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 reliance;
- 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 reliance between Participating Authorities (PA). Such reliance 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[1]; (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 is 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 guideline for the procedure of pre-accession. This process 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 Process is recommended if the interested Competent Authority:

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

[1] Reference is made to « Competent Authorities » as this relates to the terminology used in the PIC Scheme. This term is equivalent to “National Regulatory Authority (“NRA”)” as used in other documents in connection with the PIC/S Pre-Accession process in line with WHO terminology (see also Glossary REF).

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 Process serves to provide help to fully understand what is the GMP Regulatory Compliance Programme as defined in the Audit Checklist (PS/W 1/2005 (Rev. 3)) as well as in the Questionnaire for Assessment (PS/W 1/2011 (Rev. 1)). The Pre-Accession Process is not a form of consultancy. As such, there will be no review of the outcome of gap analysis performed and the possible corrective actions undertaken by the pre-applicant, by the assigned Rapporteur.

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 provide the PAA with all appropriate information, including the pre-accession process and fees. For noting, 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 official letter 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. The appointment of the Rapporteur(s) marks the official start of the pre-accession process as from which the normal 2-year timeframe and the maximum 4-year status as Pre-Applicant start to run.

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

- to develop a timetable for the Pre-Accession process and online meetings, to be agreed with the PAA. This includes dates for developing the agreed timetable is shared with the Sub-Committee on Compliance (SCC) and for the Committee.
- after the PAA completed the e-module to address outstanding questions with regards to the requirements of any indicators of the Audit Checklist
- to ensure the good understanding by the PAA of indicators by reviewing the results of the quiz, question the PAA on the critical components of the Audit checklist

- the recommendation is shared with the Committee regarding the completion of the process with the PAA. This information should be also shared with the PAA.
- After this step, the Committee is offering to the PAA to keep the status of Pre-Applicant which cannot exceed 4 years in total.

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 videoconferences) to go through this process.

2.4 After the completion of the Pre-Accession procedure, the PAA shall decide on the next steps, such as:

- To complete the Audit Checklist and self-assessment Questionnaire;
- 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;

2.5 The normal timeframe for the pre-accession process is two calendar years after the designation of the Rapporteur and Co-Rapporteur(s) (if any) by the Committee.

2.6 The PAA will have to pay an annual fee as defined in the PIC/S Financial Rules. The fee is due as from designation of the Rapporteur(s).

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

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 pre-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). The PAA 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 1

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, completion of the pre-application e-module and quiz? 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 successful completion of the process and understanding of the indicators The Committee has to be informed.

Name of the Rapporteur

Date of the report