INTERNATIONAL TRADE ADMINISTRATION

AHWP TC Technical Training Workshop

November 3, 2012

Chinese Taipei

Overview of Global Issues and Activities Related to Counterfeit/Falsified Medical Products

Presented by:

Jeffrey Gren, Director, Office of Health and Consumer Goods, U.S. Department of Commerce

Introductory Comments

- I am delighted to a speaker during the AHWP Annual Meeting Technical Training Workshop
- I am a strong supporter of AHWP, I have worked with AHWP since it started 17 years ago, and I am extremely impressed with AHWP's progress and global impact
- I have spoken during past AHWP annual conferences, but today I will cover a different topic - counterfeit/falsified medicines

Presentation Outline

1. Introductory Comments and the Global Counterfeit/Falsified Medicines Problem
2. APEC Combating Counterfeit/Falsified Medical Products Initiatives
3. Ongoing Global Mitigating Activities
4. Global API Concerns (China and India)
5. Comments Concerning Counterfeit/Falsified Medical Devices
6. Summary and Conclusions

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

Introduction - The Global Counterfeit Medicines Problem

- Factors leading to this increase in falsified/counterfeit medicines include:
  - Increase in criminal activity and level of sophistication
  - High profit level (even higher than for narcotics)
  - Internet provides a marketing vehicle for criminals to distribute counterfeit medicines
  - Lack of penalties, enforcement, and coordination in prosecution in many overseas markets have created conditions for counterfeiting to grow

Introduction – The Global Counterfeit Medicines Problem Continued

- Globalization of the pharmaceutical industry has contributed to the ready supply of APIs (active pharmaceutical ingredients) for counterfeiters, as manufacturing of APIs and finished dosage form medicines shifts from developed to lesser developed countries
- Counterfeiting impacts all aspects of the pharmaceutical industry - patented drugs, generic drugs and OTC medications
- Globalization of the pharmaceutical industry has also contributed to the growth of substandard medicines

The Global Counterfeit Medicines Problem Continued

- Twenty years ago most counterfeit medicines did not contain medicinal ingredients, currently a large percent of counterfeit medicines contain real APIs and excepients
- What is scary is the counterfeiters are often using real pharmaceutical ingredients since they are seeking repeat business. Of course, all counterfeit medicines are unsafe and may not have the correct ingredients
- In developed markets, such as the U.S. and Europe, the majority of counterfeit medicines are distributed through the Internet
- Several studies have documented that the vast majority of medicines distributed through the Internet are illegal, counterfeit or substandard

Introduction - Definitional Issues:

- Old WHO: In the case of medical products, includes the deliberate and fraudulent mislabeling with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging
- WHO IMPACT Initiative Derailed in 2011
- Current WHO Definition – SSFFC - "Substandard/Spurious/Falsely-Labeled/Falsified/Counterfeit Medical Products"

APEC-Funded Drug Safety – Past Activities

- During 2008 and 2009 APEC LSIF organized three Asia drug safety and security seminars - January 2008 and March 2008 in Singapore and a February 2009 seminar in Mexico City
- Findings of the APEC drug quality seminars were presented to APEC Ministers
- An APEC Counterfeit Medicines Action Plan was developed that has been endorsed by the APEC LSIF Planning Group during September 2010

APEC LSIF Anti-counterfeit Medicines 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 counterfeit medicines

APEC LSIF Anti-counterfeit Medicines Action Plan (cont'd)

- Many counterfeit medicines enter APEC economies through Internet sales. Monitoring 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 counterfeit/falsified medicines public awareness is important for patients, health professions, regulators, custom officials and law enforcement officials

APEC LSIF Drug Safety Action Plan – Future Activities

- The APEC LSIF Regulatory Harmonization Steering Committee (RHSC) - Supply Chain Roadmap addresses medical product safety including implementation of the APEC LSIF Anti-Counterfeit Medicines Action Plan
- APEC LSIF RHSC workshop to take place May 22 - 23, 2013 in Korea as an Asian Harmonization Center Workshop - focus medical product safety public awareness and the development of a Single Point of Contact System (SPOC)
- Future workshops being considered include:
  - Internet Medicines Crime
  - Good Distribution Practices for Medicines
  - API Regulatory Practices to stop counterfeit/falsified APIs and the use of APIs in counterfeit medicines

Summary of the Global Active Pharmaceutical Ingredient (API) Concerns

- During the past 30 years there has been dramatic shifts in the location of the production of APIs and dosage form medicines. These changes have significantly increased the risks associated with the export of APIs and dosage form medicines
- China has been a major player in this global shift and China is currently the world's largest global supplier of APIs and has one of the fastest growth rates for generic dosage form medicine production. India is the second largest supplier, followed by Italy as the third largest global supplier
- Global cooperation is needed concerning the regulation and the shipment of APIs from one country to another since APIs are ending up in the hands of criminals that traffic counterfeit medicines

Summary of Global API Concerns (cont'd)

