Snapshots of IO Practices

Compliance Mechanism

Organisation(s): Pharmaceutical Inspection Co-operation Scheme (PIC/S)

The Snapshots of IO Practices present examples of specific efforts undertaken by an international organisation to work towards more effective international instruments. They aim to highlight examples of practices within the five focus areas of the Partnership of International Organisations for Effective International Rulemaking (IO Partnership), namely the variety and development of international instruments, their implementation, evaluation, ensuring stakeholder engagement, and co-ordination among IOs. The snapshots are submitted by the secretariats of the relevant international organisations implementing the relevant practice. The practices were compiled by the OECD Secretariat and focal points of the IO Partnership (UNCITRAL, OIE, WHO, ISO, WCO, BIPM, and SIECA), with a brief review to ensure consistency and comparability of the information provided within the snapshots. The inclusion of a practice in these snapshots implies no endorsement or assessment of that practice on the part of the OECD Secretariat or the focal points of the IO Partnership.

1	Overview of the Practice	Answers	Comments and intersections
1.1	Organisation	Pharmaceutical Inspection Co-operation Scheme (PIC/S)	
1.2	Area of relevance among the IO partnership focus themes (variety of instruments, implementation, stakeholder engagement, evaluation, co-ordination)	Implementation	
1.3	Name of the Practice	Compliance Mechanism	
1.4	Name of person(s) completing the template	Daniel Brunner (Daniel.Brunner@picscheme.org)	

2	Description of the Practice	Answers	Comments and intersections
2.1	Please describe the practice shortly, providing information on its core features.	PIC/S has a compliance programme covering the assessment and re-assessment of Members and Applicants. This includes a gap analysis as well as a review of the GMP (Good Manufacturing Practice) inspection system against PIC/S requirements. The gap analysis and review is done according to standardised procedures and tools, which include a qualitative review of the documentation and an on-site assessment visit of the country to ensure that policies and procedures, as prescribed by PIC/S, are effectively applied. The compliance is verified against 78 indicators (critical, very important and important). To be considered as equivalent, Members and Applicants must comply with all indicators: https://www.picscheme.org/en/activites-compliance	
2.2	What are the objectives of the practice?	To ensure continued compliance of Members and Applicants with PIC/S requirements, not only when they join but also after their accession. For the frequency of the reassessment, see 2.9.	
2.3	What have been the key results of the practice?	Compliance to PIC/S requirements indicates that Members have an equivalent GMP inspection sytem. This is key to mutual trust, which in turn allows for mutual reliance between Members in line with the PIC/S Guidance on GMP Inspection Reliance. This allows not only to maximise inspectional resources but also to strengthen the protection of public health by ensuring effective, high-quality and comparable GMP inspections for the quality of regulated pharmaceutical products.	

2.4	In what year was the practice introduced?	The assessment of Members is provided in the treaty of 1971, which establishes the Pharmaceutical Inspection Convention. With the exception of Guidelines on Accession, no formal procedures existed until 2000. This is also the year where the reassessment of Members (Joint Reassessment Programme) was introduced.	
2.5	Has the practice been updated/reformed since then? If yes, when and how has it evolved over time?	Yes, the procedures were continuously revised and improved. In 2000, with the introduction of the Joint Reassessment Programme, procedures on the on-site (re)assessments were adopted. In 2005, an audit checklist was introduced containing the (now 78) indicators / requirements that Members and Applicants must meet. An interpretation guide to these indicators was adopted in 2020. A training of auditors was organised in 2014 and recorded. It is mandatory for any auditor to follow the recorded training.	
2.6	What do you consider to be the primary strengths of the practice?	It allows for a fair assessment of both Members and Applicants against the same criteria and according to the same procedures. It forces Members to continuously improve their inspection system. As the professional inspections ensure that medicine are safe for the patients, this is in the interest of public health.	
2.7	What do you consider to be the main challenges faced during the implementation of the practice?	One of the main challenges is that auditors and auditees must have the same understanding of the requirements. This is addressed by the interpretation guide on the audit checklist; the training of auditors (who assess both Members and Applicants); and the introduction of a pre-accession procedure, which allows potential Applicants to get a fair understanding of PIC/S requirements.	

