

The Deadly World of Fake Drugs

This document provides an overview of the many seizures of fake drugs around the globe. Compiling data from the manufacture, sale, and distribution of fake and substandard drugs from over 100 countries, this document illustrates the global nature of the trade, and highlights the riskiest regions. While it is impossible to determine the scale of the problem, the examples below illustrate that the trade in fake and poor-quality medicines is far too large, and far too deadly, to be ignored.

The Deadly World of Fake Drugs

The burden of fake and substandard drugs is not evenly distributed across the globe. Even where reporting systems are weak and the media is not free, most reported instances of substandard medicines occur in poorer countries, where poor regulation allows criminals to easily infiltrate weak supply chains. Although rich nations face fewer breakdowns in their regulation and supply systems, they are certainly not safe from this threat. This document provides a plethora of examples of the manufacture, sale, and distribution of fake and substandard drug examples from all over the world. Where possible, data has been summarized to report problems at the continental, regional and national levels. Although no comprehensive data on the magnitude of the counterfeit drug trade exists, this document illustrates the breadth, depth, and danger of the problem globally.

Many of these examples were compiled from local news sources. Countries without a free press may not appear at all in the following pages, but it is doubtful that the lack of evidence reflects an inconsequential number of substandard drugs. It is much more likely that these locations have a major problem with counterfeit and substandard drugs but data for these locations are simply unavailable. Evidence we do have suggests that counterfeit products are as much a problem in locations without a free press as they are elsewhere. In fact, in some countries like North Korea, counterfeiting operations are part of a vast, government-sponsored enterprise.

Some stories of major counterfeiting rings involve numerous countries. Since the reader may only be interested in a specific countries, key statistics from the study are quoted in each location they pertain to, resulting in some overlap.

Finally, because of the nature of the literally hundreds of sources cited in this section, it is inevitable that there will be a confusion of definitions. What one reporter, government agency, police statement, pharmaceutical company, academic researcher and others may call a fake product, their peers may not. For this reason, the reports in this chapter should not be viewed as necessarily comparable. In some instances it is possible to tell the claims made apart but overall it is not, and therefore is rarely attempted. With this major caveat in mind, this document hopefully provides a useful detail of the widespread and dangerous nature of dangerous medicines.

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I. Developed Countries

North America

Counterfeit medication is a recognized and well-documented problem in the United States. A major case recorded in 1937, involved the deaths of than one hundred Americans after consuming medicine that contained the dangerous solvent diethylene glycol.¹

Since then, a great deal of information has been gathered with regard to the prevalence of fake drugs in the United States, including extensive enforcement records, media reports and comprehensive studies. But while the size of the market is certainly lower than one percent, exactly how much lower is impossible to determine. In 2003, the Pharmaceutical Security Institute (PSI), a partnership of pharmaceutical companies, reported the value of seized counterfeit and diverted drugs in the United States to be roughly USD 200 million.² Since 2003, most sources indicate the value has increased.

The most commonly counterfeited drugs are “lifestyle” drugs, including erectile dysfunction medications, weight loss drugs, Botox, and hair regeneration products. In addition, psychotropic drugs, high-cholesterol treatments, AIDS medications, and more common medicines such as aspirin and anti-histamines are also frequently counterfeited.

Most of the counterfeit and substandard drugs found in the United States are probably purchased online, but fakes have managed to infiltrate the legitimate supply chain as well. For instance, in early 2001, counterfeit Serostim, an AIDS drug, was found in two California pharmacies, and in 2003, fake Lipitor (a medication for high cholesterol) was discovered in pharmacies across the US.^{3,4}

While locally produced counterfeits have been discovered, drug seizures indicate that the majority of fakes are either imported from countries like China and India or smuggled across the Mexican and Canadian borders.

Several agencies, including the US FDA’s Counterfeit Drug Task Force, the Drug Enforcement Agency (DEA), and Customs and Border Protection, regularly conduct seizures of counterfeit pharmaceuticals. In a notable drug bust in 2004, customs seized 3,000 packages of suspected counterfeits. 180 of the packages were analyzed, revealing that 67 percent contained drugs that either were never approved by the FDA or had been withdrawn from the US market for safety

¹ Bate, Roger. “Making A Killing: The Deadly Implications of the Counterfeit Drug Trade.” *AEI Press* (2008), available at http://www.aei.org/docLib/20080520_MakingAKillingnew.pdf (accessed Mar 5 2010).

² Buzzeo, Ronald W. “Counterfeit Pharmaceuticals and the Public Health.” *The Wall Street Journal* (Oct 4 2005), available at: http://online.wsj.com/ad/article/cigna/SB112838268960659014.html?mod=sponsored_by_cigna (accessed Mar 5 2010).

³ Appleby, Julie. “Fake Drugs Show Up in US Pharmacies.” *USA Today* (Mar 14 2003), available at http://www.usatoday.com/money/industries/health/drugs/2003-05-14-fakedrug-cover_x.htm (accessed Mar 5 2010).

⁴ “FDA Uncovers More Fake Lipitor.” *USA Today* (Jun 3 2003), available at http://www.usatoday.com/news/health/2003-06-03-fake-lipitor_x.htm (accessed Apr 9 2010).

reasons. 28 percent contained controlled substances banned from importation, and 5 percent of the packages contained no API.⁵

In November 2009, a national crackdown uncovered nearly 800 packages of alleged fake or suspicious prescription drugs (including Viagra for erectile dysfunction), Vicodin (a pain reliever), and Claritin (an anti-histamine)), and 68 allegedly unauthorized online pharmacies were shut down. Some of the drugs had as much as three times the amount of API than is typically prescribed, while others contained no API at all or consisted of harmful substances like drywall material, antifreeze and yellow highway paint.⁶

Enforcement officials are especially alert in places with high levels of international travel. For example, in Miami, investigators found ten different types of counterfeit drugs in the period from 2001 to 2003. Among these drugs were anemia medications Procrit and Epogen, a schizophrenia drug Zyprexa, an antifungal Diflucan, and AIDS drugs Serostim, Combivir and Retrovir.⁷ In October 2009, a shipment containing 21,600 Viagra pills was seized at Miami International Airport, and was determined to contain counterfeits that originated in India.⁸

In addition to drug seizures, there have been many convictions of counterfeiters in the US. In January 2009, a Chinese man was sentenced to 6½ years in prison for distributing counterfeit and misbranded medicines.⁹ Later that year, a Dallas man was convicted for conspiring to distribute counterfeit erectile dysfunction drugs and received a maximum sentence of 10 years in federal prison and a USD 250,000 fine.¹⁰

The most common way that counterfeit and substandard drugs infiltrate the US market is probably through the Internet, usually from international sources. A 2004 study by the US Government Accountability Office found that four out of twenty-one medicines ordered from websites outside the United States or Canada were counterfeit.¹¹ None of the foreign pharmacies—located in a range of countries, including Argentina, Costa Rica, India, Spain, and

⁵ Spake, Amanda. “Fake Drugs, Real Worries.” *U.S. News & World Report* (Sep 12 2004), available at <http://health.usnews.com/usnews/health/articles/040920/20internet.htm> (accessed Mar 5 2010).

⁶ Mui, Ylan Q. “Crackdown Targets Counterfeit Drugs.” *The Washington Post* (Nov 20 2009), available at <http://www.washingtonpost.com/wp-dyn/content/article/2009/11/19/AR2009111904229.html> (accessed Mar 5 2010).

⁷ Appleby, Julie. “Fake Drugs Show Up in US Pharmacies.” *USA Today* (Mar 14 2003), available at http://www.usatoday.com/money/industries/health/drugs/2003-05-14-fakedrug-cover_x.htm (accessed Mar 5 2010).

⁸ “Fake Viagra Seized in Miami.” *The CNN Wire* (Oct 23 2009), available at <http://cnnwire.blogs.cnn.com/2009/10/23/fake-viagra-seized-in-miami/> (accessed Feb 23 2011).

⁹ “Dallas Man Convicted for Distributing Counterfeit Pharmaceutical Drugs.” *U.S. Immigration and Customs Enforcement* (Mar 23 2009), available at <http://www.ice.gov/news/releases/0903/090320portland.htm> (accessed Feb 23 2011).

¹⁰ “Dallas Man Convicted for Distributing Counterfeit Pharmaceutical Drugs.” *U.S. Immigration and Customs Enforcement* (Mar 23 2009), available at <http://www.ice.gov/news/releases/0903/090320portland.htm> (accessed Feb 23 2011).

¹¹ “Internet Pharmacies: Some Pose Safety Risks for Consumers.” *United States Government Accountability Office Report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate* (Jun 2004), available at <http://www.gao.gov/new.items/d04820.pdf> (accessed Mar 5 2010).

Pakistan—including pharmacy labels that provided instructions for dosage, few included warning information, and some displayed evidence of improper handling.¹²

While most online pharmacies that peddle counterfeit drugs are foreign-run organizations, some are based in the US. In October 2006, the DEA arrested eleven employees of a Georgia-based drug manufacturer that was selling fake pharmaceuticals over the Internet to US consumers. The group's revenues topped USD 19 million.¹³ Also that year, the Federal Bureau of Investigation (FBI) busted a Philadelphia-based Internet pharmacy that smuggled an estimated 2.5 million doses of drugs into the United States from India, including Vicodin, anabolic steroids, and amphetamines.¹⁴ In October 2009, during the height of the H1N1 influenza outbreak, the US FDA purchased and analyzed five products represented online as Tamiflu; all were found to be fakes.¹⁵ One of the orders came from India in an unmarked envelope with loose white pills that were found to contain only talc and acetaminophen.¹⁶

Some counterfeiters in the US have been found to be using their fraudulent revenue to support terrorism. In March 2006, the US Joint Terrorism Task Force—an interagency initiative led by the FBI—charged nineteen people with operating a counterfeit drug ring that conducted business in Lebanon, Canada, China, Brazil, Paraguay, and the US.¹⁷ Profits from the sales of counterfeits and other contraband were used to support the terrorist group Hezbollah.^{18,19}

¹² "Internet Pharmacies: Some Pose Safety Risks for Consumers." *United States Government Accountability Office Report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate* (Jun 2004), available at <http://www.gao.gov/new.items/d04820.pdf> (accessed Mar 5 2010).

¹³ "US Counterfeit Drug Scam Used Internet Spam." *The Pharma Letter* (Oct 9 2006), available at <http://www.thepharmalletter.com/file/88322/us-counterfeit-drug-scam-used-internet-spam.html> (accessed Feb 23 2011).

¹⁴ "International Internet Drug Ring Shattered." *Medical News Today* (Apr 24 2005), available at <http://www.medicalnewstoday.com/articles/23363.php> (accessed Mar 5 2010).

¹⁵ Atkins, William. "FDA Warns of Fake Online H1N1 Drugs." *iWire* (Oct 18 2009), available at <http://www.itwire.com/science-news/health/28602-fda-warns-of-fake-online-h1n1-drugs> (accessed Mar 5 2010).

¹⁶ Atkins, William. "FDA Warns of Fake Online H1N1 Drugs." *iWire* (Oct 18 2009), available at <http://www.itwire.com/science-news/health/28602-fda-warns-of-fake-online-h1n1-drugs> (accessed Mar 5 2010).

¹⁷ Liang, Bryan A. "Safety of Drug Supply: Tougher Laws Needed to Stem Counterfeit Drug Rings." *Daily Transcript* (May 4 2006), available at www.sddt.com/News/article.cfm?SourceCode=20060503crd (accessed Mar 5 2010).

¹⁸ Liang, Bryan A. "Safety of Drug Supply: Tougher Laws Needed to Stem Counterfeit Drug Rings." *Daily Transcript* (May 4 2006), available at www.sddt.com/News/article.cfm?SourceCode=20060503crd (accessed Mar 5 2010).

