



INTERNATIONAL
T R A D E
ADMINISTRATION

APEC LSIF INITIATIVES – Medical Devices Global Regulatory Harmonization and Anti-counterfeit Medical Product Global Cooperation

**APEC LSIF Regulatory Harmonization
Steering Committee, Hiroshima, Japan
March 3-4, 2010**

Presented by:
Jeffrey L. Gren
Director, Office of Health and
Consumer Goods

Presentation Outline

- **Introductory Comments**
- **Global Medical Devices Regulatory Training Goals and Objectives**
- **APEC and GHTF Training - Results and Future Plans**
- **APEC Anti-counterfeit Medical Product Activities - Results and Future Plans**
- **Proposed APEC LSIF Anti-counterfeit Medical Products Action Plan**
- **Summary and Conclusions**

Global Medical Devices Regulatory Harmonization Training Goals and Objectives

- To educate APEC medical devices regulators from “non-founding” GHTF member countries economies in the process of developing or updating regulatory regimes
- To provide background and conceptual understanding of the how the GHTF founding member economies (U.S., Canada, the European Union, Japan and Australia) regulate and monitor medical devices
- To provide an understanding of GHTF Study Group guidance documents

GHTF Training Benefits

- GHTF training programs are coordinated closely with the Asian Harmonization Working Party (AHWP), the Latin American Harmonization Working Party (LAHWP), and the Pan American Health Organization (PAHO)
- Regulators benefit from a harmonized global medical device regulatory system because it eliminates redundant reviews, creates an opportunity to share information on product safety, and results in a more efficient regulatory regime
- Industry benefits from a harmonized medical device regulatory system because it eliminates redundant requirements that do not contribute to safety
- The net result is improved trade in medical devices and safer products for consumers

Past GHTF Regulatory Harmonization Training Events

- March 1999 – APEC Funded Seminar Singapore
- May 2001 – APEC Funded Seminar Singapore
- June 2005 – APEC Funded Seminar Bangkok, Thailand
- May 2006 – APEC Funded Seminar Santiago, Chile
- October 2007 – GHTF Organized Latin American Seminar, Washington, D.C.
- February 2008 – APEC Funded Seminar KL, Malaysia
- March 2009 – ASEAN Seminar Penang, Malaysia
- May 2009 – APEC Funded Seminar Toronto, Canada
- September 2009 – APEC Funded Asia Delegation Visit to Australia
- September 2009 – USDOC Funded Seminar Brasilia, Brazil

APEC/GHTF Regulatory Events: Results

Participants in past GHTF training have reported that:

- Seminars useful to develop strategies to advance the use of GHTF guidance documents
- Participating economies have moved toward the Standard Technical Evaluation Dossier (STED) model
- ASEAN countries likely to continue adopting GHTF guidance documents in the next three to ten years
- Participating countries have requested support in implementation of new or revised regulatory regimes

APEC/GHTF Regulatory Training Results

- Attendees have expressed an interest in future regional training seminars or seminars held in conjunction with future GHTF conferences
- The following economies have revised or are in the process of revising their medical device regulatory regimes based on GHTF principles:
 - Malaysia
 - Singapore
 - Hong Kong
 - ASEAN countries as part of ASEAN ACCSQ Medical Device Products Working Group (i.e. Thailand, Indonesia and Philippines)
 - Saudi Arabia

APEC/GHTF Training: Topics Covered During Past Seminars

- Study Group 1 – Pre-market Evaluation
 - Definition of a Medical Device
 - Essential Principles of Safety and Performance of Medical Devices
 - Principles of Medical Device Classification
 - Role of Standards in Assessment of Medical Devices
- Study Group 2 – Post Market Surveillance
 - Adverse Event Reporting
- Study Group 3 – Quality Systems
 - Quality Management Systems: History and Evolution
 - Implementation of Risk Management Principles
- Study Group 4 – Auditing and Overview of GHTF
- Study Group 5 – Clinical Evidence

