PIC/S 1/95 (Rev. 4)
19 November 2007

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)

PIC SCHEME

1. The Pharmaceutical Inspection Co-operation Scheme (hereinafter referred to as "Scheme") is hereby established as an Association under the Swiss Code of Civil Law (Art. 60 ff). For registration purpose, the Scheme shall be referred to as "Pharmaceutical Inspection Co-operation Scheme – Association de Droit Suisse".

2. For the purpose of this Scheme "medicinal product" means:

   (a) any pharmaceutical [1], medicine or similar product intended for human or veterinary use which is subject to control by health legislation in the manufacturing country or in the importing country, and

   (b) any active pharmaceutical ingredient [2] (API) or excipient which the manufacturer uses in the manufacture of a product referred to in sub-paragraph (a) above.

I. Purpose of the Scheme

3. The purpose of this Scheme 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 of medicinal products and associated activities with a view to maintaining the mutual confidence and promoting quality assurance of inspections,

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 of medicinal products and the testing of medicinal products by official control laboratories,

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1 Also referred to as "dosage form" or "drug product"

2 Also referred to as "drug substance"

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

f) to extend the co-operation to other competent authorities having the national arrangements necessary to apply equivalent standards and procedures with a view to contributing to global harmonisation.

II. Participating Authorities [3]

4. This Scheme is open for participation by competent authorities (hereinafter referred to as "Participating Authorities") having 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.

5. The Participating Authorities should in particular 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 [4] (or equivalent) as well as other current guides, guidelines, explanatory notes and recommendations, adopted under the Scheme 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 [5].

6. The inspection system of each Participating Authority shall be re-evaluated on a regular basis in line with the PIC/S Joint Reassessment Programme [6] or equivalent programmes [7].

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3 The Participating Authorities are listed in document PS/INF 21/2002.

4 See PE 009

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

6 See PS/W 9/2000

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

III. Organisation

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

The PIC/S Committee

8. 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 the Scheme,

(b) make recommendations and proposals for the amendment, up-dating and improvement of standards of good manufacturing practice currently applied under the Scheme,

(c) promote co-operation between the competent authorities to facilitate the application of the Scheme,

(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 e.g.:
- seminars 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, hospital pharmacy, biotechnologically manufactured medicinal products,

(h) promote the exchange of experience between, and mutual training for, personnel of official control laboratories,

(i) discuss and decide on the participation of competent authorities of other countries,

(j) make proposals for amendments to the Scheme,

(k) contribute to the development of new Guides and Guidance documents applicable to GMP e.g. for different types of manufacture [8],

(l) promote global harmonisation of GMP,

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

(m) adopt annual budgets and approve financial accounts in line with financial procedures,

(n) elect the Executive Bureau,

(o) negotiate and conclude agreements.

9. The Committee shall adopt its own rules of procedure [9] as well as financial procedures [10].

10. Associated Partners may be invited to attend Committee meetings [11]. The Committee may also invite representatives from inspectorates, which are in the process of acceding to the Scheme, to attend meetings as guests.

The PIC/S Executive Bureau

11. The Executive Bureau shall meet in-between meetings of the Committee and as often as necessary in order to:

(a) prepare meetings of the Committee,

(b) implement the Committee's decisions and recommendations,

(c) monitor the Scheme's activities, including its financial situation, and

(d) prepare the annual budget.

12. The composition and election of the Executive Bureau are defined in the rules of procedure referred to in paragraph 9.

The PIC/S Secretariat

13. A Secretariat shall be appointed by the Committee to deal with the services and meeting facilities. It may also provide secretariat services to other organisations.

IV. Amendments

14. This Scheme may be amended by unanimous consent of the Participating Authorities.

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9 See PH/PS 9/97

10 See PS/W 1/2004

11 See Guidelines on Partnership (PS/W 19/2006)

V. Accession

15. A request for participation in the PIC Scheme, expressing willingness to accept the Scheme, shall be addressed to the Secretariat together with detailed information on:

(a) the national laws regulating the manufacture and control of medicinal products,

(b) the national GMP rules applied to the manufacture of medicinal products,

(c) the national inspection system with regard to the control of the manufacture of medicinal products,

(d) the structure and organisation of the inspectorate and their quality system, as well as

(e) any other relevant information which could help the Participating Authorities in the understanding of the whole system.

16. The Secretariat shall notify all Participating Authorities of the request and circulate the relevant information received.

17. The provisions contained in the Guidelines for Accession to the PIC Scheme [12] shall be followed.

18. The Committee shall decide on the participation of an authority in this Scheme. Such decision requires the consent of all Participating Authorities.

19. The participation shall become effective on a date determined by the Committee.

20. The Secretariat shall communicate the effective date of the participation to all parties concerned.

VI. Withdrawal

21. A Participating Authority may withdraw from this Scheme by giving three months' notice in writing to the Secretariat, which shall notify all the other Participating Authorities.

VII. Suspension

22. If one of the Participating Authorities does not fulfil any more the requirements of the Scheme or does not participate in the meetings and in the financing of the Scheme, the Committee may decide to suspend the operation of the Scheme 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

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12 See PIC/S 1/98

Participating Authorities, decide to exclude the Authority concerned from the Scheme with immediate effect.

VIII. Termination

23. The Participating Authorities may decide to terminate the Scheme by unanimous consent. In that case, the remaining assets of the Scheme shall be returned to them according to the last key applied for membership fees.

IX. Reorganisation

24. 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 4 above); and (iii) has retained the Quality System and Staff (in accordance with paragraph 5 above).

25. Authorities emerging from a reorganisation, which are competent in accordance with paragraph 4 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

26. This Chapter applies to manufacturers of medicinal products [13], as defined in paragraph 2 of the present Scheme, which have been inspected by a Participating Authority regardless of the location of the manufacturing site.

27. The sharing of information under this Scheme shall be fully voluntary. There is no obligation for a Participating Authority to share information under this Scheme with another Participating Authority.

28. The aim of sharing information under the Scheme 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 information on whether medicinal products have been produced in accordance with the GMP requirements applied under this Scheme.

29. Information shared under this Scheme 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 under this Scheme.

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13 Including APIs

30. The sharing of information under the Scheme shall be subject to national law, supranational law (e.g. EU or ASEAN Treaties) and other legally binding agreements (e.g. EU – Third Country MRA).

31. It shall not affect the exchange of GMP certificates (i) between the Participating Authorities of countries party to ASEAN or the European Economic Area (EEA) and (ii) between the latter and their respective Mutual Recognition Agreement (MRA) partners.

32. Upon written request, the following information is shared under the Scheme on a purely voluntary basis: GMP compliance, inspection report (for the format, see PI 013), corrective actions, plan of a company, correspondence, follow-up, etc.

33. Information shared under this Scheme 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.

XI. Rapid Alerts and Recalls arising from Quality Defects

34. 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 [14].

XII. Revenues

35. PIC/S' revenues normally consist of:

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

36. PIC/S accounts shall normally be audited annually.

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14 i.e. in accordance with PI 010