



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

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ANNUAL REPORT 2017

Prepared by the Secretariat



**Leading the international development, implementation
and maintenance of harmonised GMP standards and
quality systems of inspectorates in the field of medicinal
products**

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What is PIC/S?

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was established in 1995 as an extension to the Pharmaceutical Inspection Convention (PIC) of 1970 (see Annex 1). PIC/S is a non-binding co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. On 31 December 2017, PIC/S comprised 49 Participating Authorities from all continents. For the list of PIC/S Participating Authorities, see Annex 2.

PIC/S' mission is "to lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products". This will be achieved by harmonising inspection procedures worldwide, by developing common standards in the field of GMP, by providing training opportunities to inspectors and by facilitating co-operation and networking between competent authorities, regional and international organisations, thus increasing mutual confidence.

A Committee of the Participating Authorities' representatives (PIC/S Committee) supervises the operation of the Scheme. All decisions are taken unanimously. The Committee is assisted in its task by (i) various Sub-Committees; (ii) an Executive Bureau, which steers the Organisation in-between meetings; and (iii) a Secretariat, which assists PIC/S bodies in their duties.

This is the Annual Report of PIC/S' activities in 2017.

ANNUAL REPORT 2017

THE YEAR IN A NUTSHELL

Successful chairmanship for MHRA

1. 2016 was the second year of the chairmanship of Mr Paul Hargreaves from the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA).



2. It was also another busy year for PIC/S, which culminated with the accession of three new Participating Authorities (PAs) – see paragraph 6 below. Rarely have so many new Members joined PIC/S in one single go! In addition, PIC/S adopted under the chairmanship of Mr Hargreaves a Road Map for the period 2018-20 (see paragraphs 4-5 below).

Photo: Mr Paul Hargreaves, PIC/S Chairman

3. In 2017 the PIC/S Committee met twice: first in Geneva (Switzerland) on 9-10 February 2017, and then in Taipei City (Chinese Taipei), on 11-12 September 2017, in conjunction with the annual PIC/S Seminar hosted by Taiwan Food and Drug Administration (TFDA).

Road-Map for 2018-2020

4. At its meeting in Taipei, the PIC/S Committee adopted a Road Map for the period 2018-20. The Road Map results from two "Strategy Meetings" of the Executive Bureau: the first in Nusa Dua (Indonesia) in October 2015 and the second in Manchester (UK) in July 2016. Based on the strategic orientations defined by the EB, the Secretariat prepared a strategic plan ("Road Map") for a 3-year period, which was actively discussed by the Committee prior to being adopted in Taipei. A public version of the Road Map will be prepared by a dedicated Working Group (see para. 141).

5. The PIC/S Road-Map is a non-binding policy paper highlighting the future strategic orientations of PIC/S for the period 2018-2020. It aims at further developing the following goals:

- 1) Offering a training academy to all inspectors by means of the PIC/S Inspectorates' Academy (PIA);
- 2) Facilitating the exchange of GMP information by mutual confidence based on the equivalence of PIC/S Participating Authorities (i.e. Members);
- 3) Identifying PIC/S' next challenges and addressing them, notably by:
 - Enhancing PIC/S' Sub-Committee (SC) structure;
 - Strengthening the PIC/S Secretariat and implementing an effective human resourcing strategy; and
 - Identifying new income streams, which will yield the required funding necessary to finance PIC/S' projects.

Concerns with draft EU GMP Guidelines for ATMPs

11. Throughout the year, PIC/S continued to express concerns regarding patients' safety in the light of the EU draft Guidelines on GMP for Advanced Therapies Medicinal Products (ATMPs). These concerns were voiced in writing as well as orally to the European Commission (EC), notably at the occasion of a teleconference on 4 July 2017 between the EC and the PIC/S ad-hoc Working Group on ATMPs. While some progress was made by the EC in addressing some of the issues raised by PIC/S, a number of concerns remained, notably because diverging GMP standards could be introduced thus potentially leading to internationally non-harmonised GMP requirements for ATMPs.

12. This initiative by the EC in the field of ATMPs requires a revision of EU GMP Guide Annex 2 (Biological Products), which will result in the PIC/S GMP Guide and the EU GMP Guide no longer being equivalent unless the PIC/S GMP Guide is amended¹. Since 1989, both Guides have been developed in parallel and systematically kept aligned on the basis of a harmonised consultation procedure between PIC/S and the European Medicines Agency (EMA).

New tool to strengthen reliance

13. At the request of the International Coalition of Medicines Regulatory Authorities (ICMRA), the PIC/S Committee agreed to take over the output from the ICMRA GMP project, which consists in a new, voluntary Standard Operating Procedure. This SOP aims at maximising inspection resources in order to enable increased reliance on other trusted Regulatory Authorities for the GMP compliance of overseas facilities. This new tool should have a positive impact on the number of foreign inspections having the same scope.

Election of Executive Bureau (2018-19)

14. In 2017 the PIC/S Executive Bureau (EB) met twice: first in Geneva (Switzerland) on 9 February 2017, and then in Taipei City (Chinese Taipei), on 11 September 2017. EB meetings are traditionally devoted to the preparation of the Committee's meeting as well as to discussions on financial, administrative and staff related issues as well as strategic orientations.

15. At its meeting in Taipei, the PIC/S Committee elected Mr Boon Meow Hoe (Singapore / HSA) as Chairman for the period 2018-2019. Mr Boon has been an active and long standing Member of the PIC/S Committee (since 2001). He is the first PIC/S Chairman from Asia in PIC/S' history. His election reflects the growing influence of Asian Regulatory Authorities in PIC/S. Singapore / HSA was the first Regulatory Authority from Asia to join PIC/S in 2000 and was then followed by eight other Asian Regulatory Authorities.

¹ A PIC/S Working Group on the revision of Annex 2 was established in early 2018.



Outgoing PIC/S Chairman (2016-2017), Mr Paul Hargreaves (UK / MHRA), welcoming incoming PIC/S Chairman (2018-2019), Mr Boon Meow Hoe (Singapore / HSA).

16. The PIC/S Committee also renewed the composition of the PIC/S Executive Bureau, which will assist the Chairman in his task as from 1 January 2018.
17. The Executive Bureau Members for the period 2018- 2019 will be:
- Mr Boon Meow Hoe (Singapore / HSA), PIC/S Chairman;
 - Ms Anne Hayes (Ireland / HPRA), PIC/S Deputy Chairperson and Chair of the Sub-Committee on Compliance (SCC);
 - Mr Paul Hargreaves (United Kingdom / MHRA), immediate past PIC/S Chairman;
 - Mr Jacques Moréнас (France / ANSM), Chair of the Sub-Committee on Training (SCT);
 - Mr Paul Gustafson (Canada / RORB), Chair of the Sub-Committee on GM(D)P Harmonisation (SCH);
 - Dr Andreas Krassnigg (Austria / AGES), Chair of the Sub-Committee on Expert Circles (SCEC);
 - Mr Ger Jan van Ringen (Netherlands / IGJ), Chair of the Sub-Committee on Budget, Risk and Audit (SCB);
 - Mr Mark Birse (United Kingdom / MHRA), Chair of the Sub-Committee on Communication (SC COM) ; and
 - Ms Susan Laska (US FDA), Chair of the Sub-Committee on Strategic Development (SCSD).

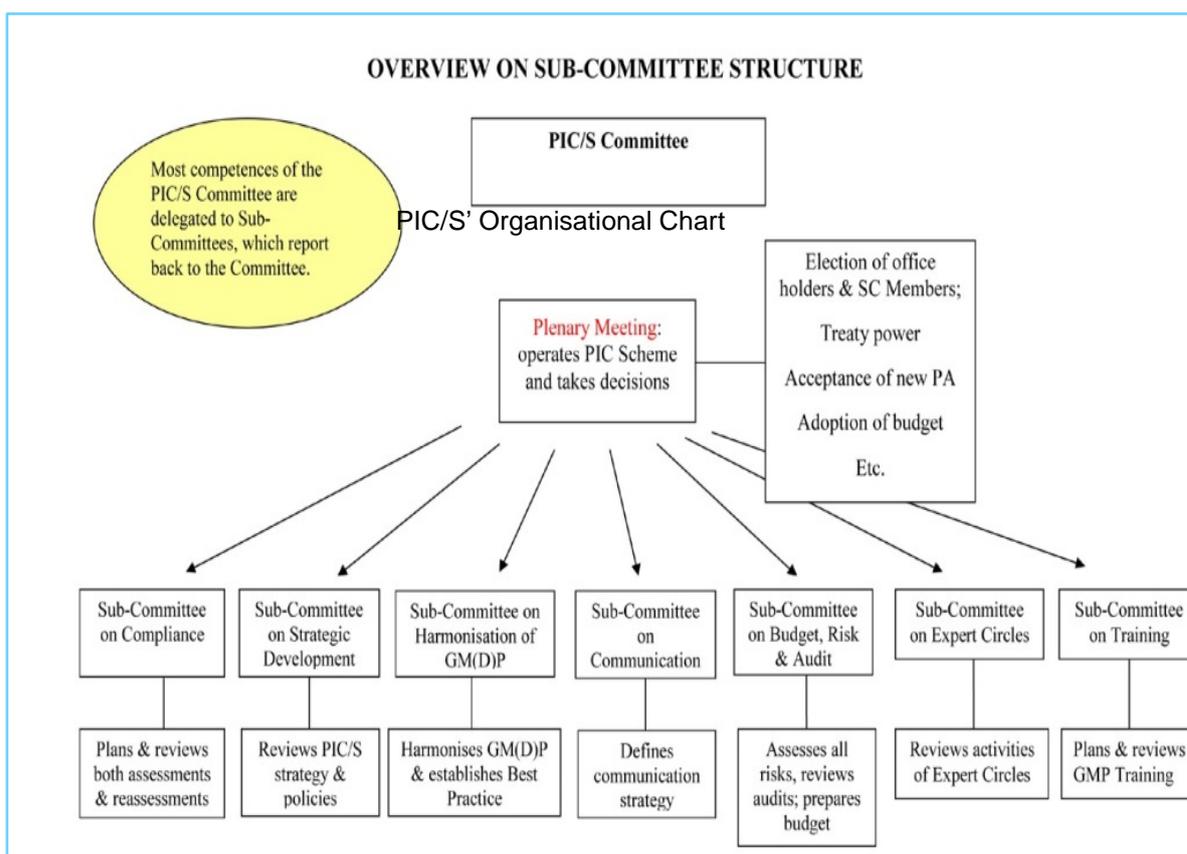
PIC/S Sub-Committee Structure

18. Since 2014, PIC/S has established seven Sub-Committees (SC) in the following fields: Training (SCT); Expert Circles (SCEC); Strategic Development (SCSD); Compliance (SCC); GM(D)P Harmonisation (SCH); Budget, Risk and Audit (SCB) and Communication (SC COM).

