COUNTERFEIT MEDICINES

IN LEGITIMATE SUPPLY CHAINS

A <u>study</u> by University of California, San Diego School of Medicines & the Pharmaceutical Security Institute (PSI)

COUNTERFEIT MEDICINES CAN BE FOUND EVERYWHERE:



On the street...



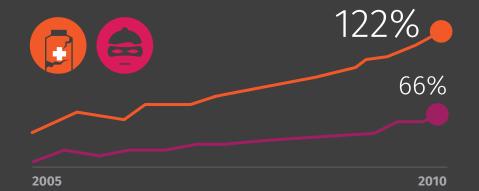
...on the Internet...



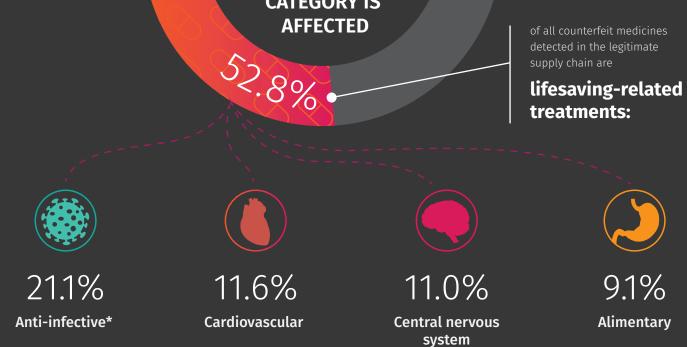
...and even in the legitimate supply chain.

THE SCOPE, PRODUCTION, DISTRIBUTION AND SALES OF COUNTERFEIT MEDICINES ARE INCREASING:

Analysis of reports over a five year period - from 2005 to 2010 - indicates that counterfeit medicines increased by 122% while diversion and theft increased by 66%.



EVERY THERAPEUTIC CATEGORY IS



*including both branded and generic anti-infectives/antibiotics, such as anti-malarial

ROUTE OF ADMINISTRATION:



77.3% were oral dosage formulations

15.4% were injectable biologicals

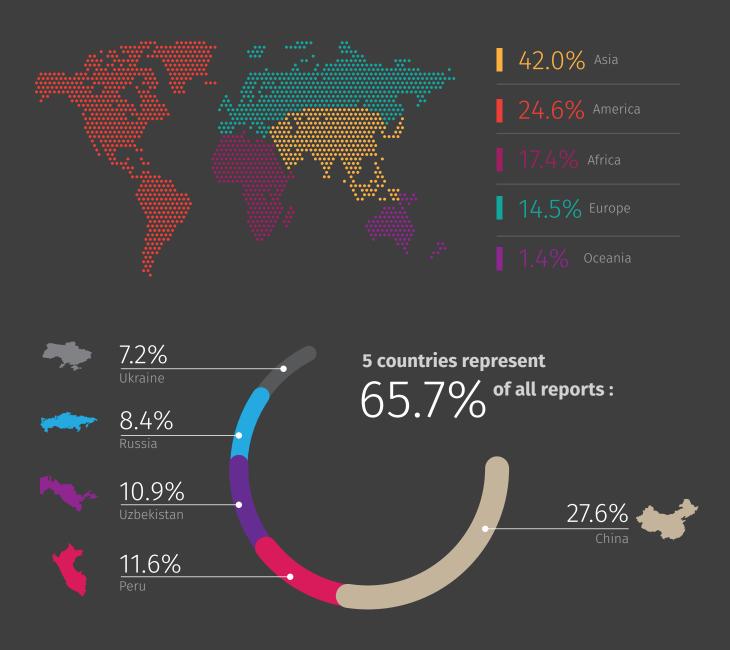
REPORTS ON COUNTERFEIT MEDICINES ARE LACKING. BASED ON PSI REPORTING SYSTEM ANALYSIS FOUND THAT:

35.2% more than one-third of the nations in the world had their legitimate supply chain compromised

51.3% of the reports contained

SOURCES OF REPORT SHOW A GREAT DIFFERENCE BETWEEN REGIONS:

Middle income markets were most represented



Improvements in surveillance, including detection of security breaches, data collection, analysis, and dissemination are urgently needed to address the public health need to combat the global counterfeit medicines trade

CONCLUSIONS:

Three key needs emerged from this study:

- greater consistency, standardization and robust data collection for analysis,
- enhanced reporting by countries,
- increased details in the reports.

RECOMMENDATIONS:

- development and coordination of a "single point of contact" system comprised of relevant country authorities to conduct surveillance and reporting counterfeit incidents to a central global system,
- development of a "graded best practices" set of guidelines supporting ongoing training, capacity building, technical assistance, data sharing, and partnership. These guidelines should be developed in

cooperation with regulatory authorities, law enforcement, customs, pharmaceutical companies, academic institutions, and other stakeholders.



1 <u>Mackey TK, Liang BA, York P, Kubic T. Counterfeit Drug Penetration into Global Legitimate</u> Supply Chains: A Global Assessment. Am J. Trop. Med. Hyg; 2015; doi:10.4269/ajtmh.14-0389 [advanced online publication]