PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

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PIC/S ROAD MAP 2018 – 2020

PUBLIC SUMMARY

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I. OVERVIEW

PIC/S' mission is "to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products." In furtherance of this mission, the PIC/S Committee has adopted a strategic plan, which serves as a "Road Map" for the next three years (2018-2020), to guide the work of the Organisation and its Members. The Road Map is an internal, non-binding policy paper. This is a condensed summary of the original document. The Road Map focusses on three goals:

- **Training Inspectors:** Enhancing and implementing the PIC/S Inspectorates' Academy (PIA) to provide training to all inspectors;
- **Sharing Information**: Facilitating the exchange of GMP information by mutual confidence based on the equivalence of PIC/S Participating Authorities (i.e. Members)[1]; and
- **Strengthening the Organisation:** Identifying and addressing emerging organisational challenges, notably by;
  - Improving communication (both internally and externally);
  - Enhancing PIC/S' Sub-Committee (SC) structure;
  - Strengthening the PIC/S Secretariat and implementing an effective human resourcing strategy; and
  - Identifying new income streams, which will yield the required funding necessary to finance PIC/S' projects.

Achieving these goals is in line with long-term strategic objectives of PIC/S, notably:

- To further promote the international harmonisation and interpretation of GMP standards as well as the harmonisation of inspection procedures;
- To ensure the continued compliance of Acceding and Participating Authorities with PIC/S requirements;
- To strengthen PIC/S governance and resources; and
- To review and assess PIC/S outputs.

II. TRAINING INSPECTORS – PIC/S Inspectorates' Academy (PIA)

Having a trained and well-informed inspectorate is essential for PIC/S members to meet their public health protection responsibilities related to medicines. For years, PIC/S has relentlessly worked for the international harmonisation of GMP standards for ensuring quality of pharmaceuticals. The uniform training of PIC/S GMP inspectors within and across countries is critical to ensure that all inspectors assess GMP consistently. To achieve this, to build on traditional methods of providing training, such as webinars and seminars, PIC/S launched the PIC/S Inspectorates' Academy (PIA) in 2016, which is a web-based training structure. The PIA allows training resources to be leveraged across Participating Authorities.

[1] "Participating Authorities" are Medicines Regulatory Authorities, which are Members of PIC/S.

To enhance the PIA, PIC/S will:

- Identify training needs and develop appropriate tools and add to the PIA database.
- Identify and integrate additional training materials from Members.
- Establish instruments to measure efficacy of training events.
- Conduct webinars and other forms of training (both live and recorded) for the PIA.
- Build the PIC/S library of documents related to GM(D)P from Members and Partner Organisations to complement the PIA.

III. SHARING INFORMATION

Increasing reliance on complex global supply chains by the pharmaceutical sector stresses inspectorates' limited resources and makes it difficult to thoroughly assess facilities involved in pharmaceutical manufacturing, testing, distribution, and other regulated activities. Thus, regulatory authorities need to leverage resources and information where possible. Sharing of information is essential, but this is based on confidence and trust in the information and the source of the information. Continued compliance of Participating Authorities to PIC/S requirements is a prerequisite to maintain equivalent GMP systems and mutual confidence. To facilitate the exchange of GMP information by mutual confidence based on the equivalence of PIC/S Participating Authorities, PIC/S will:

- Focus on ensuring compliance of Participating Authorities by conducting timely assessments through the Joint Reassessment Programme (JRP).
- Increase the pool of auditors for the JRP.
- Identify other means to receive relevant updates from PIC/S members related to GMP and other PIC/S activities to better manage reassessments, including considering desktop re-assessments.
- Build on the GMP reliance framework on equivalency that was transferred from the International Coalition of Medicines Regulatory Authorities (ICMRA) and identify/establish tools for increasing mutual confidence and use of GMP information.

IV. STRENGTHENING THE ORGANIZATION

PIC/S membership has increased in number and geographical breadth and the scope of the issues that PIC/S addresses to support Members has grown as well. PIC/S is now part of a wider international network of organisations and is a leader in the global landscape of ensuring pharmaceutical quality through inspection and compliance. As an organisation, PIC/S must adapt to meet these modern demands and future challenges to support Members and secure PIC/S' role internationally. To identify and address emerging organisational challenges, PIC/S will:

- Improve communication among members regarding planned inspections, inspectional findings, and identification of manufacturing sites.
- Identify and implement activities to raise the profile and prominence of PIC/S at a global level, including presentations, partnering, and other outreach.
- Enhance PIC/S' SC structure, participation, roles of working groups, and reporting of the work of the SC.

- Strengthen the PIC/S Secretariat and implement an effective human resourcing strategy.
- Identify new income streams, which will yield the required funding necessary to finance PIC/S' projects.

V. PATH FORWARD

The successful implementation of the Road Map will enable PIC/S to become a stronger, efficient, and effective global leader in furthering pharmaceutical quality, inspection, and compliance. At a time where Participating Authorities are subject to budget constraints, the necessity increases to act as "one Team" and share the workload for foreign inspections and training. These activities demonstrate PIC/S' true added value of "international regulatory co-operation."

PIC/S has developed an Action Plan and identified a set of priorities and specific projects for the successful implementation of this Road Map. Over the course of 2018-2020, these activities will be implemented and PIC/S will report on the status and progress in achieving the goals. The full support and help of Members and Participating Organisations on these activities is essential to successfully meet the objectives of the PIC/S Road Map and position PIC/S to carry on its mission now and in the future.

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