Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Asia Harmonization Working Party

Strategic Objectives & Directions

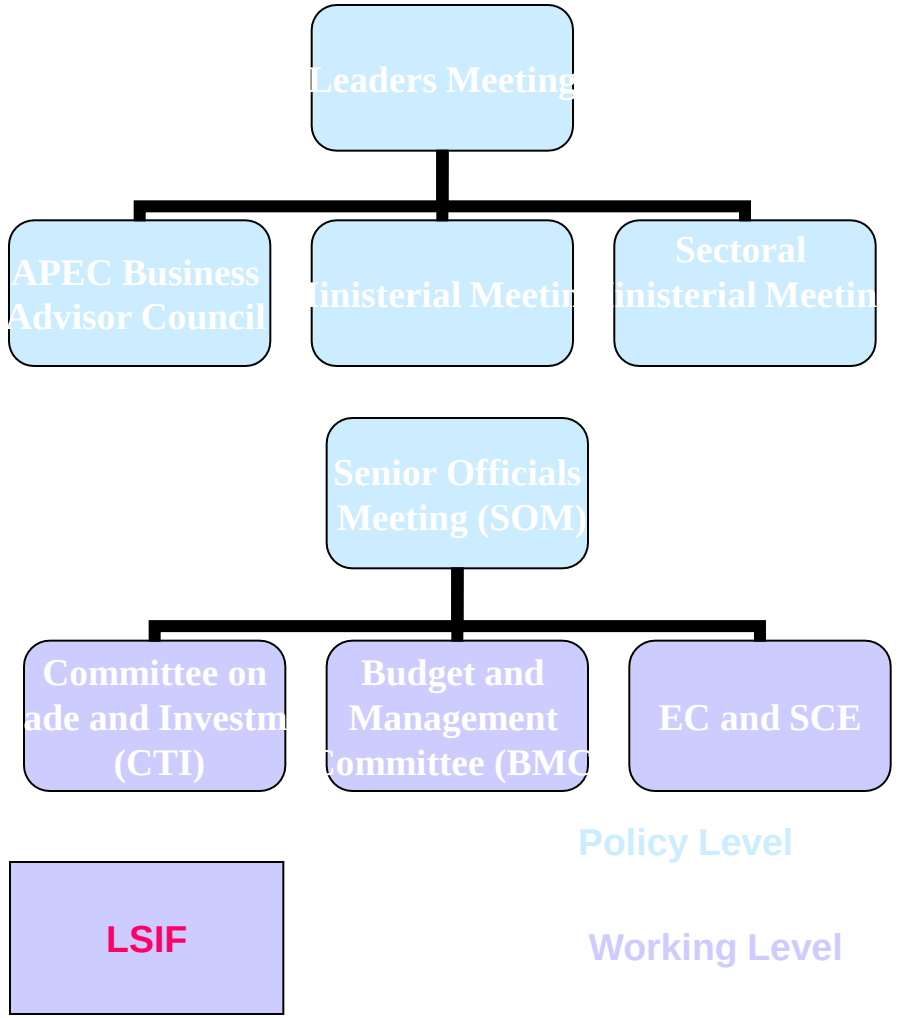
March 1 & 2, 2012
AHWP TC Meeting
Singapore

Update of Regional/Global Regulatory Harmonization Initiatives

Asia Pacific Economic Cooperation (APEC)

Life Science Innovation Forum(LSIF): an enabler of harmonization:

- Created following endorsement by APEC Leaders in 2002
- Recognized importance of *life sciences innovation* in promoting public and economic health
- From outset, harmonization seen as prerequisite to fostering innovation



Asia Pacific Economic Cooperation (APEC)

Life Science Innovation Forum(LSIF): an enabler of harmonization:

