Regulatory Agility During and After COVID-19

10th APAC Regulatory Affairs Session
13 April 2021

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CoRE
Centre of Regulatory Excellence
@ Duke-NUS Medical School

Scope

- Enabling Good Regulation in the Asia-Pacific
- Pre-COVID-19 Regulatory Trends
- Regulatory Agility during COVID-19
- Regulatory Trends to 2030
- Advancing Regulatory Agility & Innovation

Good Regulation is an Enabler

Regulation impacts global & national socio-economic-political environment

Regulation as an enabler

- Health Products
- Health Services
- Industries that impact health

Promotes access to:

- Essential medicines, medical devices and vaccines
- High quality health services
- Health-promoting environment

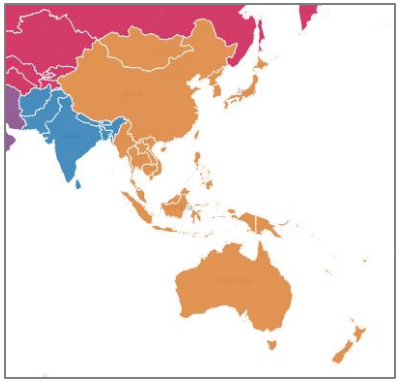
Health Systems Benefits & Outcomes

Economic Benefits & Outcomes

Ensuring sustainable development

Asia-Pacific Regulatory Landscape

Three Key Challenges



1. Insufficient regulatory knowledge and capacity

2. Fragmented national regulatory requirements

3. Lack of regulatory science and policy innovation

Lack of regulatory professional capability and know-how affects both government and industry

Lim JCW. *Strengthening Health Products Regulatory Systems to Enhance Access to Quality Health Products in the Asia-Pacific.* Therapeutic Innovation & Regulatory Science 2018, Vol. 52(6) 751-754. DOI: 10.1177/2168479018769285.

Asia-Pacific Regulatory Landscape

Constraints to Regulatory Science and Policy Innovation

1. Lack of **appropriate incentives** to take informed risks in innovating or implementing new regulatory paradigms

2. Lack of **exposure** to newer regulatory systems/policy initiatives to appreciate what this requires within local contexts

3. Lack of **strategy and advocacy skills** to propose appropriate models for implementation to higher or other levels of government

Asia-Pacific Regulatory Enablers

1. Adopt **risk-based approaches** to help overcome resource limitations

2. Promote **regulatory cooperation**, recognition and reliance to facilitate convergence and harmonisation

3. Develop **regional platforms** for engagement, collaboration and capacity building

Lim JCW, Chan CL, Green A. *Global Challenges in Regulatory Capacity and Capability Building: Extrapolating Lessons Learned From the HSA*. Clinical Pharmacology & Therapeutics, Advance on line publication, November 20, 2018. DOI: 10.1002/cpt.1253

Global Trends impacting Regulatory Science since 2010

1. Expanding digital health opportunities due to rapidly advancing Infocomm Technology (ICT), e.g. AI, block-chain

2. New and enhanced treatment modalities and platform technologies, e.g. innovative & advanced therapies, vaccines

3. Precision medicine and personalised healthcare

4. Demand for responsive, on-demand healthcare

5. Accelerating health products access through multilateral cooperation

6. **Increasing importance of adopting agile approaches**

Pre-COVID-19 Regulatory Trends

1. Steady development of **regulatory convergence initiatives** supporting regulatory agility and regulatory science & policy development

2. Strengthening of **WHO initiatives** in cooperation, convergence & Good Reliance Practice

3. **Pan-global organisations**, e.g. ICMRA

4. **Regional initiatives**, e.g. APEC LSIF RHSC* with KPI identification to track convergence progress, ASEAN harmonisation efforts

   * Life Sciences Innovation Forum Regional Harmonisation Steering Committee

5. **Cross-regional initiatives**, e.g. ACCESS Consortium (Australia, Canada, Switzerland, Singapore, UK)

6. **Academic capacity building and think tank centres**, e.g. APEC RHSC COEs*, PMDA Asia Training Center, Duke-NUS CoRE

   * Centers of Excellence

Regulatory Agility during COVID-19

- National Regulatory Authorities (NRAs) facilitated access to essential COVID-19 health products through **effective, agile regulation**

  Mak TK, Lim JCW, Thanaphollert P, Mahlangu GN, Cooke E, Lumpkin MM. ***Global regulatory agility during covid-19 and other health emergencies****. BMJ. 2020*

