Regional Alignment in Asia Pacific - a Perspective from the Chair of the APEC Regulatory Harmonization Steering Committee (RHSC)

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Context

• Much effort underway at international, regional and economy level to strengthen capacity and efficiency of NRAs in carrying out ability to protect and promote public health

• Question: are such efforts effective as they could be?

• Question: what role is APEC playing in trying to advance such efforts?
APEC region: very active in terms of regulatory harmonization

- Consider: APEC region includes a number of important regional harmonization initiatives, including ASEAN (drugs and devices) and AHWP (devices), PANDRH (drugs)
- Consider: 4/5 of GHTF founding members and 2/3 of ICH parties from APEC economies
- Consider: efforts of individual APEC economies in contributing to development and implementation of harmonized guidelines and standards
Overview of APEC

• Asia-Pacific Economic Cooperation (APEC) created in 1989
• 21 member economies
• Goals: Promote trade, sustainable economic growth and prosperity of member economies through policy alignment and economic and technical cooperation
• Unique forum, operating on basis of
  – Non-binding commitments, open dialogue and equal respect for views of all participants
  – Decisions by consensus
APEC MEMBER ECONOMIES

Source: APEC
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
LSIF an **enabler** of harmonization

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

- Ability to access APEC funds to advance projects
- Voluntary basis for engagement: ensures participation of those economies interested and committed to cooperation
- Linkages to international harmonization initiatives: since 2004 sits on the ICH Global Cooperation Group
- Tripartite structure / complementary roles: government, industry, academia
- To date, sponsored many workshops on ICH and GHTF guidances
However...

Despite progress made, recognition that LSIF has not been used to its full potential in promoting regulatory harmonization and cooperation
Lima, Peru 2008
– an important milestone

Series of recommendations, including two of strategic importance:

– Support for the establishment of the APEC Harmonization Center (AHC)

– Creation of a Regulatory Harmonization Steering Committee (RHSC)
APEC Harmonization Center

• **APEC-wide resource** to enhance and sustain harmonized and capacity building efforts by:
  – conducting research and surveys
  – providing educational programs
  – publishing and web posting
  – establishing networks and exchanges

• Operates under the authority of LSIF, with direction from RHSC and an international advisory board
RHSC: Mandate and Goals

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

- *Proactively* identifying and prioritizing projects seen to be of greatest value

- In partnership with AHC, strengthen 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*, notably drugs and devices
RHSC Members

• Regulators from Canada, China, Chinese Taipei, Japan, Republic of Korea, Peru, Thailand and USA with official observers from Mexico and Singapore

• Industry representatives from drug and medical device sectors

• Director of APEC Harmonization Center
Strategic Framework
Coordinated approach to promote regulatory convergence

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

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

- Workshop as diagnostics
- Act upon recommendations from workshop, including true training sessions aimed at acquiring new skill or knowledge
- Regional vs. individual country approach whenever possible
- Events open to non-APEC economies
- Sustainability, including AHC and annual curriculums
- Make use of available technologies and AHC website to maximize access and reuse of information
An Example: MRCTs

• June 09 and Sept. 10 workshops in Seoul served as a diagnostic of challenges, issues, opportunities
• Led to a series of recommendations on addressing challenges to MRCT
• Recommendations considered by RHSC in developing project proposals leading to concrete, directed actions as part of proposed MRCT roadmap
RHSC Workplan for 2011-2012

- Multi-regional Clinical Trials/Tripartite Initiative
- Good Review Practices and the exchange and use of regulatory information
- GHTF workshops (2 proposals: Japan, US)
- Pharmaceutical quality:
  - supply chain
  - ICH Quality by Design
- [Falsified medical products]
- Pharmacovigilance
- Biosimilars
- Stem cells (prospective harmonization)
- 6th Pan-Asian Regulatory Conference (IFPMA/DIA/AHC), April 2011
Building a Better Harmonization Model

Development (Stds, Guidances)

- ICH WGs

Interface

- GCG
- Reg Forum

Key Enabler:

APEC Harmonization Center + RHSC

+ NRAs: Australia, Brazil, China, Chinese Taipei, India, Korea, Russia, Singapore

APEC Economies and beyond
Summary

• Important new developments within APEC in advancing regulatory harmonization and cooperation in a more strategic, sustainable and effective manner
• Directed towards concrete, complementary actions
• Ultimate goal: contribute to public health and innovation in an increasingly challenging regulatory environment