添付資料2　　PIC/Sの品質システム要求

PIC/S PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

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

PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PI 002-3
25 September 2007

RECOMMENDATION

ON

QUALITY SYSTEM REQUIREMENTS FOR PHARMACEUTICAL INSPECTORATES

Editor: PIC/S Secretariat

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1. DOCUMENT HISTORY

Adopted by the PIC/S Committee on	24 October 2000
Entry into force of PI 002-1 on	1 January 2001
Entry into force of PI 002-2 on	1 October 2004

2. INTRODUCTION

2.1 One of the main purposes of the Pharmaceutical Inspection Co-operation Scheme is to facilitate the exchange of information on national inspections in respect of the manufacture and, where relevant, wholesale distribution of medicinal products. The general requirements for National Pharmaceutical Inspectorates are to fulfil the requirements of National Legislation and of the relevant EU Directives for EU/EEA countries. Specific obligations of inspections as contained in national law and if any European Directives (for the EU/EEA countries), must be included in the National Inspectorate's quality systems.

2.2 This document outlines the quality system requirements for GMP Pharmaceutical Inspectorates. It is intended that each GMP Pharmaceutical Inspectorate uses the document as the basis for developing and implementing its own quality system and for preparing its own quality manual. In addition to providing a basis for self-assessment and a reference document for use by external assessors, establishing and maintaining an effective quality system will generate confidence within and between GMP National Pharmaceutical Inspectorates in the assessment of compliance with good manufacturing practice and/or good wholesale distribution practice.

2.3 National GMP Pharmaceutical Inspectorates, the European Commission (EC), the European Medicines Agency (EMEA) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) should co-operate with one another in exchanging experiences in the maintenance and operation of quality systems and in the further development of this document.

2.4 Only on a voluntary basis, this document could be useful for other inspectorates assessing compliance with GXP or for the inspection of pharmacies.

2.5 In preparing this text, the following documents were used (or noted):

EN 45004 : 1995	General criteria for the operation of various types of bodies performing inspections;
EN 45012 : 1998	General requirements for bodies operating assessment and certification/ registration of quality system;
ISO 9001-2000	Quality management systems-Requirements;
ISO 9004-2000	Quality management systems: guidelines for performance improvements;

ISO 19011 : 2002	Guidelines for quality and/ or environmental managerial systems auditing;
PI 002-1 : 2000	PIC/S Recommendations on quality system requirements for pharmaceutical inspectorates;
October 2003	EU Revised Compilation of Community procedures on administrative collaboration and harmonisation of inspections;
1998	Proceedings of the PIC-PIC/S seminar on quality systems for pharmaceutical inspectorates.

3. PURPOSE

3.1 The primary purpose of a quality system is to ensure that adequate quality standards are maintained. The purpose of adopting a common standard for quality system requirements is to achieve consistency in inspection standards between GMP National Pharmaceutical Inspectorates and thus to facilitate mutual recognition of and mutual confidence between those Inspectorates. This standard should help facilitate the implementation of the EEA Joint Audit Programme and PIC/S Joint Re-assessment Programme.

3.2 Each GMP national inspection service should use this document as the basis for developing its own quality system, so that inspection activities within each inspection service are carried out in accordance with a system which is compatible with systems of the other Participating Authorities.

4. SCOPE

4.1 This document specifies the quality system requirements for National pharmaceutical inspection services concerned with good manufacturing practice activities.

4.2 Where wholesale inspections are required by national legislation to be carried out by GMP National Pharmaceutical Inspectorate Service, this document specifies the quality system requirements for National Pharmaceutical Inspection Services competent for the inspection of good wholesale distribution practice of medicinal products.

