



**PHARMACEUTICAL INSPECTION
CO-OPERATION SCHEME ***

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* 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 in Cape Town and 12 November 2019 in Toyama (with entry into force on 1 January 2020).

**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 Medicines Regulatory Authorities;

Determined to have effective inspection systems in place, which comply with strict quality system requirements;

Having considered that PIC/S offers an attractive platform to respond to the challenges of globalisation, which makes it necessary to further increase harmonisation efforts in setting regulatory requirements, inspecting and evaluating compliance with Good Manufacturing and Distribution Practice (GMDP), licensing manufacturing sites and wholesalers, identifying and recalling defective batches;

Recognising that such efforts require increased co-operation and reliance between Medicines Regulatory Authorities, 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 ff). 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).
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 enjoy the same rights and obligations.

4. PIC/S is a legally non-binding arrangement between Medicines Regulatory Authorities, or other bodies representing those ¹, competent for the inspection of medicinal products in the field of Good Manufacturing Practice (GMP).
5. 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 subparagraph (a) above.
 - "Competent Authority" means (i) a Medicines Regulatory Authority competent for GMP inspections of medicinal products; (ii) another body ⁴ deemed equivalent ⁵ by the PIC/S Committee.
 - "Participating Authority" means a Competent Authority, 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 document PS/INF 21/2002 ⁶.

I. Mission and Purpose

6. 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 is to be achieved by developing and promoting harmonised GMP standards and guidance documents; training Competent Authorities, in particular inspectors; assessing (and reassessing) inspectorates; and facilitating the co-operation and networking for Competent Authorities and international bodies.
7. 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 in the field of inspection related to the manufacture (or distribution) of medicinal products and associated activities with a view to maintaining the mutual confidence and promoting quality assurance of inspections,

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 Note [1] above

5 See Guidelines for Accession to the PIC Scheme (PS/W 14/2011) and related documents

6 Participating Authorities are also listed on <https://picscheme.org/en/members>

- (b) to provide the framework for the sharing of information and experience on a voluntary basis,
- (c) to co-ordinate mutual training for inspectors and for other technical experts in related fields,
- (d) to continue common efforts towards the improvement and harmonisation of technical standards and procedures regarding the inspection of the manufacture (or distribution) of medicinal products and the testing of medicinal products by quality control laboratories contracted by Participating Authorities,
- (e) to continue common efforts for the development, harmonisation and maintenance of GMDP, and
- (f) to extend the co-operation to other Competent Authorities having the arrangements necessary to apply equivalent standards and procedures with a view to contributing to global harmonisation.

II. Membership requirements

- 8. PIC/S is open for participation by Competent Authorities having the arrangements necessary to apply an inspection system comparable to that enforced by Participating Authorities and whose requirements and procedures could ensure the proper implementation of PIC/S and contribute to its effective operation.
- 9. The Competent Authorities should ensure that:
 - (a) the inspectors in their service have appropriate 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 ⁷ (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 inspectorate is subject to a system of quality management aimed at ensuring the maintenance of necessary standards ⁸.

7 See PE 009

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

10. Competent Authorities, which have applied for PIC/S membership and successfully completed the accession process⁹, are invited by the PIC/S Committee to become PIC/S Participating Authorities¹⁰ (for further details, see Chapter V). The inspection system of each Participating Authority shall be re-evaluated on a regular basis in line with the PIC/S Joint Reassessment Programme¹¹ or equivalent programmes¹².

III. Organisation

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

The PIC/S Committee

12. A permanent Committee composed of representatives of the Participating Authorities shall 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, up-dating 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 assurance of inspections and quality systems for inspectorates;
 - (f) promote mutual training for inspectors by means of the PIC/S Inspectorates' Academy (PIA) as well as e.g.:
 - seminars dealing with the state of the art of GMDP knowledge in all necessary fields, and
 - joint visits for the harmonisation of inspections;
 - (g) promote the exchange of experience in relation to GMDP for special categories of medicinal products e.g. human blood and tissue, medicinal gases, hospital pharmacy, biotechnologically manufactured medicinal products;

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

10 The list of Participating Authorities is available in document PS/INF 21/2002.

11 See PS/W 9/2000

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

- (h) promote the exchange of experience between, and mutual training for, personnel of quality control laboratories contracted by Participating Authorities;
 - (i) discuss and decide on the accession of Competent Authorities to PIC/S;
 - (j) make proposals for amendments to PIC/S;
 - (k) contribute to the development of new guides and guidance documents applicable to GMDP e.g. for different types of manufacture ¹³;
 - (l) promote global harmonisation of GMDP;
 - (m) adopt annual budgets and approve financial accounts in line with financial rules;
 - (n) elect the Executive Bureau;
 - (o) negotiate and conclude agreements.
13. The Committee shall adopt its own rules of procedure ¹⁴ as well as financial rules ¹⁵.
14. Associated Partner Organisations may be invited to attend Committee meetings. The Committee may also invite representatives from Competent Authorities, which are in the process of acceding or intend to accede to PIC/S, to attend meetings as guests.