19. In 2017, the Committee revised the Terms of Reference of SCs in order to allow more flexibility regarding the number of terms that SC Members can complete. The term of all SC Office Holders was so far limited to two years, “renewable normally once”. As a result, all SCs were up for renewal at end of 2017. In order to ensure continuity and stability, the Committee supported a proposal to change the rule to allow SC Members to run for more than two terms of two years. The rule remained, however, unchanged for SC Chairs and SC Deputy Chairs, who can only run for another term in the absence of candidates. The amendment of the SCs’ Terms of Reference was approved by the Committee by written procedure and entered into force on 22 May 2017.

20. Based on these new rules, the PIC/S Committee (re-)elected the Members of the PIC/S Sub-Committees for the period 2018-2019. 75 Sub-Committee office holders were (re-)elected compared with only 52 in 2015, thus representing a significant increase. The increase reflects the success of the more participative and efficient structure of PIC/S, which was established in 2014 with the new Sub-Committee structure, and the related expansion of PIC/S activities. Out of the 75 (re-)elected Sub-Committee office holders, 39 were from non-EEA PIC/S Participating Authorities.

21. The activities of the PIC/S Committee and the seven Sub-Committees are summarised in this Annual Report.



* * * * *

COMPLIANCE

22. One of the essential requirements to join PIC/S is that Competent Authorities must have *“the arrangements necessary to apply an inspection system comparable to that referred to in this Scheme and whose requirements and procedures could ensure the proper implementation of the Scheme and contribute to its effective operation”*, as stipulated in paragraph 4 of the PIC Scheme. Being equivalent is not only required for accession but all the time and duly verified during reassessments. This is why the compliance to the PIC Scheme is one of PIC/S’ most important and critical activities.

23. This task has been entrusted to the Sub-Committee on Compliance (SCC) under chairmanship of Anne Hayes (Ireland / HPRA). For the complete mandate, see box below.

The mandate of the SCC is to:

1. Co-ordinate, plan and monitor all assessments, pre-assessments, re-assessments, etc.
2. Co-operate with the Secretariat on the validation (i.e. completeness) of (pre)applications
3. Plan and review (i) the assessment of Applicants and Pre-Applicants; and (ii) the re-assessment of Participating Authorities (PA)
4. Review and assess communications from Inspectorates, which could trigger a reassessment
5. Pre-select Rapporteur / Team Leader and auditors who are appointed by the CO
6. Review reports and recommendations by Rapporteur / Team Leader
7. Monitor and review corrective actions by Applicants and Re-Assessed PA and ensure that they are followed up and fully implemented
8. Ensure consistency of assessments and re-assessments (and between them)
9. Ensure that Accession, Pre-Accession & Re-Assessment Guidelines (including Questionnaire and Checklist) are implemented / adhered to and make proposals for their amendment
10. Define and review the tools used for assessment and re-assessment of PA (e.g. the audit checklist) in close co-operation with interested parties such as the EMA Compliance Group and EU MRA Partners (in particular Health Canada)
11. Co-operate with EU Joint Audit Programme, the European Heads of Medicines Agency network and other similar initiatives in order to avoid duplication of work
12. Report back to the PIC/S Committee, as provided for in the Terms of References, and summarises discussions on on-going applications
13. Make proposals / recommendations

24. The SCC held four teleconferences on 30 January, 9 June, 30 August and 13 December 2017, during which it discussed membership applications, pre-accession applications, assessment and reassessment procedures as well as contacts with non-Members, as detailed below.

Evaluation and Re-evaluation Procedures

25. The SCC continued its discussions on the revision of the PIC/S Accession and Pre-Accession Guidelines as well as on the PIC/S Joint Reassessment Programme (JRP).

26. The Working Group on the guideline and interpretation of the Audit Checklist, which is run in co-operation with the EMA Compliance Group on the Joint Audit Programme (JAP), completed its review of the 48 critical indicators. The Working Group is led by Louise Kane (Health Canada). The next step will be to review the remaining indicators (i.e. those considered “very important” and “important”).

Membership Applications

27. In the course of 2017, PIC/S continued the assessment of the following six membership applications (in alphabetical order):

Armenia / SCDMTE

28. Armenia's Scientific Center of Drug and Medical Technologies Expertise (SCDMTE) applied for PIC/S membership on 8 September 2017, further to addressing the CAPA resulting from the PIC/S pre-accession gap analysis conducted in 2013. The application is not complete yet.

Brazil / ANVISA

29. The Rapporteur for the assessment of the membership application of Brazil's Agência Nacional de Vigilância Sanitária (ANVISA) is Mark Birse (UK / MHRA), who is assisted by Ana-Rita Martins (Portugal / INFARMED I.P.), Co-Rapporteur.

30. Following an important, internal reorganisation, Brazil / ANVISA was invited to re-apply in order to comply with PIC/S Accession Guidelines. The current application by Brazil / ANVISA was left open until it re-submits a new membership application.

Iran / IFDA

31. Based on a follow-up visit by the Rapporteur, Paul Sexton (Ireland / HPRA), and the Co-Rapporteur, Kasra Ghasemi (UNICEF), in Tehran on 14-19 July 2017, the Committee invited Iran's Food and Drug Administration (IFDA) to join the PIC Scheme and become PIC/S' 50th Participating Authority from 1 January 2018. As part of its post-accession obligations, Iran/ IFDA will include reference to the PIC/S GMP Guide in its law. CAPAs following the initial on-site assessment visit on 12-16 September 2015 have been successfully implemented, including those regarding the Quality System and the inspection of traditional medicines.



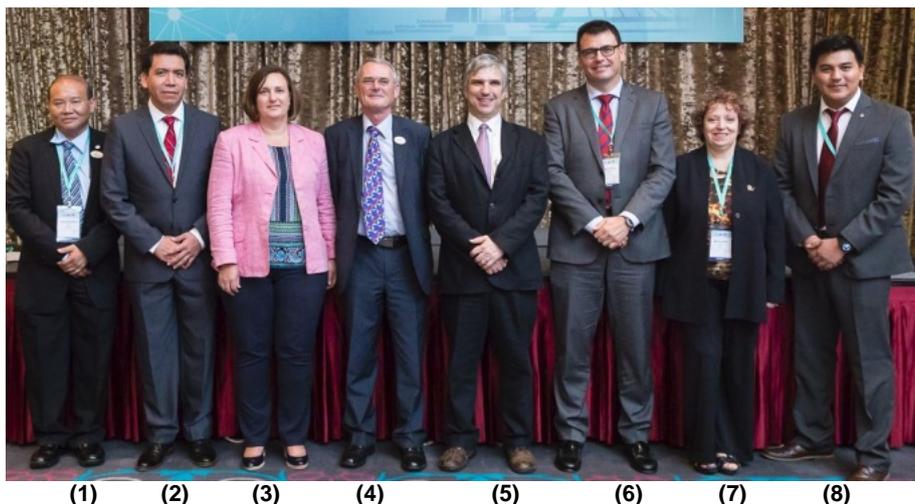
From left to right: PIC/S Deputy Chairman Mr Boon Meow Hoe (Singapore / HSA), PIC/S Chair of the Sub-Committee on Compliance, Ms Anne Hayes (Ireland / HPRA), Dr Amin Motallebyghomi (Iran / IFDA), Dr Zohre Bazaz (Iran / IFDA), PIC/S Chairman Mr Paul Hargreaves (UK / MHRA).

Italy (Vet) / DGSAF

32. The Rapporteur, Jason Todd (UK / VMD), completed the paper assessment of Italy's Directorate General for Animal Health and Veterinary Medicinal Products (DGSAF), which was essentially based on the audit performed within the EMA Joint Audit Programme and subsequent CAPAs. Their implementation will be checked on site and a GMP inspection on sterile and/or biological products will be observed as part of the on-site assessment visit planned in 2018.

Mexico / COFEPRIS

33. The Rapporteur, Manuel Ibarra (Spain / AEMPS), carried out a follow-up visit in Mexico City on 18-20 July 2017, during which he ascertained that all CAPAs have been duly implemented following the on-site assessment visit on 25-29 January 2016. As a result, the Committee invited Mexico's Federal Commission for the Protection Against Sanitary Risks – Ministry of Health (COFEPRIS) to join the PIC Scheme and become PIC/S' 52nd Participating Authority from 1 January 2018.



The representatives of Mexico / COFEPRIS, Mr Mario Alanís (5); Mr Marcos Solis (2) and Mr Mario Perez (8); with the PIC/S Chairman, Mr Paul Hargreaves (UK / MHRA) (4); the PIC/S Deputy Chairman, Mr Boon Meow Hoe (Singapore / HSA) (1); the PIC/S Chair of the Sub-Committee on Compliance, Ms Anne Hayes (Ireland / HPRA) (3); the Rapporteur, Mr Manuel Ibarra (Spain / AEMPS) (6); and one of the assessment team members, Ms Marisa Delbò (Italy / AIFA) (7).

Turkey / TMMDA

34. An on-site assessment visit of the Turkish Medicines and Medical Devices Agency (TMMDA) took place on 13-21 February 2017. The assessment visit was led by the Rapporteur, Anne Hayes (Ireland / HPRA), assisted by the Co-Rapporteur, Michel Keller (Switzerland / Swissmedic). It included additional Audit Team Members from Argentina / ANMAT, Malaysia / NPRA, and New Zealand / Medsafe. There were no major issues. As a result, the Committee invited Turkey / TMMDA to join the PIC Scheme and become PIC/S' 51st Participating Authority from 1 January 2018.



