



Asia-Pacific  
Economic Cooperation

# ICH: GCG Report Life Sciences Innovation Forum

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Sumol Pavittranon PhD  
Dept. of Medical Sciences  
Ministry of Public Health  
Thailand  
APEC RHI

# Background

- Life Sciences Innovation Forum
  - A tripartite mechanism
  - Working to address key health challenges in the APEC region
  - Striving for a more holistic approach to life sciences development

## Timeline

- October 2002: Ministers & Leaders launched LSIF in Los Cabos, Mexico
- November 2004: Ministers & Leaders approve Strategic Plan in Santiago, Chile
- November 2005-present: Strategic Plan implementation phase
- Annual LSIF meeting

# LSIF for harmonization and enhanced regulatory performance include:

- The ability to apply for project funds and seek endorsement from senior officials, ministers and leaders on recommended actions
- The complementary roles played by government, industry and academia
- Linkages to international harmonization initiatives and between the various harmonization efforts within the APEC region
- The APEC principle of voluntary engagement, which ensures the participation of those economies interested and committed to cooperative activities.

# Regulatory authorities, industry, academia effort to:

- Engage key players in identifying strategies, roles, mechanisms and projects of greatest value to the region
- Promote synergies and coordination of effort
- Optimize benefit derived from interactions with international harmonization initiatives
- Develop mechanisms to sustain training and capacity-building work
- Better prioritize annual and longer term plans and projects

# LSIF VII August 3-4, 2009, SINGAPORE Report

- *More than 200 participants*
- *2 days meeting*
- *Host by Min of Public Health, Singapore*
- *Preside by H.E. Khaw Boon Wan, Minister of Health, Singapore*
- *H.E. Suwit Khunkitti, LSIF Chair, Minister of Env. & Nat. Res. Thailand*
- *Preceded by Health Info Technology Meeting*

# Key Judgements for Ministers & Leaders

- ***The Importance of a Multi-Disciplinary Approach to Health and Health Innovations and approaches***
- ***Sustaining and Deploying Health Innovations Effectively***

# LSIF recommends that Ministers:

- Support the review of *the Enablers of Investment Checklist* for enablers of biologics development and deployment that would optimize the sector's performance.
- Reaffirm the central role of regulators in assuring timely access to high quality, safe and effective medical products and support the development of a multi-year strategic plan and projects for achieving regulatory harmonization among APEC member economies.
- Endorse the Terms of Reference and forward work plan of the Regulatory Harmonization Steering Committee.

# LSIF VII Summary

## The Innovation Landscape:

- The Importance of a Multi-Disciplinary Approach
- The Challenge and Promise of Biologics
- The information Technology as a Health Enabler
- The Health Impacts of Environmental Change

# LSIF VII Summary

- The Importance of Detection and Prevention
- Financing for R&D in an economic downturn
- The Value of Health Innovation – Health, Economic Development, and Trade Facilitation
- Regulatory Harmonization ( Mike Ward)

# Next LSIF VII 2010 in Japan



# Seoul, June 09: Important Milestone

- Outcomes:
  - Inauguration of the APEC Harmonization Center (AHC)
  - Creation of a Regulatory Harmonization Steering Committee (RHSC)
  - Successful workshop on MRCTs
  - Series of recommendations on harmonization projects

# LSIF VII Accomplishments

- Gained better understanding of APEC project approval process
- Confirmed RHSC membership
- Finalized RHSC terms of reference
- Reviewed series of project proposals
- Developed Press Release
- Developed recommendations for endorsement by LSIF

# RHSC called upon the LSIF to endorse:

- Terms of Reference for the RHSC
- The development of a strategic plan for the advancement of harmonization and capacity building efforts
- A multi-year proposal from Chinese Taipei on best regulatory practices
- A self-funded AHC-sponsored Biosimilars workshop (held September 16-17, 2009 in conjunction with BIO Korea)
- A project proposal for a workshop on Stem Cells
- The development and submission of a proposal on Multi-regional Clinical Trials in 2010

# Outstanding Actions

- Finalize the AHC guidelines document, the duties of the AHC advisory board and confirm board membership
- Develop and implement training and communication strategies
- Conduct a mapping exercise of existing and planned initiatives and key players in the area of harmonization and capacity building as a prerequisite to adopting a more effective, coordinated approach

# Outstanding Actions (2)

- Establish a permanent secretariat to support the RHSC
- Develop a procedures document that will operationalize the work of the RHSC, to include:
  - Project assessment process and APEC funding approval guide
  - Formation of subcommittees and ad hoc working groups
  - Operations of a permanent secretariat
  - Etc.

# RHSC Membership

- SC chaired by a regulatory authority from an APEC member economy and comprise up to 12 members representing a cross-section of LSIF expertise, including:
  - up to 7 from regulatory authorities (including the Chair)
  - Director of the AHC
  - 4 from industry
- Chair of the LSIF Planning Group serves as special advisor

# Current membership

- Regulators authorities from Canada, China, Chinese Taipei, Republic of Korea, Peru, Thailand, U.S.
- 2 representatives each from pharmaceuticals and device industry
- Director of AHC

