PIC/S 1/95 (Rev. 7)

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME *

© PIC/S 2026
Reproduction prohibited for commercial purposes.
Reproduction for internal use is authorised,
provided that the source is acknowledged.

* First adopted by the PIC/S Committee on 2 November 1995 in Geneva and subsequently amended on 8 October 2002 in Montebello, 2 June 2003 in Bratislava, 11 November 2003 in Geneva, 19 November 2007 in Singapore, 7 November 2011 in Cape Town, 12 November 2019 in Toyama and on 2 November 2026 in Istanbul (with entry into force on 2 November 2026).

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)

PIC SCHEME

We, the Members of the Pharmaceutical Inspection Co-operation Scheme (PIC/S),

Having considered that medicinal products, whether exported or not, should be produced according to appropriate standards in the interest of public health, whether for humans or animals;

Recognising that in order to protect public health, the manufacturing of medicinal products necessitates strict quality management, which can only be ensured by independent, third-party inspections carried out by Regulatory Authorities (RA);

Determined to have effective Good Manufacturing Practices Regulatory Compliance Programme (GMPRCP) in place, which comply with strict quality management system requirements;

Having considered that PIC/S offers an effective platform to respond to the challenges of globalisation and to promote inspection reliance that strengthen supply resilience, it becomes essential to further increase harmonisation efforts in setting regulatory requirements. This is done by inspecting and evaluating compliance notably with Good Manufacturing Practice (GMP), licensing manufacturing sites, identifying and recalling defective batches;

Recognising that such efforts require increased co-operation and reliance between RA, whether they are Members of PIC/S or not;

Have agreed on the following:

1. PIC/S is hereby established as an Association under the Swiss Code of Civil Law (Art. 60 and following). It is legally registered in Geneva (Switzerland) with the "Registre du Commerce" under the name "Pharmaceutical Inspection Co-operation Scheme – Association de Droit Suisse" (Swiss federal no: CH-660.9.587.004-3) and consequently subject to Swiss law.

2. Although international by its membership and activities, PIC/S does not have the legal status of an International Organisation, as defined under Public International Law.

3. PIC/S is a purely scientific and technical organisation. It is a non-political, non-discriminatory organisation. All Members have the same rights and obligations.

4. The working language of PIC/S is English. These Articles may be prepared in French and English. For registration with the Geneva Commercial Register, the French version shall be used. For the internal governance and operation of PIC/S, the English version shall be used as the working version, provided that it shall be interpreted consistently with the registered French version.

5. PIC/S is a legally non-binding arrangement between RA, or other bodies representing those[1], competent to inspect medicinal products in the field of Good Manufacturing Practice (GMP).

6. For the purpose of PIC/S,

- "medicinal product" means:

  (a) any pharmaceutical[2], medicine or similar product intended for human or veterinary use which is subject to control by health legislation, and

  (b) any active pharmaceutical ingredient[3] (API) or excipient which the manufacturer uses in the manufacture of a product referred to in sub-paragraph (a) above.

- "Good Manufacturing Practices regulatory compliance programme" (GMPRCP) means the overall system established by a Regulatory Authority to ensure compliance with Good Manufacturing Practices, including the GMP inspection process and the associated legislative, regulatory, organisational and quality system arrangements[4].

- "Regulatory Authority" (RA) means (i) a competent Authority in charge of the GMPRCP; (ii) another body[5] deemed equivalent[6] by the PIC/S Committee.

---

[1] Some Participating Authorities are not Medicines Regulatory Authorities (e. g. co-ordinating / representing those).

[2] Also referred to as "dosage form" or "drug product".

[3] Also referred to as "drug substance".

[4] See PS/W31/2019.

[5] See Note [1] above.

[6] See Guidelines for Accession to the PIC Scheme (PS/W 14/2011) and related documents.

- "Participating Authority" (PA) means a RA, which has applied for PIC/S membership, has been found to comply with PIC/S requirements, and has acceded to PIC/S. For the List of Participating Authorities, see the PIC/S website (https://www.picscheme.org).