- **Regulatory Agility** refers to adoption of *risk-based, context-driven approaches* and *regulatory cooperation* predicated on *sound scientific evidence and information*

- Involves non-traditional approaches to robust regulatory decision-making while not compromising safety, quality and efficacy

- "Agility" is preferable to "flexibility" which may connote unsafe cutting of corners

Regulatory Agility during COVID-19

- The pandemic has advanced
  (a) ***regulatory coordination and information exchange***
  (b) use of ***reliance, referencing*** **and** ***convergence***

- Speedy vaccine approval facilitated by
  (a) ***parallel development*** processes
  (b) ***rolling data reviews***
  (c) ***emergency use authorisations*** and ***conditional approvals***
  (d) on-going adverse event and ***real world monitoring***

- Use of *regular virtual & online meetings* by WHO, ICMRA, regional regulatory groupings and NRAs

The COVID-19 Crisis as an Opportunity to Strengthen Global Regulatory Coordination for Sustained Enhanced Access to Diagnostics and Therapeutics. Clinical and Translational Science. 13 Dec 2020. DOI: 10.1111/cts.12954

Regulatory Agility during COVID-19

- *Emergency use authorisation and conditional approval approaches* for new diagnostics, therapeutics and vaccines while awaiting more data for full approval

  https://www.duke-nus.edu.sg/core/think-tank/core-regulatory-perspective/making-sense-of-emergency-use-authorisations-(euas)-for-covid-19-vaccines-and-considerations-for-the-road-ahead

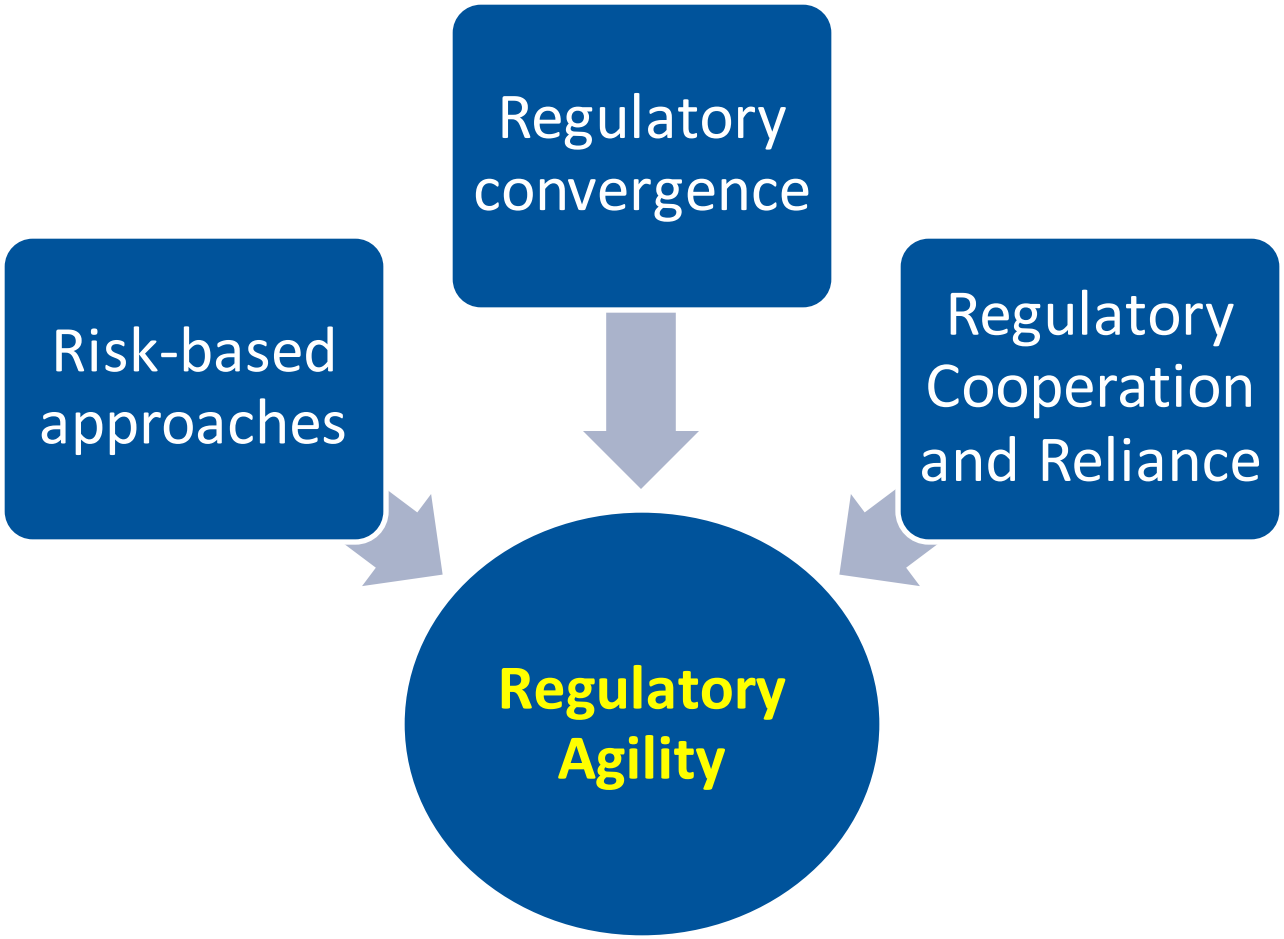
- Preliminary guidelines on *updating currently available vaccines* for *new SARS-CoV-2 variants* by NRAs (e.g. US FDA, EMA) and regulatory consortia (e.g. ACCESS)