Future APEC/GHTF Training Plans

- GHTF Ad Hoc Training Committee, Chairperson Jan Welch, US FDA – Exploring Possible Future Partners for GHTF Training Programs
- August 2010 – APEC Funded Delegation Visit to the U.S. and Canada
- Possible Follow-up to March 2009 ASEAN Workshop
- Possible Follow-up to September 2009 Brazil Workshop
- Possible future APEC Regulatory Harmonization Project with Asia and Latin American Seminars (proposal anticipated to be submitted to APEC during 2010 for seminar program during 2011 and 2012)

APEC-Funded Anti-counterfeit Medical Product Activities – Results and Future Plans

- Under the APEC Life Science Innovation Forum there is an anti-counterfeit medical products initiative
- The spread of counterfeit medical products is a significant problem facing APEC economies, and through joint cooperation we hope we can make an impact on this problem
- US DOC and USFDA have worked together on several APEC anti-counterfeit medical product activities

APEC Funded Anti-counterfeit Medical Product Activities – Results and Future Plans (cont'd)

- During 2008 and 2009 US DOC and USFDA organized three Asia anti-counterfeit medical product seminars – January 2008 and March 2008 in Singapore and a February 2009 seminar in Mexico City
- The seminars had over 300 participants
- Attendance during three seminars included regulators, customs, law enforcement and judicial officials, as well as industry representatives
- During August 2008 and July 2009 we presented findings of the APEC Anti-counterfeit medical product seminars to APEC Ministers and an APEC Anti-counterfeit Action Plan was developed
- We are hopeful that the APEC Anti-counterfeit Medical Products Action Plan will be endorsed by the APEC Planning Group on March 5 in Hiroshima

Proposed APEC LSIF Anti-counterfeit Action Plan – Major Findings

- Strong cooperation among APEC economies is critical
- Cooperation within each APEC economy between regulators, customs, law enforcement, judicial and industry is also critical
- APEC economies should work together to collect data on counterfeit medical products
- APEC economies should establish harmonized legislation and penalties for prosecuting medical product counterfeiters

Proposed APEC LSIF Anti-counterfeit Action Plan Major Findings (cont'd)

- Many counterfeit medicines enter APEC economies through Internet sales. Better Internet prevention and education strategies are needed
- Track and trace technologies are important, but may not be the sole solution
- Cooperation on the global shipment of ingredients used in the production of counterfeit medicines is needed
- APEC cooperation on counterfeit medical product public awareness is also needed

Proposed APEC LSIF Anti-counterfeit Action Plan - Implementation

- The U.S. has submitted a new proposal to begin implementation of the APEC Anti-counterfeit Medical Project Action Plan
 - A workshop on detection technologies for counterfeit medical products and APEC cooperation to stop the global shipment of counterfeit medicines and ingredients used by counterfeiters to produce counterfeit medicines
 - An exhibition of counterfeit medical product detection technologies
- The U.S. is also working on another APEC project to take place in Washington, D.C. during 2011, the U.S. APEC Host Year
- The 2011 project will include a workshop on counterfeit medical product public awareness and establishing single points of contact for public awareness and investigations

Proposed APEC LSIF Anti-counterfeit Action Plan - Implementation

- We anticipate continuing to develop and modify the APEC Anti-counterfeit action plan during future APEC funded events
- We also anticipate future APEC activities beyond 2011
- We will continue to work closely with the World Health Organization International Medical Products Anti-counterfeiting Task Force (WHO IMPACT) in implementing future APEC Anti-counterfeit programs

Summary and Conclusion

- During my presentation I covered the following:
 - APEC/GHTF Medical Devices Training Goals and Objectives
 - Past APEC/GHTF Medical Devices Regulatory Training Results
 - APEC Anti-counterfeit Medical Products Results and Future Plans
 - APEC Anti-counterfeit Medical Products Action Plan



INTERNATIONAL
T R A D E
ADMINISTRATION

Jeffrey L. Gren

Director

Office of Health And Consumer Goods

International Trade Administration

U.S. Department of Commerce

tel: 202/482-2410

fax: 202/482-0975

jeffrey.gren@trade.doc.gov

<http://www.trade.gov/td/health>