The representatives of Turkey / TMMDA, Mr Fatih Tan (5), Ms Gülsen Yilmaz (3), Mr Muhammed Enes Demir (6), with the PIC/S Chairman, Mr Paul Hargreaves (UK/MHRA) (4), the PIC/S Deputy Chairman, Mr Boon Meow Hoe (Singapore / HSA) (2) and the Rapporteur as well as PIC/S Chair of the Sub-Committee on Compliance, Ms Anne Hayes (Ireland / HPRA) (1).

Pre-Accession Applications

35. PIC/S' Accession Guidelines provide for the possibility for a Competent Authority to ask PIC/S to carry out a pre-assessment by a PIC/S auditor. This includes a gap analysis on the basis of which a recommendation may be given to the Competent Authority either to apply for membership or to take the necessary measures in order to comply with PIC/S requirements.

36. In the course of 2017, the following 3 pre-accession applications were under review:

Kazakhstan / CCMPA

37. At its meeting in Taipei, the Committee reviewed the gap analysis on Kazakhstan's Committee for the Control of Medical and Pharmaceutical Activities (CCMPA), which applied for pre-accession on 1 November 2013. The gap analysis, conducted by the Rapporteur, Rosmarie Neeser Zaugg (Switzerland / Swissmedic), highlighted a number of areas, which Kazakhstan / CCMPA has been invited to address if they plan to submit a membership application to PIC/S. The pre-accession process of Kazakhstan / CCMPA has been closed.

Russian Federation / Minpromtorg and FSI SID&GP

38. On 28 August 2017, the Ministry of Industry and Trade of the Russian Federation (Minpromtorg Russia) and the Federal State Institution "State Institute of Drugs and Good Practices" (FSI "SID & GP") jointly submitted a pre-accession application. At its meeting in Taipei, the Committee appointed Jacques Morénas (France / ANSM) as Rapporteur and Michel Keller (Switzerland / Swissmedic) as Co-Rapporteur.

39. An informal meeting took place on 11 September 2017 between the PIC/S Executive Bureau and a Russian Delegation comprising Minpromtorg Russia and FSI "SID & GP" in order to get a better understanding of the Russian GMP system and discuss PIC/S requirements.

Saudi Arabia / SFDA

40. On 31 July 2017, the Saudi Food and Drug Authority (SFDA) submitted a pre-accession application. At its meeting in Taipei, the Committee appointed Jacques Morénas (France / ANSM) as Rapporteur and Muhammad Lukmani Ibrahim (Malaysia / NPRA) as Co-Rapporteur.

Pakistan / DRAP

41. On 18 September 2017, the Drug Regulatory Authority of Pakistan (DRAP) submitted a pre-accession application. A Rapporteur will be appointed in 2018.

Reassessment of Participating Authorities

42. In order to ensure that both new members and existing members of PIC/S fulfil the same requirements, high quality standards are maintained and GMP Inspectorates remain equivalent, a Joint Reassessment Programme (JRP) was introduced in 2000 under which existing PIC/S members are reassessed for equivalence on a regular basis. The JRP is run in parallel with the EU's Joint Audit Programme (JAP) and uses the same tools. JAP assessments and JRP reassessments are deemed equivalent.

The JRP assessments and reassessments are also combined with the MRA Maintenance program of Health Canada, which are following a similar approach and contribute to saving in resources for regulators and reducing the burden for the audited party.

Re-assessment of Malaysia / NPRA

43. The on-site re-assessment visit of Malaysia / NPRA took place on 12-13 and 15-16 October 2015 under the leadership of Anne Hayes (Ireland/HPRA). Following the audit, several exchanges on Corrective and Preventive Actions (CAPA) took place. All CAPAs were successfully addressed. At its meeting in Geneva, the Committee endorsed the report and the recommendation of the Assessment Team that Malaysia / NPRA is equivalent. The reassessment of Malaysia / NPRA was thus closed.

Re-assessment of US FDA

44. US FDA was subject to an assessment by the EU on 14-18 September 2015, during which no inspection was observed. In order to be deemed equivalent to a PIC/S re-assessment, an observed inspection was carried out by the Rapporteur, Mark Birse (UK / MHRA) on 29 November – 2 December 2016 in Philadelphia (USA). The report was reviewed by the PIC/S Committee at its meeting in Geneva and the EU assessment, with this observed inspection, was deemed equivalent to a PIC/S re-assessment.

Re-assessment of Australia / TGA and Singapore / HSA

45. The planned re-assessments of Australia / TGA and Singapore / HSA took place immediately after the 2017 Seminar on 18-22 September 2017. The reports will be made available to the PIC/S Committee in 2018 after having been reviewed by the SCC.

Planned Re-assessments

121. The Committee also decided to reassess in 2018 Argentina / INAME, Switzerland / Swissmedic and Ukraine / SMDC and nominated the respective re-assessment teams.

46. The re-assessment of South Africa / MCC was postponed due to organisational changes (MCC being replaced by a new regulatory authority, SAHPRA).

Non-Members

47. Close contacts were kept with a number of non-Members.

48. A meeting between a PIC/S Delegation and a Delegation from the China Food and Drug Administration (CFDA), led by Vice Minister Mr Wu Zhen, took place in Geneva (Switzerland) on 5 December 2017. The purpose of this meeting was to discuss legal and other issues in relation with CFDA's possible plans to submit a membership application.

49. Bulgaria / BDA officially enquired whether PIC/S would consider the assessment of BDA under the EMA JAP, if it applied for PIC/S membership. As recommended by the SCC, the Committee agreed that PIC/S would follow the same approach as with Italy (Vet) / DGSAF, i.e. a facilitated accession process through a partial assessment taking into account the JAP audit when completed.

GMDP

50. The harmonisation of Good Manufacturing Practice (GMP) and – more recently – of Good Distribution Practice (GDP) is at the very heart of PIC/S. The main reasons for adopting common standards are:

- ◆ to ensure the maintaining of high standards of quality assurance in the development, manufacture and control of medicinal products;
- ◆ to promote uniformity in licensing decisions;
- ◆ to promote consistency and uniformity of inspections;
- ◆ to facilitate the removal of barriers to trade in medicinal products.

51. The main instrument for harmonisation has been the PIC/S GMP Guide, which PIC/S is striving to keep equivalent in terms of GMP requirements with the EU GMP Guide. Close co-operation with the EMA is thus essential.

52. The mandate of the Sub-Committee on the Harmonisation of GM(D)P (SCH), chaired by Paul Gustafson (Canada / RORB), is to harmonise GMP, establish best inspection practices and harmonise the interpretation of GMP to ensure consistency in inspection / audit practices. For the complete mandate, see box below.

The mandate of the SCH is to:

1. Harmonise GM(D)P and establish best inspection practices
2. Ensure the harmonisation and the equivalence of the PIC/S GMP Guide with the EU GMP Guide
3. Encourage the uniform interpretation and application of GM(D)P
4. Co-operate and work closely together with the EMA, the GMDP IWG, the EDQM and WHO in the field of GM(D)P harmonisation and best practices
5. Co-ordinate with the PIC/S – EMA Liaison Officer and the EMA representative the involvement of PIC/S Experts in EMA GMDP IWG on revision of the GMP Guide, Annexes, Q&A and other relevant guidance documents
6. Make proposals for the drafting of new guidance documents (Aide-Memoire, recommendations, etc.) on the basis of best inspection practices and co-ordinate their revision
7. Review activities, mandates, etc. of Working / Drafting Groups dealing with the harmonisation of GM(D)P – in particular Joint Drafting Groups working on the revision of the EU-PIC/S GMP Guide
8. Harmonise the interpretation of GMP to ensure consistency in inspection / audit practices
9. Supervise the finalisation of guidance documents arising from PIC/S Seminars
10. Identify possibilities for promoting international harmonisation in the field of GM(D)P

- | |
|---|
| <p>11. If the Chair of the SCH is not attending EMA GMDP WG meetings, appoint a Liaison Officer</p> <p>12. Report back to the PIC/S Committee, as provided for in the Terms of References, and make proposals / recommendations</p> |
|---|

53. The SCH held four teleconferences on 18 January, 22 June, 28 September and 14 December 2017, during which it discussed the revision of the PIC/S GMP Guide and the drafting of guidance documents. It also monitored and reviewed the work carried out by a number of Working Groups, detailed below.

Working Groups under the SCH

54. Seven Working Groups are operating under the SCH.

(Ad Hoc) Working Group on Advance Therapy Medicinal Products (ATMPs)

55. The Working Group on Advance Therapy Medicinal Products (ATMPs) was established in 2015 in order to draft an Aide-Memoire to support the inspection of ATMPs facilities. However, due to developments in the EU (see below), it was put on hold and then dismantled at the PIC/S Committee meeting in Taipei.

56. In parallel, an Ad Hoc Working Group on ATMPs has been established in order to advise the PIC/S Committee on the European Commission's draft Guidelines on ATMPs, which have been developed by a Joint Drafting Group including Members from the EMA Committee for Advanced Therapies (CAT) and the Inspectors Working Party on GMDP (IWP). Although the PIC/S-EMA Joint Consultation Procedure provides for a consultation of PIC/S when the EU GMP Guide is revised, this was not the case during the revision of Annex 2 and the drafting of the EC's Guidelines on ATMPs.

57. As a result, PIC/S proposed to the EC to establish a joint working party with the EMA IWG on GMP in order to produce an internationally harmonised GMP Guide for ATMPs. However, the EC did not reply to this offer².

58. PIC/S presented its concerns regarding the EC draft Guidelines on ATMPs in writing as well as orally, notably during a teleconference between the EC and PIC/S experts of the Ad Hoc Working Group took place on 4 July 2017. The outcome of the meeting was summarised and shared through an exchange of letters between the EC and PIC/S.

² A PIC/S Working Group on the revision of Annex 2 was established in early 2018, in which the EMA will be represented.

