

Counterfeit Drugs: Protecting the Medication Supply

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Today's Program

- Identify ways that counterfeit drug products enter the US distribution system
- Explain risks associated with product counterfeiting & its impact on patients and their caregivers
- Review regulatory and law enforcement actions that address the safety of the drug supply chain in the US
- Discuss potential business advantages, beyond product safety, that could potentially result from the implementation of track and trace technologies
- Discuss the role of the student pharmacist, pharmacist, and pharmacy team in preventing counterfeit medication in the US supply chain

What are counterfeit drugs?

“[A] drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark...of a drug manufacturer, processor...or distributor other than the person...who in fact manufactured, processed...or distributed , such drug and which thereby falsely purports or is represented to be the product of...such other drug manufacturer, processor...or distributor.”

US FDC Act

Pharmaceutical Security Institute Definition

Counterfeit medicines are products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product. This definition applies to both branded and generic products.

WHO Delineates...

- Fake Packaging, Correct Quantity of Correct Ingredient (Clone)
- Fake Packaging, Wrong Ingredient
- Fake Packaging, No Active Ingredient
- Fake Packaging, Incorrect Quantity of Correct Ingredient
- Genuine Packaging Wrong Ingredient
- Genuine Packaging, No Ingredient
- Genuine Packaging, Incorrect Quantity of Correct Ingredient

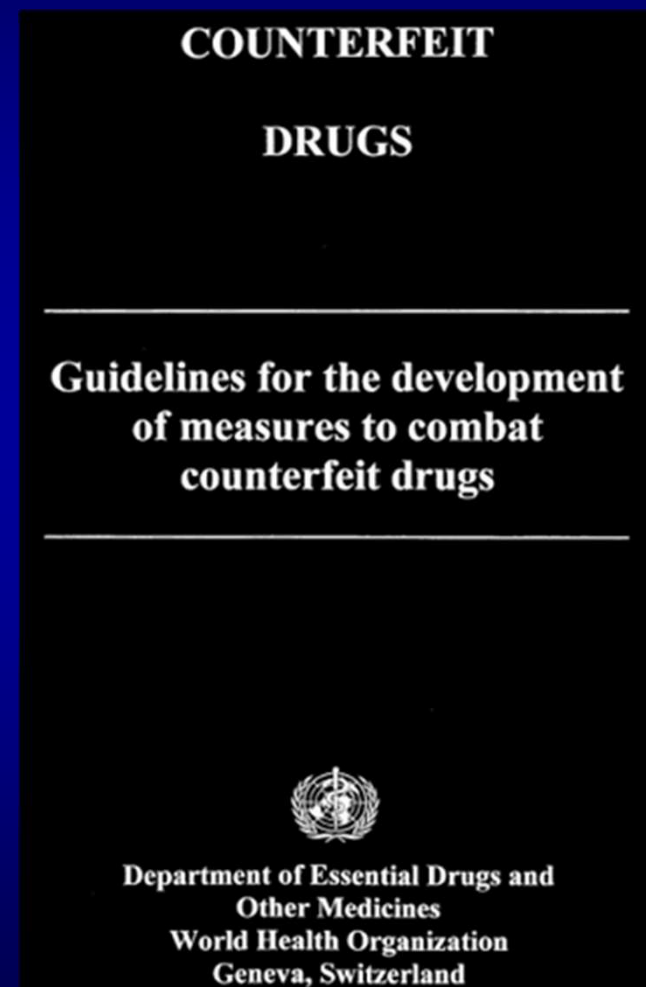
WHO: Counterfeit Drugs Kill

<http://www.who.int/impact/FinalBrochureWHA2008a.pdf>

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Extent of the Problem is Large