¹⁹ "For Hezbollah: Cheap Smokes, Fake Viagra." *The Vancouver Sun* (Sep 21 2007), available at <http://www.canada.com/vancouver/news/story.html?id=70dfb2cd-83ff-4f0f-b6db-f49f8c8b0228> (accessed Mar 12 2010).

Europe

There are few fake and substandard drugs in most European countries for reasons similar to those articulated above for the United States: quality producers dominate the market, supply chains are generally well regulated, and officials provide strong oversight and strict enforcement when pharmaceutical standards are violated. Still, preventing fakes from entering or travelling through the two dozen European territories is a constant challenge for enforcement officials. The data estimating the prevalence of counterfeits in Europe, which is summarized and then presented in detail below, is based on comprehensive regional studies, individual country studies, enforcement records, and reported incidents.

According to a 2010 report sponsored by drug company Pfizer, ‘Cracking Counterfeit Europe,’ the market for counterfeit medicines in Europe has quadrupled in size over the past five years, and is now worth an estimated USD 14.3 billion a year. In 2009, European authorities seized 11 million counterfeit medications.²⁰

Most of the counterfeit drugs in Europe are imported from China, India, Pakistan, and other Asian countries, and some European countries act as transit points for drug smugglers. Pockets of local production also exist in poorly regulated states, such as Spain and Russia.

Many European countries have stepped up enforcement efforts along borders in recent years to prevent counterfeits from entering European countries and infiltrating global supply chains. In 2009, during a two month operation against counterfeit and illegal medications, Belgian customs agents seized more than 2.2 million counterfeit painkillers and anti-malaria pills.²¹

Due to the high cost of registered pharmaceuticals, more Europeans are buying their medicines outside of authorized channels. As many as a fifth of Europeans buy prescription drugs from unregistered sources, including internet pharmacies. Many Europeans appear to be aware of the risks they are taking when they make unlawful medication purchases. According to a study conducted in 2009, one European in 20 believes they have received a counterfeit prescription drug in the past.²² Despite a fairly high level of awareness, many purchasers claim that time constraints, financial concerns, and a preference for anonymity encourage people to purchase medications through unconventional avenues despite the risks.

Northern Europe

Counterfeit and substandard drugs are increasingly pervasive in Northern Europe, particularly in Ireland, Finland, and the United Kingdom. Strict regulation and enforcement in many of these countries closes much of the legal markets to fakes, but criminal organizations routinely exploit lax transit laws and weak supply chains to import illegal drugs into even the highly regulated

²⁰ Myers, Daryl. “One European in Five Buys Counterfeit Medicine.” *Le Figaro* (Feb 17 2010), available at <http://plus.lefigaro.fr/note/one-european-in-five-buys-counterfeit-medicine-20100217-141835> (accessed Mar 31 2010).

²¹ Smith, Jeremy. “EU Coordinates Customs Services to Seize Fake Pills.” *Reuters* (Dec 16 2008), available at <http://www.reuters.com/article/idUSL33548320081216> (accessed Apr 2 2010).

²² “Survey Reveals European’s Views on Counterfeits.” *Securing Pharma* (Nov 25 2009), available at <http://www.securingspharma.com/40/articles/300.php> (accessed Apr 2 2010).

United Kingdom. Many of the illegal drugs purchased in Northern Europe are bought via internet pharmacies, which are easily accessible throughout the region, but seem to have been particularly problematic in Ireland, as explored further below.

Though fake drugs undoubtedly pose the greatest threat in this region, substandard paracetamol and tuberculosis drugs have also been reported in Northern Europe.

Estonia

In 2001, a total of 71 anti-tuberculosis drug samples were obtained from National TB programs, hospitals, and local pharmacies from 6 countries including Estonia and analyzed using Thin Layer Chromatography, Ultra Violet, and confirmatory techniques by U.S. CDC and FDA. Tests revealed that 10% of all the samples, including 13% rifampicin (for TB), were substandard, containing less than 85% of stated content. More FDCs, 21% (5/24), than single drug samples, 13% (2/16), were substandard.²³

Finland

Finland appears to have a larger problem with counterfeit medicines than most other EU countries. In early 2007, Finnish customs officials confiscated 140,000 counterfeit drugs entering the country, a sizable number for a population of 5.2 million.^{24,25} Finland's long, sparsely regulated Russian border and lax transit laws make it an attractive transit point for fake pharmaceuticals.²⁶ As of 2010, Finland's transit laws allow for the unrestricted transit of medicines; shipments of imported medicines were only investigated if the patent-holder of a particular medicine filed a complaint with Finnish officials.²⁷

Ireland

In 2007, the lucrative fake medicine trade in Ireland was valued at over USD 165 million, and the problem is reportedly growing.²⁸ In 2007, roughly 349 shipments of counterfeit drugs were seized by Irish police, the Gardaí, in conjunction with the Irish Medicines Board (IMB).²⁹ In

²³ Laserson, Kayla F., et al. "Substandard Tuberculosis Drugs on the Global Market and their Simple Detection." *The International Journal of Tuberculosis and Lung Disease (Abstract)* 5(5): 448-54 (2001), available at <http://www.ncbi.nlm.nih.gov/pubmed/11336276> (accessed Feb 10 2011).

²⁴ "Counterfeit Medicines Pass through Finland to World Markets." *Helsingin Sanomat* (Jun 14 2007), available at <http://www.hs.fi/english/article/Counterfeit+medicines+pass+through+Finland+to+world+markets/1135228018377> (accessed Mar 29 2010).

²⁵ "The Population of Finland in 2007." *Statistics Finland* (Mar 28 2008), available at http://www.stat.fi/til/vaerak/2007/vaerak_2007_2008-03-28_tie_001_en.html (accessed Feb 10 2011).

²⁶ "Counterfeit Medicines Pass through Finland to World Markets." *Helsingin Sanomat* (Jun 14 2007), available at <http://www.hs.fi/english/article/Counterfeit+medicines+pass+through+Finland+to+world+markets/1135228018377> (accessed Mar 29 2010).

²⁷ Bate, Roger. "Making a Killing: The Deadly Implications of the Counterfeit Drug Trade." *The American Enterprise Institute Press* (2008), available at http://www.aei.org/docLib/20080520_MakingaKillingnew.pdf (accessed 10 Feb 2011).

²⁸ Carty, Ed, and Walsh, Anne-Marie. "Crime Gangs Getting Rich on Fake Medicines." *Independent* (Feb 22 2007), available at <http://www.independent.ie/national-news/crime-gangs-getting-rich-on-fake-medicine-56263.html> (accessed Mar 31 2010).

²⁹ O'Sullivan, Róisín. "Counterfeit Drugs." *Life Sciences Review, Business and Finance* Issue 2 (2009), available at <http://www.businessandfinance.ie/index.jsp?p=239&n=243&a=690> (accessed Mar 31 2010).

2008, only a year later, this number was 11 times larger, with 3,800 seizures recorded by police officials.³⁰

Pfizer's 2010 report ranked Ireland a disturbing 6th largest consumer of counterfeit drugs in Europe. The report estimated that the domestic market for counterfeits may be worth more than USD 115 million per year. Analysts speculate that increased internet penetration into Ireland has enabled more Irish consumers to purchase medication for personal use over the internet to save money and time.³¹ These online pharmacies routinely market counterfeit products which are bought all over Ireland. Other drugs purchased online contain too little, or none, of the active ingredient, and a few have even been found to contain rat poison, boric acid and lead paint.³² In 2008, the most commonly counterfeited drugs bought online and seized were fake Viagra, Viagra imitations, steroids, and Valium (for anxiety disorders).³³

In recent years, Irish customs agents have intercepted over 800 kilos of counterfeit and illegal medications sent through the post.³⁴ The Irish Revenue Investigations and Prosecutions department indicated most came from Bangladesh and China. In the first half of 2009, customs agents impounded nearly 220,000 more fakes.³⁵

Illegally imported medicines, as we've seen earlier in the book, often run hand in glove with counterfeit products. Irish law prohibits purchasing prescription medications over the internet or by mail order, but such purchases remain common.³⁶ According to the 2009 Irish Medicines Board (IMB) annual report, large quantities of anti-impotence drugs, prescription-level vitamins, antibiotics, anabolic steroids, body building products, and weight-loss pills are illegally imported and seized every year.³⁷ In 2008, 88,279 tablets, 106,443 capsules, 22.5 liters of liquid and 40g of creams were seized by inspectors following increased cooperation between customs and

³⁰ O'Sullivan, Róisín. "Counterfeit Drugs." *Life Sciences Review, Business and Finance* Issue 2 (2009), available at <http://www.businessandfinance.ie/index.jsp?p=239&n=243&a=690> (accessed Mar 31 2010).

³¹ O'Sullivan, Róisín. "Counterfeit Drugs." *Life Sciences Review, Business and Finance* Issue 2 (2009), available at <http://www.businessandfinance.ie/index.jsp?p=239&n=243&a=690> (accessed Mar 31 2010).

³² "Warning over Counterfeit Drugs in Ireland." *Sligo Today* (Feb 16 2010), available at <http://www.sligotoday.ie/details.php?id=7839&PHPSESSID=c0926ac2d61c29afbdf7573e0cee3> (accessed Mar 31 2010).

³³ O'Sullivan, Róisín. "Counterfeit Drugs." *Life Sciences Review, Business and Finance* Issue 2 (2009), available at <http://www.businessandfinance.ie/index.jsp?p=239&n=243&a=690> (accessed Mar 31 2010).

³⁴ Simmons, Richard. "Irish Customs Have Intercepted 0.8 Tonnes Of Fake Meds." *UKMEDIX* (May 21 2009), available at http://www.ukmedix.com/viagra/irish_customs_have_intercepted_08_tonnes_of_fake_meds4687.cfm (accessed Mar 31 2010).

³⁵ Simmons, Richard. "Irish Customs Have Intercepted 0.8 Tonnes Of Fake Meds." *UKMEDIX* (May 21 2009), available at http://www.ukmedix.com/viagra/irish_customs_have_intercepted_08_tonnes_of_fake_meds4687.cfm (accessed Mar 31 2010).

³⁶ O' Regan, Eilish. "Rise in Seizures of Illegally Imported Medicines." *Independent* (Dec 16 2008), available at <http://www.independent.ie/national-news/rise-in-seizures-of-illegally-imported-medicines-1576242.html> (accessed Mar 31 2010).

³⁷ O' Regan, Eilish. "Rise in Seizures of Illegally Imported Medicines." *Independent* (Dec 16 2008), available at <http://www.independent.ie/national-news/rise-in-seizures-of-illegally-imported-medicines-1576242.html> (accessed Mar 31 2010).

excise officials and the police.³⁸ The biggest exporters of illegal medicinal products were reportedly India and China.

