



PS/W 1/2011
2 Annexes
22 July 2011

**QUESTIONNAIRE FOR
COMPETENT AUTHORITIES
TO BE USED FOR ASSESSMENT,
REASSESSMENT AND SELF-
EVALUATION**

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Annex 1: Questionnaire

Annex 2: List of Documents to Support the Questionnaire

1. Introduction

- 1.1 This document should be used by:
- (i) Competent Authorities wishing to accede to PIC/S and going through a pre-accession process (see § 9 of Accession Guidelines);
 - (ii) Competent Authorities applying for PIC/S membership and going through an accession process (see § 16 of Accession Guidelines);
 - (iii) PIC/S Participating Authorities being reassessed under the Joint Reassessment programme;
 - (iv) Competent Authorities for their own self-assessment.
- 1.2 Upon request, the Secretariat provides the Authority with all appropriate information including a questionnaire and a list of supporting documents.

2. Purpose

- 2.1 The purpose of this document is to provide guidance on the information and documentation to be submitted in order to ensure (i) equivalency in the way Authorities are assessed and (ii) consistency in the way the information and documentation is presented and evaluated.

3. Scope

- 3.1 This document is applicable for the (i) pre-accession of interested Competent Authorities (ii) assessment of Applicants; and (iii) re-assessment of Participating Authorities.

4. Questionnaire / Self-Assessment

- 4.1 The Questionnaire (Annex 1) must be properly filled in and completed in English.
- 4.2 When ever possible, clear and detailed cross-references (e.g. to SOPs or national legislation) must be indicated thus facilitating the work of the assessor(s) / auditor(s).
- 4.3 Competent Authorities applying for PIC/S membership should attach an official, signed letter with the Questionnaire expressing the will of the Competent Authority to join PIC/S and to go through the accession procedure.
- 4.4 The filled-in Questionnaire should be returned together with the PIC/S Audit Checklist (PS/W 1/2005), which is used as a self-evaluation tool and which allows the Competent Authority to verify whether it complies with PIC/S requirements.

5. List of Documents

- 5.1 Applicants and Authorities under (re-)assessment should provide the supporting documents listed at Annex 2 together with the Questionnaire in order to support it.
- 5.2 Competent Authorities going through a pre-accession process must not provide any supporting documents to the Questionnaire. However, they should at least indicate whether the documents are available as well as the document reference.

6. References

PIC/S 1/95 Pharmaceutical Inspection Co-operation Scheme
PS/W 14/2011 Guidelines for the Accession to the PIC Scheme
PS/W 1/2005 Audit Checklist

7. Revision History

Version Number	Reason(s) for Revision
PS 2/99	Original version
PS 2/99-1	Change of the PIC/S Secretariat's e-mail address
PS 2/99-2	Change of the PIC/S Secretariat's co-ordinates
PS 2/99-3	Change of the PIC/S Secretariat's postal address
PS/W 1/2011	Merger of application form and questionnaire; harmonisation with the Joint Reassessment Programme and the Audit Checklist; introduction of the notion of "self-evaluation".

* * * * *

Questionnaire

Complete the questionnaire and return to:

Pharmaceutical Inspection Co-operation Scheme (PIC/S)
14, rue du Roveray
CH-1207 Geneva (Switzerland)
E-mail: info@picscheme.org

1. Applicant (*name of authority*)

2. Address

3. Country

4. Phone

5. Fax

6. E-mail

7. Web Site

8. Contact person (*name and title*)

9. Purpose: This questionnaire is submitted as a self-evaluation for:

- a) PIC/S pre-accession
- b) PIC/S membership application
- c) PIC/S reassessment

10. Scope: The Applicant is competent for the inspection of medicinal products:

- a) for human use
- b) for veterinary use
- c) for both human and veterinary use