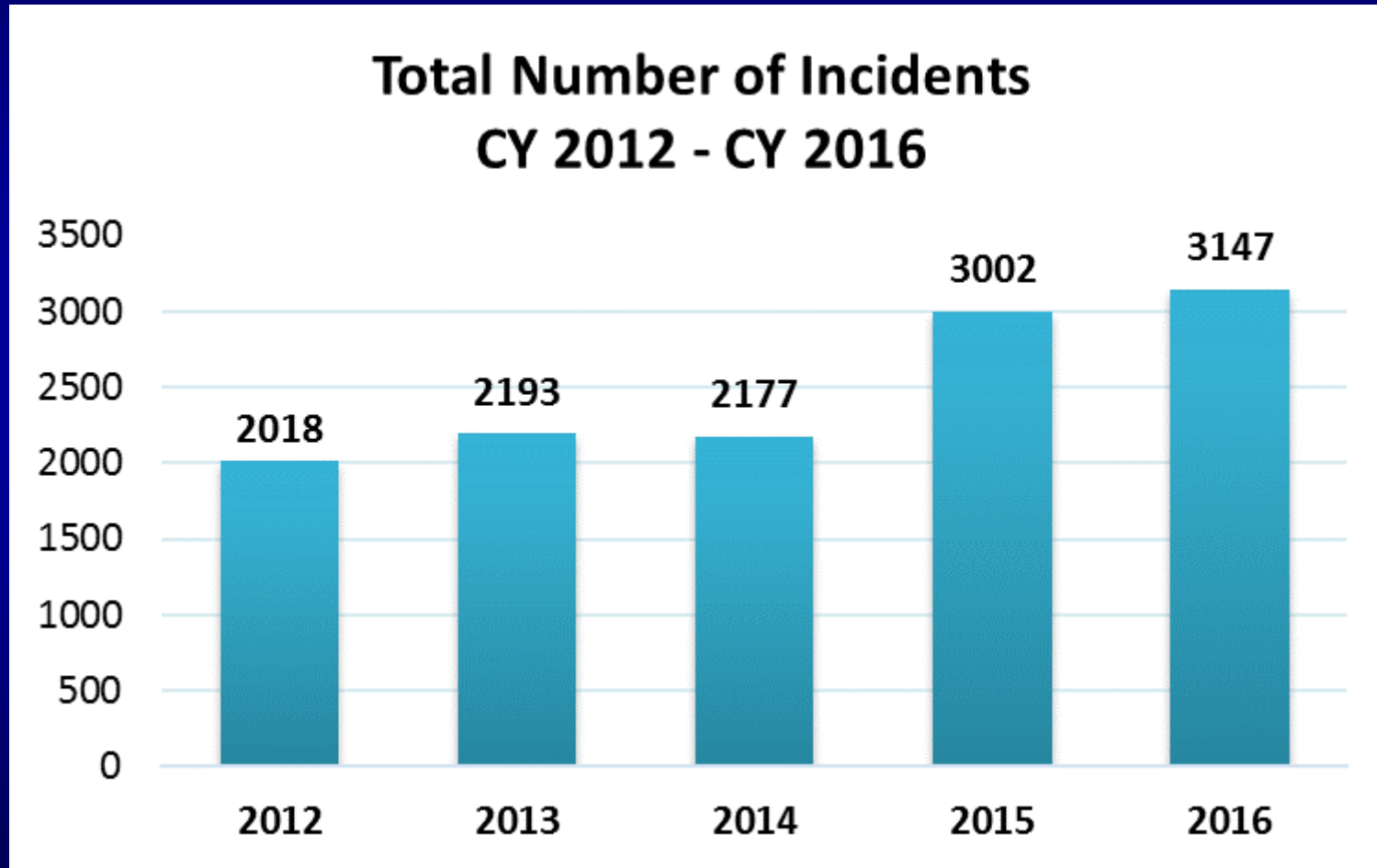
- It has been estimated by the WHO that counterfeit drugs comprise 6 to 10 percent of the world market.
- Estimated to be \$200 billion market. (WSJ)
- In some countries this rate is > 50% and you are more likely to receive a counterfeit product than authentic
- A number of deaths globally (China, Cambodia, Nigeria, etc) have been attributed to “fake” medications used to treat malaria, meningitis, etc
- WSJ: June 18, 2015, Guest Voices: Transparency Needed to Combat Counterfeit Drugs