Latvia

While there are no data on counterfeits, the presence of substandard drugs has been documented in Latvia. A total of 71 anti-TB drug samples obtained from National TB programs and hospital and local pharmacies from 6 countries, including Latvia, were analyzed by U.S. CDC and FDA. Overall, 10% of all samples, including 13% rifampicin, were substandard, containing less than 85% of the stated content. Furthermore, a greater number of fixed-dose combinations, 21% (5/24), were substandard than were single drug samples, 13% (2/16).³⁹

United Kingdom

When fake versions of anti-impotence and obesity drugs were discovered in 2004, U.K. health officials claimed it was the first time counterfeit drugs had breached the British supply chain since 1994.⁴⁰ In recent years, however, there have been more reports of counterfeits in the U.K., with nine known cases of fake drugs reaching patients in the U.K. between 2004 and 2007, and twelve cases between 2005 and 2009.⁴¹

Most counterfeits enter the supply chain at the wholesale level and are then sold to British pharmacies and health facilities. Most of the packs are very persuasive and accurate reproductions of the original, so much so that only when the product is critically analyzed or adverse reactions to the drug are reported is it realized that the counterfeits have been substituted for the originals.⁴²

Fakes have made their way into the legitimate supply chain in the U.K. For instance, in July 2005, the Medical and Healthcare Products Regulatory Agency (MHRA) found 70 packets of counterfeit Lipitor, with forged packaging and proper identification numbers, in the facilities of two different UK wholesalers. By the time of seizure, 2,500 packets of the fake Lipitor had already infiltrated the National Health Service supply chain before MHRA's discovery.⁴³ In May

³⁸ O' Regan, Eilish. "Rise in Seizures of Illegally Imported Medicines." *Independent* (Dec 16 2008), available at <http://www.independent.ie/national-news/rise-in-seizures-of-illegally-imported-medicines-1576242.html> (accessed Mar 31 2010).

³⁹ Laserson, Kayla F., et al. "Substandard Tuberculosis Drugs on the Global Market and their Simple Detection." *The International Journal of Tuberculosis and Lung Disease (Abstract)* 5(5): 448-54 (2001), available at <http://www.ncbi.nlm.nih.gov/pubmed/11336276> (accessed Feb 10 2011).

⁴⁰ "Fake Obesity Drugs are Discovered." *BBC News* (Sep 2 2004), available at <http://news.bbc.co.uk/2/hi/health/3622400.stm> (accessed Mar 27 2008).

⁴¹ Lewcock, Anna. "MHRA Launches New Action Plan to Combat UK Counterfeit Hub." *In-Pharma Technologist* (Nov 26 2007), available at <http://www.in-pharmatechnologist.com/Industry-Drivers/MHRA-launches-new-action-plan-to-combat-UK-counterfeit-hub> (accessed Feb 10 2011).

⁴² O'Sullivan, Róisín. "Counterfeit Drugs." *Life Sciences Review, Business and Finance* Issue 2 (2009), available at <http://www.businessandfinance.ie/index.jsp?p=239&n=243&a=690> (accessed Mar 31 2010).

⁴³ "Warning about Continued Dangers of Counterfeit Prescription Drugs from NABP." *Pharma Marketletter* (Jan 22 2007), available at http://goliath.ecnext.com/coms2/gi_0199-6185512/Warning-about-continued-dangers-of.html (accessed Feb 10 2011).

2007, the MHRA was forced to recall batches of fake schizophrenia and hypertension drugs after they were discovered to have been counterfeited with forged French packaging.⁴⁴

An 18 month operation run by the Northern Ireland Health Department, Interpol and IMPACT, discovered counterfeit steroids, 130,000 Benzylpiperazine (BZP) tablets, human growth hormones and 10,000 tablets for erectile dysfunction.⁴⁵ In March 2009, raids by the MHRA in the Middlesbrough area led to the seizure of USD 773,000 worth of suspected counterfeit medicines, including treatments for erectile dysfunction, anxiety and weight loss, and to the arrest of four people; the counterfeits reportedly originated from China.⁴⁶ In late 2009, an investigation by a computer security firm, Sophos, revealed that groups of organized Russian criminals were selling counterfeit Tamiflu to British citizens who were finding it difficult to obtain the drug through NHS due to extremely high demand caused by the swine flu epidemic.⁴⁷ In early 2010, London police found 70,000 pills worth USD 946,972 of counterfeit Viagra, Cialis, and Levitra on a raid on a house in Basford. Police arrested two suspects, the medicine had been shipped from China to be sold over the internet.⁴⁸

Internet Sales:

The largest counterfeit-drug bust in the United Kingdom to date occurred when British customs officials unearthed a conspiracy to supply millions of pounds worth of counterfeit Viagra and hair loss drugs over the internet; fakes were shipped to factories in Britain, repackaged and sold online to customers in thirty-five countries, including UK, USA and Canada.⁴⁹

In March 2009, the MHRA seized more than USD 386,500 worth of counterfeit, unlicensed, withdrawn medicines and controlled drugs during raids on five locations in Stoke-on-Trent, one of which was running what was believed to be a million dollar illegal online medicines business.

Yet the MHRA has noted that, in recent years, criminals have shifted focus from using the Internet to sell small quantities of fake (predominantly lifestyle) drugs to individuals, to targeting pharmaceutical wholesalers, especially those that supply public entities such as hospitals or aid organizations. In the summer of 2007, the MHRA was forced to issue drug alerts to health-care professionals for Plavix, a blood thinner; Zyprexa, a treatment for schizophrenia; and Casodex, a

⁴⁴ "Fake Parallel Trade Drugs Hit UK, Product Recalls Issued by the MHRA." *The Pharma Letter* (Jun 4 2007), available at <http://www.thepharmalletter.com/file/11288/fake-parallel-trade-drugs-hit-uk-product-recalls-issued-by-the-mhra.html> (accessed Feb 10 2011).

⁴⁵ "Counterfeit Drugs Seized During International Week of Action." *Northern Ireland Executive* (Nov 23 2009), available at <http://www.northernireland.gov.uk/news/news-dhssps/news-dhssps-Nov-2009/news-dhssps-23112009-counterfeit-drugs-seized.htm> (accessed Mar 31 2010).

⁴⁶ "Four Arrested in Middlesbrough Counterfeit Medicine Raids." *The Northern Echo* (Mar 30 2009), available at http://www.thenorthernecho.co.uk/news/crimeediting/4245645.Four_arrested_over_counterfeit_medicine_seizure/ (accessed Mar 31 2010).

⁴⁷ Sharma, Rasik. "Russian Crime Gangs Selling Fake Tamiflu Online." *Top News* (Nov 16 2009), available at <http://topnews.co.uk/2728-russian-crime-gangs-selling-fake-tamiflu-online> (accessed Mar 31 2010).

⁴⁸ "Two Men Arrested after Basford Fake Medicine Raid." *This is Nottingham* (Oct 9 2009), available at <http://www.thisisnottingham.co.uk/homenews/men-arrested-Basford-fake-medicine-raid/article-1408509-detail/article.html> (accessed Mar 31 2010).

⁴⁹ "Gang Guilty of Fake Viagra Scam." *BBC News* (Sep 17 2007), available at http://news.bbc.co.uk/2/hi/uk_news/6999160.stm (accessed Mar 27 2008).

hormone treatment for prostate cancer. By targeting wholesalers, counterfeiters are able to capture larger and more lucrative markets efficiently. The wholesale price for a pack of twenty-eight Casodex pills in Britain is USD 260, which yields a wide profit margin to a counterfeiter for such therapeutic drugs.⁵⁰

Eastern Europe

Eastern European countries are believed to be both major sources and consumers of counterfeit medications. Legal penalties in the region vary from country to country, with higher legal penalties in countries such as Russia and weaker legislation against fakers in countries like the Czech Republic and the Ukraine. Despite strict penalties, Russia remains a major producer of counterfeits for the entire European region. Some countries in the region, such as Belarus and Hungary, have seen a significant decrease in the prevalence of counterfeits in recent years through increased surveillance efforts and stricter import and regulatory laws.

Drugs most commonly seized in the region include lifestyle pills like anti-impotence drugs, vitamins, and diet pills, as well as life saving medication such as anti-stroke pills, antibiotics, and cardiovascular medications. According to one report, more than 20% of the pharmaceutical market value in many of the former Soviet republics is consumed by counterfeit medicines, which is close to levels found in poorer developing countries.⁵¹

Belarus

In 2002, 118 cases of counterfeit medicines were reported in Belarus.⁵² But according to Belarus media, due to comprehensive measures taken by the country's Health Ministry to combat the problem, the prevalence of fakes in Belarus has declined. In fact, according to a 2005 study conducted by the Republican Center for Examination and Tests in Healthcare, counterfeit medicines were reported in the country only twice in 2003, and once in 2004.⁵³ In 2008, *no* counterfeit drugs were reported to the Belarusian Health Ministry.⁵⁴

In Belarus, the Act on Medicinal Products prohibits the importation of low-quality medicines and counterfeit medicines. In general, importation and distribution of medicines are under strict state control.⁵⁵ For instance, all the medicines that enter Belarusian drugstores undergo obligatory

⁵⁰ "Factory for Fake Prescription Drugs." *The Sunday Times* (Sep 23 2007), available at <http://www.timesonline.co.uk/tol/news/uk/health/article2511583.ece> (accessed Mar 27 2008).

⁵¹ "Fact Sheet – Counterfeit Medicines." *World Health Organization* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Jan 21 2010).

⁵² "Summary of Selected IPR-Related News Stories." *The Coalition for Intellectual Property Rights* (Mar 31 2005), available at <http://www.cipr.org/news/news.php?nid=18> (accessed Mar 31 2010).

⁵³ "Summary of Selected IPR-Related News Stories." *The Coalition for Intellectual Property Rights* (Mar 31 2005), available at <http://www.cipr.org/news/news.php?nid=18> (accessed Mar 31 2010).

⁵⁴ "No Counterfeit Drugs were found in Belarus in 2008." *Belarusian Telegraph Agency* (Feb 4 2009), available at <http://news.belta.by/en/news/society?id=330057> (accessed Feb 10 2011).

⁵⁵ Liessem, Alexander, and Kozlova, Anna. "Life Sciences 2010 – Legal Framework and Current Issues – Belarus." *BNT Legal and Tax Consultancy in Central and Eastern Europe* (2010), available at http://www.bnt.eu/uploads/files/publikationen/andere_publikationen/2009-11-30%20Life%20Sciences%20Belarus%20upload%20Anna%20En.pdf (accessed Mar 24 2010).

state quality control tests. In 2008, the laboratories of the Health Ministry checked more than 112,000 consignments of drugs, 65 of which were banned.⁵⁶ Government restrictions have kept counterfeiting and illegal distribution of medications a rarity in Belarus. Restrictions include requiring a license for the import of medicines and maintaining rigorous standards on medicine registration and distribution.⁵⁷ The Health Ministry ensures that domestically produced drugs are of high quality by insisting all national pharmaceutical companies conform to universally accepted Good Manufacturing Practice (GMP).⁵⁸

Bulgaria

In 2008, Emil Hristov, the Executive Director of the Bulgarian Drug Agency, reported various examples of seizures of counterfeits including vitamins, antibiotics, impotence drugs and flu medications that contained only sugar.⁵⁹

The Russian media reports that counterfeits found in Russia have originated in Bulgaria.⁶⁰

Czech Republic

People have been hospitalized and have died after consuming counterfeit medicines.⁶¹ In 2009, customs authorities seized over 7,500 fake tablets in 65 cases.⁶²

According to reports, the most commonly counterfeited and illegal drugs in the Czech Republic are erectile dysfunction medicines, anabolic steroids and weight-loss medicines.⁶³ In March

⁵⁶ Liessem, Alexander, and Kozlova, Anna. "Life Sciences 2010 – Legal Framework and Current Issues – Belarus." *BNT Legal and Tax Consultancy in Central and Eastern Europe* (2010), available at http://www.bnt.eu/uploads/files/publikationen/andere_publicationen/2009-11-30%20Life%20Sciences%20Belarus%20upload%20Anna%20En.pdf (accessed Mar 24 2010).

⁵⁷ Liessem, Alexander, and Kozlova, Anna. "Life Sciences 2010 – Legal Framework and Current Issues – Belarus." *BNT Legal and Tax Consultancy in Central and Eastern Europe* (2010), available at http://www.bnt.eu/uploads/files/publikationen/andere_publicationen/2009-11-30%20Life%20Sciences%20Belarus%20upload%20Anna%20En.pdf (accessed Mar 24 2010).