11. Date

**The following questions should be completed in parallel with
the Audit Checklist (PS/W 1/2005)!**

1 - Legislative and Regulatory Requirements and Scope

1A - Empowering legislation

- a) Is there a licensing system in force for:
 - a1) Pharmaceutical manufacturers and importers?
 - a2) Wholesale distribution of medicinal products (including APIs)?
 - a3) Blood banks?
 - a4) Contract laboratories?
 - a5) Manufacturers and importers of active pharmaceutical ingredients?
 - a6) Manufacturers for clinical trials?
 - a7) Manufacturing of medicinal products for export only?
 - a8) Manufacturers of medical gases?
 - a9) Hospital pharmacies?
 - a10) Manufacturers of veterinary medicines?
 - a11) Manufacturers of traditional medicines (herbal, mineral, ...)?
 - a12) Cells and tissues banks?

- b) Is the Competent Authority fully or partially responsible for licensing and inspecting the products listed above? If not, please explain.

- c) List the groups of products which are subject to legal provisions governing medicinal products.

- d) Are dosage forms listed in the manufacturing licence?

- e) Is there any legal power for the inspectors to take samples of API, intermediate and final products?

- f) Are inspectors authorised to take evidence during inspections (i.e. photos and videos)?

- g) Are inspectors also authorised to inspect in free ports at any time? Or is a permit issued by the customs services required?

- h) Are organisations which carry out manufacture under contract inspected?

- i) Are such organisations licensed, so that they can be inspected directly, or is access to them secured only through the manufacturer for whom they work?

- j) Has the licensing authority the right to control batch release?

1B - Conflict of interest

- a) What are the requirements making sure that inspectors and other staff involved in the application are independent from inspected companies?

2 - Regulatory directives and policies

2A - Procedures for designating inspectors

- a) By which authority are the inspectors employed?
- b) What is the position of this authority within the public health service?

2B - Enforcement Policies

2C - Code of conduct/ Code of ethics

- a) Is there a code of ethics and how are inspectors bound to respect it?

2D - Training certification policies/guidelines

2E - Alert/crisis management policies/procedures/guidelines

2F - Organisational structure

- a) What connection has the Inspectorate with the licensing (drug registration) system?
- b) What connection has the Inspectorate with the structure in charge of assessing the suspected quality defects?

3 - GMP Standards

3A - Details/ scope of GMP

- a) Which GMP Standard is used as the basis for inspections?

3B - Process validation

- a) Is process validation assessed during inspections or during registration process?

4 - Inspection resources

4A - Staffing: Initial qualification

- a) What qualifications/experience are required for appointment as inspectors?

4B - Number of inspectors

- b) How many inspectors are employed
 - b1) on a full-time basis:
 - b2) on a part-time basis:

in respect of
 - b3) Manufacturers and importers for APIs?
 - b4) Manufacturers and importers for medicinal products?
 - b5) Wholesalers and distributors for medicinal products (incl. APIs)?
 - b6) Pharmacies?
 - b7) Others (describe)?

4C - Training programme

- a) Is there a training programme for inspectors on recruitment?
- a1) Is training formal?
- a2) Is training carried out alongside an experienced inspector?
- a3) Are new inspectors formally qualified to inspect in new areas?
- b) Is there a training programme for inspectors during service?
- b1) What means of training are used?
- b2) What are the main topics in which training is given?
- b3) How many days of training a year?

4D - QA mechanism to assure effectiveness of training programme

5 - Inspection procedures

5A - Inspection strategy

- a) Are inspections of APIs manufacturers product-oriented? If not, please explain
- b) Does the inspection of manufacturers of medicinal products cover:
 - b1) All activities from the purchase of materials and components to the shipment of products for sale?
 - b2) Part only of these activities? (state which)
 - b3) Laboratory examination of materials, packaging components, and products?
 - b4) Manufacturing documentation?
 - b5) Records of activities?
 - b6) Buildings and equipment - layout and sanitation?
 - b7) Personnel recruitment and training?
 - b8) Quality Management System?
- c) Are inspectors:
 - c1) Allowed a free hand to conduct inspections as seems best to them?
 - c2) Given an Aide-Memoire to guide them through the inspection?
 - c3) Required to work through a check list of matters to be examined?