- "Participating Organisation" (PO) means an organisation other than a RA that performs inspections based on legislation, which has applied for PIC/S membership, has been found to comply with ad-hoc PIC/S requirements, and has acceded to PIC/S[7]. For the List of Participating Organisations, see the PIC/S website (https://www.picscheme.org).

  For the purposes of this document, references to a Participating Authority also include a Participating Organisation (PO), unless explicitly stated otherwise.

- "Associated Partner" means a Regulatory Authority or International Organisation (or part of it) which is important to PIC/S, can significantly contribute to PIC/S' goals; and has concluded a Non-Binding Partnership with PIC/S[8].

- "Members" means a Participating Authority or a Participating Organisation that adheres to the PIC/S.

- "The Directorate" means those persons in charge of directing and managing staff to whom those responsibilities have been delegated by the Executive Bureau of PIC/S.

I. Mission and Purpose

7. PIC/S' mission is to protect public health by leading the international development, implementation and maintenance of harmonised GMP standards and quality management systems of inspectorates in the field of medicinal products. This is to be achieved by developing and promoting harmonised GMP standards and guidance documents; offering world class training to inspectors of Regulatory Authorities; assessing (and reassessing) inspectorates; and facilitating the co-operation and networking for RA and international bodies.

8. The purpose of PIC/S is, with due regard to public health,

(a) to pursue and strengthen the co-operation established between the Participating Authorities and to foster the collaboration with international regulatory and harmonisation bodies in the field of inspection related to the manufacture of medicinal products and associated activities, aimed at maintaining mutual confidence, enabling mutual reliance, enhancing global convergence, and promoting quality of inspections,

(b) to provide the framework for sharing information and experiences on a voluntary basis,

(c) to co-ordinate and deliver training for inspectors and other technical experts in related fields. In particular, the PIC/S Inspectorates' Academy (PIA) promotes harmonised training, supports uniform qualification processes, and enhances inspection excellence across PA,

[7] See PS/W 9/2025.

[8] See PS/W 19/2006

(d) to continue common efforts towards the improvement and harmonisation of technical standards and procedures regarding the inspection of the manufacture of medicinal products by PAs,

(e) to continue common efforts for the development, harmonisation and maintenance of GMP, and

(f) to extend the co-operation to other RA having the necessary arrangements in place to apply equivalent standards and procedures with a view to contributing to global harmonisation.

II. Membership requirements

9. PIC/S is open for participation by RA having the arrangements necessary to apply a GMPRCP comparable to that enforced by Participating Authorities and whose requirements and procedures are such as to ensure the proper implementation of PIC/S and contribute to its effective operation.

10. The RA should notably ensure that:

(a) the inspectors in their service have received appropriate training, qualifications and experience for the tasks to be undertaken by them,

(b) the inspectors and/or the control laboratories have the power to call for the submission of quality control records and, where appropriate, samples relating to any batch of any medicinal products,

(c) the inspectorate utilises the PIC/S GMP Guide[9] (or equivalent) as well as other current guides, guidelines, explanatory notes and recommendations, adopted by PIC/S and available at http://www.picscheme.org, as the basis for inspections and authorisation of manufacturers,

(d) the operation of the GMPRCP is subject to a system of quality management aimed at ensuring the maintenance of necessary standards[10].

11. RA or other organisations, which have applied for PIC/S membership and successfully completed the applicable accession process[11], are invited by the PIC/S Committee to become PIC/S Participating Authorities[12] (for further details, see Chapter V). The GMPRCP of each Participating Authority should be re-evaluated on a regular basis in line with the PIC/S Joint Reassessment Programme[13] or equivalent programmes[14].

---

9 See PE 009.

10 See the PIC/S Recommendation on Quality System Requirements for Pharmaceutical Inspectorates (PI 002).

11 For the Guidelines for Accession to the PIC Scheme, see PS/W 14/2011 and PS/W 9/2025.

12 For the list of Participating Authorities, see the PIC/S website (http://www.picscheme.org).

13 See PS/W 9/2000.

14 E.g. the EU Heads of Agencies "Joint Audit Programme".

III. Organisation

12. The effective operation and application of PIC/S shall be ensured by the PIC/S Committee, the Executive Bureau and the Secretariat.

