Regulatory Harmonization initiatives in APEC LSIF (Life Science Innovation Forum)

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International & Asian: Pharmaceutical Harmonization Environment

- ICH / GCG (EU+JP+US)
- CEE (Central & Eastern EU)
- ASEAN+3
- GCC (Middle East)
- BIMST-EC (South Asia)
- PPWG (ASEAN)
- APEC
- LSIF
- PANDRH (Pan American)
- SADC (South Africa)
- Tripartite

Mercator Projection
Drug Harmonization Initiatives in Asia

APEC Network under ISTWG, since 1999


Partnership in Harmonization with ICH
Challenge in Implementation of ICH Clinical Guidance

• Limited regulatory resource and capacity in emerging markets
• Different interpretation for details not specified, lack of overall concept & rational of guidance, special local issues
• Segregated regional harmonization initiatives, lack of leadership and communication platform, heterogeneous regulatory environment
Formation of the Simultaneous Global Development Committee

- Recommended by PhRMA company heads of R&D
- Comprised of senior regulatory and clinical staff of PhRMA member companies, as well as other subject matter experts – inaugural Meeting March, 2008
- Interacts with All PhRMA regional technical committees to establish global regulatory advocacy policy
Simultaneous Global Development: Why?

- Significantly increased inter-agency interactions by Drug Regulatory Authorities that precludes industry participation:
  - WHO-ICDRA
  - EMEA, ASEAN
  - Tripartite Health Ministers’ Agreement (China, Korea and Japan)
Simultaneous Global Development: Why?

• And some that do not...
  – Bi-lateral and multi-lateral government initiatives impacting regulatory requirements (e.g., Asia-Pacific Economic Cooperative, or “APEC”)
  – Transatlantic Administrative Simplification Initiative
  – ICH GCG
Defining Simultaneous Global Development (SGD)

The generation of sufficient data in multiple regions/countries with the same pivotal trial protocol for the purpose of achieving simultaneous global filings and ultimately approval (the “SGD Trial”)

• Note: Initial focus is presently on simultaneous global submission . . . with global approval as an ultimate goal.
Japan’s “Basic Principles on Global Clinical Trials”

• Clarifies E-5 from Japanese perspective
  – Addresses ICH Q-11

• Based upon existing experiences (early development strategies that include Japan)

• Intended to address, in part, Japan’s drug lag
Tripartite Health Ministers’ Agreement (China, Japan, Korea)

- Recognized the need to facilitate drug development by clarifying relevant ethnic factors in clinical data
  - Prospective study contemplated to evaluate ethnic sensitivity within East-Asian populations.
- Clearly intended to address regional development issues
- Possibility of third party to join-Taiwan?
Recommendations and Conclusions in 2008 APEC LSIF (Life Science Innovations Forum)

Regulatory Harmonization session

• LSIF recommends that Ministers and Leaders endorse and support the establishment of the APEC Harmonization Centre (by Korea)

• LSIF supports the proposed feasibility study of the exchange between economies of evaluation reports (proposed by Chinese Taipei)

• LSIF agrees to established a Regulatory Steering Committee within the LSIF structure (proposed by Canada)
RHSC Mandate and Goals

• The RHSC, in partnership with the AHC, will seek to establish/strengthen linkages with harmonization initiatives, training organizations and other key players in efforts to promote complementary actions and most effective use of resources
• Activities to be undertaken in accordance with a strategic plan to be developed by the SC
• Products within remit of SC: medical life science products (notably drugs and devices)
APEC Harmonization Center (AHC)

- Non-profit institute would serve to enhance and sustain the implementation of harmonized standards and regulatory best practices by:
  - conducting research and surveys
  - providing educational programs
  - publishing and web posting
  - establishing networks and exchanges among participants and other international institutions

- Operate under aegis of LSIF, with direction from international advisory board
- Korea will sponsor $800,000 per year
- LSIF events organized in Seoul marked inauguration of AHC, first meeting of RHSC and workshop on MRCTs, June 15-18, 2009
• RHSC provides strategic direction to AHC based on established regulatory priorities
• AHC Advisory Board provides technical and scientific advice to the AHC Director on the organization of specific curriculum and projects
OPERATIONAL MODEL

APEC LSIF

RHSC

AB

AHC
Building a Better Harmonization Model

Development (Standards, Guidances)

ICH WGs

Interface

Reg Forum

Key Enabler:
APEC Harmonization Center + RHSC

APEC Economies and beyond

+ DRAs: Australia, Brazil, China, Chinese Taipei, India, Korea, Russia, Singapore
Recommended Actions: Lima

- **Assessment** by member economies of current **regulatory capacity** and **resource** levels as an important step in determining appropriate regulatory strategies and models, including the adoption of harmonized standards.

- Work towards adoption of harmonized application and compatible review formats, thereby promoting a common regulatory language that supports **sharing of information, GRPs** and leveraging of resources.

- Conduct **feasibility study** on the confidential exchange and use of regulatory information.
“Best Regulatory Practice Project” – Proposed to RHSC from Taiwan

- Taiwan will sponsor $500,000 in 2 years
- Host training program (Drug an Device) targeting on regulators
- Experience sharing & Networking – APEC Pharmaceutical Evaluation Report (PER) Scheme feasibility study
A Model in the Past: PER Scheme
1979~2000 - EFTA as secretariat
APEC Pharmaceutical Evaluation Report (PER) Scheme- Regional Solution for Global Drug Development?

- Regulatory agencies with limited resources
- “Partnership” is the key word, not “mutual recognition”
- “Think globally, Act locally” – Need “Asia Regulatory Voice” for risk-benefit decision, e.g., gefinitib and rosuvastatin
APEC PER Scheme Feasibility Study

• Establish project of “APEC PER Scheme”
  – Secretariat: Taiwan
  – Steering committee: APEC Regulatory Harmonization Steering Committee
  – Choose a few marketed products to exchange assessment reports with companies permission and comments
  – Review the experience
• Endorsed by PhRMA & EFPIA
Future Perspectives on Pharmaceutical Regulatory Issues

• Sharing review experience
• exchange review reports of IND/NDA/IDE/PMA/BLA
  – ethnic issue study by retrospective data surveillance
  – establish *bridging study* review consensus.
  – joint review for IND
• Enhance pharmaceutical regulatory networking
  – joint training program, e.g., GRP, GCP inspections
  – communication and information sharing, e.g. ADR report
  – potentially harmonize the review process, report format, data requirement
• Establish reviewer exchange program
  – Joint training programs
Outcomes of RHSC Discussions in APEC LSIF VII, Singapore, Aug. 1-3, 2009

• Review of draft of Terms of Reference for the RHSC
• Selection of Steering Committee membership, including
  – 7 Regulatory Authorities of Canada, China, Chinese Taipei, Korea, Peru and Thailand, US
  – 4 Industry representatives (Drug and Device)
  – AHC Director, Korea
• Endorsed “Best Regulatory Practice” proposal from Taiwan
2009 The 8th Conference of APEC Network on Pharmaceutical Regulatory Science
Collaboration in New Drug Development and Drug Safety

*Recent Reform of Drug Regulatory Agency
*Clinical Trials: Partnerships
  Challenges and Solutions
*GCP Inspection
*Drug Safety Beyond the Borders
*Role of APEC in Regional Harmonization

2-4 Nov. 2009
Grand Hotel, Taipei
Department of Health
Chinese Taipei
http://www.apecnprs.org/2009/
Thank You for Your Attention