- LSIF doesn't ***produce*** harmonized guidance; but to promote use of ***existing*** international guidelines (ICH, GHTF, WHO):
- Ability to access APEC funds to advance projects
- Voluntary basis for engagement: ensures participation of those economies interested and committed to cooperation
- Linkages to international harmonization initiatives: since 2004 sits on the ICH Global Cooperation Group, and since 2012
- Tripartite structure / complementary roles: government, industry, academia
- To date, sponsored many workshops on ICH and GHTF guidance
- Important Development: June 2009 in Seoul:
  - ✓Inauguration of the APEC Harmonization Center (AHC)
  - ✓Creation of a Regulatory Harmonization Steering Committee (RHSC)

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AHC

- APEC-wide resource to enhance and sustain harmonized and capacity building efforts by:
  - conducting research and surveys
  - providing educational programs
  - publishing and web posting
  - establishing networks and exchanges
- Operates under the authority of LSIF, with direction from RHSC and an international advisory board

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RHSC

Mandate: To promote a more ***strategic***, ***effective*** and ***sustainable*** approach to harmonization on medical products by:

- ***Proactively*** identifying and prioritizing projects seen to be of greatest value
- In partnership with AHC, strengthen linkages with harmonization initiatives, training organizations and other key players to promote ***complementary*** actions and most effective use of resources

Members:

- Regulators from Canada, China, Chinese Taipei, Japan, Republic of Korea, Peru, Thailand and USA with official observers from Mexico and Singapore
- Industry representatives from drug and medical device sectors
- Director of APEC Harmonization Center

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Achievement:

- The development of Strategic Framework:
  - ➢Framework outlines strategic multi-year approach for achieving greater regulatory convergence by 2020
  - ➢Describes guiding principles and general multi-step approach
  - ➢Includes appendices for pharmaceuticals and medical devices and suggested indicators of success (reference to ICH and GHTF)
  - ➢Voluntary action: each economy proceeds at own pace
  - ➢Also includes definition of regulatory convergence

***Regulatory convergence*, within context of the framework and APEC principles of voluntary action, represents a process whereby *regulatory requirements across economies become more similar or aligned over time* as a result of the gradual adoption of internationally recognized technical guidance documents, standards and best practices.**
***Does not represent the harmonization of laws and regulations*, which is not necessary to allow for the alignment of technical requirements/approaches and greater regulatory cooperation.**