4.3 The quality system should include all activities involved in the GMP inspection process.

5. DEFINITIONS

5.1 Quality system: The sum of all that is necessary to implement an organisation's quality policy and meet quality objectives. It includes organisation structure, responsibilities, procedures, systems, processes and resources. Typically these features will be addressed in different kinds of documents as the quality manual and documented procedures, modus operandi etc

5.2	Quality Indicators	Selected data intended to be periodically observed to assist in assessing trends in performance.
5.3	Pharmaceutical Inspectorate	The National body responsible for co-ordinating and carrying out GMP inspections, including inspections of pharmaceutical manufacturers and/or wholesale distributors. If relevant, this could include making decisions concerning the issue or withdrawal of establishment licences or authorisations for their activities, the issue or withdrawal of GMP certificates, providing advice and handling suspected quality defects.
5.4	Licence:	For the purposes of this document, a licence is defined as an authorisation to manufacture and/or distribute medicinal products

6. QUALITY MANUAL

6.1 The Pharmaceutical Inspectorate should prepare and maintain a quality manual covering the elements described in this document. It is for each Pharmaceutical Inspectorate to decide on the format and style of their quality manual, but it must include, or make reference to, the quality system procedures which define the activities of the Inspectorate and the arrangements for maintaining the quality system. The reference used to complete it (as ISO or EN norms) must be quoted too.

7. ADMINISTRATIVE STRUCTURE

7.1 The structure, membership and operation of the GMP Pharmaceutical Inspectorate should be such as to enable it to meet the objectives of quality management and to ensure that impartiality is safeguarded.

7.2 The personnel of the inspection service, including sub-contracted personnel and experts, should be free from any commercial, financial and other pressures which might affect their judgement and freedom to act. The Pharmaceutical Inspectorate should ensure that persons or organisations external to the inspection organisation cannot influence the result of inspections. The system for obtaining fees should not improperly influence the inspection procedure. Rules for deontology, ethics, conflict of interest and improper influence should be clearly defined.

7.3 The relationship of the Pharmaceutical Inspectorate to other agencies and to other organisations within and outside the Inspectorate should be described where relevant.

7.4 The Pharmaceutical Inspectorate should implement a policy which distinguishes between the process of inspection and that of issuing a manufacturing licence.

7.5 Where relevant, the Pharmaceutical Inspectorate should implement a policy which distinguishes between the process of inspection and that of providing an advisory service. This service should be of benefit to all of industry and not solely to individual organisations.

8. ORGANISATION AND MANAGEMENT

8.1 Senior management of the Pharmaceutical Inspectorate should make a formal commitment to support the recommended principles embodied in this document by ensuring that the quality policy of the Inspectorate is documented, that it is relevant to the objectives of that organisation and that it is implemented.

8.2 The responsibility, authority and reporting structure of the Pharmaceutical Inspectorate should be clearly defined and documented. The structure should be defined in organisation charts and should be supported by written job descriptions for each member of staff.

8.3 There should be nominated an appropriately qualified and experienced person or persons with responsibility to carry out the quality assurance function, including implementing and maintaining the quality system. This person should have direct access to senior management.

8.4 The Pharmaceutical Inspectorate should have sufficient resources at all levels to enable it to meet its objectives effectively and efficiently. Senior management should ensure that all personnel are competent and qualified to carry out their assigned duties and that they receive appropriate training. Such training should be documented and its effectiveness assessed periodically.

8.5 There should be a system for periodic management review of the quality system. Such reviews should be documented and records should be retained for a defined period.

9. DOCUMENTATION AND CHANGE CONTROL

9.1 The Pharmaceutical Inspectorate should establish and maintain a system for the control of all documentation relating to the inspection system. This should include policies, procedures, guidelines and any documents of external origin such as regulations and directives which may direct the activities of the Inspectorate or influence the quality of its operations.

9.2 The document control system should ensure that documents are authorised by appropriate persons prior to issue and that only current versions are held by nominated individuals. A record of all relevant documents and document holders should be maintained. The system should ensure that superseded documents are withdrawn from use. Superseded documents should be retained for an appropriate and defined period.

9.3 The documentation system should ensure that any changes to documents are made in a controlled manner and are properly authorised. There should be a means of identifying changes in individual documents.

10. RECORDS

10.1 The Pharmaceutical Inspectorate should establish and maintain a system of records relating to its activities which complies with any existing regulations. If relevant, the system should include documents received from licence applicants and licence holders as appropriate.