13. Representatives of participating authorities who are members of the PIC/S Committee and the Executive Bureau serve on a voluntary basis (non-paid) for PIC/S. They are not entitled to reimbursement by PIC/S of their actual expenses or travel expenses incurred in the ordinary course of their usual duties for PIC/S, nor to any attendance fees. For tasks that go beyond the usual scope of the role for PIC/S, each member may not only claim reimbursement of his or her actual expenses and travel expenses, but may also receive appropriate compensation.

14. Paid employees of PIC/S may sit on the PIC/S Committee and the Executive Bureau only in an advisory (non-voting) capacity.

The PIC/S Committee

15. A permanent Committee composed of representatives of the Participating Authorities should meet whenever necessary but at least once a year in order to:

(a) consider measures for achieving the appropriate and effective operation of PIC/S;

(b) make recommendations and proposals for the amendment, updating and improvement of (i) GMP standards currently applied by PIC/S; and (ii) any other GxP standards or Good Practices applied on a voluntary basis;

(c) promote co-operation between the Participating Authorities to facilitate the application of PIC/S;

(d) exchange information and experience on means and methods for achieving uniform and effective inspections;

(e) promote quality management systems for the GMPRCP;

(f) promote training for inspectors by means of e.g.:
- the PIC/S Inspectorates' Academy (PIA),
- seminars, expert circles dealing with the state of the art of GMP knowledge in all necessary fields, and
- joint visits for the harmonisation of inspections;

(g) promote the exchange of experience in relation to GMP for special categories of medicinal products e.g. human blood and tissue, medicinal gases, radiopharmaceuticals, hospital pharmacy, biotechnologically manufactured medicinal products, Advanced Therapy Medicinal Products (ATMPs);

(h) promote the transfer of knowledge and experience among Participating Authorities through structured mechanisms supporting continuity, capacity building, and PIC/S memory;

(i) discuss and decide on the accession and Pre-Accession of RA to PIC/S;

(j) make proposals for amendments to the PIC/S Scheme to ensure it remains up to date;

(k) contribute to the development of new guides and guidance documents applicable to GMP e.g. for different types of manufactures[15];

(l) promote global harmonisation of GMP;

(m) adopt annual budgets and approve financial accounts in line with financial rules;

(n) elect the Executive Bureau;

(o) negotiate and conclude agreements.

16. The Committee may delegate parts of its powers to the Executive Bureau and remains free to revoke such delegations at any time. The Committee remains responsible for the diligence exercised in the selection, instruction, and supervision of the Sub-Committees Chairs who are de facto members of the Executive Bureau.

17. The Committee should adopt its own rules of procedure[16] as well as financial rules[17].

18. Associated Partner Organisations are invited to attend Committee meetings. The Committee also invites representatives from RA , which are in the process of acceding or intend to accede to PIC/S, to attend meetings as guests.

19. The annual accounts, drawn up at the end of each financial year, shall be reviewed by the supervisory body appointed by the Committee, which shall submit a written report. On the basis of this report, the Committee shall approve the accounts and decide on the discharge of the Executive Bureau and the Secretariat for the past financial year. The discharge shall only apply to facts known at the time of its granting.

The PIC/S Executive Bureau

20. The Executive Bureau should meet at least three times per year, in-between meetings of the Committee, and as often as necessary in order to:

(a) supervise PIC/S' Sub-Committees activities notably in order to ensure their coherence;

(b) implement Committee decisions and define the Committee's agenda with the assistance of the Secretariat;

(c) ensure the alignment of strategy and resources as well as propose strategic orientations and facilitate decision-making;

(d) oversee the organisation of the accounts, financial audits and financial planning including the annual budget in line with financial rules;

(e) define internal organisational structure and maintain it up to date;

(f) engage and dismiss the Directorate, subject to the Committee approval and decide upon representation powers including for entities dependent on PIC/S;

[15] In the exercise of these activities account should be taken, where appropriate, of current technical developments and work.

