



**Asia-Pacific  
Economic Cooperation**

---

2013/LSIF/WKSP1/002

**Summary of Life Sciences Innovation Forum  
Activities to Combat Counterfeit / Falsified  
Medicines**

Submitted by: United States



**Workshop on Medical Products Safety and  
Public Awareness and Establishing of a  
Single Point of Contact System  
Seoul, Korea  
22-23 May 2013**

## Summary of APEC LSIF Activities to Combat Counterfeit/Falsified Medicines

APEC Life Science Innovation Forum (LSIF) Medical Product Safety Public Awareness and Single Point of Contact System Workshop  
May 22 - 23, 2013  
Seoul, Korea

Presented by:

Jeffrey L. Gren

Director, Office of Health and

Consumer Goods, U.S. Department of Commerce

## Presentation Outline

- Introductory Comments
- APEC LSIF Anti-counterfeit Medicines Initiatives and Anti-counterfeit Medical Products Action Plan (Part of RHSC Supply Chain Roadmap)
- APEC LSIF Drug Safety and Detection Technology Workshop - September 2011, Beijing, China
- May 2013 LSIF RHSC Drug Safety Public Awareness and Single Point of Contact (SPOC) Workshop, Republic of Korea
- Other Drug Safety Global Initiatives
- Summary and Conclusion

## Introductory Comments

- **U.S. Department of Commerce (DOC)** -- Lead advocate in the U.S. Government for business
  
- **International Trade Administration (ITA)** -- Promotes U.S. trade by strengthening industry competitiveness and reducing tariff and non tariff barriers
  
- **Office of Health and Consumer Goods**
  - Medical devices, pharmaceuticals, biotechnology, health IT
  - Works with industry to understand their challenges and opportunities in overseas markets
  - Solicits the assistance of technical and industry experts on finding technical regulatory solutions in specific markets

3

## APEC LSIF Falsified/Anti-counterfeit Medical Product Initiatives and Action Plan

- During 2008 & 2009 APEC LSIF organized three medical product safety anti-counterfeit/falsified medicine seminars
- An APEC “Anti-counterfeit Medicines Action Plan” was developed based upon feedback during these seminars that has been endorsed by the APEC LSIF Planning Group (September 2010)
- The Anti-counterfeit Medicines Action Plan has been incorporated into the RHSC Supply Chain Roadmap
- The first workshop implementing this Action Plan (on the use of drug detection technologies) took place in Beijing September 2011 and the second workshop (with a focus on public awareness and single point of contact) will during the next two days in the Republic of Korea

4

## **APEC LSIF Drug Safety Action Plan Components:**

- 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 spurious medicines
- APEC economies should coordinate on legislation and penalties for prosecuting criminals making spurious drugs

5

## **APEC LSIF Drug Safety Action Plan (cont'd)**

- Many spurious medicines enter APEC economies through Internet sales. Self monitoring by internet providers and consumer education strategies are needed
- Detection technologies to identify unsafe drugs are extremely important
- Cooperation in stopping illicit trade and production on the global shipment of ingredients used in the production of spurious medicines is also needed
- APEC cooperation on spurious medicines public awareness is important for patients, health professions, regulators, custom officials and law enforcement officials

6

## APEC LSIF Drug Safety and Detection Technology Workshop – Beijing, China, September 2011

- The APEC LSIF Drug Safety and Detection Technology Workshop, took place in Beijing on September 27 and 28, 2011
- This workshop was very successful and included over 200 participants, including 100 China officials and 100 international officials
- China's State Food and Drug Administration (SFDA) and China's National Institutes for Food and Drug Control (NIFDC) were exceptional partners in organizing this workshop
- Beijing workshop results included a) enhanced APEC cooperation, b) development of a guidance document on the use of drug detection technologies, c) the development of an APEC best detection technologies practices document and d) recommendations to the APEC LSIF RHSC for future activities

7

## Korea May 22 - 23 LSIF RHSC Drug Safety Public Awareness and SPOC Workshop

- During the September 2011 LSIF Regulatory Harmonization Steering Committee meeting in San Francisco a "Concept Note" focused on drug safety and security public awareness and the development of an APEC single point of contact (SPOC) system was reviewed and endorsed
- This workshop has been funded, with US AID and AHC support, and will take place during the next two days
- We workshop will focus on the development of medical product safety (medicines and medical devices) public awareness and Single Point of Contact System (SPOC) tool kits and to document best APEC and global public awareness and SPOC practices

8

## Korea May 22 - 23 LSIF RHSC Drug Safety Public Awareness and SPOC Workshop

- The Korea Project Planning Committee and the RHSC Oversight Committee have developed these tool kits which have been distributed to delegates in advance of the workshop
- During the next two days workshop participants will break into smaller groups for interactive discussion on both tool kits
- Following the workshop both tool kits will be reviewed by the RHSC Supply Chain Oversight Committee and endorsed as APEC LSIF and RHSC documents

9

## Medical Product Safety Ongoing Initiatives and Possible Mitigating Activities

- World Health Organization Initiatives
- Partnership for Safe Medicines
- SafeMeds Alert System: [www.safemedicines.org](http://www.safemedicines.org)
- U.S. - China Pharmaceutical and Medical Devices JCCT Subgroup
- U.S. State Dept. funding of country-specific projects on outreach and education – such as India Project Hope Project
- Global Pharmacopeia Cooperation
- APEC LSIF and Regulatory Harmonization Steering Committee

10

## Drug Safety Ongoing Initiatives and Possible Mitigating Activities

- INTERPOL Patient Safety and Criminal Investigation Cooperation Activities
- USPTO and U.S. Justice Department Training for Judges and Law Enforcement Personnel
- World Bank Regulatory Harmonization Efforts - Current Focus Africa
- US Pharmacopeia US AID Funded Quality of Medicines Program
- Medicrimes (Council of Europe)

11

## Conclusion and Summary

- During my presentation I covered the following topics:
  - APEC LSIF Anti-counterfeit Medical Products Action Plan (part of RHSC Supply Chain Roadmap)
  - APEC LSIF Beijing 2011 Drug Safety and Detection Technology Workshop
  - May 2013 LSIF RHSC Drug Safety Public Awareness and Single Point of Contact (SPOC) Workshop, Republic of Korea
  - Other Drug Safety Global Initiatives

12

## Conclusion and Summary

- APEC LSIF is a leader in global efforts to combat unsafe medical products including falsified/counterfeit medical products
- The RHSC Roadmap on Global Medical Product Quality and Supply Chain Integrity, the Anti-counterfeit Medical Products Action Plan and the development of medical product safety public awareness and SPOC toolkits are examples of this leadership
- I am looking forward to a productive workshop during the next couple of days