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
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 VIII 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 pre-requisite to adopting a more effective, coordinated approach
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.
• 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