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Topic: The Impact of Globalization of the Pharmaceutical Industry on the Spread of Counterfeit Medical Products

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Outline

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- The impact of globalization of the pharmaceutical industry
- The substandard and counterfeit medicines global problem
- DOC anti-counterfeit medical product activities
- Possible solutions
- Summary and conclusions

Introduction

- U.S. Department of Commerce (DOC) is the advocate for business in the U.S. government and DOC's international trade role is to promote U.S. trade by strengthening industry competitiveness and reducing trade barriers
- I direct the Office of Health and Consumer Goods and my office focuses on medical devices, pharmaceuticals, biotechnology, and a wide array of consumer goods products
- An outcome of the globalization of the pharmaceutical industry is a significant increase in substandard and counterfeit medicines

Introduction (cont'd)

- During the past several years DOC has been very active in the global battle to stop the spread of counterfeit medicines and we work very closely with U.S. FDA and industry in our activities
- We are also currently exploring drug quality issues such as the global substandard medicines problem and ways that DOC can work with industry and regulators to address this problem
- The percentage of counterfeit and substandard medicines on the market increases each year as manufacturing of API and finished dosage form medicines shifts from developed to lesser developed markets

Industry Trends Impacting the Problem: Global API Manufacturing - 2004

Total Global Number of API Manufacturers Sites approximately 2,000

*Source: Newport Horizon Sourcing, October 2004

Industry Trends: Global API Manufacturing 2007

Total Global Number of API Manufacturers Sites approximately 1,144

*Source: Newport Horizon Sourcing, October 2007

Industry Trends

- IMS Health: India will be the dominant country for API production for the next 20 years, and over the next 50 years China will become more dominant for API production
- Currently most API manufacturing in India and China is for the generic drug market, but this will change over time due to:
  - lower developmental costs
  - complex synthesis capabilities
  - shifting pharmaceutical drug production
  - regulatory compliance and adherence to CGMP and CGCP

Industry Trends: Generic Production

- Generic production is growing at a faster rate than innovator drug production
- Shift in the global production of generic drugs – countries/regions with significant growth of generic production include India, China, South East Asia, Brazil, Middle East, Russia, Mexico
- According to IMS, India is currently producing about 70% of the global generic medicines.

Industry Trends: Global Pharmaceutical Manufacturing

Local pharmaceutical production capacity varies greatly among countries

Source: WHO 2004. World Medicines Situation.

Industry Trends Impacting the Problem (cont'd)

- The shift in API and finished dosage form production away from the developed markets can contribute to the counterfeit and substandard medicines problem
- The regulatory regimes and standards established by pharmacopeias are much weaker in developing and least developed countries
- It is important to note that counterfeit medicines are not limited to innovative drugs. In fact, we are seeing an increasing number of counterfeit incidences involving generic and over the counter medicines

Counterfeit vs. Substandard Drugs

- All counterfeit drugs are substandard
- Only a portion of substandard drugs are counterfeit

Counterfeit vs. Substandard Drugs

- Notably, there is a significant difference between counterfeit and substandard drugs
- WHO defines counterfeit drug as “a drug that is deliberately mislabeled with respect to identity and/ or source”
- Counterfeit drugs are produced by criminals and meet the “fraudulent and the deliberate” aspects of the WHO definition of counterfeit medicines
- Substandard drugs are medicines manufactured below established standards of safety, quality and efficacy

Counterfeit vs. Substandard Drugs (cont'd)

- However, neither counterfeit or substandard medicines generally meet regulatory requirements such as cGMPs, bioequivalence, or pharmaceutical equivalence
- The public health impact of substandard and counterfeit medicines is the same since both can have correct APIs, wrong APIs, no APIs or less than effective APIs

Counterfeit vs. Substandard Drugs

- In our view all medicines that have the potential to cause unnecessary harm to patients are unsafe
  - Counterfeit: deliberately and fraudulently mislabeled with respect to identify and source
  - Substandard: do not meet the requisite pharmaceutical regulatory / therapeutic specifications
- The substandard and counterfeit medicines problem varies significantly among countries and regions
- Countries and regions with weak regulatory oversight are more suspect to substandard medicines