Working Group on Data Integrity

59. The PIC/S Working Group on Data Integrity was established in 2015 and is co-chaired by Matthew Davis (Australia / TGA) and David Churchward (UK / MHRA). It aims at developing a PIC/S data integrity guidance document for inspectors to provide them with the basic skills for performing data integrity inspections. The draft "PIC/S Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments" (PI 041-1 (Draft 2)) was published on 10 August 2016 and implemented on a trial-basis for a period of 6 months. Participating Authorities were invited to report back on the implementation of the guidance document by the end of February 2017. The draft was then revised (PI 041-1 (Draft 3)) based on Members' comments. It will be submitted to Members again and then advanced for industry consultation.

60. The Working Group has also developed other data integrity guidance tools for inspectors such as an aide-memoire, flowchart to assist inspectors, and system specific guidance, which will be submitted to PAs once comments from the SCH have been incorporated.

Working Group on Harmonisation of the Classification of Deficiencies

61. The Working Group on Harmonisation of the Classification of Deficiencies, led by Jenny Hantzinikolas (Australia / TGA), has been mandated to draft a guidance document, which includes a tool for Inspectorates to improve harmonised risk classification of GMP deficiencies. Recommendations to facilitate harmonised compliance and enforcement approaches to address GMP non-compliance will also be included. These efforts are hoped to facilitate more consistent responses among international regulatory authorities when responding to GMP deficiencies and GMP non-compliance.

62. The first draft of the Guidance on the Classification of Deficiencies was submitted to PIC/S Members and Partner Organisations on 7 January 2016. It was also shared with inspectors during the 2017 PIC/S Seminar. The Working Group has reviewed all the comments and developed a second draft in 2017, which will be submitted to a second internal consultation in 2018.

Working Group on Annex 1 / Sterile Manufacturing

63. The PIC/S Working Group on Annex 1 was established at the Rome meeting on 15-16 May 2014. At the Paris meeting on 20-21 October 2014 the WG was merged with the EMA IWG Drafting Group with a view to jointly revise Annex 1. The joint PIC/S-EMA Drafting Group is led by Andrew Hopkins (UK / MHRA) and includes representatives of the Competent Authorities of PIC/S and EEA.

64. Following a second written consultation of PIC/S PA and EU/EEA Competent Authorities on the draft revision of Annex 1, which ended on 24 January 2017, the Working Group reviewed comments and prepared a revised draft. In parallel, the Committee endorsed a SCH Paper on the Joint Publication of PIC/S documents by both PIC/S and WHO starting with Annex 1.

65. The revision of Annex 1 was advanced to Step 2 on 20 December 2017, when it was published for public consultation jointly with the EU and WHO.

Working Group on Controlling Cross-Contamination in Shared Facilities (CCCISF)

66. The goal of the Working Group on Controlling Cross-Contamination in Shared Facilities is to draft an Aide Memoire which will focus on harmonising and standardising terminology used in relation with the control of cross-contamination in shared facilities and address questions which inspectors should ask themselves during inspections – in particular in relation with risk management. This will allow inspectors to better assess the risks of cross contamination in shared facilities.

67. A first draft has been developed by the WG, chaired by Graeme McKilligan (UK / MHRA), and submitted to Members' comments on 21 April 2017. A final draft will be circulated for adoption to Members in early 2018, once comments have been incorporated following the review by the SCH.

68. The WG has proposed to become an Expert Circle and to develop some training material (including case studies) in the form of webinars, which could be shared through the PIA. At its meeting in Geneva, the Committee agreed to turn the WG on CCCISF into an Expert Circle (see also paragraph 122).

Working Group on the Revision of PIC/S Guidance Documents for Blood

69. At its meeting in Taipei, the Committee established a Working Group with experts from Australia / TGA, Health Canada, Chinese Taipei / TFDA, EDQM, Greece / EOF, Netherlands / IGJ, and Switzerland / Swissmedic, based on a concept note prepared by the Chair of the Expert Circle on Human Blood, Tissues, Cells and ATMPs (Marisa Delbò, Italy / AIFA). The aim is to revise and merge the PIC/S GMP Guide for Blood Establishments (PE 005-3) and PIC/S Guide to Inspections of Source Plasma Establishment and Plasma Warehouses (PE 008-3) as well as to harmonise them with the EU Good Practices Guidelines for blood establishments.

Drafting Group on the revision of PI 006

70. A full revision of the PIC/S Recommendations on Validation Master Plan; Installation and Operational Qualification; Non-Sterile Process Validation; and Cleaning Validation (PI 006-3) has been initiated by a Drafting Group led by UK / MHRA and comprising Argentina / INAME, Austria / AGES, Canada / RORB and Germany / ZLG. The aim is to delete repetition with Annex 15 and provide an updated interpretation. An intermediate revision by the SCH of the same recommendations (PI 006-4) will be submitted for adoption by written procedure in early 2018.

Revision of the PIC/S and EU GMP Guides and Annexes

71. One of the main duties of the SCH is to harmonise GM(D)P guidance documents with the EU, in particular the PIC/S GMP Guide and Annexes, and to transpose EU (proposed) revisions for PIC/S purpose.

72. The revised Chapters 1 (Pharmaceutical Quality Systems), 2 (Personnel), 6 (Quality Control) and 7 (Outsourced Activities) of the PIC/S GMP Guide (PE 009-13) entered into force on 1st January 2017.

73. In 2017, the SCH actively continued to harmonise and transpose GM(D)P guidance documents. It reviewed comments in relation with the revisions of Chapters 3 (Premise and Equipment), 5 (Production), & 8 (Complaints and Recalls), which were submitted to Members' comments until 31 January 2017.

74. PIC/S experts are also involved in EMA Drafting Groups on the revision of Annex 1, 13 and 17 of the EU-PIC/S GMP Guide.

- Annex 1 (Sterile Manufacturing): See paragraphs 63-65.
- Annex 13 (Investigational Medicinal Products): The Drafting Group finalised the standalone guide on IMPs, which will replace Annex 13. The Guide was published by the EC and will be applicable once the new EU Regulation 536/2014 enters into force.
- Annex 17 (Real Time Release Testing, previously Parametric Release): following public consultation, a revised draft has been discussed. The revised draft was adopted by the EMA IWG and sent to PIC/S for adoption.

75. PIC/S also follows the work on the drafting of the EU Annex 21 (GMP Obligations for Importation to the EU). It may decide to develop a PIC/S-specific Annex.

76. Based on a proposal by the SCH, the Committee agreed in principle to establish a Drafting Group in order to develop a PIC/S equivalent Annex to EU Annex 16 (Certification by a QP & Batch Release), as there are many questions on the role and responsibility of the Qualified Person / Authorised Person. The WG has been established within the SCH and a draft has been in principle endorsed for advancing to Step 1.

Guidance Documents and Procedures

77. All PIC/S guidance documents are available on the PIC/S website <https://www.picscheme.org>.

GMP Guidance Documents

Revision of PIC/S Recommendations on Validation Master Plan; Installation and Operational Qualification; Non-Sterile Process Validation; and Cleaning Validation

78. The SCH is working on finalising an interim revision of the above-mentioned recommendations (PI 006-4 (Draft 1)), which will be submitted for adoption in 2018. For the full revision of PI 006, see paragraph 70.

GDP guidance documents

79. The PIC/S Expert Circle on GDP, led by UK / MHRA, finalised the first draft of the Aide-Memoire on Inspection of Manufacturers and Wholesale Distributors for Compliance with GDP and the first draft of a Q&A for the PIC/S GDP Guide. These first drafts were submitted to Members for comments. The Expert Circle will review the comments in 2018.

EMA guidance documents

80. In 2017, the SCH reviewed comments from Members on the following EMA guidance documents, which were transposed for PIC/S purpose:

- Guidelines on the formalised risk assessment for ascertaining the appropriate Good Manufacturing Practice for excipients of medicinal products for human use (PI 045-1);
- Guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (PI 046-1);
- Guidelines on the principles of Good Distribution Practices for active substances for medicinal products for human use (PI 047-1).

Guidance on Total Parenteral Nutrition (TPN)

81. Further to a request from the EMA IWG that PIC/S takes over a guidance on Total Parenteral Nutrition (TPN), PIC/S carried out a consultation of its PAs on whether the TPN guidance should be adopted by PIC/S as (i) a stand-alone document or (ii) as an appendix to PE 010-4 (Guide to good Practices for the preparation of medicinal products in Healthcare Establishments). (NB: TPN is subject to manufacturing authorisation in some PIC/S countries.)

PIC/S Library

82. The SCH continued its work on establishing a PIC/S library, which will include documents related to GM(D)P inspection drafted by Members and Partners and which will be integrated into the PIC/S Inspectorates' Academy (PIA).

TRAINING

83. Harmonising GMP requirements through the PIC/S GMP Guide is not sufficient to ensure a uniform interpretation and application of GMP. The training of GMP inspectors is an essential tool to achieve this goal. This is why the training of GMP inspectors is an essential activity of PIC/S. Recently, PIC/S has also opened its training programme to inspectors active in other areas such as Good Distribution (GDP), Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP).

84. The Sub-Committee on Training (SCT) is the oldest Sub-Committee and was initially established as a Working Group under the PIC/S Committee. Its mandate has remained by and large the same over the past decades – see box below.

The mandate of the SCT is to:

1. Identify training needs
2. Co-ordinate and monitor PIC/S training activities
3. Review the planning and organisation of annual training seminars, in particular:
 - propose and validate the seminar topic,
 - review the seminar programme,
 - assess the seminar report,
 - make recommendations for future seminars,
 - propose amendment to the Aide Memoire on the Organisation of Seminars (PI 003).

4. Monitor the Joint Visits Programme and the Coached Inspection Programme and carry out a review of reports in order to identify divergences on GMP interpretation and inspection practices
5. Ensure the rotation of training between the various regions, taking into consideration the expansion of PIC/S
6. Consider proposals for co-operation with professional organisations (e.g. ISPE, PDA) in the field of training
7. Report back to the PIC/S Committee, as provided for in the Terms of References, and make proposals / recommendations

85. The Sub-Committee on Training (SCT) is led by Boon Meow Hoe (Singapore / HSA) and met three times in 2017: on 11 January, 16 August and 15 September 2017. One of its main duties is to review the preparation and outcome of PIC/S training activities.

