

# **An APEC Update: Advancing Regulatory Convergence**

**2012 APEC-AHC-AHWP Joint Workshop  
Medical Device Combination Products  
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Asia-Pacific  
Economic Cooperation

# International Cooperation

- Not an end in itself - essential part of doing business in an interconnected world
- Should contribute to public health and innovation by strengthening efficiency and effectiveness of regulatory authorities, resulting in:
  - More informed, timely, transparent decisions
  - Better use of resources
  - Adoption of best practices, including risk based approaches
  - Reduction in regulatory burden

# Time for Reflection

- Much effort spent on regulatory harmonisation and cooperation, but what have we accomplished to date? Has it been enough?
- What do we mean by convergence, harmonization, equivalence?
- Will working in regional or even hemispheric blocks address challenges regulators and countries face?
- Is there a better way of doing things?

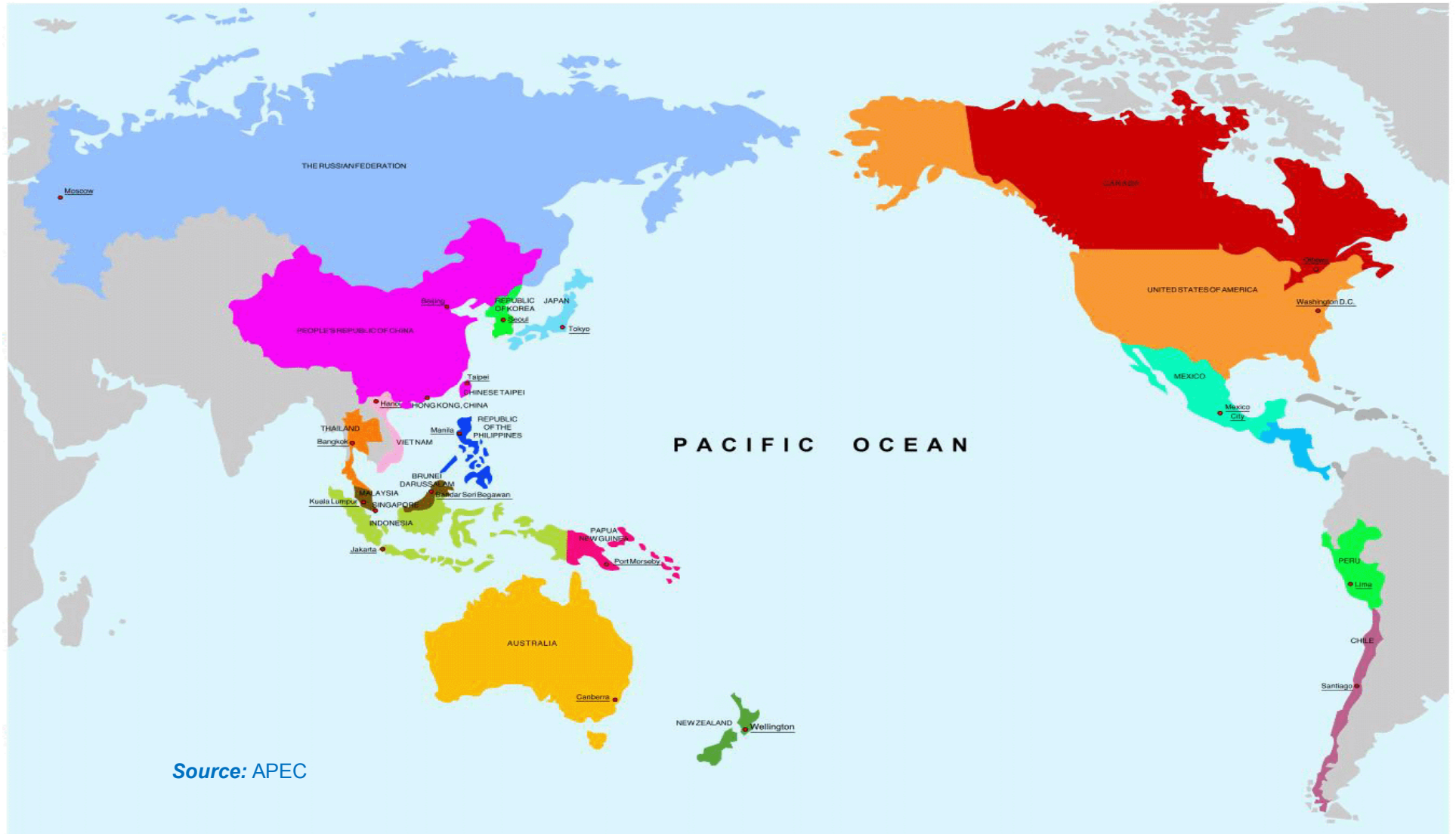
# Elements of an effective approach

- Be clear on *what* you want to achieve, with *who* and *why*
- Establish the business case
- Develop a strategy or roadmap on *how* to achieve desired outcomes
- Be practical: step-wise approach, taking account of what already exists

