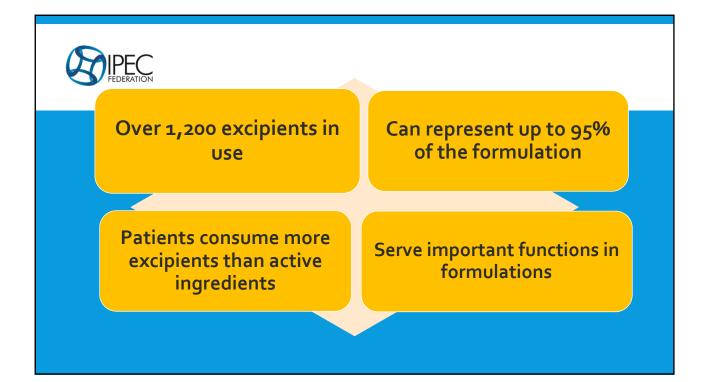
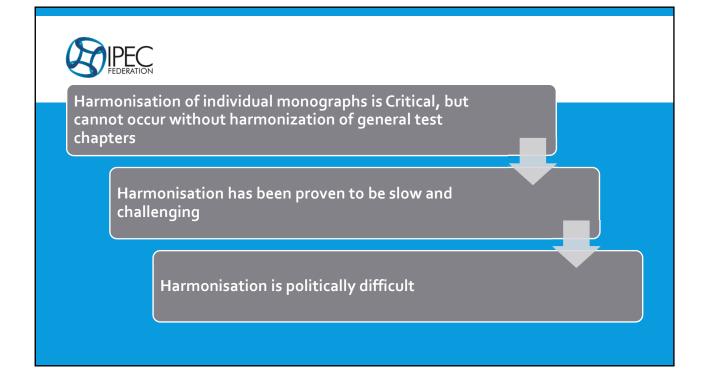
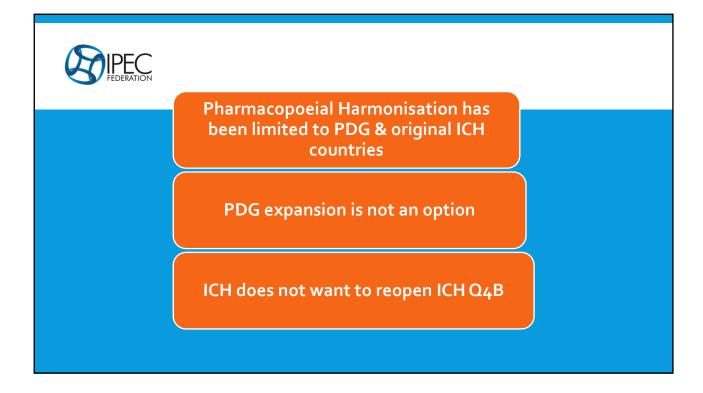
INDUSTRY PERSPECTIVE – PHARMACOPOEIAL EVOLUTION

Janeen Skutnik Wilkinson IMWP February 2020







RISKS???

Is there a true risk to patients (quality & safety) from EU or Japan visiting the USA, and then taking a medicine that was tested only to the USP requirement (or vice-versa)?

• Is there a risk on that basis alone?

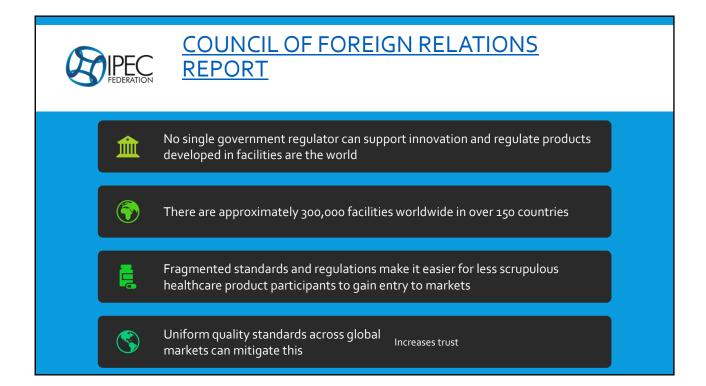
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BENEFITS OF A NEW APPROACH

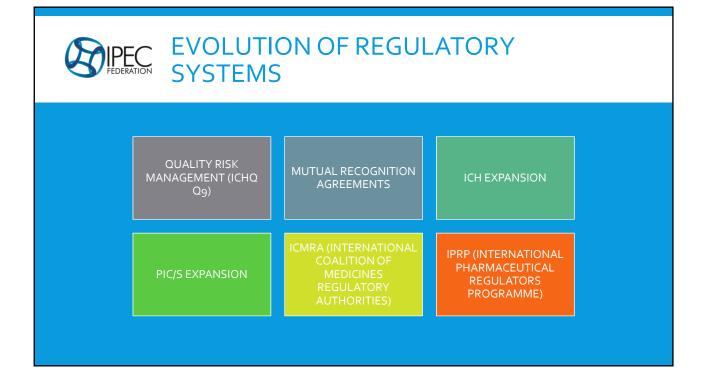
- Provides industry, regulators and patients with a single standard
- Coordination of resources (regulators/pharmacopoeias/industry)
- Clarity and consistency in quality testing
- Supports global filings and inspections

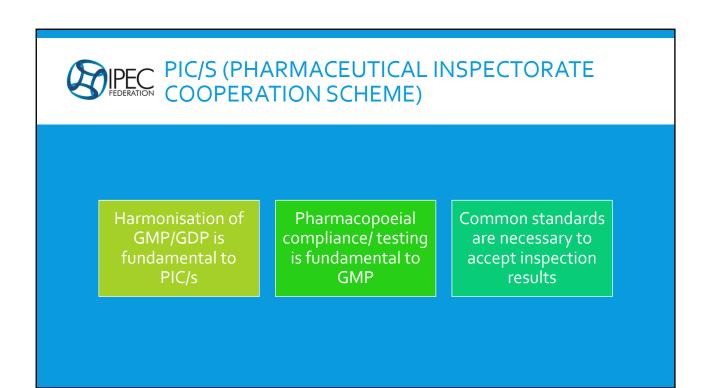
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- Supports the complex supply chain
- Facilitates the procurement process



FUNCTIONAL EQUIVALENCE		
	What is it?	 Performs the same function and provides the same utility
	How is it used?	• Allows recognition of standards where they are focused on public health, safety, quality
	Opportunities	 All compendia are focused on public health and safety







WHAT'S NEXT?

Industry supports / encourages establishing a process for engagement with the global pharmacopoeias to continue collaboration and discussions

Addition of Functional Equivalence of Pharmacopoeias into the strategic framework