In the United States

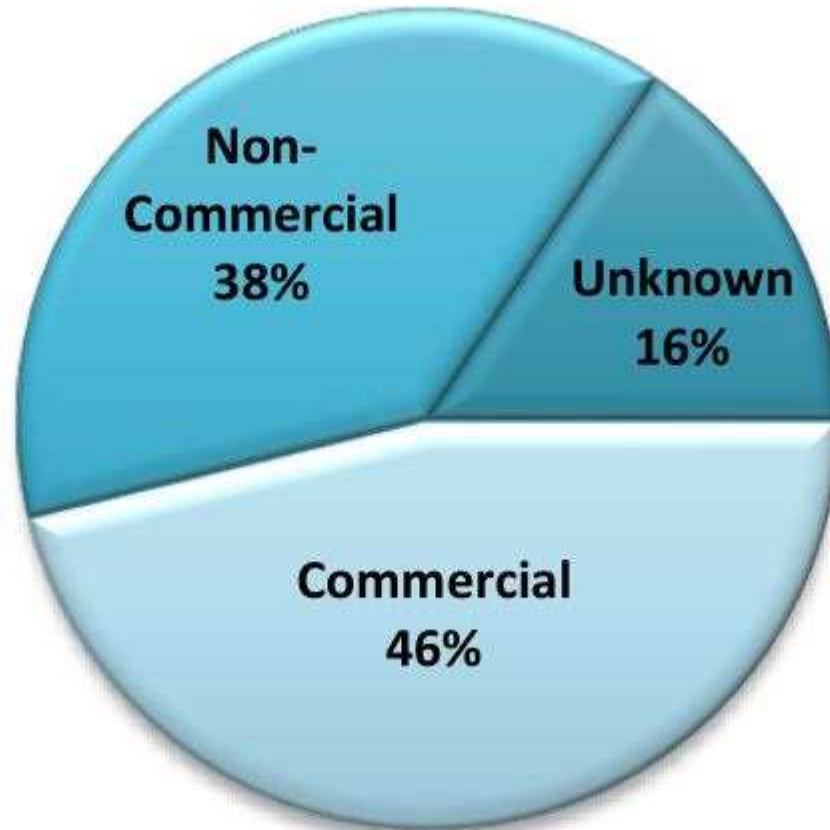
- In the U.S. the FDA has seen a four-fold increase in the number of counterfeit cases they have investigated since 2000
- PSI* reports 971 incidents in 2015, a 34% increase over 2014; declined to 520 om 2-16
- Cases are 3-5 times what was reported a decade ago.
- Counterfeit sales are increasing at nearly twice the pace of legitimate pharmaceutical sales – estimated at 13% annually by the Center for Medicine in the Public Interest.