# An example: APEC

- Asia-Pacific Economic Cooperation (APEC) created in 1989
- 21 member economies account for 40 % of world population, 54% of GDP and 44% of world trade
- Goals: Promote trade, sustainable economic growth and prosperity of member economies through policy alignment and economic **and technical cooperation**
- APEC agenda and annual work plan developed around SOMs culminating in Leaders declaration
- APEC Chair rotates annually (US 2011, Russia 2012, Indonesia 2013)

# APEC MEMBER ECONOMIES



# Life Sciences Innovation Forum

- Created following endorsement by APEC Leaders in 2002
- Recognized importance of *life sciences innovation* in promoting public and economic health
- From outset, harmonization seen as prerequisite to fostering innovation

# Unique role

Unique in that LSIF doesn't ***produce*** harmonized guidances; rather, promotes use of ***existing*** international guidances:

- Ability to access APEC funds to advance projects
- Voluntary basis for engagement: ensures participation of those economies interested and committed to cooperation
- Tripartite structure / complementary roles: government, industry, academia



# Need for change

- While LSIF sponsored workshops aimed at promoting international standards and practices, efforts were not coordinated
- Growing recognition that a different approach was necessary to promote convergence
- Discussions in Peru (2008) led to creation of Regulatory Harmonization Steering Committee (RHSC) and APEC Harmonization Center (AHC) in June 2009

# RHSC Mandate

To promote a more ***strategic, effective*** and ***sustainable*** approach to harmonization by:

- ***Proactively*** identifying and prioritizing projects seen to be of greatest value
- Strengthening linkages with harmonization initiatives, training organizations and other key players to promote ***complementary*** actions and most effective use of resources
- Products of interest: *medical products*

# Members

- Regulators from 10 APEC Economies:  
Canada, China, Chinese Taipei, Japan, Korea,  
Mexico, Peru, Singapore, Thailand, US
- Industry representatives
- Director of APEC Harmonization Center

# APEC Harmonization Center

- APEC-wide resource to enhance and sustain regulatory convergence and capacity building efforts
- Operates under the authority of LSIF, with direction from RHSC and an international advisory board
- Key enabling role in operationalizing RHSC objectives , having hosted numerous international workshops

# Greater Engagement

- RHSC recognized need to ensure engagement with all APEC economies if measures to promote regulatory convergence and cooperation are to be successful
- With this in mind, RHSC recently launched creation of a Regulatory Network
- Members would include authorities responsible for regulation of medical products not currently part of the RHSC
- Members of Network may attend any of RHSC meetings, make proposals and participate in any RHSC projects

# Greater Engagement

- Formation of industry coalitions, representing:
  - Research based pharmaceutical sector
  - Medical Devices sector
  - Generic pharmaceutical sector
  - Biotechnological products sector
- Additional “floating” membership is foreseen to accommodate future needs, for example, in the area of advanced technologies

# Greater Engagement

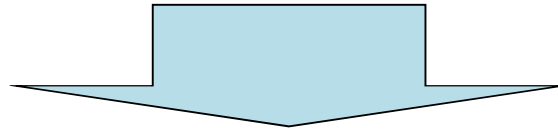
- Establishment of official liaisons with international harmonization initiatives and organizations, including AHWP, ICH, IMDRF, PANDRH, WHO, European Medicines Agency
- Reflects position that APEC should act as a catalyst for international action on issues that demand a global approach

# Strategic Framework

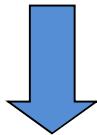
- Framework outlines strategic multi-year approach for achieving greater regulatory convergence by 2020
- Describes guiding principles and general multi-step approach
- Voluntary action: each economy proceeds at own pace
- Includes definition of regulatory convergence
- Includes appendices for pharmaceuticals and medical devices and suggested indicators of success
- Endorsed by APEC Ministers in November 2011



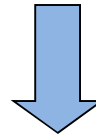
**Strategic Framework**  
Coordinated approach  
to promote regulatory convergence



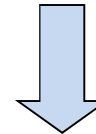
**Priority Work Areas**  
Needs assessment from diagnostic workshops  
and a roadmap for promoting best practices



