APEC LSIF Update

by
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The ICH-Global Cooperation Group Meeting
Westin Hotel Michigan Avenue, Chicago, USA
8 November 2005
Outcome

from
The APEC LSIF III Meeting
Sep.05, South Korea
The Meeting

- **Date**: September 8-9, 2005
- **Place**: Gyeongju, Korea
- **Participants**: ~280 from 15 economies
- **Host**: Korean Ministry of Health and Welfare
- **Organizer**: Korea Health Industry Development Institute (KHIDI)
APEC Key Challenges

- Growing Risk of infectious disease pandemic
- the Rise in chronic diseases
- the Aging demographic trends
Meeting’s Objective

“To identify and recommend *Priority Implementation projects* to give effect to the endorsed APEC Strategic Plan for LSI”
The Implementation Projects

- developing an Environment that fosters innovation
- providing Necessary Infrastructure for effective response and management of challenges
- building Capacity/Resources to increase and attract investment in the sector in critical areas
Priority Areas of LSI

- Research
- Regulatory harmonization
- Access to capital
- Health Services
The Final Recommendations

(1) the Extension in the region of a large-scale biomarker research collaboration and population study for the early Detection, Prevention, and Treatment of disease to include a broad spectrum of diseases of economic and health concern in the region
The Final Recommendations

(2) *Capacity building for the Harmonization of Standards and Regulatory Practices* for biomedical products and services according to international best practices where the need is most pressing and obstacles are the greatest.
The Final Recommendations

(3) Venture capital to promote the development of LSI supporting industries in emerging economies. Example include Research infrastructure; CRO; and Contract manufacturing organizations.
The Final Recommendations

(4) The development of an *Early Health Index* to identify population needs and appropriate health service interventions, and a data collection exercise to better understand the current level of investment, distribution, and allocation of Resources in health systems.
Harmonization Initiative

• The needs :- to ensure the addressing in Emerging Health and Economic Challenges

• Area of Harmonization :-
  - “Standard”, and “Regulatory Requirements & Practices”
  - “Product” and “Service”
  - “Pharmaceuticals”, “Medical Devices”, “Diagnostic”
Recommendation on Harmonization (1)

- Identify all relevant Harmonization Initiatives in the region and forward to the APEC(or LSIF) Secretariat

- Develop and Implement Harmonization Projects

- Implement existing Harmonization Guidelines with a focus on 1 or 2 areas for Training & Building Infrastructure for GCP and/or GMP
Recommendation on Harmonization (2)

- Develop Training’s Guidelines and a Funding Strategy
- Promoting region-wide APEC regulatory harmonization activities (pharmaceuticals, medical device, diagnostic)
Recommendation on Harmonization (3)

- Form a Steering Committee to oversee 2 work groups
  - Groups
    - Biomedical product
    - Medical device
  - Main activities
    - Roadmap Initiative
    - Harmonization project
Thank You

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