



Asia-Pacific
Economic Cooperation

ICH: GCG Activities in the Life Sciences Innovation Forum

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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 V 2007 Review

- LSIF V: “Developing an Integrated and Innovative Approach to Emerging Health Challenges”
- Adelaide, Australia, April 19-20, 2007
- Developed the five key themes for dialogue between LSIF experts and finance and health Senior Officials
- Recommended the creation of a multidisciplinary study on investment in health and innovation

LSIF V 2007 Review

Five Themes for Dialogue with Senior Officials

- With the continuing challenges in chronic and communicable diseases and rapid ageing, health issues are becoming central to economic and social viability
- There is a need for an integrated approach across many disciplines to address these central health, economic and financial challenges
- Increased, and/or more cost effective, investment in health innovation is likely to be necessary in all economies
- Prevention, early detection and early intervention will require higher priority in all economies
- Building and making effective use of public-private partnerships can contribute to addressing these challenges

LSIF VI August 14-15 2008, Lima, Peru Report

- *Study on the Benefits of Investment in Health Innovations*
- *Enablers of Investment Checklist*
- *Research and Innovation Contribution*
- *Regulatory Harmonization*

LSIF VI – August 14-15 2008, Lima, Peru Report

- Regulatory Harmonization
- Breakout session over two days
- KOREA APEC Harmonization Center (AHC)
- Korean Food and Drug Administration (KFDA) and the Korea Health Industry Development Institute (KHIDI)

LSIF VI – August 14-15 2008, Lima, Peru Report.

- Additional harmonization actions be taken:
 - member economies work towards the adoption of harmonized application and review formats, promoting a common regulatory language that supports the sharing of information, good review practices and the leveraging of regulatory resources.
 - a feasibility study be conducted on the confidential exchange and use of regulatory information.
- APEC support the establishment, as proposed by LSIF, of a regulatory steering committee within the LSIF structure

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 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.

Additional Request

- A senior level QC/QA expert on stem cell products for training in 2010
- Experts for the China funded ICH quality guidelines training meeting in Beijing in December 2008

Thank you for your attentions