⁵⁸ Liessem, Alexander, and Kozlova, Anna. "Life Sciences 2010 – Legal Framework and Current Issues – Belarus." *BNT Legal and Tax Consultancy in Central and Eastern Europe* (2010), available at http://www.bnt.eu/uploads/files/publikationen/andere_publicationen/2009-11-30%20Life%20Sciences%20Belarus%20upload%20Anna%20En.pdf (accessed Mar 24 2010).

⁵⁹ Hristov, Emil. "Best Practice Session: Bulgarian Drug Agency Experience with Counterfeit Medicines." *Bulgarian Drug Agency* (2008), available at <http://old.bda.bg/international/Couterfeits2EN-2.pdf> (accessed Mar 31 2010).

⁶⁰ Medetsky, Anatoly. "Fake Medicine Swamps Russia." *Vladivostok News* (Apr 7 2000), available at <http://vlad.tribnet.com/2000/ISS213/text/txt1.html> (accessed Mar 31 2010).

⁶¹ "Czech Republic Pharma: Web Sale of Counterfeit Medicines Rising." *Healthcare Briefing and Forecast, Czech Republic, Economist Intelligence Unit* (Mar 24 2010), available at http://www.eiu.com/index.asp?layout=ib3Article&article_id=1275321712&pubtypeid=1152462500&country_id=1690000169&page_title (accessed Feb 11 2011).

⁶² "Czech Republic Pharma: Web Sale of Counterfeit Medicines Rising." *Healthcare Briefing and Forecast, Czech Republic, Economist Intelligence Unit* (Mar 24 2010), available at http://www.eiu.com/index.asp?layout=ib3Article&article_id=1275321712&pubtypeid=1152462500&country_id=1690000169&page_title (accessed Feb 11 2011).

⁶³ "Campaign Against Counterfeit Medicines Launched in the Czech Republic." *PMR Pharmaceutical, Healthcare and Medical Sector in Central and Eastern Europe* (Mar 23 2010), available at

2010, Czech customs officers seized 5,200 tablets of counterfeit Viagra and Cialis, worth over USD 105,810, in a parcel from India—the largest consignment of this kind in several years.⁶⁴ In July 2008, customs officials in Kralupy and Vlatvou destroyed one ton of fake medicines. Authorities also discovered approximately one million pills intercepted in the mail mainly coming from China and India.^{65 66}

According to the Czech State Institute for Drug Control (SUKL) statistics, roughly 11% of people in the Czech Republic bought medicines over the Internet in the recent past.^{67,68} Under Czech law, however, only over-the-counter medicines can be sold over the Internet and only by registered pharmacies holding a license for the web sale, while prescription drugs must be picked up in pharmacies.⁶⁹ Nevertheless, the 50 per cent of medicines offered on suspicious websites in the country is estimated to be fake.⁷⁰

In 2007 Marcia Bergeron died from cardiac arrhythmia after taking counterfeit medicine she purchased and consumed in Canada from an online pharmacy. The medication contained high levels of metals and reportedly originated in the Czech Republic.⁷¹ In response to this growing problem, SUKL has launched an awareness campaign pertaining to counterfeit and illegal medicines in the country, with an emphasis on counterfeit drugs sold online.⁷²

http://www.ceepharma.com/?com=one_free&id=83881&hash=6e907103d65296bc43b12fb5882a4a01 (accessed Mar 31 2010).

⁶⁴ “Czech Customs Officers Seize Counterfeit Viagra from India.” *Prague Daily Monitor* (Mar 24 2010), available at <http://praguemonitor.com/2010/03/25/czech-customs-officers-seize-counterfeit-viagra-india> (accessed Mar 31 2010).

⁶⁵ Velinger, Jan. “Customs Officers Destroy Tonne of Fake-Brand Medicines.” *Radio Prague* (Jul 2 2008), available at <http://www.radio.cz/en/article/105717> (accessed Feb 3 2010).

⁶⁶ “Campaign Against Counterfeit Medicines Launched in the Czech Republic.” *PMR Pharmaceutical, Healthcare and Medical Sector in Central and Eastern Europe* (Mar 23 2010), available at http://www.ceepharma.com/?com=one_free&id=83881&hash=6e907103d65296bc43b12fb5882a4a01 (accessed Mar 31 2010).

⁶⁷ “Campaign Against Counterfeit Medicines Launched in the Czech Republic.” *PMR Pharmaceutical, Healthcare and Medical Sector in Central and Eastern Europe* (Mar 23 2010), available at http://www.ceepharma.com/?com=one_free&id=83881&hash=6e907103d65296bc43b12fb5882a4a01 (accessed Mar 31 2010).

⁶⁸ “Czech Republic Pharma: Web Sale of Counterfeit Medicines Rising.” *Healthcare Briefing and Forecast, Czech Republic, Economist Intelligence Unit* (Mar 24 2010), available at http://www.eiu.com/index.asp?layout=ib3Article&article_id=1275321712&pubtypeid=1152462500&country_id=1690000169&page_title (accessed Feb 11 2011).

⁶⁹ “Czech Republic Pharma: Web Sale of Counterfeit Medicines Rising.” *Healthcare Briefing and Forecast, Czech Republic, Economist Intelligence Unit* (Mar 24 2010), available at http://www.eiu.com/index.asp?layout=ib3Article&article_id=1275321712&pubtypeid=1152462500&country_id=1690000169&page_title (accessed Feb 11 2011).

⁷⁰ “Czech Republic Pharma: Web Sale of Counterfeit Medicines Rising.” *Healthcare Briefing and Forecast, Czech Republic, Economist Intelligence Unit* (Mar 24 2010), available at http://www.eiu.com/index.asp?layout=ib3Article&article_id=1275321712&pubtypeid=1152462500&country_id=1690000169&page_title (accessed Feb 11 2011).

⁷¹ Solomon, Sam. “BC Woman Killed by Fake Drugs Bought Online.” *National Review of Medicine* 4:13 (Jul 30 2007), available at http://www.nationalreviewofmedicine.com/issue/2007/07_30/4_policy_politics_13.html (accessed Mar 31 2010).

⁷² “Campaign Against Counterfeit Medicines Launched in the Czech Republic.” *PMR Pharmaceutical, Healthcare and Medical Sector in Central and Eastern Europe* (Mar 23 2010), available at

Producers and distributors of fake medicines currently face significant fines (up to USD 158,715), and may soon face jail time.⁷³ As of 2010, an amendment to the Penal Code is being prepared to qualify two new crimes; (1) the illegal production and distribution of medicines, for which perpetrators would face up to five years in prisons, and (2) the sale of prescription drugs on the Internet punished by up to one year behind bars.⁷⁴

Hungary

In Hungary, the pharmaceutical market is controlled by the government through its National Institute of Pharmacy (NIP). The NIP oversees the wholesale, distribution and quality of the medicines.⁷⁵ According to the NIP, in 2008, there were no counterfeit drugs in the legal market, and since internet pharmacies are banned, NIP suggests that the prevalence of counterfeits is low.⁷⁶ However, fake Viagra has been found.^{77,78}

Interestingly, despite strict regulatory standards, no legal redress is possible in Hungary if a citizen falls ill from a counterfeit medicine outside of the regulated pharmaceutical distribution chain.⁷⁹ Until recently, counterfeiting did not qualify as a criminal activity in Hungary, and the act resulted only in a comparatively low fine.⁸⁰ However, in March 2011, the Hungarian National Anti-Counterfeit Board announced that the government had passed a new law imposing stricter penalties for drug counterfeiters.⁸¹ The legislation introduces a USD 510 fine for the possession or distribution of fake or unlicensed drugs, and commissions officials to confiscate fake

http://www.ceepharma.com/?com=one_free&id=83881&hash=6e907103d65296bc43b12fb5882a4a01 (accessed Mar 31 2010).

⁷³ “Czech Republic Pharma: Web Sale of Counterfeit Medicines Rising.” *Healthcare Briefing and Forecast, Czech Republic, Economist Intelligence Unit* (Mar 24 2010), available at http://www.eiu.com/index.asp?layout=ib3Article&article_id=1275321712&pubtypeid=1152462500&country_id=1690000169&page_title (accessed Feb 11 2011).

⁷⁴ “Czech Republic Pharma: Web Sale of Counterfeit Medicines Rising.” *Healthcare Briefing and Forecast, Czech Republic, Economist Intelligence Unit* (Mar 24 2010), available at http://www.eiu.com/index.asp?layout=ib3Article&article_id=1275321712&pubtypeid=1152462500&country_id=1690000169&page_title (accessed Feb 11 2011).

⁷⁵ “Counterfeit Medicines.” *National Institute of Pharmacy, Hungary* (Nov 20 2008), available at http://www.ogyi.hu/counterfeit_medicines/ (accessed Mar 31 2010).

⁷⁶ “Counterfeit Medicines.” *National Institute of Pharmacy, Hungary* (Nov 20 2008), available at http://www.ogyi.hu/counterfeit_medicines/ (accessed Mar 31 2010).

⁷⁷ “Men Who Buy Fake Internet Drugs for ED Problems Face Significant Health Risks.” *The Medical News* (Jan 21 2010), available at <http://www.news-medical.net/news/20100121/Men-who-buy-fake-internet-drugs-for-ED-problems-face-significant-health-risks.aspx> (accessed Mar 31 2010).

⁷⁸ Desingh, Anil K. “Pharmaceutical Counterfeiting.” *Analyst* 130, 271-279 (2005), available at http://www.rsc.org/delivery/_ArticleLinking/DisplayArticleForFree.cfm?doi=b407759h&JournalCode=AN (accessed Mar 31 2010).

⁷⁹ “Counterfeit Medicines.” *National Institute of Pharmacy, Hungary* (Nov 20 2008), available at http://www.ogyi.hu/counterfeit_medicines/ (accessed Mar 31 2010).

⁸⁰ “The Hungarian National Institute of Pharmacy (Medicines Agency)—Past, Present and Future.” *Regulatory Rapporteur* 5:9 (Sep 2008), available at http://www.topra.org/files/Focus%20article%20-%20Tamas_Paal_interview%201%200.pdf (accessed Mar 31 2010).

⁸¹ “Government to take Tougher Stance on Unlicensed Drug Trade.” *Budapest Business Journal* (Feb 28 2011), available at http://bbjonline.hu/domestic/govt-to-take-tougher-stance-on-unlicensed-drug-trade_56305 (accessed May 9 2011).

medicines immediately. Those who possess prescription drugs in an excessive amount or medicines formerly withdrawn from circulation will also face fines and seizure.⁸²

The capacity of the NIP in identifying and seizing drugs remains limited, as it does not have the legal base for conducting investigations.⁸³ The Hungarian Customs and Finance Guard (Police) conduct investigations on this issue.⁸⁴

Poland

The Pharmaceutical Security Institute reported that there were 21 incidents of counterfeit drugs in Poland in 2008, the fifth highest number in the EU.⁸⁵ Poles spend roughly USD 32 million a year on fake drugs.^{86,87,88}

The most frequently counterfeited drugs are impotence medicines and anabolic supplements, diet pills, and psychoactive drugs.^{89,90} Most “fillers” in these drugs are safe placebos like sugar, but some pills have contained anti-freeze, wood polish, plaster, amphetamine, lead and other dangerous compounds.^{91, 92}

The Polish Police and Customs Service are responsible for combating fake drugs, with prosecutions undertaken by the Public Prosecutor’s Office.⁹³ According to official data published

⁸² “Government to take Tougher Stance on Unlicensed Drug Trade.” *Budapest Business Journal* (Feb 28 2011), available at http://bbjonline.hu/domestic/govt-to-tougher-stance-on-unlicensed-drug-trade_56305 (accessed May 9 2011).

