013, hosted by Hungary / NIP-GYEMSZI;
- the 1st meeting of the **Expert Circle on Good Distribution Practices** held in Helsinki (Finland), on 11-13 June 2013, hosted by Finland / FIMEA;
- the 20th meeting of the **Expert Circle on Human Blood, Tissues and Cells**, held in Taipei (Chinese Taipei), on 9-14 September 2013, hosted by Chinese Taipei / TFDA];
- **PIC/S 2013 Seminar** on “Global Supply Chains and GMP Compliance” (for both API and solid dosage forms) held in Ottawa (Canada), on 9-11 October 2013, hosted by Canada / HPFBI (for more details, see box on page 10).

37. In 2013 the PIC/S Sub-Committee on Training (SCT):

- assessed the PIC/S Pluri-annual Training Schedule for the period 2009-2012;
- discussed the potential of development and the access rights to the video-recorded training available on the PIC/S password-protected website;

- reviewed the activities of the Joint Visits Programme and Coached Inspections Programme and made some recommendations for improvements regarding the operation and participation in these training programmes;
- reviewed past and future seminars, in particular:
 - the report of the PIC/S 2012 Seminar on “Qualification and Validation: Today and Tomorrow” hosted on 3-5 October 2012 by Ukraine / SAUMP;
 - the PIC/S 2013 Seminar (see also box below);
 - the organisation of the **PIC/S 2014 Seminar** on “Dedicated facilities: yes or no?” which will be hosted by France / ANSM in Paris (France) in October 2014.
- 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 as well as the outcome of the training course for new inspectors from the Commonwealth of Independent States (CIS), which took place just after the 2012 PIC/S Seminar in Kiev (Ukraine), under the bilateral arrangement between Ukraine / SAUMP and Ireland / IMB;
- discussed various proposals of co-operation in the field of training received from Professional and Industry Organisations including ISPE, PDA and IFPMA, in particular:
 - the Course on Rapid Microbiological Methods (RMM) organised by PDA Europe in co-operation with PIC/S, in Barcelona (Spain) on 8-9 November 2012;
 - the outcome of a side meeting on 29 May 2013 between a PIC/S Delegation and Representatives of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and WHO on a proposal by IPFMA for a Regional Training Initiative on GMP Implementation.
- 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 preparations and reports of Expert Circle meetings, in particular:
 - the 20th meeting of the Expert Circle on Human Blood, Tissues and Cells hosted by Chinese Taipei / TFDA in Taipei (Chinese Taipei) on 9-14 September 2013;
 - the 2nd meeting of the 2nd Expert Circle on Quality Risk Management hosted by Hungary / GYEMSZI-NIP in Budapest (Hungary) on 23-24 May 2013;
 - the 1st meeting of the Expert Circle on Good Distribution Practices hosted by Finland / FIMEA in Helsinki (Finland) on 11-13 June 2013;
 - the preparations for the 6th meeting of the Expert Circle on APIs, which will be hosted by Italy / AIFA in Rome (Italy) on 19-21 May 2014;
 - the planned activities of the Expert Circle on Computerized Systems for 2014.

2013 PIC/S Seminar in Ottawa

The 2013 PIC/S Seminar on "**Global Supply Chains and GMP Compliance**", organised by the Health Products and Food Branch Inspectorate (HPFBI) at Health Canada, was held in Ottawa on 9-11 October 2013.

The Seminar was opened by an official welcome address by Ms Robin Chiponski, Director General of HPFBI.

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. Speakers were provided by PIC/S Participating Authorities and Partners, the International Society for Pharmaceutical Engineering (ISPE) and the Canadian Pharmacists Association.

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".

Joint Visits Programme

38. At the end of 2013, there were 15 active Joint Visit Groups under the Joint Visits Programme representing 44 inspectors from around 22 different nationalities.

PIC/S Joint Visit Groups

Another means of training inspectors of the PIC/S countries has been devised in the form of joint visits to manufacturers by inspectors of different countries. Groups of three inspectors are set up on the basis of applications sent to the PIC/S Secretariat. Each inspector is assigned within his/her group to act in turn as host for one year and guest for the other two years.

