PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

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GUIDELINES FOR THE PRE-ACCESSION PROCEDURE

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GUIDELINES FOR THE PRE-ACCESSION PROCEDURE

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1. INTRODUCTION

1.1 The Pharmaceutical Inspection Co-operation Scheme (PIC/S) has been set up in order to provide, in the interest of public health, for the co-operation between pharmaceutical inspectorates with a view to

- fostering and maintaining mutual confidence;
- promoting quality management system for inspectorates and best practices and standards in the field of inspections; and
- contributing to global harmonisation of standards of good manufacturing practice (GMP) for medicinal products, as defined in paragraph 7 of the Scheme (PIC/S 1/95 (Rev. 6)).

1.2 The Scheme is also a means of ensuring – through official inspections – that the quality of medicinal products is strictly in compliance with the marketing authorisation and GMP standards.

1.3 Paragraph 8 of the Scheme provides that "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."

1.4 The Scheme is primarily based on mutual confidence between Participating Authorities (PA). Such confidence can only be achieved on the basis of a thorough knowledge of each other's inspection systems and inspection practice and standards as well as through personal contacts between representatives (including inspectors) of the different competent authorities.

1.5 Considering (i) the many differences in GMP regulations for medicinal products; (ii) the various Quality Systems (QS) applied by interested Competent Authorities; (iii) the limited resources available within PIC/S for the assessment of new membership applications; and (iv) the need to facilitate and accelerate the accession, the accession process has been split into two distinct phases, which are: “Pre-Accession Procedure” and “Accession Procedure”.

1.6 The purpose of the pre-accession process to allow interested Competent Authorities willing to become PIC/S PA to better understand what PIC/S is and what the expectations are for becoming a PA.

1.7 Against this background and in line with the general objectives of the Scheme, the PIC/S Committee has – on the basis of practice and experience – agreed on the following guidelines for the procedure of pre-accession. This procedure is, however, meant to remain flexible in the sense that the sequence of events should not necessarily have to follow the order set out below.

1.8. The Pre-Accession Procedure is recommended if the interested Competent Authority:

a) is unsure as to whether or not it meets PIC/S requirements; and/or

b) has not introduced an inspectorate quality system as per the PIC/S recommendation (PI 002); and/or

c) does not apply the PIC/S GMP Guide (PE 009, latest edition) or equivalent guide;

d) has not regularly participated in PIC/S training activities.

1.9 Representatives from the interested Competent Authority must have the resources available to attend at least one PIC/S Committee meeting and seminar while the application is under review.

1.10 The Pre-Accession Procedure serves to identify the necessary elements of the GMP Regulatory Compliance Programme as defined in the Audit Checklist (PS/W 1/2005) to be provided by the interested Competent Authority to help it understand the gaps between PIC/S requirements and its GMP Regulatory Compliance Programme within its own territory and abroad. The Pre-Accession Procedure is not a form of consultancy and there will be no follow-up within the Pre-Accession Procedure of the corrective actions to overcome the identified gaps.

2. PRE-ACCESSION PROCEDURE

2.1 A Competent Authority (hereafter referred to as "the Pre-Accession Applicant / PAA") should contact the PIC/S Secretariat by email info@picscheme.org. The Secretariat shall

(a) provide the PAA with all appropriate information, including the pre-accession process, fees and timeframe;

(b) ask the PAA to complete the Questionnaire (PS/W 1/2011) and the Audit Checklist as a self-assessment (PS/W 1/2005) and return them to the Secretariat. (Note: all documents must be submitted in English and electronically, either as attachment to an e-mail or through a secure link like Eudralink; hyperlinks are not accepted). The contact email address supplied by the PAA should be an official email used by the inspectorate and not a personal address.

2.2 Upon receipt of an application the Secretariat will inform the Committee and will make a call for a Rapporteur to volunteer in leading the pre-accession procedure and Co-Rapporteur(s), if needed. The Rapporteur and co-rapporteur do not need to be a member of the Committee but must work for a PIC/S Participating Authority. The Rapporteur (and Co-Rapporteur(s) if needed) will be recommended by the Sub-Committee on Compliance and formally appointed by the Committee.