86. The following PIC/S training activities were held in 2017 (in chronological order):

Date	Place	Activity	Organised by
5-7 April	Melbourne (Australia)	PIC/S Expert Circle on Active Pharmaceutical Ingredients (API)	Australia / TGA
26-28 June	Seoul (Korea (Republic of))	PIC/S Expert Circle on Human Blood, Tissues, Cells and ATMPs	Korea (Republic of) / MFDS
31 July – 4 August	Yamaguchi (Japan)	PMDA-ATC GMP Inspection Seminar	Japan / PMDA (with the support of PIC/S)
13-15 September	Taipei (Chinese Taipei)	PIC/S 2017 Seminar on "Quality Control Laboratories: How to Inspect"	Chinese Taipei / TFDA
23-27 October	Dublin (Ireland)	PIC/S New Inspector Training Course	Ireland / HPRA

Annual Training Seminar

87. PIC/S arranges every year a Training Seminar for inspectors, with each Seminar dealing with a specific topic and hosted by a different PIC/S Participating Authority. The SCT, jointly with the PIC/S Committee, reviews the organisation and outcome of annual seminars in line with the PIC/S Aide Memoire on the Organisation of Seminars.

88. In 2016, the Seminar was organised by the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) in Manchester (UK) on 6-8 July 2016. The topic of the Seminar was "Inspectorates of the Future". For more details, see the Annual Report for 2016. The evaluation report, which was reviewed by the SCT, was presented at the occasion of the PIC/S Committee meeting in Geneva. As a follow-up

to the seminar, a Working Group on inspectors' travel safety was established. See paragraph 140.

89. In 2017, the Seminar was organised by the Taiwan Food and Drug Administration (TFDA) in Taipei City (Chinese Taipei) on 13-15 September 2017. The topic of the Seminar was on "Quality Control Laboratories – How to Inspect".



90. The Seminar was the first organised in Chinese Taipei since TFDA joined PIC/S in 2013. It was attended by more than 170 inspectors from more than 50 countries. All continents were represented. The Seminar was opened by the Deputy Minister, Ministry of Health and Welfare, Dr Chi-Kung Ho, along with the Director-General of TFDA, Dr Shou-Mei Wu, and the PIC/S Chairman, Mr Paul Hargreaves.

91. The Seminar consisted in a mix of presentations and workshops, during which participants were introduced to basic concepts, current and trending regulatory requirements, as well as specific quality issues which have an impact on regulatory compliance of QC labs.



PIC/S 2017 Seminar Logo



92. The Seminar programme covered topics related to GMP inspections of QC labs, including Out-of-Specification/Out-of-Trend investigations (OOS/OOT), data integrity issues and aspects of test methods validation and verification in the context of technical transfers.

93. Four workshops for inspectors followed on:
- How to inspect the QC Lab (Workshop leaders: Canada / RORB and Chinese Taipei / TFDA).
 - Harmonising the Classification of Deficiencies of Quality Control (Workshop leaders: Australia / TGA and Croatia / HALMED).
 - Technical transfer of testing methods (Workshop leaders: US FDA and Japan / PMDA).
 - OOS/OOT Investigation (Workshop leader: UK / MHRA).

94. The last day of the Seminar was mainly devoted to the outcome of the workshops. One of the main outputs will be the revision of the PIC/S Aide Memoire on inspection of pharmaceutical quality control laboratories (PI 023-2). The seminar ended with the presentation of the next seminar, which will be hosted by US FDA in Chicago (USA) on 26-28 September 2018. The seminar will be on the “Management of Risk through the Product Life-Cycle” and will focus on how to assess and manage risks from inspectional and product-cycle point of views.



2017 Seminar - Official photo with participants

Joint Visits Programme / Coached Inspection Programme

95. At the end of 2017, there were approximately 12 active Joint Visit Groups involving around 36 inspectors in the PIC/S Joint Visits Programme (JVP) and Coached Inspections Programme (CIP). The JVP and the CIP are essential PIC/S tools helping to ensure global GMP harmonisation (see box below).

96. The JVP is open to PIC/S inspectors only and is particularly appreciated by inspectors specialised in specific fields of GMP (e.g. sterile manufacturing).

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.

97. The participation in the JVP has been progressively extended from GMP inspectors to GDP, GCP³ and GVP⁴ inspectors. At the end of 2017, there were 6 active Joint Visits Groups for GCP/GVP co-ordinated by the PIC/S Working Group on GCP/GVP (see paragraphs 123-124).

98. In 2017, the Committee decided to open the JVP to GCP/GVP inspectors from PIC/S Applicant Authorities and from PIC/S countries/entities, where the competence for GCP/GVP is not with the PA.

PIC/S International Training Programme on API

99. The API International Training Programme (API ITP) is run by the Expert Circle on API (see paragraph 115). It consists of three segments: the PIC/S-PDA Q7 Training, open to regulators and industry; the Advanced Training for regulators; and the Q&A.

- Segment 1: The Q7 training, which focuses on familiarisation with ICH Q7, is for both industry and regulators; it is organised jointly by PIC/S and the Parenteral Drug Association (PDA);
- Segment 2: The advanced training on API inspection, focusing on improving the skills of inspectors and sharing approaches for addressing contemporary issues, is for regulators only;
- Segment 3: The Q&A on ICH Q7 is on the interpretation of the requirements of ICH Q7 and is open to both industry and regulators.

100. Due to limited resources, PIC/S' involvement in the three segments has alternated over the years. In addition, to allow all inspectors to benefit, the Q7 training and the advanced training on API have been recorded in view of the development of e-learning modules. The recorded training has been successfully integrated into the PIA (see paragraph 110).

101. The bulk of the Q7 training was organised in 2015: four Q7 Training courses were successfully organised and co-financed by the European Commission in Korea

3 Good Clinical Practice

4 Good Vigilance Practice / Pharmacovigilance

(Republic of); Brazil; India; and China. The location of the training was in line with PIC/S' aim to provide training in emerging, API-producing countries. In 2017, ICH approached PIC/S with a proposal to run – on behalf of ICH – a basic Q7 training programme with PDA starting with a trial course in Japan. As ICH was unable to provide any resources, PIC/S declined the offer.

102. Advanced training on API inspection is organised by the Expert Circle on APIs every 12 to 18 months on average. A total of 7 advanced trainings within the frame of the API Expert Circle meetings have been provided in the past and most of them recorded. The last advanced training was organised by Australia / TGA (see para. 115).

103. With regard to Q&A on ICH Q7, the PIC/S Committee established a new PIC/S Working Group on “API Q&A developed by PIC/S but not transferred to ICH”. It comprises representatives from Canada / RORB, EDQM, Germany / ZLG, Italy / AIFA, US FDA, and WHO. The aim of the Working Group is to use these Q&A to develop training material part for the PIC/S API International Training Programme. The project should start in 2018.

PIC/S New Inspector Training Course

104. Since 2011, Ireland / HPRA has run on behalf of PIC/S a “New Inspectors Training Course” (NITC) in Dublin (Ireland). This course is essentially designed for newly recruited inspectors. It is very popular amongst PIC/S inspectors and always well attended. Following a request by the SCT, Ireland / HPRA has agreed to conduct the NITC on a regular basis every 18 months with the support of trainers of other PIC/S PAs. A “Train the Trainer” course was also organised in 2014 in order to complement the NITC.

105. A New Inspector Training Course was organised by Ireland / HPRA in Dublin (Ireland) on 23-27 October 2017. This 5th NITC consisted of a standard 5-day long course, including practical training in a small-scale bio facility. It was run by Ireland / HPRA with the assistance of trainers from US FDA and UK / MHRA. The course, which was partially funded by PIC/S, was attended by 36 inspectors.

PIC/S Inspectorates' Academy (PIA)

106. The PIC/S Inspectorates' Academy (PIA) is a project run by the PIA Management Steering Committee (PMSC) and the SCT, both placed under the chairmanship of Boon Meow Hoe (Singapore / HSA).

107. PIA is a PIC/S initiative to set up a web-based educational centre under the PIC/S umbrella and to provide GMP training, which has been harmonised and standardised, at an international level. PIA will not only deliver general or advanced training but also serve as a platform for discussion and sharing among regulators thus contributing to global harmonisation and interpretation of GMP. It offers a single point of access to all PIC/S training activities. The initiative already benefits from a strong support from Head of Agencies, PIC/S Members (and non-Members) as well as interested Partner Organisations and Third Parties. It will be implemented in three independent stages. Progresses are monitored by the PIA Project Management Steering Committee (“PMSC”).



108. The idea to establish a professional “Inspectors’ Academy” delivering a variety of courses ranging from general training to highly specialised training for inspectors was presented for the very first time at PIC/S’ 40th Anniversary in 2011. PIA was officially established at the PIC/S Committee meeting in Paris (France) on 20-21 October 2014. At its meeting in Nusa Dua (Indonesia) on 5-6 October 2015, the PIC/S Committee adopted the official PIA logo and its motto, which is “**Inspection Excellence through Harmonised Training**”. The PIA website was launched on 18 July 2016. This marks the end of Stage 1 and the beginning of Stage 2 of PIA. Stage 2 will focus on identifying training needs, developing e-learning modules, seeking funding, etc. It will also aim at co-operating with external stakeholders as well as developing PIC/S training recognition and certificates.

109. PIA is a dedicated, protected web-based platform incorporating PIC/S training material. The PIA website is a sub-site of the PIC/S website, which went through a complete overhaul in 2016. The new web site is accessible to PIC/S inspectors on tablets and smartphones and provides higher visibility on SC activities. The PIA sub-site contains training material, mainly recorded video training, as well as a forum for inspectors to interact. Its access is password-restricted. Around 1,800 PIC/S inspectors have access to PIA, provided that they register first on-line.