⁸³ “Counterfeit Medicines.” *National Institute of Pharmacy, Hungary* (Nov 20 2008), available at http://www.ogyi.hu/counterfeit_medicines/ (accessed Mar 31 2010).

⁸⁴ “Counterfeit Medicines.” *National Institute of Pharmacy, Hungary* (Nov 20 2008), available at http://www.ogyi.hu/counterfeit_medicines/ (accessed Mar 31 2010).

⁸⁵ Eglovich, Joanne S. “EFPIA Starts Traceability Pilot Program to Combat Drug Counterfeiting.” *EuroPharma Today* (Jan 25 2010), available at <http://www.europharmatoday.com/2010/01/efpia-starts-traceability-pilot-program-to-combat-drug-counterfeiting-.html> (accessed Mar 31 2010).

⁸⁶ Prawna, Dziennik Gazeta. “Fake Drugs Flood Poland.” *Export.BY* (Feb 3 2010), available at <http://www.export.by/en/rus?act=news&mode=view&id=16692> (accessed Mar 24 2010).

⁸⁷ “The World Health Organization Estimates Poland Spends up to \$31.6M USD Annually on Fake Medicine.” *Secure Pharma Chain Blog* (Jul 24 2009), available at <http://securepharmachain.blogspot.com/2009/07/world-health-organization-estimates.html> (accessed Apr 5 2010).

⁸⁸ Prawna, Dziennik Gazeta. “Fake Drugs Flood Poland.” *Export.BY* (Feb 3 2010), available at <http://www.export.by/en/rus?act=news&mode=view&id=16692> (accessed Mar 24 2010).

⁸⁹ “Poles Spend Around Zł.100 Million on Fake Drugs, says WHO.” *Warsaw Business Journal* (Jul 13 2009), available at <http://www.wbj.pl/article-46084-poles-spend-around-zl100-million-on-fake-drugs-says-who.html> (accessed Mar 31 2010).

⁹⁰ Prawna, Dziennik Gazeta. “Fake Drugs Flood Poland.” *Export.BY* (Feb 3 2010), available at <http://www.export.by/en/rus?act=news&mode=view&id=16692> (accessed Mar 24 2010).

⁹¹ “Poles Spend Around Zł.100 Million on Fake Drugs, says WHO.” *Warsaw Business Journal* (Jul 13 2009), available at <http://www.wbj.pl/article-46084-poles-spend-around-zl100-million-on-fake-drugs-says-who.html> (accessed Mar 31 2010).

⁹² Prawna, Dziennik Gazeta. “Fake Drugs Flood Poland.” *Export.BY* (Feb 3 2010), available at <http://www.export.by/en/rus?act=news&mode=view&id=16692> (accessed Mar 24 2010).

⁹³ Rychlicki, Tomasz. “Polish Regulation on Pharmaceutical Trademarks.” *Polish IT and IP Law News* (Feb 1 2010), available at <http://rychlicki.net/en/2010/02/01/1864/> (accessed Mar 31 2010).

by the Ministry of Finance, in 2007, roughly 1,356 counterfeit packages of medicine were seized at the Polish borders, while 1,700 packages were seized within the first three months of 2008.⁹⁴ In 2009, the Customs Service confiscated over 10,500 fake drugs worth USD 53,528, mainly Viagra and Cialis (both for erectile dysfunction).⁹⁵ In July 2009, more than 1.3 million fake insulin needles were also confiscated in Poland.⁹⁶

Online pharmacies, while illegal in Poland, are attractive to Poles because they offer lower costs than traditional alternatives.⁹⁷ Most counterfeit pharmaceutical products imported into Poland by member companies originated in Asia.⁹⁸

Russia

Regardless of the hyperbole in other European locations, counterfeit drug production and availability is significant in Russia. In April 2002, Alexander Toporkov, Deputy Head of the Ministry of Health Department for State Quality Control, reported that in 2001 there were 101 documented cases of counterfeited lots in Russia and 49 cases of counterfeited medicines. Antibiotics were the most frequently counterfeited (47%), followed by drugs containing hormones (11%).⁹⁹ From May to November of 2002, the Ministry of Finance discovered 89,803 batches of counterfeit drugs worth USD 230,860.¹⁰⁰

In 2003, the Coalition for Intellectual Property Rights, an independent Russian group, conducted a survey of the Russian market and found that 12 percent of pharmaceuticals in the country were counterfeit.¹⁰¹ Local industry groups claimed this figure was greatly exaggerated, and some claimed that the actual percentage was as little as a fraction of one percent.¹⁰²

Russia's underground market is characterized by unusually well-made fakes, according to private investigators from Pfizer who surveyed the Russian market in 2006.¹⁰³ A decade ago, many fakes in Russia were produced in basements and backrooms, but most now come from the night shift at

⁹⁴ Rychlicki, Tomasz. "Polish Regulation on Pharmaceutical Trademarks." *Polish IT and IP Law News* (Feb 1 2010), available at <http://rychlicki.net/en/2010/02/01/1864/> (accessed Mar 31 2010).

⁹⁵ Prawna, Dziennik Gazeta. "Fake Drugs Flood Poland." *Export.BY* (Feb 3 2010), available at <http://www.export.by/en/rus?act=news&mode=view&id=16692> (accessed Mar 24 2010).

⁹⁶ "2 Million Counterfeit Needles Found in Europe." *The Partnership for Safe Medicines* (Aug 30 2009), available at <http://www.safemedicines.org/2009/08/2.html> (accessed Feb 11 2011).

⁹⁷ "Poland Targeted by Internet Viagra Scammers." *The Outlook* (Sep 21 2006), available at <http://www.masterpage.com.pl/outlook/200609/drugscam.html> (accessed Mar 31 2010).

⁹⁸ "Counterfeit Drugs in Europe Fact Sheet." *The Partnership for Safe Medicines* (Jul 18 2005), available at <http://www.safemedicines.org/resources/europe.pdf> (accessed Apr 2 2010).

⁹⁹ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 4 2010).

¹⁰⁰ Kwiatkowski, Alex. "Health Chiefs Tackle Phoney Drugs Market." *The Russia Journal* 468 (Dec 20 2002), available at <http://www.russiajournal.com/node/13046> (accessed Jan 21 2010).

¹⁰¹ Kramer, Andrew E. "Counterfeit Drugs Imperil Health and Profits." *The New York Times* (Sep 4 2006), available at <http://www.nytimes.com/2006/09/04/business/worldbusiness/04iht-fake.2693603.html> (accessed Jan 21 2010).

¹⁰² Kramer, Andrew E. "Counterfeit Drugs Imperil Health and Profits." *The New York Times* (Sep 4 2006), available at <http://www.nytimes.com/2006/09/04/business/worldbusiness/04iht-fake.2693603.html> (accessed Jan 21 2010).

¹⁰³ Kramer, Andrew E. "Counterfeit Drugs Imperil Health and Profits." *The New York Times* (Sep 4 2006), available at <http://www.nytimes.com/2006/09/04/business/worldbusiness/04iht-fake.2693603.html> (accessed Jan 21 2010).

legitimate pharmaceutical companies. Some drug manufacturers run legally by day but add extra shifts at night “to produce extra quantities of a certified drug that does not pass through quality control, or sophisticated copies of well-known drugs are produced, often with reduced levels of expensive active ingredients. These fakes can be exact copies or put in packaging where only a letter or two is altered on the name.”¹⁰⁴ Counterfeits produced on the side are then channeled to Russia’s domestic market and, occasionally, to Europe and the United States. Counterfeit-drug production is worth an estimated USD 300 million per year in Russia, and although the government claims counterfeiting is decreasing, a report from 2006 indicates that this is not the case.¹⁰⁵

In addition to being produced in-country, counterfeit and substandard drugs are being imported into Russia at increasing rates. According to sources in India, exports from India to countries in the Commonwealth of Independent States, including Russia, are increasing, and cross-border associations between narcotic and fake drug traffickers in Russia and India flourishing.¹⁰⁶

According to the Federal Control Service, from 2002-2005, Russian authorities seized over 1000 tons of illicitly manufactured pharmaceuticals.¹⁰⁷ In 2005, the Council of Europe and WHO reported that fake medicines in Russia were on the rise, accounting for as much as 20% of all drugs distributed. A UN survey in 2005 ranked Russia as the fifth-largest producer of counterfeit pharmaceuticals in the world, with 70 percent of these products produced domestically and the rest imported mostly from China and other Asian markets.^{108 109 110 111} In the same year, Russia ranked first in the Pharmaceutical Security Institute’s (PSI) list of separate counterfeit drug entities seized/destroyed (93 instances).¹¹²

¹⁰⁴ Parfitt, Tom. “Russia Cracks Down on Counterfeit Drugs.” *The Lancet* 368:9546, 1481-1482 (Oct 28 2006), available at <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2806%2969619-0/fulltext> (accessed Mar 24 2010).

¹⁰⁵ Parfitt, Tom. “Russia Cracks Down on Counterfeit Drugs.” *The Lancet* 368:9546, 1481-1482 (Oct 28 2006), available at <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2806%2969619-0/fulltext> (accessed Mar 24 2010).

¹⁰⁶ Bate, Roger. “Making a Killing: The Deadly Implications of the Counterfeit Drug Trade.” *The American Enterprise Institute Press* (2008), available at http://www.aei.org/docLib/20080520_MakingaKillingnew.pdf (accessed 10 Feb 2011).

¹⁰⁷ “Russia in New Crackdown on Counterfeits.” *FDA News, Daily International Pharma Alert* 2:250 (Dec 27 2005), available at <http://www.fdanews.com/newsletter/article?articleId=83366&issueId=8849> (accessed Jan 29 2010).

¹⁰⁸ Kramer, Andrew E. “Counterfeit Drugs Imperil Health and Profits.” *The New York Times* (Sep 4 2006), available at <http://www.nytimes.com/2006/09/04/business/worldbusiness/04iht-fake.2693603.html> (accessed Jan 21 2010).

¹⁰⁹ “Russia in New Crackdown on Counterfeits.” *FDA News, Daily International Pharma Alert* 2:250 (Dec 27 2005), available at <http://www.fdanews.com/newsletter/article?articleId=83366&issueId=8849> (accessed Jan 29 2010).

¹¹⁰ Sliva, Jan. “Counterfeit Drugs Deemed Threat In Europe,” *Associated Press* (Sep 22 2005), available through Lexis Nexis Academic (accessed Feb 11 2011).

¹¹¹ Parfitt, Tom. “Russia Cracks Down on Counterfeit Drugs.” *The Lancet* 368:9546, 1481-1482 (Oct 28 2006), available at <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2806%2969619-0/fulltext> (accessed Mar 24 2010).

¹¹² Kirkman, Maureen. “Counterfeit Medicines: A Danger to Public Health.” *Pharmaceutical Industry Association of South Africa Presentation* (Sep 2007), available at <http://www.docstoc.com/docs/52269819/Counterfeit-Medicines-A-danger-to-public-health> (accessed May 9 2011).