Visits are carried out in English or in a language commonly agreed by inspectors. Joint reports are drafted after each visit and sent to the Committee for evaluation.

The organisation of the joint visits has proved an excellent means for the further training of inspectors through mutual exchange of experience and a useful contribution to the maintenance of mutual confidence between competent authorities. Participants have also the possibility to discuss and compare their inspection methods and their interpretation of GMP rules.

Expert Circles & Working Groups

Expert Circle on APIs

39. The Expert Circle on APIs did not hold any meetings in 2013. However, it continued to develop and implement the 'PIC/S International API Training Programme' which comprises three segments:

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

40. In the framework of the Q7 training for both industry and regulators, PIC/S and the Parenteral Drug Association (PDA) jointly planned during 2013 Training Courses on APIs for the period 2014-2015 at several locations worldwide, involving partnerships and support from other Organisations.

41. The Expert Circle also reviewed the preparations for its 6th meeting, which will be held in Rome (Italy) on 19-21 May 2014 (hosted by Italy / AIFA).

Expert Circle on Computerised Systems

42. The Expert Circle on Computerised Systems did not meet in 2013. It continued its revision process of the "PIC/S Guidance Document on Good Practices for Computerised Systems in regulated GxP environments" (PI 011-3). A meeting is planned in 2014 to discuss the proposed revision.

Expert Circle on Human Blood, Tissues and Cells

43. The Expert Circle on Human Blood, Tissues and Cells held its 20th meeting in Taipei (Chinese Taipei), on 9-14 September 2013. It was the first ever PIC/S training meeting hosted by Chinese Taipei / TFDA since its accession to the Scheme. A total of 51 participants (including speakers) attended the meeting representing 22 countries. The meeting was on "From Idealism to Practice, Art of Management - Blood, Tissues & Cells".

Expert Circle on Quality Risk Management (QRM)

44. The Expert Circle on QRM met in Budapest (Hungary) on 23-24 May 2013. The meeting was hosted by Hungary / GYEMSZI-NIP and attended by 27 participants. The outcome of the meeting led to the planning of the organisation of advanced PIC/S QRM training sessions for the period 2014-2015.

Expert Circle on Good Distribution Practices (GDP)

45. The 1st meeting of the Expert Circle on Good Distribution Practices was held in Helsinki (Finland), on 11-13 June 2013. It was hosted by Finland / FIMEA and attracted 28 participants from 17 countries. Experts worked on the PIC/S GDP Guide and the programme on the Inspectors' Basic Training Course.

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

46. The Working Group on Annex 3 (Radiopharmaceuticals) to the "PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments" successfully completed its activities in 2013. Annex 3 was completed and published as part of the revised PIC/S Guide (PE 010-4).

Harmonisation of guidance documents

47. The PIC/S GMP Guide (PE 009-11) was revised as follows:

- Amendment of Part II: Introduction of risk management principles;
- Annex 2 (biological medicinal products for human use);
- Revision of Annex 14 (products derived from human blood or human plasma).

48. A proposal for the revision of Annex 1 to the GMP Guide (on sterile products) has been discussed. This proposed revision of Annex 1 has 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 (PI 032-2).

49. The PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE 010-4) has been revised in order to include a new Annex 3 (on radiopharmaceuticals).

50. A PIC/S GDP Guide has been prepared by the PIC/S Expert Circle on GDP, based on the EU GDP Guide, and is currently under consultation within PIC/S. This

Guide will only be a voluntary guidance document for non-EEA Participating Authorities of PIC/S, which are competent for GDP.

51. A Working Group on the international harmonisation of the classification of deficiencies was established in May 2013 under the leadership of Australia / TGA.