Counterfeiting, Illegal Diversion, Theft incidents



By Type Commercial >1,000 dosage units

Counterfeit Seizures CY 2016

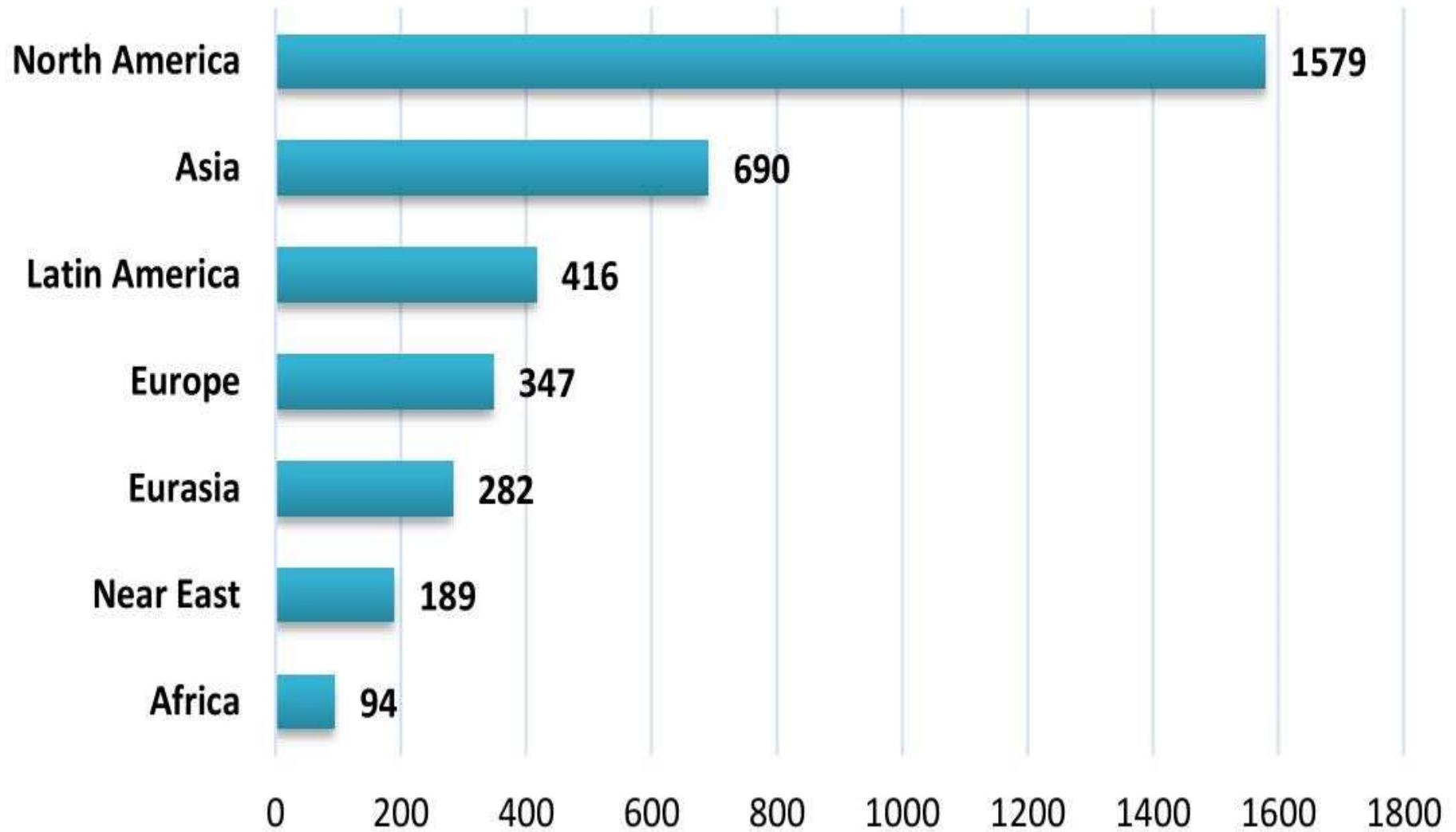


Prevalence

- Industrialized countries with effective regulatory systems (eg, US, most of EU, Australia, Canada, Japan, New Zealand)—less than 1%
- Former Soviet Union countries over 20%
- Medicines purchased over the Internet from sites that conceal their physical address are counterfeit in over 50% of cases

