APEC Roadmap to Promote Global Medical Product Quality and Supply Chain Integrity Update

Connie T. Jung, RPh, PhD
Office of Drug Security, Integrity, and Response
FDA/CDER/Office of Compliance
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APEC Roadmap to Promote Global Medical Product Integrity and Supply Chain Security

• In 2012, FDA proposed and RHSC (Regulatory Harmonization Steering Committee) submitted to APEC (Asia-Pacific Economic Cooperation) a Multiyear Project Proposal

• Proposal was approved for 5 years starting January 2013

• About a quarter of the funding comes from APEC, and the rest comes from participating RHSC members (typically, in-kind contributions)

• The approved proposal for RHSC covers:
  – Subcommittee formation led by RHSC
  – Conduct of a gap assessment between APEC members that will evaluate a number of important supply chain areas
  – Development of guidelines covering best practices, tool kits and other training materials
  – Development and initiation of a training program, including assessment tool
APEC Roadmap to Promote Global Medical Product Integrity and Supply Chain Security

• Work addresses all adulterated and misbranded drugs and to a limited extent, medical devices (SSFFC)

• Helps to ensure that patients are receiving only those products that individual member economies authorize to be on their market

• Requires much better understanding of product development, raw material sourcing, requirements of manufacturing controls, and import and export operations

• RHSC to identify a path forward toward regulatory convergence of practices necessary to ensure the integrity of marketed medical products
SOM I Meeting (1)

- Occurred January 26-29
- Angeles City, Philippines

APEC Roadmap:
- covered GDP (Abbvie), SPOC (EDQM) and Product Security (RX-360)
- had over 150 Participants from nearly every APEC Economy
- reviewing demographics - appears to be a close split between regulatory authorities and industry, including regional companies
- reviewing training surveys regarding effectiveness - audience was extremely engaged for all 3 sessions
SOM I Meeting (2)

- Meeting summary presented to RHSC and LSIF (LSIF has posted the Roadmap as a major initiative on its APEC webpage)

- All training materials, including video, have been posted at the APEC Harmonization Center’s website (www.apec-ahc.org/)

- Materials will remain there “as is” until:
  - interested parties review and comment (~ May 1 deadline) and
  - RHSC endorses or requires revisions (hopefully, NLT SOM III)
Planning for SOM III Meeting

- Plan for five (5) training programs: GMP, Import/Export, Track and Trace, Internet Sales, and Detection Technologies
- Agenda proposed
- August 24-28, 2015 dates reserved
- Plan for two tracks

- Philippines has chosen Cebu as the site
- AHC (APEC Harmonization Center) has committed to paying for most of the ex-Filipino expenses, including travel expenses for government experts participating in the training
## Project Tracking - Update

<table>
<thead>
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<th>Work Stream</th>
<th>Lead</th>
<th>Gap Assessments</th>
<th>Draft Tool Kits</th>
<th>Training</th>
<th>Effectiveness</th>
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</table>

“X” denotes that an activity is completed or in progress
APEC ABAC Track and Trace Pilot

• APEC Business Advisory Committee (ABAC) proposal using GS1 Standards

• Technical support provided by the APEC Roadmap Track and Trace Workgroup: University of Tennessee Health Science Center (UTHSC) is managing the project with industry sponsorship

• Adopted by the APEC Committee on Trade and Investment (CTI) (medical products, wine, deer fur, etc.)

• Some CTI funding also made available

• Will utilize the Single Window, APEC-wide (if not global, e.g., World Customs Organization)
  - electronic system that connects APEC importing/exporting Customs officials with regulatory agencies responsible for authorization decisions
  - increased efficiency and certainty
  - USDA led the development of the US Single Window utilizing APEC requirements
APEC Roadmap Successes So Far

- **Public–Private Partnerships (PPPs)**
  - Funds and resources
  - Expertise
  - Venues

- **Training**
  - Conducted
  - Engagement of stakeholders
  - Availability of materials (APEC Harmonization Center)

- **Prospective Outgrowths**
  - Center of Excellence for Supply Chain Security(?)
Resources

APEC/LSIF website
www.apec.org/groups/committee-on-trade-and-investment/life-science-innovation-forum

AHC website
www.apec-ahc.org/