2.3 The task of the Rapporteur with the possible assistance of the Co-Rapporteur is:

- to develop a proposed timetable, to be agreed with the PAA, that includes dates for milestones of the process to be submitted to the Sub-Committee on Compliance (SCC) and the Committee.
- to check the good understanding by the PAA of each indicator
- to verify if all indicators are covered by the PAA
- to determine if there is a need to identify gaps in any of the areas between the PAA's GMP Regulatory Compliance Programme as defined in the Audit Checklist (PS/W 1/2005) and the PIC/S requirements. This will lead to a gap analysis to be performed by the PAA used for the application process.

- to prepare a short high-level report using the template in Annex 1 after the completion of his evaluation (including feed-back provided by the PAA). The high-level report is provided to the SCC for review and should include a recommendation on whether the PAA is ready or not for lodging an application. In the case the pre-accession process cannot be completed, the Rapporteur should detail the reason(s) why. The high-level report should include as enclosure the completed and updated Audit Checklist (PS/W 1/2005) with the indication that the PAA has reached the conclusion that either (i) there is no significant gap; or (ii) if there is a significant gap highlight in the completed updated Audit Checklist for those indicators for which there is a gap to be addressed and explain the level of understanding.
- the recommendation is shared with the Committee regarding the readiness of the PAA to apply for PIC/S membership. This information should be shared with the PAA.
- the Committee has to endorse (or not) the recommendation proposed by the Rapporteur in order to formally close the PAA process. The decision made is shared with the PAA.

In order to facilitate the task, the PAA or the Rapporteur should propose a short meeting (in the country of the Rapporteur or during a PIC/S Committee meeting or through a videoconference) to discuss and complete the gap analysis.

2.4 The PAA shall then decide on the next steps, such as:

- To develop a gap analysis of its own GMP Regulatory Compliance Programme and develop CAPA to address the gaps and indicate when it anticipates applying for PIC/S membership;
- To directly apply for membership;

Note: The Rapporteur will not review the proposed CAPA. Their implementation will be verified as part of the Accession process.

2.5 The normal timeframe for the pre-accession process is two calendar years after receipt of the completed Audit Checklist and Questionnaire.

2.6 The PAA will have to pay an annual fee as defined in the PIC/S Financial Rules in exchange for the possibility to attend non-restricted part of PIC/S Committee meetings during the pre-accession process.

2.7 A pre-accession process is put on hold or suspended if the PPA is not paying its fee and/or not attending meetings.

2.7 In the event that a meeting is requested in order to complete the file, the PAA should cover the related travel costs in line with the PIC/S Travel Guidance (PS/W 9/2014).

3. PARTICIPATION IN TRAINING ACTIVITIES

3.1 The PAA shall be invited to attend PIC/S seminars and other training activities and is expected to participate. The contribution fee to the PIC/S Secretariat, which is collected as part of the seminar registration fee is defined in the PIC/S Aide Memoire on the Organisation of Seminars (see PI 003).

3.2 The PAA may also invite representatives of the PIC/S Committee to participate as speakers in GMP training seminars organised by the interested Authority for its inspectors.

4. PARTICIPATION IN PIC/S COMMITTEE MEETINGS

During the application process the PAA has the right and is expected to attend non-restricted parts of PIC/S Committee meetings as observers (no voting right). Applicants are entitled to one representative who should be familiar with GMP inspections (e.g. Chief Inspector or Senior Inspector); additional representatives may be allowed if seats are available. To ensure consistency in the discussion of the application, the same representatives should attend Committee meetings.

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Annex

SHORT HIGH-LEVEL REPORT FORMAT
FOR THE PRE-ACCESSION PROCEDURE

Short High-Level Report for
Closure of the Pre-Accession Application by
[Name of the concerned Pre-Accession Applicant]

by the Rapporteur [Name of Rapporteur]

Background related to the different main steps of the pre-application (i.e. date of the pre-application, date(s) of meeting, key exchanges of information, etc.)

Summary report of meetings during the pre-accession process. If by videoconferences or e-mail correspondence, clarify the various steps of the process.

Conclusion: the Rapporteur has to provide a proposal to the Sub-Committee on Compliance expressing her/ his opinion on the readiness of the concerned Pre-Accession Applicant to lodge an application to become a PIC/S Participating Authority.

Name of the Rapporteur

Date of the report