Project



Project



Project

**Individual projects are part of strategy & contribute to goals**  
**Move away from Ad Hoc/Individual Proposals**

# Priority Work Areas (PWAs)

- Roadmap to be developed by champion economy for each PWA
- Champions/PWAs identified to date:
  - MRCTs (Japan: completed)
  - Supply chain integrity (US: completed)
  - Good Review Practices and **Combination Products** (Chinese Taipei)
  - Biotech Products and Pharmacovigilance (Korea)
  - Cellular Therapies (Singapore)

# Regulatory Convergence

- “Regulatory convergence” represents process whereby regulatory requirements across economies become more aligned over time as a result of the adoption of internationally recognized technical guidances, standards and best practices
- Does not require the harmonization of laws and regulations
- Broader concept than “harmonization”
  - Example: Good Review Practices

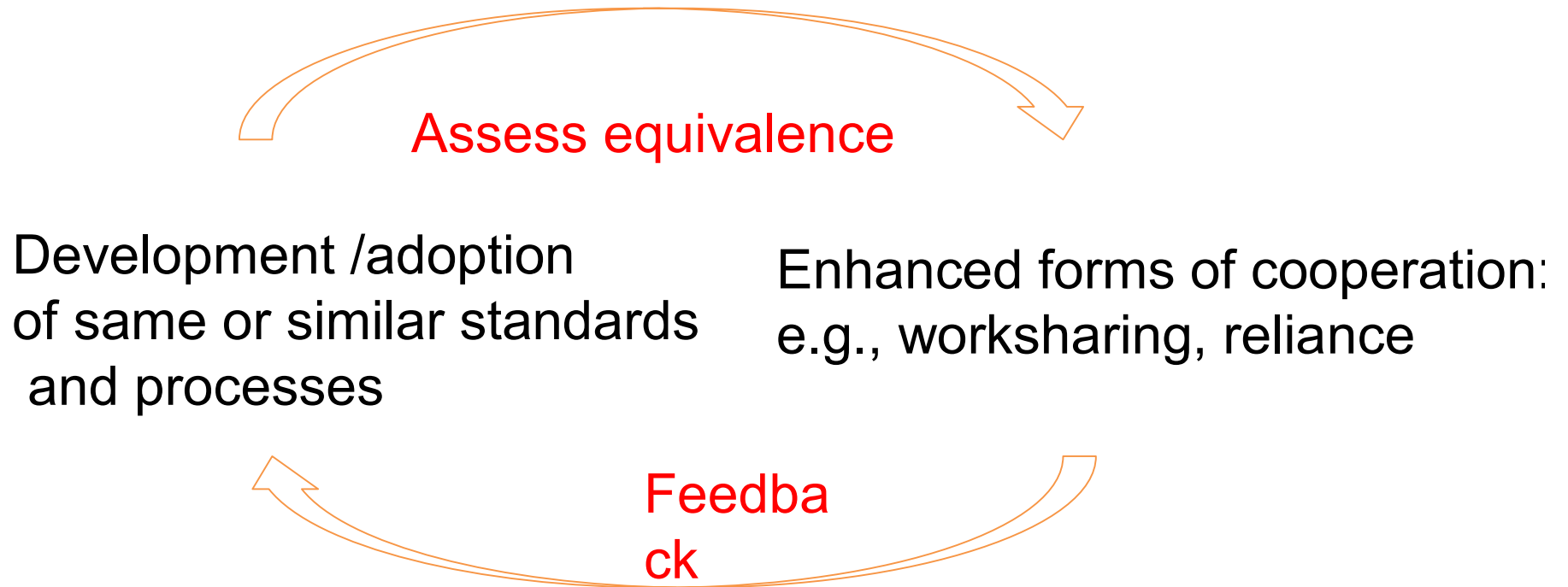
# Harmonization

- “Harmonization” represents the development and adoption of the **same** standard or requirements.
- Harmonization represents an important means of achieving regulatory convergence over time
- Example: regulatory adoption of ICH technical guidances (Step 5 of ICH process)

# Equivalence

- Two or more systems are said to be “equivalent” if, despite differences, they are expected to produce the same outcomes
- Should be established through objective means and documented
- Example: Mutual Recognition Agreements relating to conformity assessment of GMPs

# Regulatory Cooperation – “The Continuum”



Convergence: a dynamic process

Catalysts: workload, globalization, technology, public expectations

# In Summary

- International regulatory cooperation has become an essential part of dealing effectively with the challenges of an increasingly complex and global environment
- Cooperation should lead to tangible, meaningful results
- Despite challenges, some encouraging developments and trends taking place
- Maximum benefit will come from more strategic discussions, planning and action
- APEC serves as a recent model of success