52. The list of PIC/S publications is available on the PIC/S website: <http://www.picscheme.org>.

Co-operation with Associated Partners and other Organisations

Associated Partners

53. PIC/S continued to co-operate with its Associated Partners, namely **EDQM, EMA, UNICEF** and **WHO**, in the field of GMP. The partnership agreements with EDQM and UNICEF were successfully revised in order to include a clause on confidentiality.

54. Close co-operation was maintained with the European Medicines Agency (EMA), in particular in the field of harmonisation of GMP guides and guidance documents. The Joint Assessment Programme (JAP) Compliance Group of the EMA decided to set up a Drafting Group in which PIC/S will be represented. This Drafting Group will be entrusted to draft a guideline on the interpretation of the Audit Checklist which is used by PIC/S, the EMA and Canada.

55. The PIC/S-WHO Liaison Officer participated in the WHO Expert Committee on Specifications for Pharmaceutical Preparations meeting which took place in Amsterdam (Netherlands) in October 2012. WHO gave a presentation on the WHO programme for strengthening National Regulatory Authorities in the area of vaccines.

Other organisations

56. The PIC/S – ASEAN Liaison Officer reported on **ASEAN** activities was given, in particular on the 2nd Meeting of the Joint Sectoral Committee (JSC) on GMP Inspection of Manufacturers of Medicinal Products (JSC GMP MRA) which was held on 14 – 15 May 2013 in Bali, Indonesia. Indonesia / NADFC was nominated as PIC/S ASEAN Liaison Authority for the period 2014-2015.

57. PIC/S continued its internal consultations with a view of signing 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.

58. 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.

59. The PIC/S Chair participated in the **IPSE** 2012 Annual Meeting in San Francisco (USA) in November 2012 and the **PDA-EMA** joint conference in Lisbon (Portugal) in December 2012.

60. 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.

PIC/S website

61. In the course of 2013, further upgrades were performed on the PIC/S website (www.picscheme.org) including: the review of accession rights and changes in relation to the implementation of the new Sub-Committee structure, as well as several minor updates to the appearance and content of certain pages.

Change of guard

New PIC/S Chairperson

62. At its meeting in Ottawa in October 2013, 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.

63. 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 Executive Bureau

64. A new PIC/S Executive Bureau was elected in Ottawa 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 Hoemel (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).

50th Anniversary of GMP

65. 2013 marked 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, to which PIC/S is proud to have significantly contributed.

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**LIST OF PIC/S
PARTICIPATING AUTHORITIES & PARTNERS**
(as of 31 December 2013)

I - PARTICIPATING AUTHORITIES

(in the alphabetical order of the country in which they are located)

	PARTICIPATING AUTHORITY	ACRONYM
Argentina	Instituto Nacional de Medicamentos <i>(National Institute of Drugs)</i>	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 <i>(Federal Agency for Medicines and Health Products)</i>	AFMPS
Canada	Health Products and Food Branch Inspectorate	HPFBI
Chinese Taipei	Taiwan Food and Drug Administration	TFDA
Cyprus	Pharmaceutical Services	CyPHS
Czech Republic ¹	Státní Ústav pro Kontrolu Léčiv <i>(State Institute for Drug Control)</i>	SÚKL
	Ústav pro Státní Kontrolu Veterinárních Biopreparátů a Léčiv <i>(Czech Institute for State Control of Veterinary Biologicals and Medicines)</i>	ISCVBM
Denmark	Danish Health and Medicines Agency	DHMA
Estonia	State Agency of Medicines	SAM
Finland	Finnish Medicines Agency	FIMEA
France ²	Agence National de Sécurité du Médicament et des Produits de Santé <i>(National Drug and Health Products Safety Agency)</i>	ANSM
	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail <i>(French Agency for Food, Environmental & Occupational Health Safety)</i>	ANSES
Germany ³	Bundesministerium für Gesundheit <i>(Federal Ministry of Health)</i>	BMG
	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten <i>(Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices)</i>	ZLG

¹ SÚKL and ÚSKVBL count as two distinct Participating Authorities.
² ANSM and ANMV count as two distinct Participating Authorities.
³ BMG and ZLG count as one Participating Authority.

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