  https://www.duke-nus.edu.sg/core/think-tank/core-regulatory-perspective/regulatory-agility-and-global-coordination-to-meet-the-challenge-of-covid-19-variants-preparing-for-the-next-generation-vaccines

Regulatory agility should become part of **regulatory "new normal"** to support innovation and future public health challenges

The COVID-19 Crisis as an Opportunity to Strengthen Global Regulatory Coordination for Sustained Enhanced Access to Diagnostics and Therapeutics. Clinical and Translational Science. 13 Dec 2020. DOI: 10.1111/cts.12954

Building Regulatory Agility

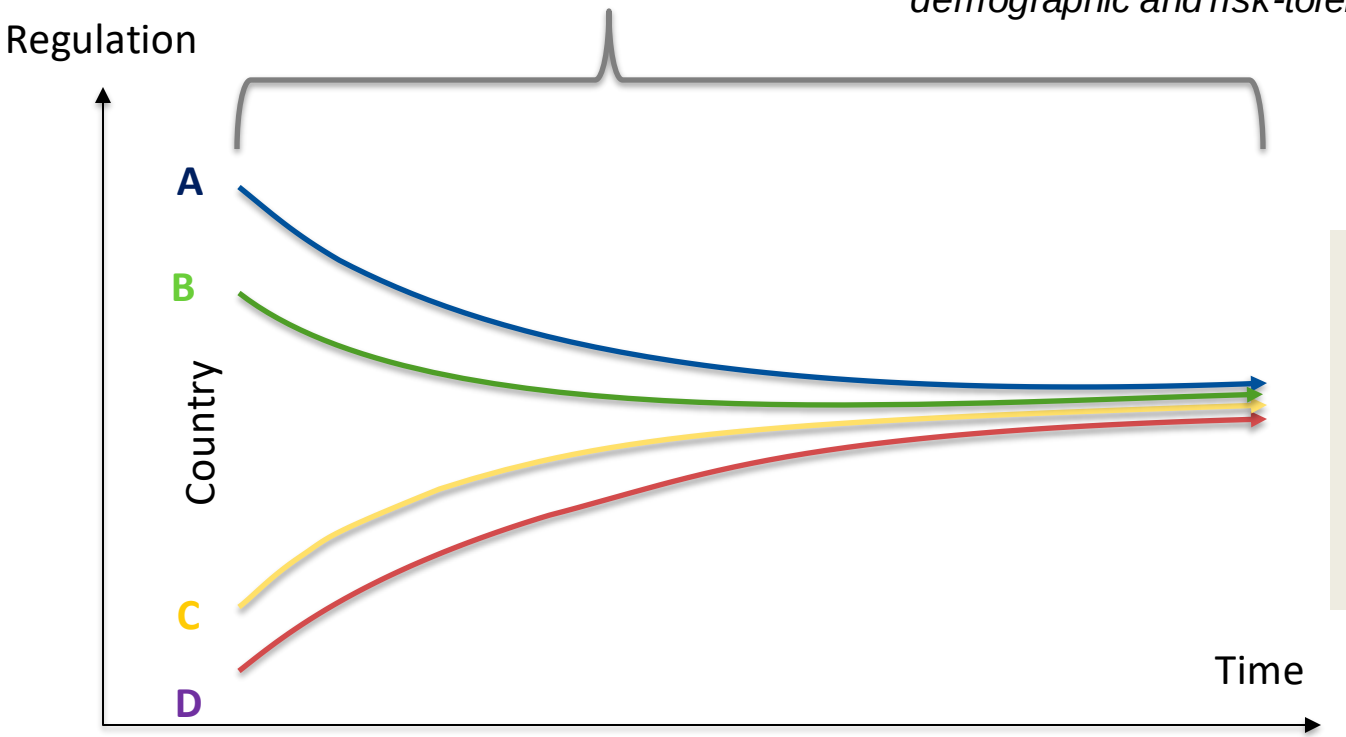


Timely Patient Access to Health Products

Convergence supports Regulatory Agility

Convergence =

*Regulatory requirements become **more aligned over time** with adoption of internationally recognised technical guidance documents, standards and scientific principles, while taking into account distinctive national legislative, demographic and risk-tolerance factors*



World Health Organization

APEC
Asia-Pacific Economic Cooperation

Regulatory Harmonization Steering Committee
APEC
Life Sciences Innovation Forum

Duke-NUS Centre of Regulatory Excellence

Enhance regional health systems & policy

Strengthen regulatory systems for health-related products in Asia-Pacific

Think Tank

Promote thought leadership and policy innovation

Advisory

Leverage expertise and networks to support stakeholders

Education

Enhance capabilities and competencies of regulatory professionals

Networking & Collaboration

Provide a neutral academic platform for engaging and connecting a diverse range of stakeholders

CoRE's Strategic Focus Areas Based on Regulatory Trends to 2030

1. **Patient Engagement** – promote patient involvement in Asia-Pacific health systems, e.g. Coalition to Advance Patient Engagement (CAPE)
2. **Digital Health** – define scope, domains and relevant regulatory frameworks
3. **Innovative Therapies** – enhance coordinated regulatory frameworks and capacity
4. **MedTech** – enhance regulatory frameworks and capacity
5. **Innovative Clinical Trials** – clarify regulatory positions, e.g. RWE, digital endpoints, interoperability, security
6. **Outbreak Vaccines, Therapeutics & Diagnostics** – promote regulatory agility & robust decision frameworks

Digital Health

(as an Example)

- Digital technologies are essential component and enabler of sustainable health systems and universal health coverage