10.2 Records shall provide detailed information about the planning and scheduling of inspections, the way in which each inspection is to be conducted, a description of the inspection process, follow-up activities and recommendations to the body responsible for issuing licences.

10.3 All records should be handled in such a way as to prevent their damage or loss and should be retained for an adequate period consistent with any legal requirements. All records should be maintained in confidence to the inspected party unless otherwise required under freedom of information legislation, or unless required under exchange of information procedures and arrangements between National Pharmaceutical Inspectorates, the EU/EEA, the EMEA and Mutual Recognition Agreement (MRA) partners.

11. INSPECTION PROCEDURES

11.1 The Pharmaceutical Inspectorate should conduct repeated inspections of manufacturers and/ or wholesale distributors and should issue inspection reports in accordance with National or European Community requirements as appropriate.

11.2 The Pharmaceutical Inspectorate should have the documented procedures and resources to enable inspection of manufacturing and wholesale distribution operations to be carried out in accordance with the official guidelines and National legislation and in accordance with a formal inspection plan. All instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work of the Pharmaceutical Inspectorate should be maintained up-to-date and be readily available to staff.

11.3 When more than one inspector is involved in an inspection, a lead inspector should be appointed to co-ordinate inspection activities. The inspection report should normally be prepared by the lead inspector and should be agreed by all participating inspectors.

11.4 Inspection report format should be in compliance with the PIC/S procedure or European model.

11.5 Report should follow the procedure above. The inspection report should be sent to the responsible person of the inspected company (preferably the authorised person or qualified person). The lead inspector and all concerned inspectors should participate in assessing the eventual reply or replies to determine the appropriateness of corrective actions and the GMP status of the company.

11.6 Observations and/or data obtained in the course of inspections should be recorded in a timely manner to prevent loss of relevant information.

11.7 Completed inspections should be reviewed to ensure that the requirements are met.

12. INSPECTION RESOURCES

12.1 Personnel

12.1.1 The Pharmaceutical Inspectorate should possess the required personnel, expertise and other resources to perform inspections of manufacturers and/ or wholesale distributors to determine their compliance with the principles and guidelines of current good practices and with the relevant legislation.

12.1.2 The staff responsible for inspections should have appropriate qualifications, training, experience and knowledge of the inspection process. They should have the ability to make professional judgements as to the conformance of the inspected party with the requirements of good practices and the relevant legislation and be able to apply an appropriate degree of risk assessment. They should have knowledge of current technology, including computerised systems and information technology.

12.1.3 The Pharmaceutical Inspectorate should establish a documented system for recruiting and training its personnel and should carry out a regular review of the training received and the training needs for each member of staff. Individual training and qualification records should be maintained.

12.2 Resources and equipment

12.2.1 The Pharmaceutical Inspectorate should have available the necessary resources and equipment to enable it to carry out its obligations effectively and efficiently.

13. INTERNAL AUDIT

13.1 The Pharmaceutical Inspectorate should carry out and document periodic internal audits of its operations to assess compliance with the requirements of the quality system. Results of internal audits and associated corrective actions should be reviewed as part of the management review process.

13.2 Internal audit processes and documents, auditors qualifications should be clearly defined (e.g. reference to ISO 19011 : 2002).

13.3 Internal audit records should be retained for a defined period.

14. QUALITY IMPROVEMENT AND CORRECTIVE/PREVENTIVE ACTION

14.1 Quality indicators

14.1.1 The Pharmaceutical Inspectorate should establish and maintain quality indicators related to its activities notably in the area of timeframe mentioned in existing EU or national regulations (e.g. licensing system for manufacturing or marketing authorizations) and/ or documentation (e.g. writing reports).

14.1.2 Quality indicators should be reviewed as part of the management review process.

14.2 Corrective/ preventive action

14.2.1 The Pharmaceutical Inspectorate should establish and maintain a procedure for the investigation of non-compliances with the quality system which are identified through internal or external audit of its activities. The procedure should include the prescribing, implementation and verification of corrective action. The procedure should cover also corrective actions arising from the investigation of complaints and other observations relating to the activities of the Inspectorate.

14.2.2 The system should include a description of the steps to be taken in assessing the need for quality improvement and preventive action.