WHO IMPACT Report 5-2008

Incidents - Regions of the World

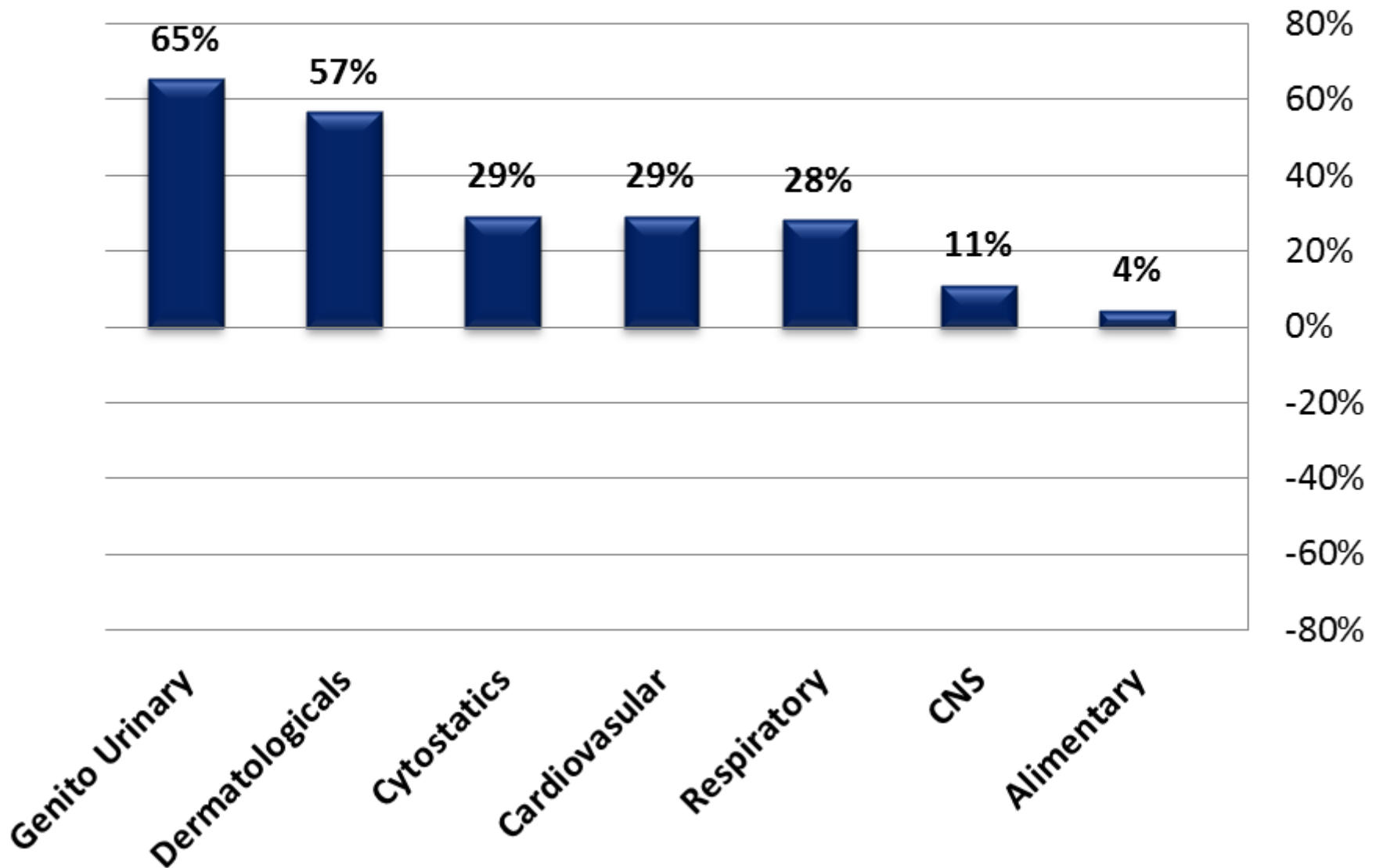


What Products?