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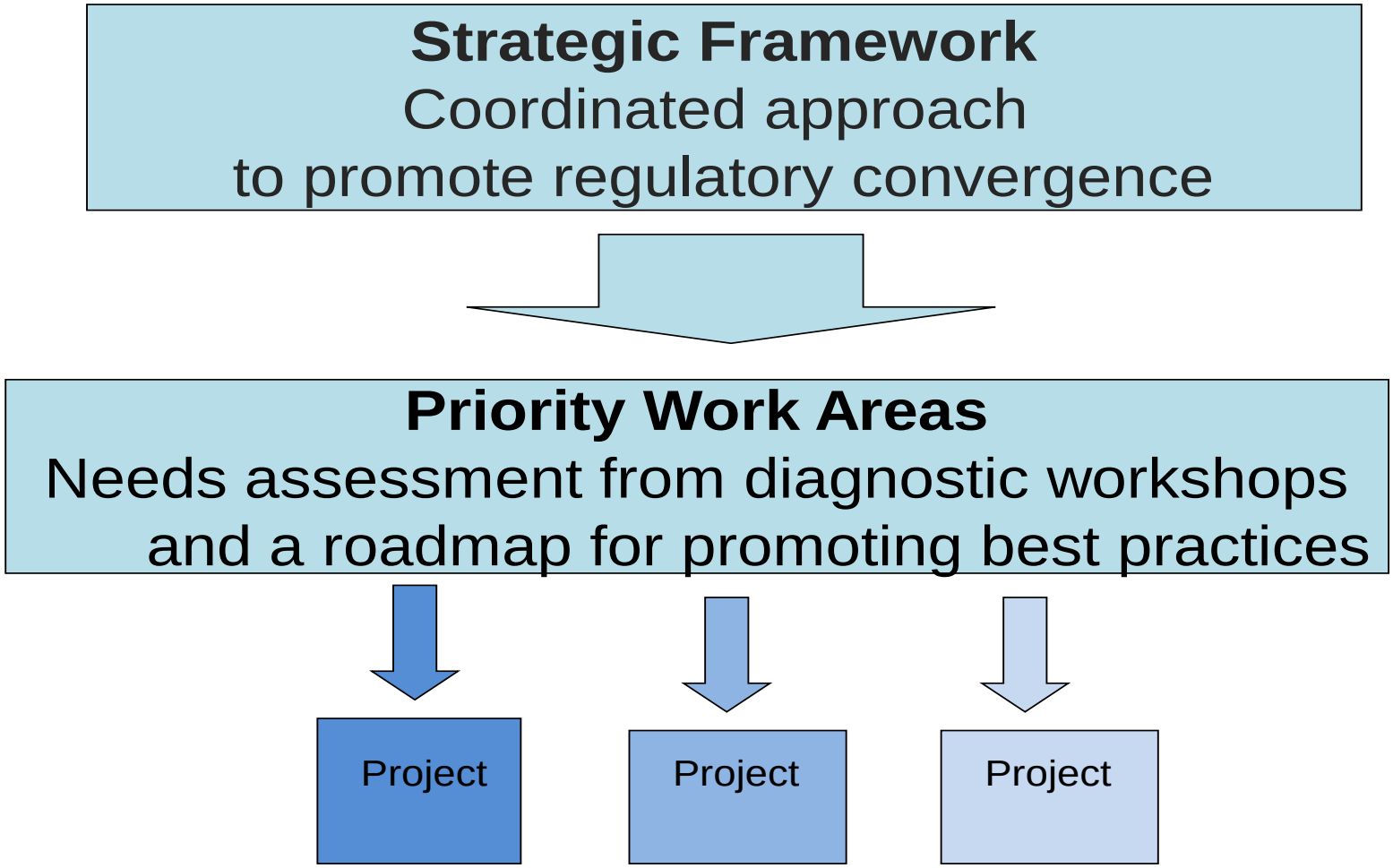

Individual projects are part of strategy & contribute to goals

Move away from Ad Hoc/Individual Proposals

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Priority Work Area (PWA)

- Define priority clusters
- Roadmap to be developed by champion economy for each PWA
- Champions/PWAs identified to date:
  - MRCTs (Japan - roadmap completed)
  - Supply chain integrity (US)
  - Pharmacovigilance (Republic of Korea)
  - Cellular Therapies (Singapore)
  - Biologics/biosimialrs (Republic of Korea)
  - Good Review Practice (Chinese Taiwan)
  - Combination products (TBC)

Training Approach

- Workshop as diagnostics
- Act upon recommendations from workshop, including true training sessions aimed at acquiring new skill or knowledge
- Events open to non-APEC economies
- Sustainability, including AHC and annual curriculums
- Make use of available technologies and AHC website to maximize access and reuse of information

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Trends:

- Developments within APEC that have implications beyond the region with the interest and participation of non-APEC region and linkage to other regional/global organizations (WHO, IMDRF, ICH, AHWP, and etc.)
- Advancing regulatory harmonization in a more strategic, sustainable and effective manner, moving away from ad hoc project to a strategic approach in contribution to overall strategic goal and objective
- Directed towards concrete, complementary actions
- Key role as an enabler: building a better global regulatory convergence model

GHTF & IMDRF

Strategic Direction

- GHTF Action Plan for 2007-2010

  – Goal 1: Guidance Implementation, initial focus on:
    - Single audits used in multiple jurisdiction
    - Improve in the operation of the National Competent Authority Report System
  – Goal 2: Organizational Logistics
  – Goal 3: Expansion
    - Involve other organizations in a manner similar to AHWP, such as Central and South America, WHO
    - Increased public available of procedures and documents
    - Development of implementation of a GHTF training plan
  – Goal 4: New Topics For GHTF Attention

- GHTF started review of strategic direction in 2010. Summary of discussion from Singapore SC meeting was submitted to “Head of Agencies”

