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A background image showing a cluster of orange, round pills in the upper left, with a single pill in sharp focus in the lower right. The pills are set against a white background with soft shadows.

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

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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

Work Stream	Lead	Gap Assessments	Draft Tool Kits	Training	Effectiveness
cGMPs (Audits and Supply Chain Controls)	EMA	X	X	SOM III?	
GDPs	Abbvie	X	X	X	?
GI/EPs (Imports/Exports)	Takeda	X	X	SOM III	
Product** Identification, Authentication and Traceability	GS1	X	X	SOM III	
Detection Technologies	China NIFDC	N/A	X	SOM III	
Internet Sales	Health Canada	X	X	SOM III	
Single Point of Contact Systems	EDQM	X	X	X	?
Clinical and Retail Pharmacy Practices	USP	X		SOM I (2016)	
Product Security	RX-360	N/A	X	X	?
Surveillance and Monitoring	WHO	N/A	X	repeat	X

“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/