

RISING GLOBAL COUNTERFEIT EPIDEMIC

Interpol warns of rising global counterfeit epidemic - Aline Plancon, the head of Interpol's counterfeit drug department, notes that "no class of drugs had been spared...It's not just primary medicines. There's also lifestyle drugs, herbal drugs, vaccines'." Similarly, [Plancon states](#) that "the business of fake medicine is attractive to criminals because the margins are significantly higher than for illegal hard drugs." A joint Interpol, WHO, and World Customs Organization operation in 2008 resulted in the seizure of 16 million counterfeit AIDS, malaria, antibiotics, and tuberculosis pills worth over \$6.6 million. [According to Interpol](#), Operation Storm lasted five months and resulted in 200 raids and 27 arrests across Southeast Asia.

News report finds that counterfeit drugs are an "international multibillion dollar black market industry" - According to a recent [ABC News report](#), counterfeit drugs are "not just an international problem, but one unfolding right here in the United States." Matthew Friedrich, the acting assistant attorney general for the Justice Department's criminal division noted that counterfeit drugs are "a serious problem, simply because of the potential for health issues, and the potential for deaths if it is not taken seriously." *ABC News* reports that counterfeit drugs are "often produced in awful conditions, lacking sanitation or any type of procedure to keep the drugs safe," and is of "growing concern to law enforcement because of the sometimes lethal consequences for patients taking medicine that doesn't perform as advertised." According to *ABC News*, consumers put their health at risk as they are often "not buying drugs at their local pharmacies, but on street corners and, increasingly, through online pharmacies." The Department of Justice's Friedrich [warns consumers](#): "If you want to go to the Internet and you find a pharmacy that is willing to sell you a prescription drug at a very low price, without a doctor having seen you, and without a prescription, watch out."

The internet and availability of sophisticated technology has led to an increase in counterfeit medicines - According to a *National Public Radio* report, the Internet and "the growth in international commerce, and easy access to sophisticated technology" has facilitated the rise of counterfeit medicines in the marketplace. Inspections help but finding fakes is like finding "a needle in a haystack." Head of the WHO Anti-Counterfeiting Task Force, Dr. Valerio Reggi, noted that inspections may not succeed in finding all counterfeit drugs. [According to Dr. Reggi](#), "no counterfeiter would manufacture one pill or even a container of pills", and "for every drug that you find, it means at least one batch. And one batch usually is between 30,000 and 60,000 tablets."

International Narcotics Control Board finds growing concerns about the unregulated market for medicines - According to the [2008 annual report](#) of the International Narcotics Control Board, which monitors compliance with UN drug conventions, "counterfeiting has become a lucrative international criminal activity." The report expresses concern about the rise in counterfeit drugs and the health risks of the Internet medicines market. According to the report, "counterfeit medicines undermine national health-care systems, result in loss of confidence in drug control and law enforcement systems and pose serious health risks to users."

GLOBAL COUNTERFEITING STATISTICS

Global counterfeit seizures up 24% in 2007 - According to recent data from the Pharmaceutical Security Institute, counterfeit medicine seizures rose 24% in 2007. Among the \$3 billion worth of counterfeit medicine seized in 99 countries were versions of 403 different prescription drugs. *Bloomberg News* [reports](#) that "copies of 19 of the world's 25 best-selling drugs" were among the counterfeit medicines seized. Counterfeit versions of a popular anti-psychotic as well as cholesterol lowering medicines were found by investigators. Many of the seized drugs "lack proper ingredients or contain incorrect and misidentified dosages." The World Health Organization (WHO) [estimates](#) that tens of thousands may be dying due to counterfeit HIV/AIDS, diabetes, and tropical disease medicines. The FDA's Director of Pharmacy Affairs Ilisa Bernstein noted that there are "counterfeiters circulating all over the world" and it is difficult to "tell how many there are because the counterfeiters

are just so good at what they do.” The FDA is unable to inspect “millions and millions and millions” of packages coming in making it “very difficult to find and catch all of these drugs that are coming in” according to Bernstein.

WHO report finds over 30% of prescription medicines in some parts of the developing world, and up to 50% from rogue internet sites are counterfeit - According to a November 2006 WHO report, “The latest estimates jointly elaborated by WHO, the OECD, and the Pharmaceutical Security Institute show that more than 30% of medicines in some areas of Latin America, South East Asia and Sub-Saharan Africa are counterfeit. In emerging economies, the proportion is estimated at 10% but in many of the former Soviet republics it can be as high as 20%. In wealthy countries, with strong regulatory mechanisms, counterfeits account for less than 1% of the market value, but 50% of illegal Internet sales are counterfeit.” According to Dr. Howard Zucker, WHO Assistant Director-General for Health Technology and Pharmaceuticals, “The impact on people’s lives behind these figures is devastating. Whether rich or poor, many patients trustingly taking medicines may end up sicker or die. In addition, precious resources spent on these medicines go to waste.”

