



APEC Regulatory Harmonization Steering Committee (RHSC) Report to Global Cooperation Group

November 8, 2011
Sevilla



RHSC Schedule

- Tuesday, September 13
 - morning First RHSC Open House
 - afternoon RHSC Training Subcommittee
- September 14-15
 - RHSC meeting



RHSC Open House

- Meant to promote awareness, encourage participation and serve as potential model for other fora
- Agenda:
 - ▣ Overview of the LSIF and RHSC
 - ▣ Overview of the APEC Harmonization Center
 - ▣ Elements of a more strategic approach:
 - Strategic Framework for Medical Products
 - Priority Work Areas and Roadmaps
 - ▣ Questions and Answers



Growing Momentum

- Participation of over dozen invited guests, including representatives from WHO, European Medicines Agency and senior industry officials
- Recommendation to extend RHSC meetings
- Reflection of:
 - ▣ growing importance of RHSC's contribution to advancing regulatory convergence within APEC **and globally**
 - ▣ volume and nature of work underway



Membership

- Changes:
 - MHLW: Mr. Yasuda replaces Mr. Shinobu Uzu
 - AHC: Dr. Ki Sung Kim replaces Dr. Kyung Won Jang as Secretary General
- Membership under review
 - Hiroshi Ischikawa (retiring)
- New Observer:
 - Dr. Nick Cappuccino representing generic drug industry
- Expression of interest from Indonesia



Priorities for San Francisco

- Review and endorsement of Strategic Framework on Regulatory Convergence of Medical Products by 2020
- Review of priority work areas (PWAs) and template for PWA roadmaps
- Review of proposed roadmaps and projects
- Consider framework for Advanced Therapies
- Review and endorsement of changes to Operating Procedures
- Discussion on assessing outcomes of projects
- Outreach



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
- Also includes definition of regulatory convergence



Strategic Framework

- Executive Summary prepared for senior officials
- Discussion around need for separate framework to guide prospective harmonization work in area of advanced therapies
- Endorsed in principle by participating RHSC members; confirming full endorsement intersessionally, prior to Leaders summit



Regulatory Convergence

Regulatory convergence, within context of 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 and standards.

Does not represent the harmonization of laws and regulations, which is not necessary to allow for the alignment of technical requirements and greater regulatory cooperation.



Roadmaps

- Strategy that guides activities related to PWA
- All projects should flow from roadmap
- Template developed to ensure completeness and consistency
- Same template serves as “concept note” which, once endorsed, would be expanded to full roadmap



Workplan

- Global Drug Integrity and Supply Chain (US)
 - ▣ Concept paper from US FDA
 - ▣ Drug Safety and Detection Technology Workshop
 - ▣ Reconsideration of proposal on Drug Safety and Anti-counterfeit Medicines Public Awareness and Single Point of Contact (SPOC)
- MRCTs – MHLW/PMDA
 - ▣ Update on implementation of MRCT Roadmap and Recommendations
- Good Clinical Practice Inspection (Thai FDA)
- Good Review Practices (TFDA)
 - ▣ GRevP Training Workshop on Medical Products and GRevP surveys
 - ▣ Roadmap



Workplan

- Biosimilars
 - Self-funded workshop (AHC/KFDA)
 - APEC funded Regulatory Harmonization Training on Quality of Biotherapeutics; Biosimilars and Quality Issues
- Pharmacovigilance (AHC/KFDA)
- Combination Products (TBC)
- Projects (underway and completed):
 - ICH Q8/9/10
 - Stem Cell QC/QA Workshop (Thailand)
 - Regional Training Seminar for Government Regulators: Implementation of GHTF Documents (MHLW/PMDA)
 - AHC/DIA/IFPMA Asia Regulatory Conference (AHC)



Key Outcomes

- Endorsement in principle of revised Strategic Framework on Regulatory Convergence of Medical Products by 2020, pending confirmation from entire membership
- Endorsement and use of roadmap template
- Review and endorsement in principle of series of concept notes and projects, including supply chain integrity, biosimilars



Key Outcomes

- Agreement to reach out to key players, including training organizations and new international medical devices regulatory forum
- Agreement on global mapping plan
- Most importantly, implementation of strategic approach and synergistic cooperation with key international partners, including WHO and European Medicines Agency



Other Progress since San Francisco

- Stem Cell QA/QC workshop for July 5-7, 2011, hosted by Thailand
- AHC-sponsored ICH Q8/9/10 workshop, October 4-5, 2011 in Seoul.
- First training session on Good Review Practices for drugs and devices, October 12-15, 2011 in Chinese Taipei (2 year project)
- Tokyo MRCT workshop highlighting Tripartite Symposium, November 1-2, 2011
- Strategic framework approved, sent to CTI approval for Leaders meeting



Thank you!

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