110. In 2017, new videos were published on the PIA website including a selection of the best presentations from the PIC/S-PDA Q7 Training delivered in several key locations around the world (see also paragraphs 99ff). Possibilities for organisations such as ISPE, PDA and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) to support PIA were further discussed. Guidelines on Third-Party Funding were drafted by the Executive Bureau. The possibility to run and register webinars under PIA was explored and a trial was carried out. In addition, the possibility for Expert Circles to develop on-line training or a learning curriculum for inspectors accessible via PIA has been discussed.

PMDA Training Course supported by PIC/S

111. Japan / PMDA organised with the support of PIC/S a second GMP Training Course from 31 July to 4 August 2017 in Yamaguchi (Japan). The course focused on the inspection of vaccines and aseptic techniques.

EXPERT CIRCLES

112. PIC/S Expert Circles have been set up by the PIC/S 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.

113. The main task of the Sub-Committee on Expert Circles (SCEC) is to review the composition and functioning as well as the various mandates of the Expert Circles. The mandate of the SCEC is detailed in the box below.

The mandate of the SCEC is to:

1. Identify the need to create / terminate Expert Circles
2. Co-ordinate and monitor activities and meetings of Expert Circles
3. Ensure that activities of Expert Circles are in line with their respective mandates, as approved by the PIC/S Committee, as well as with the Guidelines for PIC/S Expert Circles (PI 022)
4. Review the planning and organisation of Expert Circles meetings, in particular:
 - validate the yearly objectives as well as meetings' objectives
 - review the programme
 - assess the meeting report
 - make recommendations for future meetings
 - ensure that Guidelines on Expert Circles are implemented / adhered to
 - propose amendment to the Guidelines on Expert Circles
5. Report back to the PIC/S Committee, as provided for in the Terms of References and make proposals / recommendations

114. The SCEC is chaired by Andreas Krassnigg (Austria / AGES). In 2017, it held two teleconferences: the first on 18 January and the second on 2 August.

Expert Circle on API

115. The Expert Circle on Active Pharmaceutical Ingredients (API) is chaired by a triumvirate comprising Greg Orders (Australia / TGA), Florence Benoit-Guyod (EDQM) and Michel Keller (Swissmedic). Australia / TGA hosted the 8th Meeting of Expert Circle Meeting in Melbourne on 5-7 April 2017, which focused on Advanced Training for API inspectors. The meeting was attended by more than 70 participants from 24 authorities and international organisations. Several topics were discussed such as the regulation of small versus large molecule manufacturing, regulatory approaches to atypical API's, continuous processing, etc.



Group photo of the Expert Circle Meeting in Melbourne

Expert Circle on Human Blood, Tissues, Cells & ATMP

116. The Expert Circle on Human Blood, Tissues and Cells is the oldest Expert Circle in PIC/S. In 2015, the Expert Circle expanded to include Advanced Therapies Medicinal Products (ATMPs). It is chaired by Marisa Delbò (Italy / AIFA).

117. The 23rd meeting of the Expert Circle on Human Blood, Tissues, Cells and ATMPs was hosted by Korea (Republic of) / MFDS in Seoul on 26-28 June 2017. The meeting was attended by more than 70 participants from 25 authorities. Experts discussed contemporary issues in the field of blood, plasma derivatives, cells and tissues, with particular focus on ATMPs. The outcome of the mapping survey on PIC/S PA competences in the field of blood, blood components, plasma derivatives, cells and tissues as well as ATMPs was presented at the meeting. Several manufacturing facilities were also visited. This meeting was held back-to-back with the Global Bio Conference, a major pharmaceutical event on biopharmaceuticals, organised by MFDS and Korea Biomedicine Industry Association, which attracted over 1,000 participants.

118. Thanks to the work of the Expert Circle Chairperson, a first draft of a list identifying the Competent Authorities in the fields of blood, tissues and cells, and ATMPs has been established.



Expert Circle on Blood, Tissue, Cells & ATMPs in Seoul

Expert Circle on QRM

119. The Expert Circle on Quality Risk Management (QRM) was established in 2007. Between 2014 and 2016 it organised three Advanced QRM Training Courses in Tokyo (Japan), Los Angeles (USA) and London (UK).

120. Since 1st January 2017, the Expert Circle is chaired by Karmin Saadat (Austria / AGES). In Taipei, the Committee adopted a new mandate for the Expert Circle on QRM, which has been prepared by the Co-ordinating Committee.

Expert Circle on GDP

121. The Expert Circle on Good Distribution Practice (GDP) was established in 2013 and organised four meetings between 2013 and 2017. As it completed its original mandate, a new Co-ordinating Committee has been established with experts from UK / MHRA (Peter Blundell, Chair), Spain / AEMPS, South Africa / MCC and Sweden / MPA. The Co-ordinating Committee will develop a draft mandate to be adopted by the Committee as well as organise a next meeting in 2018, which Spain / AEMPS has agreed to host.

Expert Circle on Controlling Cross Contamination in Shared Facilities

122. The Expert Circle on Controlling Cross Contamination in Shared Facilities (CCCISF) was established at the PIC/S Committee meeting in Geneva on 9-10 February 2017, during which its mandate was adopted.

Working Group on GCP / GVP

123. The Working Group on Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP) was established in July 2014 with the aim to facilitate technical co-operation and harmonisation of practices (including the development of guidance and training material), capacity building and information sharing. The Working Group, led by Mandeep Rai (UK / MHRA), is very active in the field of training through the PIC/S Joint Visits Programme, allowing 3 inspectors from 3 different countries to team up in order to observe inspections in each country with a view to comparing inspections procedures and techniques.

124. In 2017, the Working Group finalised the Joint Visit Programme (JVP) Guidelines for conducting GCP and GVP Inspections, which were adopted by the PIC/S Committee.

Working Group on Medicinal Products for Veterinary Use

125. Following a survey on veterinary competencies of PIC/S PA, the Committee agreed in principle to set up an Expert Circle on medicinal products for veterinary use. An Ad Hoc Working Group led by France / ANSES and UK / VMD, has been established to draft a mandate. Discussions on this mandate continued in 2017.

Working Group on Computerised Systems

126. A call has been made in order to find additional experts for the Working Group on Computerised Systems, which was set up in 2015 to revise the PIC/S Good Practices for Computerised Systems (PI 011), in order to start the revision.

STRATEGIC DEVELOPMENT & CO-OPERATION

127. The Sub-Committee on Strategic Development was set up in 2009 in order to discuss, amongst other matters, the outcome of a survey on how to improve the operation of the Scheme. Following a suggestion by the Irish Medicines Board (now HPRA) to establish more Sub-Committees under the PIC/S Committee, the SCSD elaborated a concrete proposal on how to set up and implement a Sub-Committee structure.

128. The mandate of the SCSD is to define PIC/S' strategy and future policy and make proposals on how to improve the structure and the operation of PIC/S as well as co-operation with PIC/S Partners. For the full mandate, see box below.

The mandate of the SCSD is to:

1. Define and review PIC/S strategy and (future) policy
2. Make proposals / recommendations on how to improve the structure and the operation of PIC/S
3. Ensure the implementation of strategical policies (e.g. roadmaps such as the Blueprint) as well as strategical decisions
4. Discuss new projects for PIC/S and make proposals on the possible "expansion" of PIC/S' mandate to other areas
5. Address implementation of new projects and resource management – in particular funding (e.g. external) – in consultation with PIC/S PA and Heads of Agencies
6. Review co-operation with Partners and make proposals / recommendations for the possible improvement of the co-operation
7. Promote the participation of authorities interested in the PIC Scheme
8. Report back to the PIC/S Committee, as provided for in the Terms of References and make proposals / recommendations

129. More recently, the SCSD has taken a number of initiatives aiming at strengthening international regulatory co-operation in the field of GMP. The objective of these initiatives is to improve the sharing of GMP information between PIC/S PA as well as to facilitate mutual reliance on a voluntary basis.

130. The SCSD is chaired by Jacques Morénas (France / ANSM). It held one teleconference on 17 August 2017.

International Coalition of Medicines Regulatory Authorities (ICMRA)

131. Relations between PIC/S and the International Coalition of Medicines Regulatory Authorities (ICMRA) date back to 2014, when the Committee agreed in principle to co-operate with ICMRA in the field of GMP. In 2016, the ICMRA GMP Project dealing with the issue of "equivalence" invited PIC/S to be formally represented

in the ICMRA “GMP reliance framework on equivalency”. This project looked at possible ways to assess information using inspection reports from other authorities. At its meeting in Geneva, the Committee appointed Anne Hayes (Ireland/HPRA) as the PIC/S representative in this project.

132. In 2017 ICMRA formally proposed to PIC/S to hand over the GMP reliance framework on “equivalency”. The project consists of an ICMRA draft Guidance on GMP Inspection Reliance, which aims at maximising inspection resources by relying on other trusted Regulatory Authorities for the GMP compliance of overseas facilities. The ICMRA proposal was accepted by the PIC/S Committee at its meeting in Taipei. It also agreed in principle to take over the ICMRA Draft Guidance on GMP Inspection Reliance to be reviewed by PIC/S Participating Authorities. The consultation was launched on 30 November 2017 and will end on 31 January 2018.

Voluntary Acceptance of Same Scope Inspection Results

133. In the context of increased foreign inspections, PIC/S has taken a number of measures to reduce duplicate foreign inspections such as through the maintenance of a list of planned foreign inspections - which in 2017 included around 1,600 planned inspections globally – as well as through various procedures such as the PIC/S procedure for team inspections (PI 031-1) and the “Procedure to inform Foreign Regulatory Agencies of Foreign Inspections to be conducted in their Jurisdiction” (PI 039-1).

134. In 2014, the SCSD carried out a survey on “same scope inspections”. Same scope inspections, which are to be distinguished from multiple inspections for which industry is responsible, are GMP inspections, which have exactly the same scope and which are consequently redundant and unnecessary.

135. All PIC/S PAs participated in the survey, which covered both domestic and foreign inspections. The outcome, which was presented to Members at the PIC/S Committee meeting in Geneva in February 2017, showed clear limitations regarding the voluntary acceptance of same scope inspection results mainly due to legal reasons. The PIC/S survey and the ICMRA GMP reliance framework on “equivalency” thus face similar challenges on how to foster mutual reliance and the exchange of information.