[16] See PH/PS 9/97.

[17] See PS/W 1/2004.

(g) ensure the proper management of the Secretariat, which is carried out by the Directorate;

(h) supervise the management of PIC/S in compliance with Swiss law, the PIC Scheme and its regulations;

(i) assume tasks and exercise powers not expressly delegated for Sub-Committees for the unobstructed functioning of PIC/S.

21. The members of the Executive Bureau may validly make decisions in person, by video or telephone conference, or by any other means decided by the Committee. In-person meetings may be held in Switzerland or abroad.

22. The Executive Bureau reports to the PIC/S Committee. The composition and election of the Executive Bureau are defined in the rules of procedure[18].

23. In agreement with PIC/S Committee, the Executive Bureau may delegate part of its powers to Sub-Committees and remains free to revoke such delegations at any time. The Executive Bureau remains responsible for the diligence exercised in the instruction and supervision of the Sub-Committees.

The PIC/S Secretariat

24. A Secretariat[19] should be established by the Committee to support and facilitate the implementation of the PIC/S mission. It may also provide secretariat services to other organisations.

25. The Secretariat is managed by the Directorate.

External auditors

26. PIC/S must submit its accounts to regular audit by an auditing body if, during two consecutive financial years, two of the following values are exceeded:

    1) Total balance sheet : 10 million of francs;
    2) Turnover : 20 millions of francs;
    3) Workforce : 50 full-time jobs on average per year.

27. PIC/S must submit its accounts to a limited audit by an auditing body if a member of the association who is individually liable or required to make additional payments so requests.

28. All persons responsible for auditing the annual and consolidated accounts are liable to PIC/S and to each of its members for any damage caused by an intentional or negligent breach of their obligations (art. 755 al. 1 Swiss Code of Obligations).

[18] See PS/W 1/2006.

[19] See PS/W 12/2009.

IV. Amendments

29. The PIC/S Scheme may be amended by unanimous consent of the Participating Authorities.

V. Accession and Pre-Accession

Accession

30. A RA, as defined in paragraph 5, may submit a request for accession in PIC/S, expressing consent to accept PIC/S. The request should be addressed to the Secretariat together with information required under the Guidelines for Accession to PIC/S[20].

31. The Secretariat should inform all Participating Authorities of the request.

32. The Committee should decide on the accession of a RA in PIC/S. Such decision requires the consent of all Participating Authorities.

33. The participation should become effective on a date determined by the Committee.

34. The Secretariat should communicate the effective date of the participation to all parties concerned.

Pre-Accession

35. A RA wishing to engage in the pre-accession process may submit a request to the Secretariat in accordance with the Guidelines for Pre-Accession to PIC/S[21].

VI. Withdrawal

36. A Participating Authority may withdraw from PIC/S by giving three months' notice in writing to the Secretariat, which shall inform all the other Participating Authorities.

VII. Suspension / Exclusion

37. If a Participating Authority no longer fulfils the requirements of the PIC/S Scheme, fails to comply with its obligations, including participation in meetings or financial contributions, or if, through its actions and behaviour, it or its representatives undermine the proper functioning, objectives, or reputation of PIC/S, the Committee may, in accordance with the PIC-PIC/S Committee Rules of Procedure[22], decide to:

    - suspend its participation in PIC/S for a specified period;
    - extend such suspension or
    - proceed with exclusion from PIC/S, with immediate effect.

38. The Committee may also suspend or exclude a representative of a PA whose actions or behaviour are incompatible with the objectives, principles, policies, or reputation of PIC/S, including violations of rules of conduct or of the principles of non-politicisation

[20] See PS/W 14/2011; PS/W 9/2025.

[21] See PS/W 12/2019.

[22] PH/PS 9/97.

or non-discrimination, as further detailed in the PIC-PIC/S Committee Rules of Procedure.