EU COUNTERFEIT STATISTICS

EU counterfeit medicine article seizures rose 118% in 2008- According to the [European Commission](#), counterfeit medicine article seizures rose 118% in 2008 in the European Union, and 8.9 million counterfeit medicine articles were seized by EU custom officials. Cholesterol, blood pressure, and osteoporosis drugs were among the counterfeit medicines seized by customs officials. According to the European Commission, the largest supplier of counterfeit drugs was India, followed by Syria, the United Arab Emirates (UAE), Ukraine, and China. Given the increase in number of medicines seized in 2008, the European Commission states that “medicines now represent the third largest specific product category in terms of quantities of intercepted articles.” In recent years, the number of counterfeit medicines seized in the EU has grown significantly. [In 2007](#), 4.1 million counterfeit pharmaceuticals were seized by EU custom officials, representing an increase of 51% from 2006. [In 2009](#), the number of medical product cases in the EU increased [compared to 2008](#).

34 million counterfeit drugs seized at EU borders over two month period - Over just a [two month period](#) in 2008, the European Commission seized 34 million counterfeit pills including antibiotics, cancer, cholesterol and anti-malaria medicines across EU borders. Twenty-seven countries in the EU participated in the “MEDI-FAKE” initiative which resulted in millions of counterfeit medicines being seized including “antibiotics, anti-cancer, anti-malaria and anti-cholesterol medicines, as well as painkillers, Viagra and drug precursors.” According to the European Commission, the MEDI-FAKE action resulted in “biggest seizure of illegal medicines ever recorded in Europe: 2,200,000 counterfeit medicine tablets were seized, of which 1,600,000 were painkillers and 600,000 were anti malaria pills” at the Brussels, Belgium airport.

UK COUNTERFEIT STATISTICS

The U.K. has issued ten (10) recalls of counterfeit medicines since 2004 - The MHRA has issued ten recalls of counterfeit medicines that reached the pharmacy and patient level, and discovered five cases in which counterfeits [reached wholesalers](#) since 2004. Since 2006 the MHRA [has seized](#) over £6 million of counterfeit medicines in the U.K. In 2007, the MHRA in conjunction with the European Medicines Agency (EMA) announced the recall of batches of three medications, including a drug to treat schizophrenia and bipolar disease, a blood-thinning drug and a prostate cancer drug, following the discovery of counterfeit tablets in the legitimate supply chain. All three counterfeit medicines entered the legitimate supply chain via the parallel distribution trade, according to the MHRA. These recalls marked the first time Class 1 recalls (patient level recall) were carried out in the U.K., [according to](#) MHRA’s head of enforcement Mick Deats.

The U.K.'S MHRA uncovers £250,000 of fake medicines in online pharmacy investigation - In March 2009, the MHRA's enforcement team seized more than £250,000 worth of counterfeit medicine in five locations in the U.K. [According to](#) the MHRA's Head of Operations Danny Lee-Frost, the online pharmacy, www.pharm2u.com, has been selling "a massive range of medicine from weight and hair loss tablets, to anti-depressants, powerful painkillers and even anabolic steroids." Lee-Frost also noted that the medicines recovered are "just the tip of the ice-berg" of a business that "could be generating a turnover in excess of a couple of million" pounds. By purchasing medicine online, consumers risk taking medicine in which "dosages could be either too high or too low, or worse, the tablet could contain dangerous ingredients such as brick dust from a cement mixer" according to Lee-Frost.

News report finds, "UK is the most vulnerable country in Europe to counterfeiting" - According to a [January 2007 report](#) in *The Independent*, "Counterfeit drugs are flooding into Europe from across the world. Customs seizures published in November listed them as a separate category for the first time, in an indication of the growing trade." The figures showed that more than 560,598 packets of fake medicines were seized last year in 148 operations, twice the rate in 2004. Three-quarters were imported from India, 7 per cent from Egypt and 6 per cent from China. According to a report by the School of Pharmacy at the University of London, "the UK is the most vulnerable country in Europe to counterfeiting owing to the high level of "parallel importing" drugs sold to a foreign country and then imported into Britain and the fact that English is an international language."