In 2006, Russia's Federal Service for Health Sphere Supervision (FSHSS) reported that 10% of all drugs on the Russian market were counterfeit, though other sources estimate that the real figure could be much higher.¹¹³ In December 2006, Russia's health ministry estimated that counterfeit pharmaceuticals worth USD 250-300 million were being sold in the country every year, including antibiotics, cardiovasculars, and gastrointestinal medications.¹¹⁴

In 2006, Russian Federal Agency for Monitoring Health and Social Development, Roszdravnadzor, began revoking wholesalers' and retailers' licenses when counterfeit drugs were found in their stocks. From January to July 2006, 90 licenses were terminated and 20 annulled.¹¹⁵ During unscheduled inspections of pharmaceutical wholesalers and pharmacies, in the first half of 2006 Roszdravnadzor found 32 designated fake medicines, the largest proportion of which were antibiotics (38%).¹¹⁶ During a 10-day investigation, "Operation Pharmacologist," in 2006, police found that the number of violations exceeded the number reported in 2005 by 12 times; most violations were found in municipal drugstores (3,000) and kiosks (8,500).¹¹⁷ Police also reported 642 cases of biologically active additives being sold through kiosks which, according to the first deputy for the Interior Ministry, did not conform to the Russian safety standards.¹¹⁸

In 2007, police and inspectors from Roszdravnadzor raided a rundown Moscow warehouse and found an estimated USD 2 million dollars' worth of counterfeits of popular, mostly foreign-produced drugs including the antibacterial co-trimoxazole.¹¹⁹

In 2008, the Deputy Chairman of the Committee on health care protection of the State Duma, Professor Alexander Chukhraev, estimated that between 10 to 12 percent of medicines sold in pharmacies were counterfeit, signaling the counterfeits are not only a problem in the informal markets but have penetrated the official health sector in Russia as well.¹²⁰ For instance, in 2006 a chief physician at a large research hospital in Siberia admitted that he and his colleagues

¹¹³ "Fact Sheet – Counterfeit Medicines." *World Health Organization* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Jan 21 2010).

¹¹⁴ "Russian Probe Finds Fake Drug Market Big." *United Press International* (Dec 1 2006), available at http://www.upi.com/Science_News/2006/12/01/Russian-probe-finds-fake-drug-market-big/UPI-13711164997533/tab-listen/ (accessed Feb 3 2010).

¹¹⁵ "Russia Wants to 'Sort Out' Counterfeits, Again." *SCRIP News* (Jun 23 2006), available at <http://www.scripnews.com/home/news/Russia-wants-to-sort-out-counterfeits-again-64211> (accessed Jan 29 2010).

¹¹⁶ "Roszdravnadzor to Inspect Russia's Pharmaceutical Traders for Counterfeits." *SCRIP News* (Aug 23 2006), available at <http://www.scripnews.com/home/news/Roszdravnadzor-to-inspect-Russias-pharmaceutical-traders-for-counterfeits-65555> (accessed Feb 1 2010).

¹¹⁷ "Russian Probe Finds Fake Drug Market Big." *United Press International* (Dec 1 2006), available at http://www.upi.com/Science_News/2006/12/01/Russian-probe-finds-fake-drug-market-big/UPI-13711164997533/tab-listen/ (accessed Feb 3 2010).

¹¹⁸ "Russian Probe Finds Fake Drug Market Big." *United Press International* (Dec 1 2006), available at http://www.upi.com/Science_News/2006/12/01/Russian-probe-finds-fake-drug-market-big/UPI-13711164997533/tab-listen/ (accessed Feb 3 2010).

¹¹⁹ Bate, Roger. "Making a Killing: The Deadly Implications of the Counterfeit Drug Trade." *The American Enterprise Institute Press* (2008), available at http://www.aei.org/docLib/20080520_MakingaKillingnew.pdf (accessed 10 Feb 2011).

¹²⁰ "Counterfeit Drugs: A Threat to Russia's Security." *The Moscow News* (Oct 6 2008), available at <http://www.mnweekly.ru/national/20080610/55332994.html> (accessed Jan 21 2010).

unknowingly administered roughly 3,000 doses of fake Cavinton, a preventative anti-stroke remedy, made in its genuine form by Gedeon Richter of Hungary.¹²¹ In 2007, the Duma state passed a bill that will amend a clause in the national criminal code and calls for stricter punishments for people who produce, trade, store, transport, or import counterfeit drugs. The current maximum sentence is 10 years, but if the amendment is passed, the sentence would be extended to 15 years.¹²² In April 2010, the Duma passed new Federal Law “On the Circulation of Pharmaceuticals.” Among a number of other stipulations, the bill would streamline the registration process of the domestic pharmaceutical industry in order to make Russian medicines more affordable, thus discouraging counterfeit production and sale. The bill also established a January 2014 deadline for Russian manufacturers to comply with GMP standards of the EU.

Most of the fake drugs in Russia are high volume, low cost antibiotics, which turn an enormous profit when copied in bulk.¹²³ The variety of fakes in Russia range from a basic mix of glue, chalk and sugar to nearly exact chemical replicas of complex pharmaceuticals.¹²⁴ In 2009, four executives of Bryntsalov A, a pharmaceuticals company, were given suspended sentences and fined approximately USD 900-1,500 after being found guilty of counterfeiting more than 50 brands of medicines.¹²⁵

The underground market for prescription medications in Russia is distinguished from other black drug markets for being at the forefront of a new trend of exceedingly high quality fakes. Even private investigators from Pfizer, who surveyed the Russian market in 2006, admitted that they found fakes of exceptional quality, some of the finest they had ever seen.¹²⁶ Although thus far it appears that quality has remained high, there is little incentive for counterfeiters to maintain quality, especially since counterfeiting is only a civil liability, not a criminal one, and the fines are negligible.¹²⁷ While roughly 20 percent are estimated to come from abroad, the rest of the fake copies are thought to be made domestically, some by fully licensed “legitimate” producers, which are themselves making an extra profit on the side using low quality chemical components.^{128,129}

¹²¹ Kramer, Andrew E. “Counterfeit Drugs Imperil Health and Profits.” *The New York Times* (Sep 4 2006), available at <http://www.nytimes.com/2006/09/04/business/worldbusiness/04iht-fake.2693603.html> (accessed Jan 21 2010).

¹²² “Russia’s Parliament Proposes Longer Jail Sentence for Counterfeiting.” *SCRIP News* (May 16 2007), available at <http://www.scripnews.com/home/news/Russias-parliament-proposes-longer-jail-sentence-for-counterfeiting-34004> (accessed Feb 3 2010).

¹²³ Schofield, James. “Counterfeit Pharmaceuticals Flood Russian Market.” *British Medical Journal* 322:7302 (Jun 30 2001), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1173354/> (accessed Jan 21 2010).

¹²⁴ Kramer, Andrew E. “Counterfeit Drugs Imperil Health and Profits.” *The New York Times* (Sep 4 2006), available at <http://www.nytimes.com/2006/09/04/business/worldbusiness/04iht-fake.2693603.html> (accessed Jan 21 2010).

¹²⁵ “Pharmaceuticals Executives Given Suspended Sentences for Counterfeit Medicines,” *MosNews* (Apr 3 2009), available at <http://www.mosnews.com/money/2009/04/03/751/> (accessed Feb 3 2010).

¹²⁶ “Pharmaceuticals Executives Given Suspended Sentences for Counterfeit Medicines,” *MosNews* (Apr 3 2009), available at <http://www.mosnews.com/money/2009/04/03/751/> (accessed Feb 3 2010).

¹²⁷ Parfitt, Tom. “Russia Cracks Down on Counterfeit Drugs.” *The Lancet* 368:9546, 1481-1482 (Oct 28 2006), available at <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2806%2969619-0/fulltext> (accessed Mar 24 2010).

¹²⁸ “Counterfeit Drugs: A Threat to Russia’s Security.” *The Moscow News* (Oct 6 2008), available at <http://www.mnweekly.ru/national/20080610/55332994.html> (accessed Jan 21 2010).

¹²⁹ Schofield, James. “Counterfeit Pharmaceuticals Flood Russian Market.” *British Medical Journal* 322:7302 (Jun 30 2001), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1173354/> (accessed Jan 21 2010).

Substandard drugs are also common throughout Russia. An official at Roszdravnadzor stated that in 2007, 146 types of poor quality medicines were removed from the shelves of Russian pharmacies.¹³⁰

According to polls, 40% of Russians believed that they were taking either substandard or counterfeit medicines in 2008.¹³¹

Ukraine

The limited information available on Ukraine¹³² suggests that the prevalence of counterfeit drugs is between 20% and 40%, with some reports claiming that the percentage in certain drug classes may be as high as 80%.¹³³ If such a high rate is correct, it is probably due to a general lack of control over the import and distribution of pharmaceutical products in the country, despite national legislation for the control of the pharmaceutical market.¹³⁴ It is likely that counterfeits have permeated Ukraine's domestic market through its long, shared border with Russia.¹³⁵

Ukraine, like many other Eastern European countries, does not currently consider counterfeiting medicine a criminal offence.¹³⁶ While medicines can be seized from chemists and hospitals if they constitute a health risk for Ukrainians, their producers and importers cannot be prosecuted under the current legal structure.¹³⁷

At the end of 2009, Ukraine's State Inspectorate for Quality Control of Medicinal Products tried to tighten the reporting responsibilities of pharmaceutical manufacturers by increasing reporting

¹³⁰ "Counterfeit Drugs: A Threat to Russia's Security." *The Moscow News* (Oct 6 2008), available at <http://www.mnweekly.ru/national/20080610/55332994.html> (accessed Jan 21 2010).

¹³¹ "Pharmaceuticals Executives Given Suspended Sentences for Counterfeit Medicines," *MosNews* (Apr 3 2009), available at <http://www.mosnews.com/money/2009/04/03/751/> (accessed Feb 3 2010).

¹³² Harris, Julian. "Ukraine Government Provoking Rise in Fake Medicines?" *International Policy Network Health Blog* (Nov 27 2009), available at http://policynetwork.blogs.com/fightingdiseases/counterfeit_and_substandard_medicines/ (accessed Mar 31 2010).

¹³³ Taylor, Phil. "Ukraine Seeks Greater Control Over Pharma Sector." *Securing Pharma* (Nov 17 2009), available at <http://www.securingspharma.com/40/articles/289.php> (accessed Mar 31 2010).

¹³⁴ Chinwendu, Olike. "The Fight Against Fake Drugs by NAFDAC in Nigeria." *44th International Course in Health Development, Royal Tropical Institute* (Sep 24 2007), available at <http://www.search4dev.nl/document/193922> (accessed Feb 11 2011).

¹³⁵ Harris, Julian. "Ukraine Government Provoking Rise in Fake Medicines?" *International Policy Network Health Blog* (Nov 27 2009), available at http://policynetwork.blogs.com/fightingdiseases/counterfeit_and_substandard_medicines/ (accessed Mar 31 2010).

¹³⁶ "Ukraine Struggles Against Fake Drug Trade." *Kiev Ukraine News Blog* (Jun 11 2007), available at <http://news.kievukraine.info/2007/06/ukraine-struggles-against-fake-drug.html> (accessed Mar 31 2010).

¹³⁷ "Ukraine Struggles Against Fake Drug Trade." *Kiev Ukraine News Blog* (Jun 11 2007), available at <http://news.kievukraine.info/2007/06/ukraine-struggles-against-fake-drug.html> (accessed Mar 31 2010).

requirements on drug stocks.¹³⁸¹³⁹ However, current political dynamics have jeopardized the reform process.¹⁴⁰

Western Europe

Fake medicines are a small but constant challenge for countries in Western Europe. According to a 2010 Pfizer-sponsored survey, Western Europeans spend an estimated USD 14.3 billion per year on illicitly sourced medicines, many of them counterfeit.¹⁴¹

The most commonly counterfeited medicines include lifestyle drugs like anti-impotence medications, weight loss pills, high cholesterol drugs, and painkillers; life-saving medications for cardiovascular disease, diabetes, and AIDS; and psychotropic drugs. It also appears that most of the fake drugs are imported.