- For example, under Chinese law all APIs produced for medicinal use are required to be registered with China's State Food and Drug Administration (SFDA) and the manufacturer must comply with SFDA GMPs
- Some Chinese bulk chemical companies, however, are not complying with this requirement
- The problem is that criminals producing counterfeit/falsified medicines have access to APIs, that are not available to them through normal legal channels
- Unregistered bulk chemicals made in China and other global locations, that are in fact APIs or have an intended use as APIs, are readily available over the Internet and a trade shows, often with claims that they have medicinal use

Summary of Global API Concerns (cont'd)

- DOC has worked with the Drug Information Association (DIA) in organizing a Regulation of API Workshop in May 2012 during the DIA annual China conference and DIA id organizing follow-up workshops
- The discussions during the May 2012 workshop was very useful in understanding the China API situation
- China has taken significant actions to begin addressing this problem including shutting down websites selling APIs and enhanced enforcement activities
- DOC has also discussed the regulation of APIs with China SFDA during meetings of the China - US JCCT Pharmaceutical and Medical Devices Subgroup
- We are also exploring the production and distribution of APIs in India and DIA is planning to organize a regulation of APIs workshop in India

Counterfeit/Falsified Medicines Ongoing Initiatives and Mitigating Activities

- WHO Initiatives
- Partnership for Safe Medicines
- SafeMeds Alert System: www.safemedicines.org
- APEC Life Science Innovation Forum (LSIF) Anti-counterfeit Medicines Action Plan
- APEC LSIF Regulatory Harmonization Steering Committee - Roadmap on Global Medical Product Quality and Supply Chain Integrity
- U.S. - China Pharmaceutical and Medical Devices JCCT Subgroup
- U.S. - India HTCG Biotechnology and Life Sciences Working Group

Counterfeit/Falsified Medicines Ongoing Initiatives and Mitigating Activities

- U.S. State Department funding of country-specific projects on outreach and education about counterfeit drugs
- INTERPOL Patient Safety and Criminal Investigation Cooperation Activities
- U.S. Patent and Trademark Office (USPTO) and U.S. Justice Department Training for Judges and Law Enforcement Personnel
- Word Bank Regulatory Harmonization Efforts - Current Focus Africa
- US Pharmacopeia US AID Funded Quality of Medicines Program
- ASEAN Combating Counterfeit Medical Products Training Activities Under a US – Singapore Training Initiative

Counterfeit/Falsified Medicines Ongoing Initiatives and Mitigating Activities

- I would like to read a paragraph from the APEC LSIF Regulatory Harmonization Steering Committee Roadmap on Global Medical Product Quality and Supply Chain Integrity
- “Perhaps no issue in more impacted to APEC economies than the import and export rules applicable to the international movement of medical products. For a number of reasons many countries have stringent import restrictions, but less strict requirements on exports. After all, one APEC economy's export is another's import."

Comments Related to Counterfeit/Falsified Medical Devices

- By far, most counterfeit medical products are drugs, including patented, generic and OTC medicines
- Medical devices are counterfeited, but to a much lower extent than drugs
- The types of medical devices most frequently counterfeited are medical test kits, invitro diagnostics, component parts for imaging equipment, contact lenses, surgical sutures, and latex products (gloves & condoms)
- In general medical devices are more difficult to counterfeit than drugs due to the technologies used and there is also a problem in some markets with substandard medical devices, especially in markets without a rigorous medical device regulatory regimes

Comments Related to Counterfeit/Falsified Medical Devices

- Due to difference in the ways medical devices are counterfeited and the lower incidence, addressing the counterfeit medical devices problem requires different strategies and activities
- While there has been some global meetings focused on counterfeit medical devices, almost all global activities have focused on drugs
- For example, the APEC May 2013 Korea workshop I mentioned earlier will cover drugs and medical devices
- In discussions I have had with medical devices regulators and industry representatives, the degree of counterfeiting of medical devices varies significantly by country, region and product, and this is currently not viewed as a high priority problem

Comments Related to Counterfeit/Falsified Medical Devices

Examples:

- Singapore had a problem with counterfeit contact lenses, completed an extensive investigation and ran a public awareness campaign educating consumers
- A medical imaging producer had a problem with counterfeit component parts (semiconductors)
- Saudi Arabia has seen an increase in the incidences of counterfeit medical devices
- Great Britain had a incident of counterfeit condoms
- There was a problem with counterfeit surgical sutures in Europe
- There have been incidences of counterfeit testing kits in the U.S.

Summary and Conclusions

- During my presentation I covered the following:
  - Introductory Comments
  - APEC Medical Product Safety Initiatives
  - The APEC Anti-counterfeit Medicines Action Plan
  - The Global API Concerns
  - Comments Related to Counterfeit/Falsified Medical Devices

- Counterfeit/Falsified medicines is a significant growing global problem and I am confident that the global programs and cooperative activities taking place will make an impact to stop the spread of unsafe medicines

INTERNATIONAL
TRADE
ADMINISTRATION

Jeffrey L. Gren
Director
Office of Health And Consumer Goods
International Trade Administration
U.S. Department of Commerce
tel: 202/482-2470
fax: 202/482-0975
jeffrey.gren@trade.gov
http://www.ita.doc.gov/td/health