The PIC/S Executive Bureau

15. The Executive Bureau shall meet in-between meetings of the Committee and as often as necessary in order to:
- (a) monitor PIC/S' activities;
 - (b) review the annual budget in line with financial rules ¹⁶;
 - (c) propose strategic orientations and facilitate decision-making;
 - (d) supervise the Secretariat and act as an employer for its staff.
16. The Executive Bureau reports to the PIC/S Committee. The composition and election of the Executive Bureau are defined in the rules of procedure ¹⁷.

13 In the exercise of these functions account shall be taken, where appropriate, of current technical developments and work.

14 See PH/PS 9/97

15 See PS/W 1/2004

16 See PS/W 1/2004

17 See PS/W 1/2006

The PIC/S Secretariat

17. A Secretariat¹⁸ shall be appointed by the Committee to deal with the services and meeting facilities. It may also provide secretariat services to other organisations. The Secretariat shall in particular (a) prepare meetings of the Committee, and (b) implement the Committee's decisions and recommendations.

IV. Amendments

18. PIC/S may be amended by unanimous consent of the Participating Authorities.

V. Accession and Pre-Accession

Accession

19. A Competent Authority, as defined in paragraph 5, may submit a request for participation in PIC/S, expressing consent to accept PIC/S. The request shall be addressed to the Secretariat together with information required under the Guidelines for Accession to PIC/S¹⁹ such as:
- (a) the laws regulating the manufacture and control of medicinal products;
 - (b) the GMP rules applied to the manufacture of medicinal products;
 - (c) the inspection system with regard to the control of the manufacture of medicinal products, as defined in paragraph 5;
 - (d) the structure and organisation of the inspectorate and their quality system.
20. The Secretariat shall inform all Participating Authorities of the request and make available the relevant information received.
21. The provisions contained in the Guidelines for Accession to PIC/S²⁰ shall be followed.
22. The Committee shall decide on the participation of a Competent Authority in PIC/S. Such decision requires the consent of all Participating Authorities.
23. The participation shall become effective on a date determined by the Committee.
24. The Secretariat shall communicate the effective date of the participation to all parties concerned.

18 PS/W 12/2009

19 See PS/W 14/2011

20 See PS/W 14/2011

Pre-Accession

25. A Competent Authority wishing to be pre-assessed may address a request to the Secretariat in line with the the Guidelines for Pre-Accession to PIC/S ²¹.

VI. Withdrawal

26. 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

27. If one of the Participating Authorities does not fulfil any more PIC/S requirements or does not participate in the meetings and in the financing of PIC/S, the Committee may decide to suspend the operation of PIC/S in relation to that Authority for a given period during which the Authority in question should take appropriate action to remedy the situation. If at the end of this period the situation has not changed satisfactorily, the Committee may, with the consent of all other Participating Authorities, decide to exclude the Authority concerned from PIC/S with immediate effect.

VIII. Termination

28. The Participating Authorities may decide to terminate PIC/S by unanimous consent. In that case, the remaining assets shall be donated to a non-for-profit Organisation in line with PIC/S' financial rules.

IX. Reorganisation

29. The PIC/S Committee shall 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 successors of the previously Competent Authority; (ii) is fully competent (in accordance with paragraph 8 above); and (iii) has retained the Quality System and Staff (in accordance with paragraph 9 above).
30. Authorities emerging from a reorganisation, which are competent in accordance with paragraph 8 above, will be either reassessed under the PIC/S Joint Reassessment Programme (or equivalent) or invited to apply for PIC/S membership.

21 See PS/W 12/2019

X. Sharing of information

31. This Chapter applies to all information shared in PIC/S, which is classified (e.g. restricted, confidential) in line with PIC/S' classification policy ²².
32. In line with the PIC/S Guidance on GMP Inspection Reliance ²³, the sharing of information in PIC/S shall be fully voluntary. There is no obligation for a Participating Authority to share information with another Participating Authority ²⁴.
33. The aim of sharing information in PIC/S is to facilitate the risk management made by each Participating Authority on whether to carry out or not 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.
34. Information shared in PIC/S is not binding for the Participating Authority which has requested it. Each Participating Authority shall remain competent on how to use the shared information. There is no obligation to accept the conclusions from another Participating Authority in PIC/S.
35. The sharing of information in PIC/S shall 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 shall not affect the exchange of GMP certificates under such treaties and agreements.
36. Upon written request of a Participating Authority, the following information can be shared on a purely voluntary basis: GMP compliance, inspection report (for the format, see PI 013), corrective action plan, plan of a company, correspondence, follow-up, etc.
37. Information shared in PIC/S shall not extend to:
 - (a) data concerning financial and commercial matters;
 - (b) data concerning technical "know-how" (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.

22 See PS/W 12/2006

23 See PI 048

24 This is also applicable for the sharing of information between (i) PIC/S Participating Authorities on the one hand and Competent 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).

38. 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

39. 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 ²⁵.

XII. Revenues

40. PIC/S' revenues normally consist of:
- annual membership contributions from Participating Authorities,
 - voluntary donations,
 - revenues from special services.
41. PIC/S accounts shall normally be audited annually.

25 i.e. in accordance with PI 010