VIII. Termination

39. All Participating Authorities may decide to terminate PIC/S by unanimous consent.

40. In that case, the available assets shall be entirely allocated to another organisation pursuing a public-interest purpose similar to that of PIC/S and which benefits from the tax exemption. Under no circumstances may the assets be returned to the founders, members, donors or their relatives, nor may they be used for their benefit, in whole or in part, and in any way whatsoever.

IX. Reoganisation

41. The PIC/S Committee should examine on a case-by-case basis the reorganisation of Participating Authorities, notably in the case of merger with or separation from another Authority. The examination should take into account whether an Authority emerging from such reorganisation (i) is the legal successor of the previously Regulatory Authority; (ii) is fully competent (in accordance with paragraph 9 above); and (iii) has retained the Quality Management System and Staff (in accordance with paragraph 10 above).

42. Authorities emerging from a reorganisation, which are competent in accordance with paragraph 9 above, will be either reassessed under the PIC/S Joint Reassessment Programme (or equivalent) or invited to apply for PIC/S membership.

X. Sharing of information

43. This Chapter applies to all information shared in PIC/S, which is classified (e.g. restricted, confidential) in line with PIC/S' classification policy[23].

44. In line with the PIC/S Guidance on GMP Inspection Reliance[24], the sharing of information in PIC/S should be fully voluntary. There is no obligation for a Participating Authority to share information with another Participating Authority[25].

45. The aim of sharing information in PIC/S is to facilitate the risk management performed by each Participating Authority on whether or not to carry out an inspection. It gives Participating Authorities the possibility to share in confidence any information e.g. on whether medicinal products have been produced in accordance with the GMP requirements applied in PIC/S or whether such products are due for inspection (so called GMP inspection reliance).

46. Information shared in PIC/S is not binding for the Participating Authority which has requested it. Each Participating Authority should remain competent on how to use the

---

[23] See PS/W 12/2006.

[24] See PI 048.

[25] This is also applicable for the sharing of information between (i) PIC/S Participating Authorities on the one hand and Regulatory Authorities having applied for membership and Partner Organisations on the other hand; (ii) Competent Authorities having applied for membership and Partner Organisations (and between themselves).

shared information. There is no obligation to accept the conclusions from another Participating Authority in PIC/S.

47. The sharing of information in PIC/S should be subject to legal requirements such as laws, decrees, and treaties – including regional integration treaties (e.g. EU or ASEAN) and Mutual Recognition Agreements. It should not affect the exchange of GMP certificates under such treaties and agreements.

48. Upon written request of a Participating Authority, the following information can be shared on a purely voluntary basis: GMP compliance, inspection report, corrective action plan, plan of a company, correspondence, follow-up, etc.

49. Information shared in PIC/S should not extend to:

(a) data concerning financial and commercial matters;

(b) data concerning technical "know-how" or any other trade secret;

(c) data concerning research information;

(d) personal data other than those relating to the duties of the persons concerned;

(e) information related to an official investigation which may jeopardise enforcement activities.

50. Participating Authorities herewith undertake to respect the confidentiality of information shared in PIC/S. They also undertake to avoid any potential or real conflict of interests with activities and issues under discussion at PIC/S. The undertaking applies to the Participating Authority and to its employees, who shall abide to the Rules of Procedure of the relevant PIC/S bodies.

XI. Rapid Alerts and Recalls arising from Quality Defects

51. If a Participating Authority discovers in the course of its inspection duties, or otherwise, particular circumstances which cause a medicinal product to be of imminent and serious danger to the public, it shall immediately communicate its findings to the Participating Authorities[26].

XII. Revenues

52. PIC/S' revenues normally consist of (but not exclusively) from :

- annual membership contributions from Participating Authorities,
- voluntary donations,
- revenues from special services.

53. PIC/S accounts shall be reviewed annually by a supervisory body appointed by the Committee and may be subject to audit in accordance with the applicable statutory requirements.

---

[26] i.e. in accordance with PI 010.