14.2.3 Corrective and preventive actions should be documented and records should be retained for a defined period.

15. COMPLAINTS

15.1 The Pharmaceutical Inspectorate should establish and maintain a procedure for dealing with complaints relating to its activities, or those of its personnel, and any contracted persons or organisations. The procedure should describe the application and verification of corrective action arising from the investigation of complaints.

15.2 Records should be maintained of all complaints received and actions taken and should be retained for a defined period.

16. ISSUE AND WITHDRAWAL OF LICENCES AND GMP CERTIFICATES

16.1 The Pharmaceutical Inspectorate should establish and maintain a system for the issue and withdrawal of licences and GMP certificates, or for advising about the issue and withdrawal of licences and GMP certificates, as appropriate.

16.2 Licence and GMP certificate applications should be assessed and determined in a timely manner and within any time limits imposed by National or European Community requirements. Where time limits are imposed, inspection activities should be included in the total time taken to determine the application.

16.3 There should be a documented system for taking appropriate action against a licence / or a GMP certificate notably in the event of an adverse inspection report. The system should include descriptions of the actions available to the Inspectorate; such actions may include suspension or revocation of the licence and/or the GMP certificate(s). There should be a system for assessing compliance of an organisation with imposed licensing action.

16.4 The system should include a description of the appeals procedure available to licence holders.

16.5 If the licensing system is not part of the Pharmaceutical Inspectorate, the latter should establish and maintain defined liaison with it to obtain and guarantee targets quoted in paragraphs 16.1 to 16.3.

17. HANDLING SUSPECTED QUALITY DEFECTS AND RAPID ALERT SYSTEM

17.1 The Pharmaceutical Inspectorate should establish and maintain a system for handling of reports of suspected quality defects in medicinal products as defined in a related Standard Operating Procedure or the related Community procedure.

17.2 The Pharmaceutical Inspectorate should establish and maintain a system for issuing Rapid Alert as defined in a related Standard Operating Procedure or the related Community procedure.

17.3 The Pharmaceutical Inspectorate should establish and maintain an updated list of all performed recalls.

17.4 If the organization in charge of handling suspected quality defects and rapid alert system is not part of the Pharmaceutical Inspectorate, the latter should establish and maintain defined liaison with it to obtain and guarantee targets quoted in paragraphs 17.1 and 17.2.

18 LIAISON WITH THE OFFICIAL MEDICINE CONTROL LABORATORY (OMCL)

The Pharmaceutical Inspectorate should establish and maintain defined liaison with the OMCL(s) of its own Participating Authority in order to exchange information concerning the quality of medicinal products existing on the national market. In particular, an SOP should define sampling processes for starting material and medicinal products.

19. SUB-CONTRACTING AND ASSESSING

19.1 The Pharmaceutical Inspectorate should normally carry out the GMP inspections for which it is responsible and whilst it may sub-contract some of its work it cannot sub-contract any of its accountability. Sub-contracted personnel or experts may be employed as part of an inspection team to assist or advise in a technical capacity, but that team should normally be led by a GMP lead inspector. Sub-contracted personnel should be bound by the requirements of the quality system and there should be a written contractual agreement between the parties.

19.2 Persons or organisations to whom inspection activities are contracted out and experts should be free from any commercial or financial pressures which might affect their freedom to act. They should follow defined rules to avoid conflict of interests and regarding ethic and deontology. Senior management of the Pharmaceutical Inspectorate should ensure that these persons are appropriately qualified and experienced and that they are independent of any organisations which they might be asked to inspect.

20. PUBLICATIONS

20.1 The Pharmaceutical Inspectorate should have at its disposal an updated list of licensed manufacturers and/ or wholesale distributors. The list should be made available to authorised bodies when requested.

21 REVISION HISTORY

Date	Version Number	Reasons for revision
15.06.2004	PI 002-2	Amendment made to bring PIC/S recommendation in line with the EU document on quality system requirements; deletion of the Appendix (guidelines for documenting a quality manual); change in the Editor's co-ordinates.
25.09.2007	PI 002-3	Change in the Editor's co-ordinates.