2.8	Does the practice have a formal/normative basis within the organisation or is it conducted informally? Does this basis make the practice mandatory or voluntary? If there is formal basis, please provide the relevant link or documentation.	It is very formal and based on a large number of procedures and documents, which are partly publicly available (see https://picscheme.org/en/accessions-accession). The assessment and re-assessment are mandatory. Exceptions are possible, if a Member has already been assessed under a similar compliance programme and the assessment report is shared with PIC/S.	
2.9	At what frequency is the practice applied? i.e. is it conducted once or on an iterative basis?	An assessment takes place upon receipt of a membership application and must be completed within a 6-year timeframe. A reassessment of a Member is organised every 5-7 years on average, unless there is an important change in the organisation (e.g. restructuring).	
2.10	Is this practice applied systematically, (e.g. with respect to every normative instrument, according to specific criteria or on an ad hoc basis)?	Yes - the practice applies to all Applicants and Members, without exception.	
2.11	Please provide specific details or examples to illustrate the practice (including supporting links and documents).	The assessment and reassessment reports are confidential.	
3	**Design of the Practice**	**Answers**	**Comments and intersections**
3.1	Who designed the practice (e.g. Was it developed internally, in collaboration with other organisations, etc?)	The practice was developed internally in close co-operation with Health Canada, which issued an Evaluation Guide for GMP Regulatory Compliance Programme (this served as a basis for the audit checklist), and the European Medicines Agency (EMA), which has a similar audit programme (Joint Audit Programme).	

3.2	Which stakeholders were engaged with in the design of the practice?	Members and EMA (Partner Organisation) only	
3.3	How long did it take to design the practice?	The practice has been developed over several decades. The bulk of procedures were issued during the period 2000-2005.	
3.4	What resources were needed to design the practice initially (i.e., staff, budget etc.)?	The procedures were developed by Members of the PIC/S Committee; the PIC/S Sub-Committee on Compliance and ad-hoc Working Groups, with the support of the Secretariat. Costs cannot be estimated.	
3.5	What challenges were encountered during the design of the practice and how were they overcome?	The main challenge was to ensure that the PIC/S Compliance Programme remained aligned and equivalent to the EMA Joint Audit Programme and Canada's MRA Compliance Programme. This was addressed by establishing Joint Working Groups or mutual consultation.	The establishment of Joint Working Groups and mutual consultation with Health Canada and the EMA, to ensure their alignment with the PIC/S Compliance Programme, represents an intersection between stakeholder engagement (WG3), the development of international instruments (WG2), and co-ordination among IOs (WG5 – with respect to the EMA).
3.6	Has the practice been tested before implementation (i.e. pilot phase)? If yes, please describe.	The first assessment dates back to the 1970s. At the time, there was no procedure in place. In other words. the practice preceded the procedures. As a result, testing was not necessary, as the procedures reflected current practice. When needed the procedures were revised to match changes in practice.	

4	Implementation of the Practice		Comments and intersections
4.1	Which units are responsible for implementing the practice within your IO?	The Sub-Committee on Compliance (SCC) – see https://picscheme.org/en/activites-compliance	
4.2	Are IO members involved in implementing the practice? If so, how?	Yes. Auditors are provided by Members.	
4.3	Are external actors beyond the organisation or its membership involved in implementing the practice? If so, how?	No.	
4.4	Which resources are needed to implement the practice (e.g., staff and budget)?	The costs for hosting an assessment or reassement visit by an Audit Team are borne by the auditee. This covers normally the flight tickets to the auditee's country, internal flights and transportation as well as accommodation and food for approximately 3-4 auditors on average. The costs for the auditors to carry out the audit (i.e. the related working hours for the audit, the travelling time, etc.) are taken over by the Members (each Member pays for the time that his/her auditor is devoting to the audit).	
5	**Outputs and Evaluation of the Practice**	**Answers**	**Comments and intersections**
5.1	Has the practice been evaluated or reviewed?	The practice is continuously monitored by the Sub-Committee on Compliance (SCC), which also addresses issues arising during an audit. The PIC/S Committee reviews and adopts the audit reports, the amendments to the procedures, the work of the SCC, etc.	

5.2	If yes, who carried out the evaluation (please specify whether it was done internally or externally)	The internal review is done mainly be the SCC in line with its mandate, see https://picscheme.org/en/activites-compliance Due to the confidentiality of audit reports, an external evaluation of the PIC/S Compliance Programme is impossible.	
5.3	If yes, please describe the evaluation methodology? (e.g. were any quantitative or qualitative indicators/criteria used to measure/assess the outcomes of the practice?).	The internal review is mainly based on the 78 indicators (requirements) of the audit checklist and whether the auditee has provided the necessary evidence that an indicator is met. If an indicator is not met or partially met, the auditee must provide a Corrective and Preventative Action Plan (CAPA) to address the identified gap. The CAPA is again assessed by the Audit Team and the SCC. There is no systematic review of the PIC/S Compliance Programme as such.	
5.4	If yes, what were the conclusions of the evaluation,and has the practice evolved subsequently? If possible, please attach related documents or provide a link.	N/A	
6	**Additional comments and information**	**Answers**	**Comments and intersections**
6.1	Is there any more information or documentation that would be valuable to share in relation to the practice (e.g. links, reports, meeting minutes, supporting documents)?	No.	
	Sources		