Though stringent customs keeps a great deal of these fakes from travelling through their territories, some counterfeits do get through. Some countries are introducing intricate bar code systems, while others have launched awareness campaigns to warn consumers about the dangers of counterfeit and sub-standard drugs.

Belgium

Belgium appears to be a major shipping hub for counterfeit or substandard medications coming en route from Asia to other parts of the world, particularly Africa. In December 2000, Belgian customs seized 57,600 packs of fake antimalarials, 15,400 packs of fake antibiotics en route from China to Nigeria.¹⁴² In an even bigger case, in October 2008, customs officers at the Brussels airport seized more than 2.2 million counterfeit pills destined for Africa, the biggest seizure of fake medication in Europe to date.^{143, 144} Some were blister packs of counterfeit painkillers, reportedly sent in three shipments by a company based in Mumbai, India, and were bound for two companies in Togo.¹⁴⁵

¹³⁸ Taylor, Phil. "Ukraine Seeks Greater Control Over Pharma Sector." *Securing Pharma* (Nov 17 2009), available at <http://www.securingspharma.com/40/articles/289.php> (accessed Mar 31 2010).

¹³⁹ Taylor, Phil. "Ukraine Seeks Greater Control Over Pharma Sector." *Securing Pharma* (Nov 17 2009), available at <http://www.securingspharma.com/40/articles/289.php> (accessed Mar 31 2010).

¹⁴⁰ Taylor, Phil. "Ukraine Seeks Greater Control Over Pharma Sector." *Securing Pharma* (Nov 17 2009), available at <http://www.securingspharma.com/40/articles/289.php> (accessed Mar 31 2010).

¹⁴¹ Hirschler, Ben. "Europeans Spend Billions On Fake Medicines: Survey." *Reuters* (Feb 16 2010), available at <http://www.reuters.com/article/idUSTRE61F00F20100216> (accessed Apr 2 2010).

¹⁴² Akunyili, Dora, et al. "The Global Threat of Counterfeit Drugs." *Arts and Opinion* 6:5 (Nov 5 2007), available at http://www.artsandopinion.com/2007_v6_n5/counterfeitdrugs.htm (accessed Apr 20 2010).

¹⁴³ "Africa-Bound Fake Drugs Seized in Belgium." *ABC News* (Oct 4 2008), available at <http://www.abc.net.au/news/stories/2008/10/04/2382035.htm?site=news> (accessed Apr 20 2010).

¹⁴⁴ Tagliabue, John. "Shipments of Fake Pill Seized." *The New York Times* (Oct 2 2008), available at http://www.nytimes.com/2008/10/03/world/europe/03briefs-SHIPMENTSOFF_BRF.html?_r=1&ref=world (accessed Mar 31 2010).

¹⁴⁵ Tagliabue, John. "Shipments of Fake Pill Seized." *The New York Times* (Oct 2 2008), available at http://www.nytimes.com/2008/10/03/world/europe/03briefs-SHIPMENTSOFF_BRF.html?_r=1&ref=world (accessed Mar 31 2010).

France

General information regarding the prevalence of fakes in the domestic market is minimal; most customs reports and police seizures reveal that the illicit drugs passing through France are bound for Latin America or Africa. In 2004, for instance, French customs agents seized 542,000 fake drugs.¹⁴⁶ 350,000 copies of Cialis tablets and 50,000 doses of fake Viagra headed from Syria to Honduras were seized in France in late 2008.¹⁴⁷ In a separate incident in December 2008, French customs officials at the Charles de Gaulle Airport seized yet another shipment of roughly 224,000 fake Viagra and Cialis pills, valued at USD 3.5 million.¹⁴⁸ In early 2006, 200,000 counterfeit tablets of Viagra were discovered at Charles de Gaulle Airport Paris, which originated in India and were destined for the Dominican Republic.¹⁴⁹

Domestic problems revolve around erectile dysfunction medicines. During a three-week period in March 2006, officials seized 360,000 imitation tablets of Viagra, originating from India.¹⁵⁰ Fake heart medications, were found in 2007 by the Agence Française de Sécurité Sanitaire des Produits de santé (AFSSAPS).¹⁵¹

According to a Pfizer study, the underlying problem of counterfeits in the country is the fact that roughly 14% of French consumers, 6.9 million people, buy prescription drugs outside of authorized channels, due to reasons of time constraints and convenience (32%), for price purposes (32%), and for anonymity purposes (27%). Roughly 35% of French respondents in the 2010 survey also admitted they did not know there was risk associated with buying a prescription drug without prescription; and 82% said they never would have purchased such drugs if they had known there was a chance the drug could have been fake.¹⁵²

¹⁴⁶ “Counterfeit Drugs in Europe Fact Sheet.” *The Partnership for Safe Medicines* (Jul 18 2005), available at <http://www.safemedicines.org/resources/europe.pdf> (accessed Apr 2 2010).

¹⁴⁷ “Major Fake Drug Hauls in France, Seized in Transit.” *The Pharma Letter* (Dec 1 2008), available at <http://www.thepharmaletter.com/file/16777/major-fake-drug-hauls-in-france-seized-in-transit.html> (accessed Feb 10 2011).

¹⁴⁸ “224,000 Fake Anti-Impotence Pills Seized.” *Reuters* (Jan 7 2008), available at <http://www.reuters.com/article/idUSN0739368520080107> (accessed Apr 23 2010).

¹⁴⁹ “Major Fake Drug Hauls in France, Seized in Transit.” *The Pharma Letter* (Dec 1 2008), available at <http://www.thepharmaletter.com/file/16777/major-fake-drug-hauls-in-france-seized-in-transit.html> (accessed Feb 10 2011).

¹⁵⁰ “Major Fake Drug Hauls in France, Seized in Transit.” *The Pharma Letter* (Dec 1 2008), available at <http://www.thepharmaletter.com/file/16777/major-fake-drug-hauls-in-france-seized-in-transit.html> (accessed Feb 10 2011).

¹⁵¹ “Contrefaçon de Médicaments: Rappel de Deux Lots de Médicaments par Mesure de Précaution.” *Emballage Digest* (Feb 14 2007), available at <http://www.emballagedigest.fr/blog.php?2007/02/14/4799-contrefacon-de-medicaments-rappel-de-deux-lots-de-medicaments-par-mesure-de-precaution> (accessed Feb 11 2011).

¹⁵² “Cracking Counterfeit.” *Pfizer* (Oct 2008), available at <http://www.pfizer.co.uk/sites/PfizerCoUK/Media/Documents/The%20Cracking%20Counterfeit%20report.pdf> (accessed Feb 11 2011).

Germany

In 2003, German customs officials seized 40,000 fake Viagra tablets, labeled ‘Diagra’, at a harbor in Hamburg, worth a reported USD 261,732.¹⁵³ In 2009, German customs authorities smashed a counterfeit ring across five cities selling millions of fake male potency tablets online, originating from India and other Asian countries; 46,000 pills destined for mail-order distribution were seized and seven people were arrested. Authorities froze bank accounts in Austria, Switzerland, Spain, Belgium, France and Turkey believed to be used by the ring and confiscated four luxury vehicles and USD 21,000 dollars in cash.¹⁵⁴

Information on counterfeits in the legitimate supply chain in Germany is minimal. However, in 2002 fake versions of anti-rejection pharmaceuticals (used by patients after organ transplants) were found in the legal distribution chain in Germany. According to reports, the fakes had been consigned to several German distributors by a Swiss-company acting as an intermediary, after the drugs passed through several other European countries.¹⁵⁵ In a separate incident in early 2003, German authorities raided a major wholesaler and seized two pallets of counterfeit AIDS drugs, valued at almost USD 1.33 million. Authorities suspected the products were sold outside the EU and that the complete packaging, including capsules, was replaced with counterfeits to make it look like products for marketing in Germany. Incriminating evidence led officials to a post office box company in Switzerland and illuminated connections with Israel.¹⁵⁶

Netherlands

Netherlands is often a point of transit for fake drugs headed to other European nations. For instance, in May 2005, 70 boxes of counterfeit Lipitor were seized in Rotterdam. Some boxes had already made their way to the United Kingdom.¹⁵⁷

Counterfeits also penetrate domestic supply chains. For instance, in July 2009, the Netherlands Health Care Inspectorate issued a warning about counterfeit insulin pens that were being circulated in the country; some 200,000 counterfeit needles were introduced to the Netherlands from a wholesaler in Malaysia, who claimed that the needles derived from Iran. The supply line

¹⁵³ “Germans Intercept Fake Viagra.” *The IP Kat* (Sep 3 2003), available at <http://ipkitten.blogspot.com/2003/09/germans-intercept-fake-viagra.html> (accessed Apr 2 2010).

¹⁵⁴ “Germany Smashes Fake Viagra Ring: Customs.” *AFP* (Jun 24 2009), available at <http://www.google.com/hostednews/afp/article/ALeqM5gavaX09rihdwDGcNB7eFpjseyfvQ> (accessed Apr 2 2010).

¹⁵⁵ “Impacts de la Contrefaçon et de la Piraterie en Europe.” Centre d’Études Internationales de la Propriété Industrielle (Jul 9 2004), available at http://ec.europa.eu/home-affairs/doc_centre/crime/docs/study_ceipi_counterfeiting_fr.pdf (accessed Feb 11 2011).

¹⁵⁶ “Großbrazzia bei Pharma-Händlern wegen Gefälschter Medikamente.” *Der Spiegel* (Mar 22 2003), available at <http://www.spiegel.de/spiegel/vorab/0,1518,241678,00.html> (accessed Apr 2 2010).

¹⁵⁷ Lister, Sam. “Heart Pills Recalled As Fakes Are Found.” *The Times* (Jul 29 2005), available at <http://www.timesonline.co.uk/tol/news/uk/article549317.ece> (accessed Apr 5 2010).

could not be traced beyond that point.¹⁵⁸ The counterfeits were easy to spot because the packaging information was in English rather than Dutch, and contained no barcode.¹⁵⁹

In 2006, the Dutch Healthcare Inspectorate warned consumers not to buy Tamiflu over the Internet as Tamiflu capsules containing lactose and vitamin C, but no active substance, had been found by Dutch officials.¹⁶⁰ The Dutch situation is representative of a major problem throughout Western Europe; roughly 12 percent of people in the Netherlands buy medicines from unauthorized channels, such as internet pharmacies. This greatly increases the risk of purchasing substandard or counterfeit medications.¹⁶¹

Switzerland

In 2009 Swissmedic, the Swiss surveillance authority for medicines and medical devices, claimed there were no instances of counterfeit agents infiltrating official Swiss drug distribution channels.¹⁶² However, Switzerland is demonstrably one of the most important transit points for fake medications entering the European Union.¹⁶³ EU pharmaceutical counterfeiting data shows that almost 40 percent of fake medicines seized by the EU in 2007 originated in Switzerland, more than the United Arab Emirates and even India.^{164,165} Mainly because Switzerland is a transit destination for counterfeits bound for the markets of other countries. For instance, in February 2010, over 17,000 boxes of counterfeit medical pills that originated from Mauritius and Singapore, including drugs to treat schizophrenia and to prevent cardiovascular diseases, were seized by customs officials in a warehouse in Switzerland.¹⁶⁶ Sources in Geneva indicated that

¹⁵⁸ “Health Care Inspectorate Warns of Counterfeit Insulin Needles.” *The Partnership for Safe Medicines* (Jul 9 2009), available at <http://www.safemedicines.org/2009/07/warning-for-counterfeit-insulin-pens-.html> (accessed Apr 2 2010).

¹⁵⁹ “Health Care Inspectorate Warns of Counterfeit Insulin Needles.” *The Partnership for Safe Medicines* (Jul 9 2009), available at <http://www.safemedicines.org/2009/07/warning-for-counterfeit-insulin-pens-.html> (accessed Apr 2 2010).

