

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Mutual Recognition Agreements and Reliance in the Regulation of Medicines
Information Gathering Session

AGENDA

Friday, 7 June 2019

4:30pm Irish Standard Time/BST, 5:30pm CEST, 11:30am EDT, 9:30am MDT, 8:30am PDT

Please contact Kelly Choi (kchoi@nas.edu) to register for this meeting

4:30pm IST

OPENING REMARKS

Alastair Wood, Committee Chair

COMMITTEE SELF-INTRODUCTIONS (in this order)

- David Beier
- Katherine Bond
- Martha Brumfield
- Gavin Huntley-Fenner
- Others TBC

4:40 pm

OPENING REMARKS

Anne Hayes, PIC/S Deputy Chair

John Lynch, Director of Compliance, Health Products Regulatory Authority (Ireland)

4:55 pm

CLARIFYING POINTS & DISCUSSION BASED ON GUIDING QUESTIONS

- Briefly describe the work, structure, membership criteria, and membership of PIC/S
 - What is the role of PIC today?
 - Can you explain the role of PIC/S in enhancing recognition and reliance among NRAs of similar maturity?
 - Can you describe the PIC/S Rapid Alert System?
 - Are there other formal or informal activities of PIC/S that could help diminish public health risks and facilitate MRAs?
- Have you seen any informal practices of PIC/S members that have led to improved efficiencies?
- What sorts of challenges and opportunities have you noticed that national medicines regulatory authorities face when implementing mutual recognition agreements or enhancing reliance on each other's work?
- Given that "PIC/S is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal

products for human or veterinary use," *if something is agreed upon in PIC/S, how sure can one be that this will be implemented in all PIC/S member countries?*

- Can you describe how you verify that the inspectorates match the criteria, including inspectorate's competencies and functionality to join PIC/S? How your assessment is harmonized with WHO Global Benchmarking Tool (GBT) and would inspectorates included in PIC/S be automatically WHO level 4 maturity?
- PIC/S membership is rather diverse – it has inside ICH founding (US FDA, European Commission (EMA) and MHLW/PMDA from Japan) and standing (Health Canada and Swissmedic) regulatory members who implement all ICH standards and also those who may be either regulatory members (such as ANVISA/Brazil, and NMPA/China) or regulatory observers (such as COFEPRIS/Mexico, NPRA/Malaysia, SHPRA/South Africa etc.) who do not implement all ICH standards. And several PIC/S members such as Thailand and Argentina are not among any category of ICH members, including observers.

Given this diversity:

- Among PIC/S members, there are regulators who follow all ICH standards, some ICH standards and there are those who are not associated with ICH and likely do not follow any ICH standards. How do you think this situation is affecting collaboration and mutual recognition amongst PIC/S members?

5:30pm

Adjourn

PIC & PIC/S

The Pharmaceutical Inspection Co-operation Scheme (PIC/S)— informal agreement among health authorities— was established in 1995 as an extension to the Pharmaceutical Inspection Convention (PIC) of 1970—a formal treaty among countries, with restricted membership. They function together.

PIC/S is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. PIC/S presently comprises [52 Participating Authorities](#) coming from all over the world (Europe, Africa, America, Asia and Australasia).

PIC/S aims at harmonising inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to inspectors. It also aims at facilitating co-operation and networking between competent authorities, regional and international organisations, thus increasing mutual confidence. This is reflected in PIC/S' mission which is ***to lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products.***

This is to be achieved by developing and promoting harmonised GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing (and reassessing) inspectorates and facilitating the co-operation and networking for competent authorities and international organisations.