5B - Pre-inspection preparation

- a) Must the manufacturer submit a Site Master Plan (equivalent to PIC/S) to inspectors prior to the inspection?

5C - Format and content of inspection reports

- a) Is there a classification system for deficiencies (e. g. critical, major, others)?
- b) Are the reports of the inspectors:
 - b1) Usually in writing?
 - b2) General or detailed?
 - b3) Signed by the inspectors?
 - b4) Communicated to manufacturer?
 - b5) Confidential?
 - b6) PIC/S format?
 - b7) Reviewed by supervisors or quality control?

- b8) Are Site Master Files assessed as part of the reports?
- b9) Is there a time limit for issuing the list of deficiencies?
- b10) Is there a time limit for issuing the report?

5D - Inspection methodology

- a) What is inspected and how many sites in each case?
 - a1) Manufacturers of medicinal products in the country?
 - a2) Manufacturers abroad?
 - a3) Other sites abroad? (describe which)
 - a4) Wholesalers of medicinal products / API?
 - a5) Importers of dosage forms?
 - a6) Blood, cells, tissues banks?
 - a7) Contract laboratories?
 - a8) Manufacturers and importers of APIs?
 - a9) Manufacturers of investigational medicinal products?
 - a10) Manufacturers of medicinal gases?
 - a11) Manufacturers of medicinal products for veterinary use?
 - a12) Manufacturers of traditional medicines?
 - a13) Hospitals which manufacture?
 - a14) Pharmacies which manufacture?
 - a15) State organisations?
 - a16) Other - describe?

- b) How frequently are inspections made? If inspections are planned according to quality risk management principles, please explain the approach.

- c) How are inspections normally performed?
 - c1) System-based (i.e. global compliance to GMP)?
 - c2) Product oriented?
 - c3) Problem oriented?

- d) Is assistance of experts used? (when appropriate)
 - d1) During inspections?
 - d2) For laboratory advice?
 - d3) Others? (describe)

5E - SOP for conducting inspections

- a) How are inspectors instructed in the purpose and conduct of inspections?
- b) Are some or all of these instructions in writing?

5F - Inspection procedures - Post-inspection activities

- a) Are the findings of the inspectors as contained in their report conclusive or subject to confirmation?
- b) Who defines the period within which the deficiencies found by inspectors are to be rectified?

- c) How do the inspectors check if corrective actions have been taken within the given time frame?
- d) In which cases are follow-up inspections carried out?
- e) Are actions on the findings taken by the inspector, or the Inspectorate and/or some other body? If the latter, which body?

5G - Inspection procedures – Storage of inspection data

6 - Inspection performance standard

6A - Performance standards

- a) How is the performance of the inspectors assessed?

7 - Enforcement powers and procedures

7A - Provision for written notice of violations

7B - Non-compliance management

- a) Which courses of actions are available?
 - a1) Informal pressure to alter buildings, equipment, manufacturing and analytical procedures? (state which)
 - a2) Formal action to:
 - (i) Change a registration or authorisation?
 - (i.a) For the concerned product(s)?
 - (i.b) For the manufacturer/ importer of the concerned product(s)?
 - (ii) Suspend a registration or authorisation?
 - (ii.a) For the concerned product(s)?
 - (ii.b) For the manufacturer/ importer of the concerned product(s)?
 - (iii) Revoke a registration or authorisation?
 - (iii.a) For the concerned product(s)?
 - (iii.b) For the manufacturer/ importer of the concerned product(s)?
 - (iv) Suspend the sale of a product or products?
 - (v) Recall a product from the market?
 - (vi) Bring the matter before the courts for a legal remedy? If so, what remedy/remedies?
 - (vii) Other? - (describe)
- c) Formal actions with respect to distributors of medicinal products / API
- d) Can actions listed above be taken on the basis of inspection findings alone or is it necessary to first demonstrate that a product is deficient?
- e) What is required to demonstrate that a product is deficient?
 - (i) Results from a laboratory examination of the product?
 - (ii) Evidence of plant or process failure derived from the manufacturer's records?

