



**Asia-Pacific
Economic Cooperation**



Harmonization for a Healthier World

- Establishing an APEC Harmonization Center in Seoul

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Background

APEC support harmonization efforts of International Harmonization Organizations such as ICH & GHTF

Essential Action toward Harmonization

requires more practical experience and information sharing between industry-regulator and between regulators

needs to provide more information and education to regulators and industry experts in more systematic way with best practices and advanced guidelines

Therefore, at APEC LSIF VI, **Korea** proposed to member economies of APEC to establish an

APEC Harmonization Center (AHC)

Definition of AHC

International in status, non-profit in management **Center** organized and operated to enhance the harmonization level of therapeutic products to the advanced standards and regulatory practices under the **aegis of APEC LSIF**

Develop and disseminate **Harmonization Models** across the Asia-Pacific Region

Establish **cooperative networks** for Harmonization by linking regulators, industry experts, institutions, investors and policy makers

What AHC will do

Survey & Research

Conduct **research** and **survey** to define challenges and opportunities of harmonization / identify education demands

Providing Education

Provide education programs to regulators, policymakers and industry from interested APEC economies

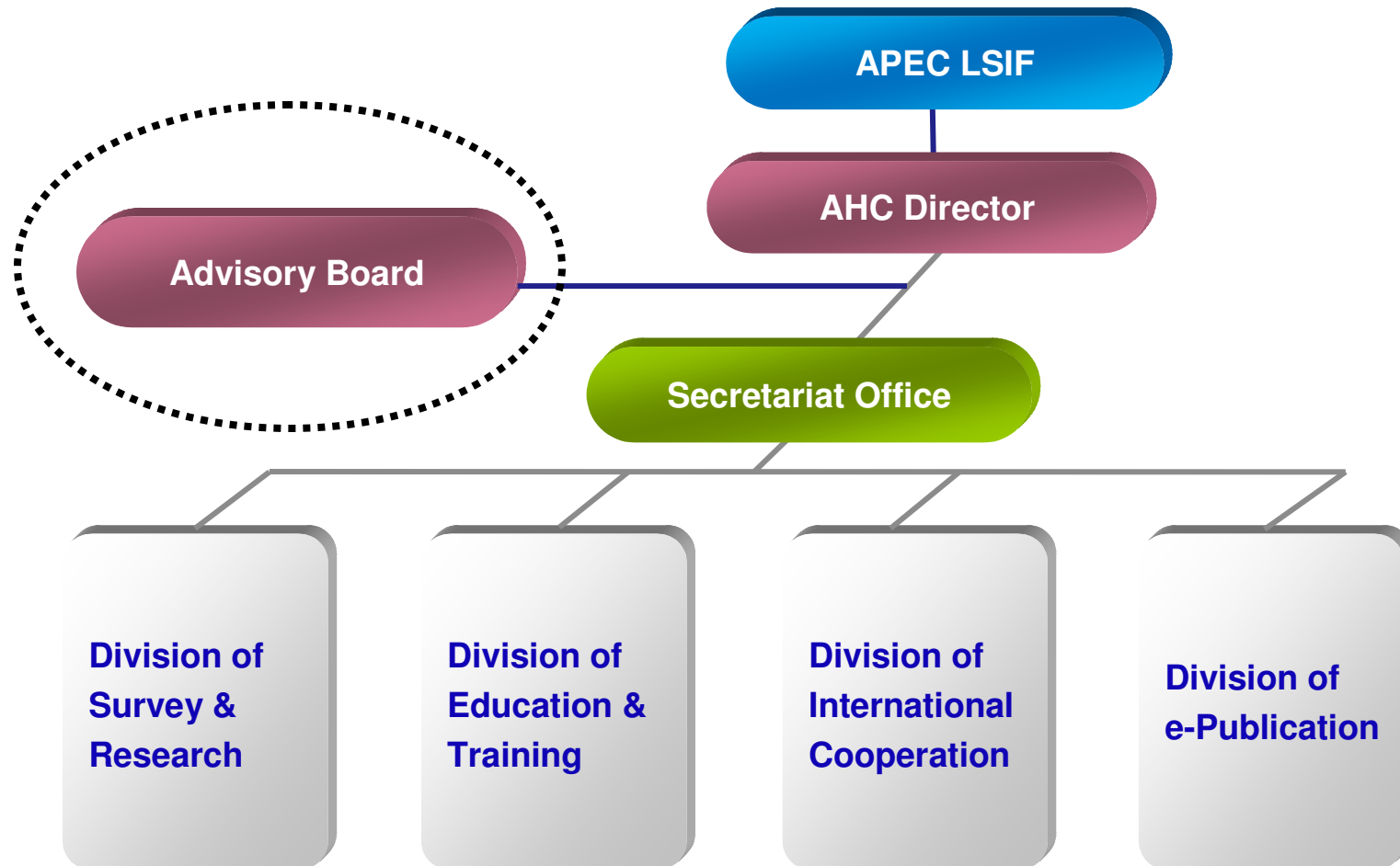
e-Publication & Website

Develop and disseminate journals and reports of AHC

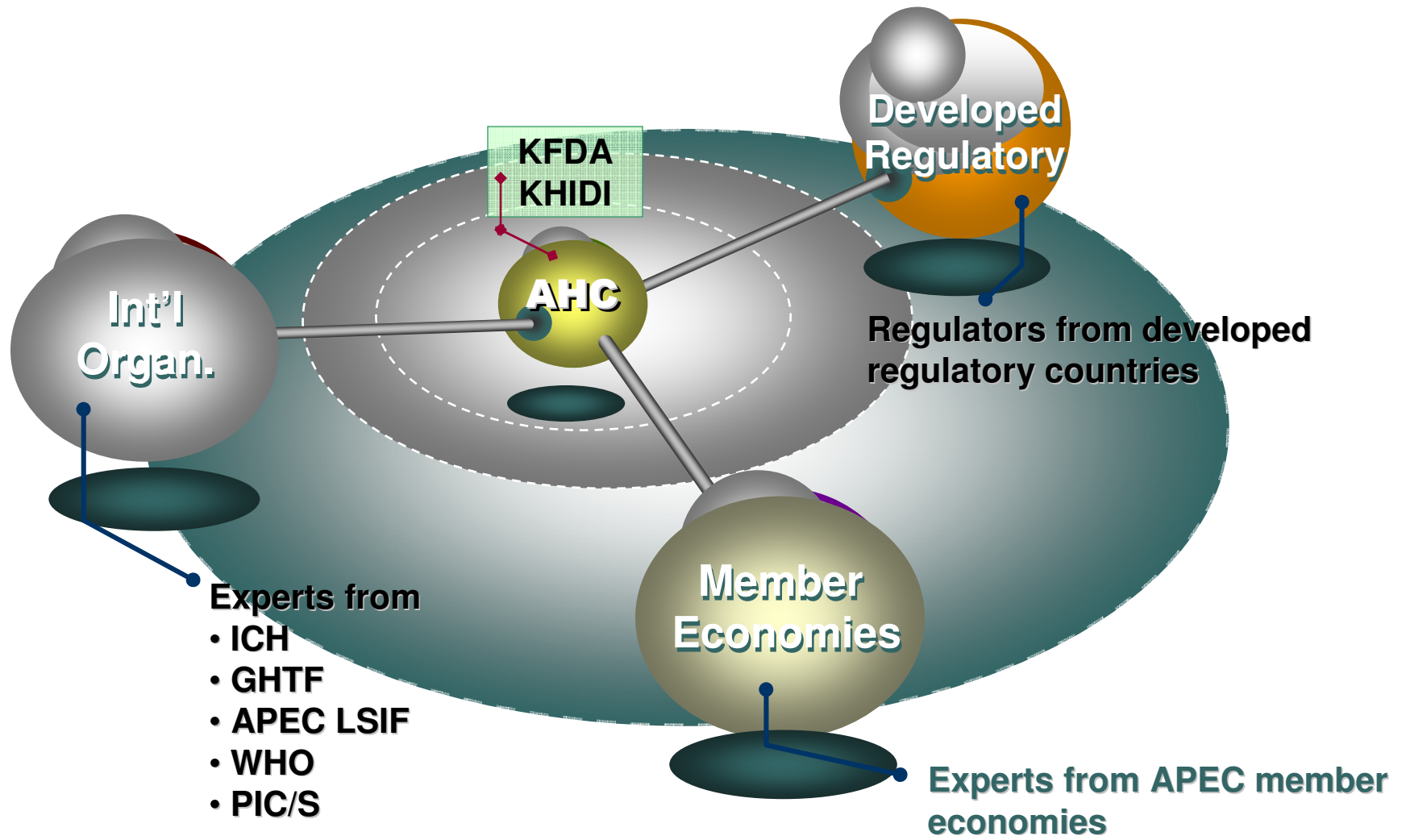