Advantages and Privileges of PIC/S Membership

136. Based on an SCSD proposal, the Committee discussed back in 2015 whether to extend the advantages and privileges of Members to Applicants and Partner Organisations. Members agreed in principle on the following:

- Membership benefits needed to be more clearly defined with respect to training activities as well as to financial aspects;
- Participation in PIC/S Working Groups was a Member-only privilege;
- The PIC Scheme should be amended to allow Partner Organisations to apply as Members.

137. The above principles were further discussed and implemented in 2016-17:

- With regard to membership benefits, the Committee endorsed a proposal by the SCSD that the ratio of Members' fees to non-Members fees should be 1:2 (e.g. for Seminars or Expert Circle meetings). This was applied for the first time at the 2017 PIC/S Seminar in Taipei.
- With regard to the participation of Partner Organisations in PIC/S Working Groups (WGs) as well as in PIC/S Sub-Committees (SCs), this will remain possible but as "guests" only. The Committee revised the Terms of Reference of SCs, which are now also applicable to WGs.
- With regard to the proposal to allow the Inspectorates of Partner Organisations to join PIC/S, the Committee agreed in principle to allow the Inspectorates of Partner Organisations to join PIC/S as full Members, subject to the clarification of accession criteria – in particular the compliance to the PIC/S checklist of indicators. Since this will require an amendment of the Scheme, the Committee, on the recommendation of the SCSD, agreed to first consult Partner Organisations in order to inquire on the interest of their inspection units in joining PIC/S as Participating Authorities and on the absence of legal obstacles.

Working Groups operating under the SCSD

Unique Facility Identifiers (UFI)

138. The PIC/S Working Group on the Unique Facility Identifiers (UFI) for drug establishments was established in 2016 following a survey by US FDA showing that PIC/S PAs use different systems. Different systems will give different locations and thus increases the risk of "shadow factories". The identification of companies through a UFI will allow PIC/S to have a harmonised and consistent system to localise a manufacturing site.

139. In 2017, the Committee adopted the mandate of the Working Group on UFI at its meeting in Taipei. The Working Group is led by US FDA and consists of representatives of Canada / RORB, EDQM, EMA, Spain / AEMPS and UK / MHRA.

Travel Safety

140. The Working Group on inspectors' travel safety was established following the 2016 Seminar in Manchester. The Working Group, led by Australia / TGA, comprises representatives from Canada / RORB, EDQM, Indonesia / NADFC, Ireland / HPRA, Netherlands / IGZ, Sweden / MPA, Thailand / Thai FDA, UK / MHRA, US FDA, and Brazil / ANVISA⁵. The aim is to consider means to mitigate health or security issues affecting inspectors. These means will be summarised in an Aide Memoire. In 2017, the Working Group started drafting its mandate. As the Australian representative resigned in November 2017, a new Chair had to be found.

Road Map Summary

141. At its meeting in Taipei, the Committee appointed a drafting group in charge of summarising the Road Map (see paragraphs 4-5), which will be led by US FDA. It

⁵ Applicant Authority

consists of representatives of Australia / TGA, Canada / RORB, Germany / ZLG, Switzerland / Swissmedic, Ukraine / SMDC and US FDA.

Co-operation with Associated Partners and other Organisations

Associated Partners (EDQM, EMA, UNICEF and WHO)

142. PIC/S continued to co-operate with its Associated Partners, namely EDQM, EMA, UNICEF and WHO.

143. Close co-operation was maintained with the European Medicines Agency (EMA), in particular in the field of harmonisation of GMP guides and guidance documents.

144. The European Directorate for the Quality of Medicines & Healthcare (EDQM), UNICEF and the World Health Organization (WHO) continued to actively contribute to the PIC/S list of planned foreign GMP inspections. PIC/S and WHO also agreed on the possibility to issue jointly a number of GMP guidance documents in the future.

145. The former PIC/S Chairperson, Dr Joey Gouws (South Africa / MCC), chaired the 52nd WHO Expert Committee on Specifications for Pharmaceutical Preparations, which was held in Geneva (Switzerland) on 16-20 October 2017. The former PIC/S Chairperson, Helena Baião (Portugal / INFARMED IP), represented PIC/S at the WHO Expert Consultation Regulatory strengthening and convergence for medicines in Manila (Philippines) on 17-18 May 2017.

Other organisations

APAC

146. The PIC/S Deputy Chairman, Boon Meow Hoe (Singapore / HSA), was invited by JPMA to the Asia Partnership Conference of Pharmaceutical Associations (APAC) in Tokyo (Japan) on 5-6 April 2017.

ASEAN

147. Thailand / Thai FDA, the current ASEAN Liaison Authority, provided an update on activities in ASEAN, which are of interest to PIC/S. This was notably the case of the discussions on the ASEAN Sectoral Mutual Recognition Arrangement (MRA) on GMP Inspection of Manufacturers of Medicinal Products. In 2016, the FDA Philippines submitted an application to become a listed ASEAN Inspection Service. A Panel of Experts (POE) was established, which comprised Singapore as Rapporteur and 3 Co-Rapporteurs from Indonesia, Malaysia, and Thailand. The POE made a paper assessment in 2017. An on-site assessment visit, which will comprise two observed inspections (sterile and non-sterile), will take place in Q1 of 2018. In 2017, Vietnam signalled its intention to become a listed ASEAN Inspection Service and an application will be submitted in the near future to the Joint Sectoral Committee on the ASEAN Sectoral MRA on GMP Inspection of Manufacturers of Medicinal Products (JSC GMP MRA).

148. Following the third PIC/S – ASEAN Forum, held in Nusa Dua (Indonesia) on 8 October 2015, discussions between PIC/S and ASEAN continued by written procedure on ways to institutionalise co-operation. In 2017, following a PIC/S proposal, both parties agreed in principle to negotiate a non-binding exchange of letters or e-

mails, which will serve as a basis for co-operation between PIC/S and the ASEAN Pharmaceutical Product Working Group (PPWG).

Heads of EEA Medicines' Agencies

149. Under the framework of a letter of agreement between PIC/S and EU/EEA Heads of Medicines Agencies (HMA), which entered into force on 15 August 2016, PIC/S and HMA continue to co-operate in exchanging information in the context of the EEA Joint Audit Programme (JAP) of GMP Inspectorates and the PIC/S Joint Reassessment Programme (JRP) of Participating Authorities, which ensures that both new and current PIC/S Participating Authorities meet the same requirements. PIC/S and HMA also recognise that in the EEA context the EEA JAP and the PIC/S JRP are deemed equivalent. Audit schedules are also exchanged between the two parties with a view to avoid any duplication and foster mutual acceptance and recognition of audits as well as maintain equivalent auditing tools and programmes, including joint training of auditors.

ICH

150. A meeting between the PIC/S Executive Bureau and a Delegation from the Secretariat of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) took place on 9 February 2017. Discussions focused on areas of mutual interest where PIC/S and ICH could work jointly, in particular on PIC/S and ICH training activities including the PIC/S– PDA training programme on ICH Q7. ICH was invited to attend the PIC/S Committee meeting as special guest.

151. PIC/S applied in December 2016 to become an ICH Observer. At its meeting in Montreal (Canada) on 1 June 2017, ICH approved the request made by PIC/S to become an Observer. The PIC/S representative to ICH is David Churchward (UK / MHRA), who attended the ICH Assembly in Geneva (Switzerland) on 11-16 November 2017.

152. The Committee was updated on work currently carried out by ICH, which impacts on GMP inspectors, in particular on Q12. Q12 (Pharmaceutical Product Lifecycle management) may potentially impact on inspection resources. The PIC/S representative to ICH will monitor this issue.

ICMRA

153. PIC/S continued to co-operate with the International Coalition of Medicines Regulatory Authorities (ICMRA). For more details, see paragraphs 131-132.

ISPE

154. PIC/S was invited to the ISPE Europe Annual Conference on 3-6 April 2017 in Barcelona (Spain), where it was represented by former PIC/S Chairperson, Helena Baião (Portugal / INFARMED IP). PIC/S was also invited to the ISPE Japan Affiliate Annual Meeting on 18-19 May 2017 in Toyama (Japan), where the SC COM Deputy Chairman, Harry Rothenfluh (Australia / TGA) made a presentation.

PDA

155. The PIC/S Chairman attended the 2nd Europe Annual Meeting of PDA in Berlin (Germany) on 13-14 June 2017 and the PIC/S Deputy Chairman, Boon Meow Hoe

(Singapore / HSA) attended the 2017 PDA Modern Biopharmaceutical Processing Conference on 28-29 November 2017 in Singapore.

BUDGET, RISK & AUDIT

156. The Sub-Committee on Budget (SCB) was established back in 2004. With the introduction of the new Sub-Committee structure in 2014 its mandate has been widened in order to encompass issues related to risk and audit. For the full mandate, see box below.

The mandate of the SCB is to:

1. In line with good governance:
 - 1.1 Assess regulatory risk, financial risk, reputational risk and risk management and make proposals / recommendation to minimise such risk
 - 1.2 Appraise the performance, efficiency, effectiveness and adequacy of internal and external controls
 - 1.3 Evaluate internal and external audits and the implementation of their recommendations
 - 1.4 Ensure that PIC/S adheres to good governance practices
2. In line with PIC/S' Financial Rules (PS/W 1/2004):
 - 2.1 Establish a budget proposal to the PIC/S Committee
 - 2.2 Propose updates and amendments of the Financial Rules to ensure effective financial administration, the exercise of economy and consistency in financial reporting
 - 2.3 Maintain an internal financial control and examine financial transactions in order to ensure:
 - (i) the regularity of the receipt, custody and disposal of all funds and other financial resources of PIC/S;
 - (ii) the conformity of commitments and expenditures with the budget voted by the PIC/S Committee;
 - (iii) the efficient and economic use of the resources of PIC/S.
 - 2.4 Avoid any duplication with the external auditor
3. Report back to the PIC/S Committee, as provided for in the Terms of References and the Financial Rules, and make proposals / recommendations

157. The Sub-Committee on Budget, Risk and Audit (SCB) is chaired by Ger Jan van Ringen (Netherlands / IGJ). It held two teleconferences on 23 May and 10 August 2017, during which it reviewed the PIC/S accounts and prepared the budget, as detailed below. It also reviewed the financial part of the report of the 2016 Seminar.