- WHO promotes Infocomm Technology in health development through research, guidelines, capacity, policy and advocacy support
- Wide scope and issues, e.g. AI, Mobile Health, Big Data Analytics, RWE, Blockchain, Cybersecurity, Interoperability, Software as Medical Device, Electronic Health Records…….
- All have regulatory implications and challenges

Due to multi-stakeholder interest and lack of legacy regulatory frameworks, opportunity exists for coordinated solutions

Digital Health Lessons from COVID-19

- **Enhance data inter-operability** – diverse data capture formats, standards and platforms hinder scientific insights
- **Strengthen data confidentiality and security to build trust** – security and confidentiality are intrinsically linked
- **Promote equal access to health innovation** – avoid accentuating digital divide in public health emergencies
- **Build trust through transparency and good communication** – to blunt fake news and disinformation

https://futureproofinghealthcare.com/experts-think/digital-health-covid-19-pandemic-could-be-kickstarter-we-needed

These impact and are impacted by regulatory frameworks and agility

7 Pre-requisites for Regulatory Agility

1. **Trust -** fundamental for adoption of *innovative therapies (e.g. vaccines)*, assuring *patient data confidentiality*, and advancing *personalised digital health & telemonitoring solutions*

2. **Transparency** – data capture and use

3. **Training** – level up regulatory capabilities for therapeutic and policy innovations

4. **Testing** – regulatory sandboxes, e.g. telemedicine

5. **Trans-national bodies** – for coordination, convergence and information exchange, e.g. WHO, ICMRA, APEC

6. **Transfer** - cross-jurisdictional frameworks to promote interoperability and data exchange

7. **Timeliness**

Advancing Regulatory Agility & Innovation

To advance regulatory agility and innovation over the next decade:

- **Institute Regulatory Enablers** – risk-based regulation, regulatory cooperation, regulatory stakeholder platforms, capacity building

- **Benchmark** other countries' regulatory frameworks but understand context, e.g. *APAC Personalised Health Index*
  https://futureproofinghealthcare.com/asia-pacific-personalised-health-index

- **Apply COVID-19 Lessons for Agile Regulation** - risk-based, cooperation, sound scientific evidence

- **Commit to Collaborate**

Thank You