International Cooperation

Develop cooperative networks with other international organizations, countries and fora

Structure & Function



Advisory Board



Financing

The government of **Republic of Korea** has committed to serving as “Foundation Sponsor” of **AHC** in 2009

KFDA and **KHIDI** also affirm their commitment to making significant, continued contribution **annually** to support **AHC**

AHC will ask to **APEC** funds for travel **eligible economies** to attend the **inaugural workshop** of **AHC** on coming June

AHC welcomes and will recognize other interested governments, institutions, corporations and foundations who provide financial support for its program as sponsors

Plan & Schedule

Announced establishment plan of AHC (Aug. 08, APEC LSIF)

Organizing an early stage Advisory Board (Nov. 08)

H.E. Myung-bak Lee, the President of Republic of Korea, will announce Korea's willingness to support AHC (Nov. 08, APEC Leaders Meeting)

Inauguration Ceremony and Symposium (June, 2009)

Consecutively after ICH Yokohama Meeting June 6-11
Venue will be wonderful place in Seoul

Summary

AHC will provide a platform to address and solve priority concerns of APEC member economies on regulatory harmonization by supporting access to the best practices and guidelines, resulting improvement of quality, safety and efficacy of therapeutic products

Promotes the collaborative actions and wide information exchanging activities among participants

Facilitates international trade of therapeutic products

Contribute to enhance health status of APEC economies



Thank you
for your attention