2016 Accounts

158. The regular audit of the 2016 financial accounts by the external auditor, Moores Refidar S.A. was combined with a special audit on the “accounting processes and internal control system”, which took place on 3-4 April 2017. The outcome of the audit was very positive: no major issue was raised and only some minor changes were suggested by the auditors. The Committee noted the conclusions of the auditors, in particular that:

- the accounting records and the financial statements for 2016 complied with the Swiss law and the Association’s Financial Rules;
- the control system existed and was effective; and
- the financial situation of PIC/S was “strong”, as shown in the balance sheet (no debt and a considerable amount of cash and cash equivalent).

159. The Committee approved the Statement of Accounts for the Financial Year 2016 and agreed to transfer the 2016 balance to the PIC/S Reserve Fund. It discharged the Secretary of his responsibility for the 2016 accounts and adopted a partial revision of the Financial Rules based on the external auditor’s suggestion.

2017 Accounts

160. The SCB reviewed the status of income and expenditures of the 2017 accounts during the year. The Committee appointed the external auditor, Moores Refidar S.A., for the financial audit of the 2017 accounts.

2018 Budget and beyond

161. The Committee approved the 2018 Budget for an amount of CHF 664,400 as well as a 3-year budget plan (PS/W 13/2017) for the period 2018-2020.

162. The Committee also endorsed in principle an increase of the annual fees of Members and (Pre-) Applicants as from 2019 based on a review of the SCB.

COMMUNICATION

163. PIC/S regularly communicates on its activities through press releases, annual reports and its web site. Good communication between Participating Authorities through PA representatives is one of PIC/S’ recognised benefits, which derives from membership. Communication has also become an important tool to promote PIC/S. As a result, the PIC/S Committee has decided to establish a specific Sub-Committee on Communication.

164. The mandate of the SC COM is to (i) monitor PIC/S’ public relations and the exchange of information; and (ii) to define a communication strategy in order to better promote PIC/S and its key role in the field of inspections. For the complete mandate, see box below.

The mandate of the SC COM is to:

1. Monitor PIC/S' public relations and the exchange of information
2. Define a communication strategy to better promote PIC/S
3. Monitor and propose changes to the PIC/S web site
4. Work on improving communications with PA, in particular with Heads of Agencies, as well as PIC/S Partners
5. Identify the most suitable speakers for (regional or international) conferences where PIC/S has been invited to speak
6. Report back to the PIC/S Committee, as provided for in the Terms of References and make proposals / recommendations

165. The Sub-Committee on Communication (SC COM) held one teleconference on 25 July 2017 under the chairmanship of Mark Birse (MHRA / UK).

Stakeholder mapping

166. The SC COM carried out a stakeholder mapping survey and developed a stakeholder mapping tool for PIC/S. The mapping aims at identifying all stakeholders of PIC/S and their respective importance.

PIC/S standard presentation

167. A new template for the current PIC/S standard presentation as well as several modules are currently under development.

Rapid Alert

168. At its meeting in Geneva, the Committee adopted a revision of the PIC/S "Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects" (PI 010-5) in order to align it with the recently revised EU RA. The revised procedure entered into force on 1 July 2017.

169. The Committee also decided to establish a joint PIC/S-EMA Working Group to discuss proposals by US FDA and Ireland / HPRA on quality defects and Rapid Alerts procedures. It includes non-EEA PIC/S experts from Australia / TGA, Health Canada, South Africa / MCC and US FDA.

PIC/S Web Site

170. New recorded video training was made available on the PIA sub-site of the PIC/S website. At the end of 2017, the PIA site offered close to 500 training documents and 200 hours of video-recordings of PIC/S trainings. Through the PIA, PIC/S inspectors also have access to guidance documents from Professional Associations such as ISPE as well as to the Compilation of all PIC/S documents.

Foreign Inspections

171. The list of foreign inspections planned in 2017 was updated twice in the course of the year. The list includes around 1,600 planned foreign inspections by over 30 Inspectorates (including EDQM and UNICEF).

List of GM(D)P Inspectors

172. The list of GM(D)P Inspectors, employed by PIC/S PA and Partner Organisations, was revised by the Secretariat in the course of the year.

Communications from Participating Authorities

173. A number of PA took advantage of PIC/S Committee meeting in Manchester to inform the Committee on important changes or projects concerning their Agencies / Inspectorates.

174. EMA and US FDA reported on the finalisation of a Mutual Recognition Agreement on GMP. The MRA entered into force on 1st November 2017 but will be in a transition phase until July 2019. The authorities will assess each other's pharmaceutical legislation, guidance documents and regulatory systems as part of the agreement. The European Commission confirmed in June 2017 that the US FDA had an equivalent GMP system. The US FDA will assess each EU Member State Authority individually until July 2019. As of November 2017, the FDA had confirmed the capability of eight EU Member States. The MRA covers products manufactured in the territories of the EU and the United States of America and manufacturers in third countries inspected by the Regulatory Authority of either party on a 'voluntary acceptance' basis.

175. The accession of US FDA to PIC/S in 2011 and the resulting confidence building process, which allowed US FDA as well as EU Competent Authorities (most of which are also PIC/S Participating Authorities) to familiarise with each other's GMP regulatory system, greatly facilitated the conclusion of the EU-US MRA.



PIC/S Committee meeting in Taipei

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**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.

The Convention's Contracting States realised in the early 1990s that because of an incompatibility between the Convention and European law, it was not possible for new countries to be admitted as Members of PIC. Australia was the last country which was able to become a Member of the Convention in January 1993.

Consequently, a new arrangement called "Pharmaceutical Inspection Co-operation Scheme" (or PIC Scheme) was established on 2 November 1995. 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 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.

LIST OF PIC/S PARTICIPATING AUTHORITIES
(as of 31 December 2017)

(in the alphabetical order of the country / entity 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 Canada - Regulatory Operations and Regions Branch (<i>Santé Canada - Direction générale des opérations réglementaires et des régions</i>)	RORB
Chinese Taipei	Taiwan Food and Drug Administration	TFDA
Croatia	Agency for Medicinal Products and Medical Devices of Croatia (<i>Agencija za lijekove i medicinske proizvode</i>)	HALMED
Cyprus	Pharmaceutical Services	CyPHS
Czech Republic ⁶	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 Medicines Agency	DKMA
Estonia	State Agency of Medicines	SAM
Finland	Finnish Medicines Agency	FIMEA
France ⁷	Agence nationale de sécurité du médicament et des produits de santé (<i>French National Agency for Medicines and Health Products Safety</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

⁶ SÚKL and ÚSKVBL count as two distinct Participating Authorities.

⁷ ANSM and ANSES count as two distinct Participating Authorities.

Germany ⁸	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
Greece	Εθνικός Οργανισμός Φαρμάκων (<i>National Organization for Medicines</i>)	EOF
Hong Kong SAR	Pharmacy and Poisons Board of Hong Kong	PPBHK
Hungary	National Institute of Pharmacy and Nutrition (NIPN)	NIPN
Iceland	The Icelandic Medicines Agency	IMA
Indonesia	National Agency for Drug and Food Control	NADFC
Ireland	Health Products Regulatory Authority	HPRA
Israel	Institute for the Standardization and Control of Pharmaceuticals	ISCP
Italy	Agenzia Italiana del Farmaco	AIFA
Japan ⁹	Ministry of Health, Labour and Welfare	MHLW
	Pharmaceuticals and Medical Devices Agency	PMDA
	Japanese Prefectures	-
Korea (Republic of)	Ministry of Food and Drug Safety	MFDS
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 Regulatory Agency	NPRA
Malta	Medicines Authority Malta	MAM
Netherlands	Inspectie voor de Gezondheidszorg en Jeugd (<i>Health and Youth Care Inspectorate</i>) ¹⁰	IGJ
New Zealand	Medicines and Medical Devices Safety Authority	Medsafe
Norway	Norwegian Medicines Agency	NOMA

⁸ BMG and ZLG count as one Participating Authority. All German Medicinal Authorities, which are listed on the ZLG web site, are considered as PIC/S Participating Authorities and are represented in PIC/S by ZLG.

⁹ MHLW, PMDA and the Japanese Prefectures count as one Participating Authority. The Japanese Prefectures are represented by MHLW.

¹⁰ The competence for GMP/GDP inspections in the Netherlands is allocated to the central authority, the Health and Youth Care Inspectorate (IGJ). IGJ is the PIC/S Participating Authority representing GMP/GDP for human as well as veterinary medicinal products. IGJ performs national and international GMP/GDP inspections representing the Health and Youth Care Inspectorate - Pharmaceutical Affairs as well as the Medicines Evaluation Board - Veterinary Medicinal Products Unit, which is mandated to issue GMP certificates on behalf of the Ministry of Economic Affairs.

Poland	Chief Pharmaceutical Inspectorate	CPI
Portugal	Autoridade Nacional do Medicamento e Produtos de Saúde IP (<i>National Authority of Medicines and Health Products IP</i>)	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 de Medicamentos y Productos Sanitarios (<i>Spanish Agency for Medicines and Medical Devices</i>) ¹¹	AEMPS
Sweden	Medical Products Agency	MPA
Switzerland	Swiss Agency for Therapeutic Products	Swissmedic
Thailand	Food and Drug Administration	Thai FDA
Ukraine	State Service of Ukraine on Medicines and Drugs Control	SMDC
United Kingdom ¹²	Medicines and Healthcare Products Regulatory Agency	MHRA
	Veterinary Medicines Directorate	VMD
United States of America	United States Food and Drug Administration	US FDA

¹¹ The competence for GMP/GDP inspections in Spain is shared between the central authority, Spanish Agency for Medicines and Medical Devices (AEMPS), and the Spanish regional authorities, which count as one PIC/S Participating Authority. All Spanish Medicinal Authorities, which are listed on AEMPS' web site, are considered as PIC/S Participating Authorities and are represented in PIC/S by AEMPS.

¹² MHRA and VMD count as two distinct Participating Authorities.