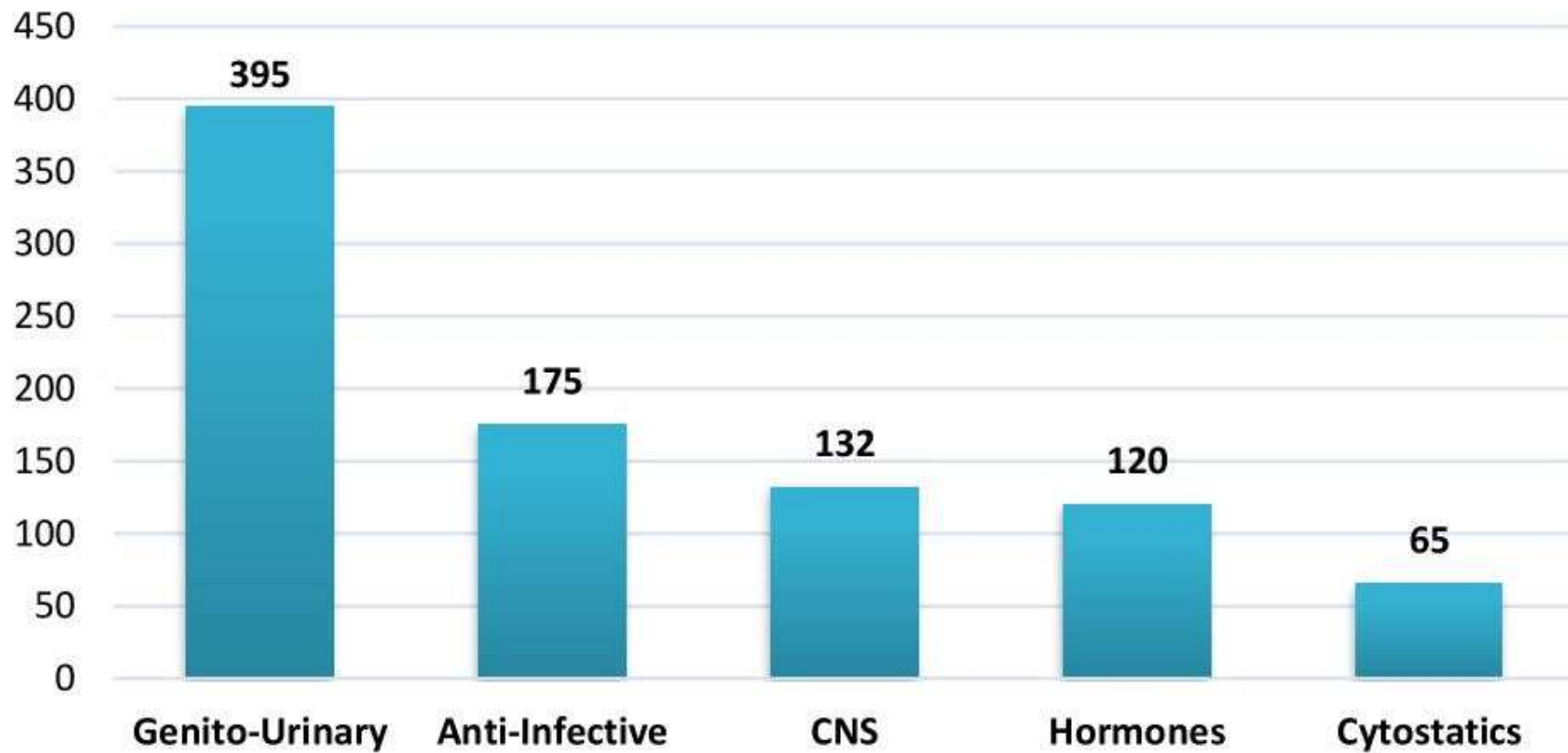
- Both brand and generic
- Lifestyle drugs
- Cancer agents
- Antibiotics
- Statins
- Hormones, steroids
- Glucose strips
- Developing countries: HIV/AIDS, malaria, TB