- (iii) Evidence of failure of the product in use?
- f) If a product is shown to be deficient:
 - (i) Is action limited to the manufacturing batch from which the deficient sample was taken?
 - (ii) Or can action be taken against other batches of the same product?
 - (iii) Or can action be taken against other/all products whose manufacture employs the same process(es)?
 - (iv) Or can action be taken against all activities of the manufacturer, for example, by suspension of his manufacturing authorisation?

7C - Appeal mechanism

- a) Does the manufacturer have right of appeal against the actions described in Sub-Component 7B, letter d, e and f?
- b) What action may be taken following an appeal?
- c) Do you have similar actions concerning API (including manufacturers, importers and wholesalers)?

7D - Other measures

8 - Alert and crisis systems

8A - Alert mechanisms

- a) When an allegedly defective medicinal product is discovered, must the company notify the Competent Authority and is the Inspectorate involved in any subsequent action?
- b) Notifications of an allegedly defective product are commonly received from where?

8B - Crisis management mechanisms

- a) Which of the following courses of action are used for suspected product quality defects:
 - a1) Warn users to examine stocks for possible defects?
 - a2) Suspend sales?
 - a3) Suspend use?
 - a4) Recall?
 - a5) Other? (describe or see 7Ba2)
- b) If a recall is decided upon, does the Competent Authority (or other body) have a legal power to order it to be carried out? If not, what power does it have?
- c) If a recall is decided upon, does the Competent Authority (or other body):
 - c1) Advise the manufacturer as to his best course of action, leaving that action for him to carry out?
 - c2) Carry out the recall itself?

8C - Alert performance standards

9 - Analytical capability

9A - Access to laboratories

- a) The Competent Authority has its own Official Control Medicines Laboratory or has access to it?

9B - SOPs for analytical support

9C - Validation of analytical methods

10 - Surveillance programme

10A - Sampling and audit procedure

10B - Recall monitoring

10C - Consumer complaint system

10D - Adverse reaction reporting system/ procedures

10E - Drug product defect reporting system/ procedures

11 - Quality management system

11A - Quality management system

- a) Has the Competent Authority / the Inspectorate a quality management system?
- b) Is it a formal system and if so which guidelines/standards have been followed?
- c) When was the quality management system implemented?
- d) Is the Competent Authority/ the Inspectorate accredited/certified (by whom)?

PIC/S-specific components

- a) What languages are the inspectors able to speak? Knowledge in English?
- b) Availability of funds and ability to attend PIC/S Committee meetings (twice a year), seminars (1x / year), other training events (Expert Circles, Joint Visits Programme, etc) as well as to participate in the (re-)assessment of authorities?
- c) Ability to pay the PIC/S annual fee?

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List of Supporting Documents

to be submitted in English

- I National legislation enabling inspections, licensing, sampling and testing and recalls**
- II Information requested from companies prior to undertaking GMP Inspections e.g. Site Master File**
- III GMP standard if different from PIC/S, EU or WHO GMP Guides (the document should be submitted)**
- IV The number of manufacturers/wholesalers currently inspected and licensed/registered showing type of medicinal products (incl. APIs) manufactured
NB: A list (or access to the relevant database) should be given during the on-site assessment**
- V Copy of Quality Manual**
- VI List of SOPs**
- VII Programme for introduction and ongoing training for inspectors**
- VIII Names of inspectors carrying out GMP inspections on full-time or part-time bases including any specialist inspectors**
- IX Main professional requirements for inspectors, senior/principal inspectors, chief inspector (The CVs of inspectors should be made available during the on-site assessment)**
- X SOP for how to carry out inspections**
- XI Report format if different from PIC/S format**
- XII Statistical information on numbers of inspections carried out**

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