Snapshots of IO Practices

Guidelines on Professional Organisations

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)	Stakeholder Engagement	
1.3	Name of the Practice	Guidelines on Professional Organisations	
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.	The Guidelines on Professional Organisations describe how to co-operate with these organisations, notably when organising joint training events (for regulators and industry). The Guidelines are not publicly available but can be requested from the Secretariat (info@picscheme.org).	The application of the Guidelines on Professional Organisations to the conduct of joint training events represents an intersection between stakeholder engagement (WG3) and the implementation of international instruments (WG2). In particular, this involves the use of stakeholder engagement tools for the purpose of capacity-building exercises – an assistance mechanism, in the typology of the Compendium.
2.2	What are the objectives of the practice?	To facilitate the co-operation with other organisations in the field of pharmaceutical manufacturing, which are important to PIC/S and which can significantly contribute to PIC/S' goals.	
2.3	What have been the key results of the practice?	To avoid the duplication of activities in the same field, to facilitate synergies with other players and to increase PIC/S' visibility.	
2.4	In what year was the practice introduced?	2013	
2.5	Has the practice been updated/reformed since then? If yes, when and how has it evolved over time?	No	

2.6	What do you consider to be the primary strengths of the practice?	It has allowed PIC/S to co-host significant events, which PIC/S would not have been able to organise on its own, mainly due to resource constraints and logistical reasons. PIC/S is an organisation for regulators only while professional associations are for industry. Joint training events allow to reach out to both audiences and avoid unnecessary duplications.	
2.7	What do you consider to be the main challenges faced during the implementation of the practice?	Considering that the events allow to train jointly industry and regulators, the main issue is the potential risk that industry influences regulators regarding e.g. standards which are to benefit of patients, the outcome of inspections, etc. When attending such events, inspectors follow their national rules on conflict of interests. Such rules are not harmonised and there can be differences in how to avoid conflict of interest. However, they all provide minimum rules, which are verified by PIC/S during the assessment of new Members and the reassessment of existing Members (see PIC/S IO Practice on Implementation). The potential risk of conflict of interests is in any case limited in PIC/S due to the fact that industry is not represented at all in PIC/S Sub-Committees and Working Groups, which elaborate GMP guidance. Industry is only consulted, once PIC/S Members, representing Regulatory Authorities, have reached a consensus on draft standards. As a result, it is more difficult for industry to influence the initial drafting phase, which is the most critical in the development of standards.	
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?	The practice is based on non-binding guidelines.	

	If there is formal basis, please provide the relevant link or documentation.		
2.9	At what frequency is the practice applied? i.e. is it conducted once or on an iterative basis?	The practice is applied , when a request for co-operation is received by PIC/S. The frequency is irregular and depends on PIC/S' priorities in terms of training, e.g. when a significant change is made to GMP rules, there is usually a need to organise training. While PIC/S GMP rules are continuously revised, most changes are made to adapt rules to technological development. Significant changes to the PIC/S GMP Guide take place every 5-10 years on average. The last joint training took place in 2015: at the time it was considered that in order to improve the compliance of industry to PIC/S GMP requirements on Active Pharmaceutical Ingredients (API), it was necessary to organise joint training for industry and regulators in countries, which are the main producers of API, notably China and India. This was financially supported by the European Commission (EC). Currently, the PIC/S is revising, together with EMA and WHO, its Annex 1 to the GMP Guide on sterile manufacturing. Once the revision has been completed, it is expected that training will have to be organised, possibly jointly with industry.	
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)?	The practice is applied systematically when an occasion arrises.	

2.11	Please provide specific details or examples to illustrate the practice (including supporting links and documents).	PIC/S has developed an International Training Programme in the field of Active Pharmaceutical Ingredients (API ITP) and organised Training Courses, open to regulators and industry, jointly with the Parenteral Drug Association (PDA), a professional industry organisation in the field of pharmaceuticals. In 2015, four training courses were successfully organised with the financial support of the European Commission. The courses took place in: - Korea (Republic of) on 22-23 January 2015; - Brazil on 10-12 February 2015; - India on 14-18 September 2015; - China on 23-24 November 2015. The success and impact of the trainings largely exceeded expectations, particularly in terms of participants (over 600 participants). The training courses also took place in two key regions for API manufacturing (India and China), which are not Members of PIC/S.	The development and delivery of the International Training Programme in the field of Active Pharmaceutical Ingredients (API ITP), in concert with the Parenteral Drug Association (PDA), illustrates an intersection between stakeholder engagement (WG3), implementation (WG2), and co-ordination across international organisations (WG5). The joint ITP conducted in concert with the PDA, and on the basis of material support of the European Commission, representing a dual form of co-ordination which encompasses both co-operation in the implementation of instruments (joint programmes on the basis of shared strengths – i.e. the overarching, practical knowledge of PIC/S and the targeted technical expertise of the PDA) and in the provision of assistance (pooling of financial resources with the European Commission).
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 Guidelines were developed internally by the PIC/S Committee.	
3.2	Which stakeholders were engaged with in the design of the practice?	None.	

3.3	How long did it take to design the practice?	Less than 1 year.	
3.4	What resources were needed to design the practice initially (i.e., staff, budget etc.)?	The Secretariat prepared a first draft, which was then reviewed by Members. The resources involved were minimal.	The involvement of PIC/S Members in the production and refinement of the Guidelines on Professional Organisations illustrates an intersection between the development of international instruments (WG1) and stakeholder engagement (WG3), and underlines how organisations can work to strengthen the interface between IOs and their constituents.
3.5	What challenges were encountered during the design of the practice and how were they overcome?	None	
3.6	Has the practice been tested before implementation (i.e. pilot phase)? If yes, please describe.	A number of events, organised jointly with professional organisations, took place before the guidelines were adopted. In other terms: the guidelines emerged from living practice.	
4	**Implementation of the Practice**		**Comments and intersections**
4.1	Which units are responsible for implementing the practice within your IO?	It is up to the PIC/S Committee to implement the Guidelines.	

4.2	Are IO members involved in implementing the practice? If so, how?	Yes. Training events organised by PIC/S are hosted by PIC/S Members, involve experts from PIC/S Members as "trainors" (speakers or workshop co-ordinators), and have PIC/S inspectors as audience. The same is valid for training events co-hosted with professional organisations; the only difference is that responsibilities are shared in terms of organisation and the audience includes both regulators and industry.	
4.3	Are external actors beyond the organisation or its membership involved in implementing the practice? If so, how?	Yes, professional organisations which co-organise events with PIC/S (professional organisations are defined as not-for-profit organisations consisting of professionals active in specific fields of pharmaceutical manufacturing).	See the intersection identified in 2.1.
4.4	Which resources are needed to implement the practice (e.g., staff and budget)?	For every event, organised jointly with a professional organisation, a non-binding agreement is negotiated. This involves mainly the Sub-Committee on Training (SCT) as well as the Secretariat.	
5	**Outputs and Evaluation of the Practice**	**Answers**	**Comments and intersections**
5.1	Has the practice been evaluated or reviewed?	Yes, the practice has been evaluated internally.	

5.2	If yes, who carried out the evaluation (please specify whether it was done internally or externally)	The review of the series of joint training events, organised in 2015, has been done by the PIC/S Sub-Committee on Training as well as the PIC/S Committee, which have come to the conclusion that the organisation of joint events with professional associations has been a successful tool but is resource-intensive. Without external financial support, e.g. by donors, it is difficult for PIC/S to deliver in terms of resources. The Guidelines as such have not been reviewed.	
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?).	N/A	
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		