Therapeutic Categories Counterfeit Incidents

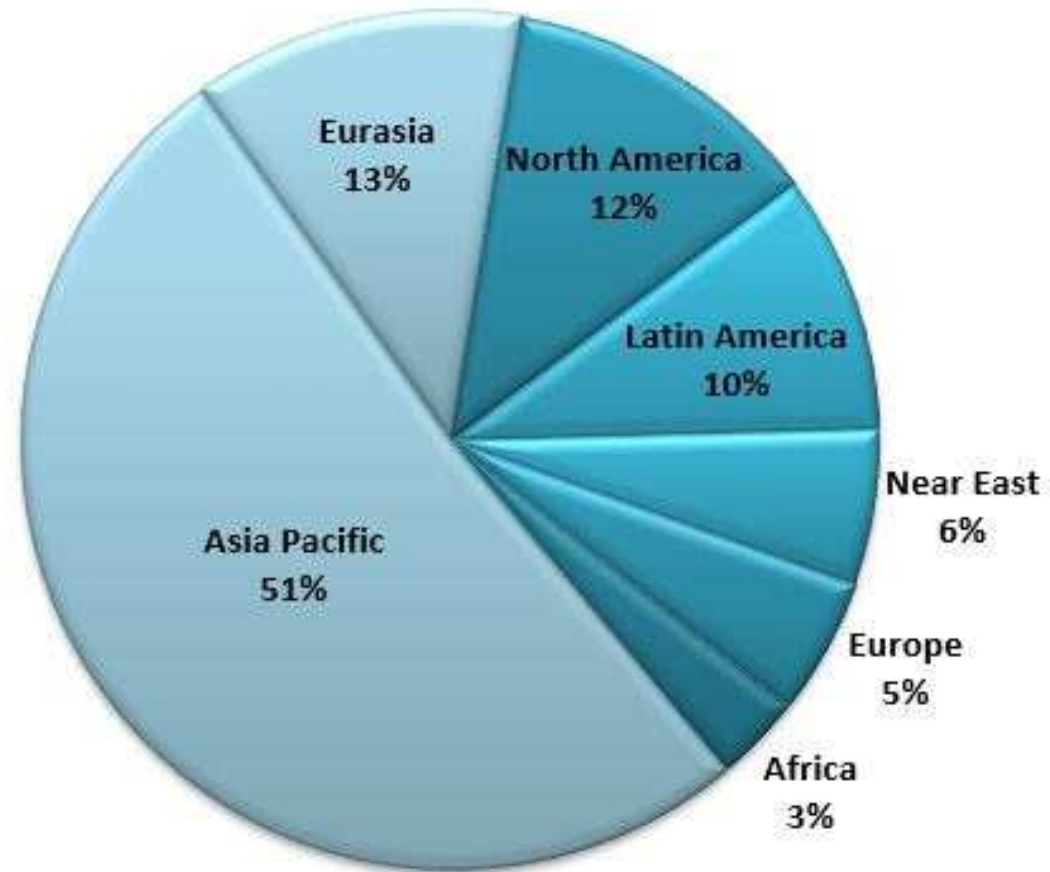
Percent Change CY 2015



CF Incidents & Therapeutic Categories Top Five - CY 2016



Arrests by Region CY 2016





About Partnership For Safe Medicines

Criminals make billions of dollars creating and selling counterfeit drugs around the world, and those products make their way into the United States. They duplicate the exact packaging, look and taste of the real thing. They can be difficult to detect, but detecting them is important. Counterfeit drugs can be a death sentence for the patients who end up taking them. Fake drugs deny patients treatment that can alleviate suffering and save lives, promote drug resistant strains of disease and may cause dangerous or deadly reactions to undeclared drug ingredients.

Comprised of 75 non-profit organizations, the Partnership for Safe Medicines (PSM) is a public health group committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard or otherwise unsafe medicines.

PSM follows a set of principles to support quality assurance programs and establish a drug distribution system that is without compromise. It is our hope that through these guidelines we can reduce the number of counterfeit drugs that defraud patients and deny them therapies that can alleviate suffering and save lives. Our principles include:

- Unifying the fight against counterfeit drugs
- Securing and protecting the pharmaceutical supply chain
- Regulation of online sellers

Our members are dedicated to protecting the safety of American consumers by curbing the manufacturing and sale of dangerous counterfeit drugs. Our goal is for all consumers to be aware that counterfeit medicines do exist, they are not safe and together we can take action to avoid them.

PSM works with patient advocacy groups and consumer groups to raise awareness of counterfeit drugs within the United States and to

Manufacturing Site in Latin America

TABLETING MACHINE



Manufacturing Site in Latin America

BLISTER CUTTER AND SEALING MACHINE

