



**Asia-Pacific
Economic Cooperation**

2019/CSOM/014app09

Agenda Item: 3

Appendix 9 - LSIF RHSC KPI Infographic: Regulatory Convergence of Drug & Vaccine Approvals

Purpose: Information
Submitted by: CTI Chair



**Concluding Senior Officials' Meeting
Singapore
7 December 2019**

Regulatory Convergence of Drug & Vaccine Approvals

How does regulatory convergence benefit our economies?



Protects people's safety

When we take advantage of testing, inspections, and reviews already done by high-performing regulators around the region, we can efficiently ensure approved products are both effective and safe, and work together to watch for safety issues in our collective population.



Attracts investment

When we shorten burdensome procedures and adopt best practices by trusting the processes of high-performing regulators, we can reduce uncertainty and delays so that both local and international firms find it easier to do business in our economies, invest their capital, and create jobs.



Makes products available

When we leverage the assessment work already done by high-performing regulators on a particular life-saving product, we can approve that product more quickly and ensure it is readily available on the market to those who need it.



Prevents corruption

When we avoid duplicate inspections and lengthy approval procedures, we can reduce the time it takes to respond to an application, so we prevent opportunities for corrupt or dishonest behavior.



Saves public resources

When we tap into the expertise and work of other high-performing regulators around the region, we can avoid unnecessary duplication and limit wasteful spending so we save our precious public health resources for use elsewhere.



Improves global standing

When we share the load with other regulators and join international initiatives, we show our willingness to cooperate and support best practices, which strengthen the global community and enable investment in our economies.



Example: Good Manufacturing Practices (GMP) Certificates

To certify a firm's compliance with GMP, usually a team of regulators must travel internationally to the economy where the manufacturing is located and stay on-site for as many as 14 days in some economies to conduct facility inspections. Sometimes the assessment may require multiple trips. But when we recognize a GMP certificate from another regulator we trust, we can ensure inspection efforts are not duplicated unnecessarily, which saves time and money and allows us to focus efforts on facilities of concern.

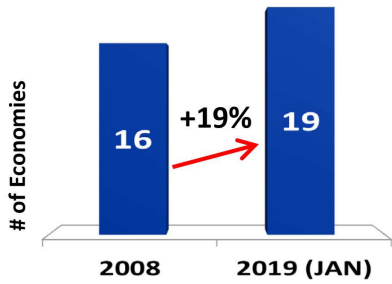
About the APEC LSIF Regulatory Harmonization Steering Committee

Since 2008, the Regulatory Harmonization Steering Committee (RHSC), under the APEC Life Sciences Innovation Forum (LSIF), has gathered regulatory authorities, industry, and academia to support regulatory convergence in APEC—a voluntary process whereby the regulatory requirements across economies become more aligned over time as authorities adopt internationally recognized technical guidance, standards and scientific principles, and common or similar practices and procedures. The RHSC is chaired by Japan and the United States. This survey is conducted annually by the APEC Harmonization Center (AHC) with support from the APEC LSIF Secretariat.

Regulatory Convergence of Drug & Vaccine Approvals

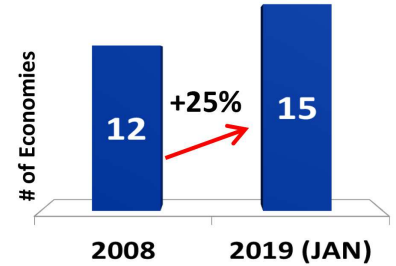
How are we progressing towards our objective to achieve the maximum feasible level of regulatory convergence by 2020?

Engaging in Information Sharing

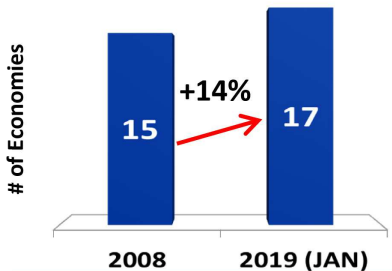


Information sharing and confidentiality commitments help build trust among regulators, strengthening the partnerships required to achieve regulatory convergence.

Establishing Confidentiality Commitments

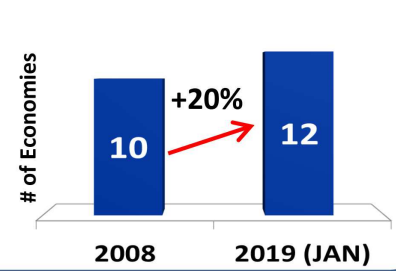


Sharing Good Manufacturing Practices (GMP) Certificates

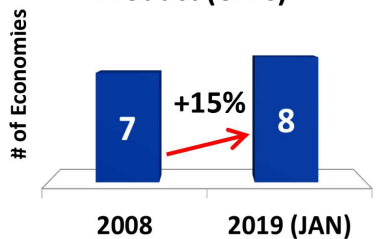


Acceptance of others' GMP certificates and participation in MRAs require real, practical collaboration. Increases in these over time are the hallmarks of convergence.

Establishing Mutual Recognition Agreements (MRAs)

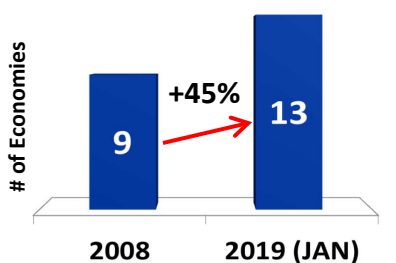


Minimizing Requirements for Certificates of Pharmaceutical Product (CPPs)

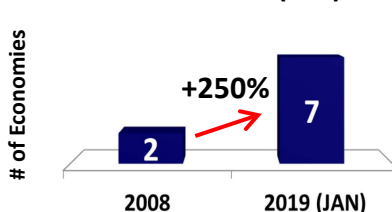


Streamlining requirements for CPPs and allowing a single license to cover multiple sites are other common practices that when widely adopted indicate convergence.

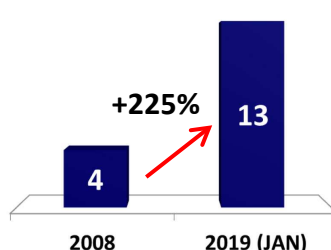
Allowing Multiple Sites in a Single License



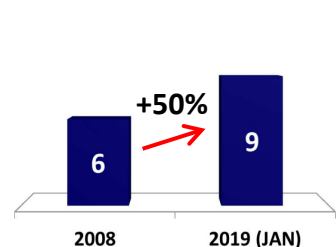
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)



Pharmaceutical Inspection Cooperation Scheme (PIC/S)



International Pharmaceutical Regulators Programme (IPRP)



Joining regulatory convergence initiatives builds confidence and trust among regulators and enhances the necessary capacity to undertake regulatory convergence. They are the foundations to achieving our objective.

Note: Data illustrated above for drugs and vaccines only. Medical devices forthcoming.

About the APEC Training Centers of Excellence for Regulatory Science

Beginning in 2012, the APEC LSIF RHSC designed Training Centers of Excellence for Regulatory Science as a sustainable model for the continued training efforts needed to facilitate regulatory convergence by 2020 and beyond. Centers of Excellence and their workshops are developed and implemented by academia, regulators, industry, and science organizations. In 2019, there are 12 Centers of Excellence across 7 APEC economies hosting 23 workshops, which will train hundreds of regulators.