Counterfeit vs. Substandard

- The consequences of the use of either counterfeit or substandard medicines is the same:
  - Direct harm to patients
  - Therapeutic failure
  - Weakens public confidence in health system
  - Affects reputation of supply chain

Counterfeit vs. Substandard Drugs (cont'd)

- There are no reliable statistics to measure global impact of counterfeit and substandard medicines
- 10-20 years ago most counterfeit medicines had no APIs
- Now increasing number of counterfeit medicines contain real APIs

Counterfeit vs. Substandard Drugs (cont'd)

- A single global figure is misleading
- Developed markets with strong regulatory oversight are estimated to have less than 1-2% of the drug supply as counterfeit. However, 1-2% of the U.S. or EU drug supply is a huge number

Counterfeit vs. Substandard Drugs (cont'd)

- Internet sales of drugs is a huge problem – a recent study cites that 63% of drugs purchased on the internet are counterfeit and all are illegal
- Much of the world (SE Asia, Africa, China, Latin America) has areas where patients regularly encounter counterfeit and substandard medicines
- A US Pharmacopeia 2004 study of medicines in SE Asian countries documents that selected drugs tested had a 25 - 75% incidence of substandard or counterfeit

Counterfeit Vs. Substandard Drugs

The most expensive drug is the one that does not work!!

Counterfeit Medical Devices

- Most of the counterfeit medical products focus has been on counterfeit pharmaceuticals.
- There is clearly significantly more reporting incidences for counterfeit pharmaceuticals than for counterfeit medical devices
- However, there is an increasing number of incidences of counterfeit medical devices
- Based upon feed back from industry the most frequent incidences for counterfeit medical devices are in IVD reagents and solutions, contact lenses, medical test kits, combination products (medical devices and drugs), and component parts, such as semi-conductors used in medical imaging equipment

DOC Involvement / Activities

- DOC/FDA led Anti-Counterfeiting Task Force
- APEC Life Science Innovation Forum activities, such as anti-counterfeit medical product Asia and Latin America seminars (with USFDA)
- U.S. - China Pharmaceutical and Medical Devices JCCT Subgroup
- U.S. - India HTCG Biotechnology and Life Sciences Working Group

Potential Solutions

- Global cooperation among health regulations, customs, law enforcement and industry to stop the flow of counterfeit pharmaceutical ingredients
- Global cooperation on plant inspections/audits – no one country can do this alone
- Regulators need to enforce standards, and take action against poor performances
- Manufacturers need to be responsible for product quality

Potential Solutions (cont'd)

- Continue global harmonization efforts, including training and harmonized standards (ICH and country or region specific activities)
- Encourage track and trace technologies, verification of ingredient programs, authentication technologies to protect supply chain integrity
- Continue to focus on regional dialogues – APEC, ASEAN, PAHO, WHO, PANDRA, etc.
- World Health Organization (WHO)

Potential Solutions (cont'd)

- "Partnership for Safe Medicines" is a coalition of patients, physicians, pharmacists, universities, industry, and other professional organizations, committed to protecting the public from counterfeit – Avoid – Detect – Report
- SafeMeds Alert System: www.safemedicines.org Countries can sign up to participate
- Risk of doing nothing – prevalence of substandard and counterfeit medicines **will** continue to grow

Summary and Conclusions

- The globalization of the pharmaceutical industry has contributed to an increase in counterfeit and substandard medicines
- Notably, the global shift in the production of API and finished dosage form medicines adds to the global counterfeit and substandard medicines problem
- Any meaningful solution requires cooperation and coordination among various stakeholders, including customs, regulators, law enforcement, and industry

Summary and Conclusions (cont'd)

- Progress is being made, but a focused global approach is needed
- I look forward to the day when we can announce there are less substandard and counterfeit medicines in the world than there were the previous year

Thank You!

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