GHTF & IMDRF

- Change of GHTF and its rationale
  - A decision as of Head of Agency meeting in Feb 2011
  - GHTF regulatory model was now substantially compete
  - Uniform implementation of the GHTF model has not been fully achieved
  - Current GHTF membership is not reflective of the changing of global market
  - Achieving harmonized regulatory requirements remain a highly desirable objective

- Direction of IMDRF
  - Regulator-led harmonization and collaboration group (management committee)
  - Membership reflect global markets: WHO, Brazil, China(TBC), India and Russia(invited but not responded)
  - Allow input and participation from industry and other stakeholders (Ad Hoc working groups)
  - Aimed at accelerate international medical device regulatory harmonization

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GHTF & IMDRF

Priority work items:

- Improve NCAR (national competent authority report) system/Report on PMS (Post market surveillance)
- Roadmap for implementation UDI
- Medical device single audit program (MDSAP) – medical device accreditation requirements and processes
- Harmonized standards (e.g. ISO)
- Regulated product submission (electronic submission, standards, and contents)

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WHO

- 1st WHO global forum on medical device held in 2010, recommendations and action plan was proposed regarding regulatory:
  - Promote global regulatory harmonization
  - Nomenclature
  - Capacity building for regulators
  - Safety information sharing (adverse events and regulatory actions)
- 2nd WHO global forum on medical device will be held in Latin America 2012
- WHO established expert panel on nomenclature
  - Mapping between two nomenclature system
  - Facilitate the free access of GMDN to regulators
- WHO training and capacity building
  - Program designed
  - Will roll out in Asia in 2012

Introduction of Draft AHWP Strategic Framework

Strategic Objectives

- Continue the momentum built in the past
- serves as a strategic guidance for various AHWP activities in the next three years (2012 -2014) under new leadership

Framework Elements

1. Membership expansion
   - Welcome nationals and regions wishing to be active participations in the on-going work of the organization
   - Invite countries and nations with experience and knowledge on medical device regulation to take leadership roles

2. Training and capacity building
   - Focusing on helping regulators and industry understand international best practice, goal to achieve regulatory convergence
   - Partnership with training partners (NGO, regional/global organizations, universities), leverage their resources and expertise
   - Develop strong curriculum, plan and review periodically review
   - Use advanced technologies

Framework Elements

3. Harmonization in key Areas based on GHTF principle
   - Significant advantage of AHWP in achieving regulatory harmonization by adopting international best practice
   - Need to identify priority areas with the most potential for success
   - Set short term goal(2011-2014) and long term goal (2014 to 2020)
     - Single adverse event reporting and post-marketing surveillance system
     - Single medical device nomenclature system
     - Single quality management system requirements, and multi acceptance of quality management system audit report by multiple competent authorities

4. Working alongside with APEC towards regional regulatory convergence goal by 2020
   - APEC endorsed strategic goal on achieving regulatory convergence by 2020
     - Outlines strategic multi-year approach for achieving greater regulatory convergence by 2020
     - Describes guiding principles and general multi-step approach
     - Includes appendices for pharmaceuticals and medical devices and suggested indicators of success
     - Voluntary action: each economy proceeds at own pace
     - Also includes definition of regulatory convergence
   - Recognized not all AHWP members are APEC members, need to develop strategic approach to achieve this regulatory convergence goal

Framework Elements

5. Increase AHWP's Global Presence
   - Partnership with IMDRF, WHO, ISO, APEC and etc.
   - Establish mechanism for effective interactions and networking, improve process of getting input and providing feedback

Critical Questions to Answer

- What are priorities of AHWP member economy
- What is meant by "harmonization"?
- How is "success" defined?
- What does harmonization "look and feel like" to regulators? To industry?
- What's the obstacles to harmonization and how to overcome them?
- To what extent is this goal dependent upon political will of regulatory harmonizaiton of member economies? How will that political will be gained?
- Emerging areas(anti-counterfeiting, remanufacturing, and etc.)
- Name in reflective of global membership