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


- 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
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
• Study on the Benefits of Investment in Health Innovations

• Enablers of Investment Checklist

• Research and Innovation Contribution

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