¹⁶⁰ “Fact Sheet – Counterfeit Medicines.” *World Health Organization* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Apr 5 2010).

¹⁶¹ Hirschler, Ben. “Europeans Spend Billions On Fake Medicines: Survey.” *Reuters* (Feb 16 2010), available at <http://www.reuters.com/article/idUSTRE61F00F20100216> (accessed Apr 2 2010).

¹⁶² “44 Fake Drug Incidents in Switzerland in 2008.” *Pharma Marketletter* (Feb 17 2009), available through Lexis Nexis Academic (accessed Feb 11 2011).

¹⁶³ “EU Voices Concern Over Swiss-Seized Medicine.” *SwissInfo* (May 19 2008), available at http://www.swissinfo.ch/eng/politics/EU_voices_concern_over_Swiss-seized_medicine.html?cid=657904 (accessed Apr 2 2010).

¹⁶⁴ Taylor, Nick. “40% of EU Counterfeit Drug Seizures of Swiss Origin.” *in-Pharma Technologist* (May 20 2008), available at <http://www.in-pharmatechnologist.com/Industry-Drivers/40-of-EU-counterfeit-drug-seizures-of-Swiss-origin> (accessed Apr 2 2010).

¹⁶⁵ “EU Voices Concern Over Swiss-Seized Medicine.” *SwissInfo* (May 19 2008), available at http://www.swissinfo.ch/eng/politics/EU_voices_concern_over_Swiss-seized_medicine.html?cid=657904 (accessed Apr 2 2010).

¹⁶⁶ McGinnis, Milissa. “Matrix of Drug Quality Reports Affecting USAID-Assisted Countries.” *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 4 2010).

the pills were not meant for the Swiss market but were to be sold in European countries, including France, Luxemburg, Belgium.¹⁶⁷

Customs reports and seizures reveal the extent to which Switzerland is increasingly being targeted as a transit country for fakes into Europe. In the first half of 2009, Swissmedic reported a 92% increase in the number of illegal medicine consignments confiscated at the border (568 shipments) in comparison with the first half of 2008.¹⁶⁸¹⁶⁹ Half of the confiscated consignments in 2009 came from Asian countries like India, China and Thailand, but around 25% came from other Western European countries.¹⁷⁰ Commonly counterfeited drugs during this time period included erectile dysfunction drugs (24%), weight loss drugs (14%), and painkillers (3%).¹⁷¹

Medical shipments from Asian countries are suspect to particularly close scrutiny. In June 2008, during a two-day operation in Zurich, customs officers intercepted every package from Asian countries like India and Thailand;¹⁷² of the 673 packages received, 145 contained medicines, almost all of which were for erectile dysfunction.¹⁷³ When scientists at Swissmedic's medical control laboratory analyzed 44 of the Viagra knockoff brands discovered during the seizures, they discovered that the chemical compositions of the fakes included banned substances, potentially dangerous levels of active ingredients, or no active ingredients at all.¹⁷⁴

In 2009, Swissmedic estimated that 50,000 illegal drug shipments are being imported by individuals into Switzerland each year, mostly through the internet from other countries.¹⁷⁵

In an effort to combat this growing problem, Switzerland joined an international campaign to combat the sale of counterfeit and illegal medicines over the internet in November 2009.¹⁷⁶

¹⁶⁷ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 4 2010).

¹⁶⁸ "Another Sharp Increase in Illegal Imports." *Swissmedic* (Jul 16 2009), available at <http://www.swissmedic.ch/aktuell/00003/01021/index.html?lang=en> (accessed Apr 2 2010).

¹⁶⁹ "Another Sharp Increase in Illegal Imports." *Swissmedic* (Jul 16 2009), available at <http://www.swissmedic.ch/aktuell/00003/01021/index.html?lang=en> (accessed Apr 2 2010).

¹⁷⁰ "Another Sharp Increase in Illegal Imports." *Swissmedic* (Jul 16 2009), available at <http://www.swissmedic.ch/aktuell/00003/01021/index.html?lang=en> (accessed Apr 2 2010).

¹⁷¹ "Another Sharp Increase in Illegal Imports." *Swissmedic* (Jul 16 2009), available at <http://www.swissmedic.ch/aktuell/00003/01021/index.html?lang=en> (accessed Apr 2 2010).

¹⁷² Neville, Tim. "Counterfeit Drugs On The Rise, Authorities Warn." *SwissInfo* (Oct 15 2008), available at http://www.swissinfo.ch/eng/science_technology/Counterfeit_drugs_on_the_rise_authorities_warn.html?cid=657852 (accessed Apr 2 2010).

¹⁷³ Neville, Tim. "Counterfeit Drugs On The Rise, Authorities Warn." *SwissInfo* (Oct 15 2008), available at http://www.swissinfo.ch/eng/science_technology/Counterfeit_drugs_on_the_rise_authorities_warn.html?cid=657852 (accessed Apr 2 2010).

¹⁷⁴ Neville, Tim. "Counterfeit Drugs On The Rise, Authorities Warn." *SwissInfo* (Oct 15 2008), available at http://www.swissinfo.ch/eng/science_technology/Counterfeit_drugs_on_the_rise_authorities_warn.html?cid=657852 (accessed Apr 2 2010).

¹⁷⁵ Brookes, Robert. "Swiss Fight Internet Supply of Illegal Medicines." *SwissInfo* (Nov 22 2009), available at http://www.swissinfo.ch/eng/index/Swiss_fight_internet_supply_of_illegal_medicines.html?cid=7705498 (accessed Apr 2 2010).

¹⁷⁶ Brookes, Robert. "Swiss Fight Internet Supply of Illegal Medicines." *SwissInfo* (Nov 22 2009), available at http://www.swissinfo.ch/eng/index/Swiss_fight_internet_supply_of_illegal_medicines.html?cid=7705498 (accessed Apr 2 2010).

During the campaign, Swissmedic succeeded in shutting down a Swiss website which offered prescription potency medication and counterfeit slimming products.¹⁷⁷

Southern Europe

Counterfeit drugs are a serious and growing problem in Southern Europe. According to a 2010 report sponsored by Pfizer, Spain alone is estimated to account for 14.3% of the European fake drug market.

The most common counterfeit drugs in this region, like in other parts of Europe, include erectile dysfunction drugs, anabolic steroids, weight loss pills, and growth hormones, most of which are purchased via online pharmacies. Other fakes frequently found in Southern Europe involve more serious medications, including cardiovascular, oncology, influenza and anti-cholesterol drugs.

Fakes have penetrated the legitimate market in some Southern European countries, such as in Portugal, but most countries in the region struggle with fake imports and in controlling counterfeits entering the country via purchases from online pharmacies and other unauthorized sources.

The only records of local counterfeit production in this area occur in Spain. Other Southern European countries, such as Malta, Portugal, and Italy, are targeted as destination countries for counterfeit drugs and as transit points for drugs moving from Asia to Western Europe.

Many Southern European governments have taken steps to combat the growing problem of fakes in this region. For instance, Italy is stepping up its efforts to make counterfeiting more expensive and less appealing for the perpetrators using “track and trace” systems. International enforcement efforts in the region have also increased in recent years, including enforcement operations like Interpol’s Pangea II operation in November 2009.

Croatia

In Croatia, no counterfeit medicines have been reported to date. However, substandard products have been detected. In early 2010, the Zagreb City Police sent the Agency for Medicinal Products and Medical Devices 34 samples of medicines, including drugs for erectile dysfunction, for testing. Twenty-three of the samples did not have marketing authorization in Croatia, and were tested with high-performance liquid chromatography (HPLC). Of these, some samples did not contain the active substance within the acceptable 95 % to 105 % margin of deviation from the declared content.¹⁷⁸ A similar study conducted the same year sampled 26 erectile dysfunction

¹⁷⁷ Brookes, Robert. “Swiss Fight Internet Supply of Illegal Medicines.” *SwissInfo* (Nov 22 2009), available at http://www.swissinfo.ch/eng/index/Swiss_fight_internet_supply_of_illegal_medicines.html?cid=7705498 (accessed Apr 2 2010).

¹⁷⁸ Martinac, Adrijana Ilić, et al. “Identification of Counterfeit Medicines for Erectile Dysfunction from an Illegal Supply Chain.” *Archives of Industrial Hygiene and Toxicology* 61:1, 69-74 (Mar 2010), available at http://hrcak.srce.hr/index.php?show=clanak&id_clanak_jezik=75542&lang=en (accessed Apr 5 2010).

medicines seized from the illegal supply. Results revealed that thirteen were substandard, and at least two, which contained none of the state ingredients, were counterfeit.¹⁷⁹

Italy

In 2009, Domenico Di Giorgio, from the Italian Medicines Agency, said the market for counterfeit drugs in Italy used to focus on "lifestyle" medicines such as Viagra and weight loss pills, but there is now a booming trade in anti-cholesterol medication and anticoagulants such as heparin.¹⁸⁰

Prior to this there are some reported instances: in 1998, 6,000 bottles of counterfeit Losec was discovered being parallel-imported into the country; in 2000, members of a criminal organization involved in pharmaceutical counterfeiting were arrested in Italy when almost 250,000 drugs and 2 tons of raw materials, worth USD 1 million, were found after having been imported from India and China, and intended for delivery to the United States.¹⁸¹

According to a survey sponsored by Pfizer and released in February 2010, Italians spend USD 4.84 billion each year on fake prescription medications, more than any other European nation. This is largely due to the fact that Italians buy drugs outside of formal sources; 37 percent of Italian residents admitted to acquiring prescription drugs without a prescription.¹⁸² The most popular fakes, according to the survey, are related to weight loss, flu, and erectile dysfunction.

Malta

Few counterfeit drugs have been reported in Malta, but evidence suggests that the country is used as a transfer point for medicines from Asia, destined for mainland Europe. In December 2006, for example, 400 packets of Plavix, a heart drug, were found by the police.¹⁸³ The medicine was not intended to be sold in Malta but was on its way to countries outside Europe, probably to be distributed in France, the United Kingdom and Switzerland.¹⁸⁴ The counterfeit packets are likely to have originated from a large medicine distributor in the UK.

¹⁷⁹ "Croatian Study Uncovers Counterfeit Medicines." *Securing Pharma* (Jul 8 2010), available at <http://www.securingpharma.com/40/articles/518.php> (accessed Jul 12 2010).

¹⁸⁰ "European Parliament Targets Online Fake Medicines." *EurActiv* (Oct 1 2009), available at <http://www.euractiv.com/en/health/european-parliament-targets-online-fake-medicines/article-185976> (accessed Apr 20 2010).

¹⁸¹ "Impacts de la Contrefaçon et de la Piraterie en Europe." Centre d'Études Internationales de la Propriété Industrielle (Jul 9 2004), available at http://ec.europa.eu/home-affairs/doc_centre/crime/docs/study_ceipi_counterfeiting_fr.pdf (accessed Feb 11 2011).

¹⁸² "Italy and Germany Top Counter Drugs Survey." *Pharmaceutical International* (Feb 16 2010), available at http://www.pharmaceutical-int.com/news/italy_and_germany_top_counterfeit_drugs_survey.html (accessed Apr 21 2010).

¹⁸³ "Lab Testing Confirms Counterfeit Drug in Malta." *MaltaMedia News* (May 20 2007), available at http://www.maltamedia.com/artman2/publish/govt_politics/article_1947.shtml (accessed Apr 5 2010).

¹⁸⁴ "Lab Testing Confirms Counterfeit Drug in Malta." *MaltaMedia News* (May 20 2007), available at http://www.maltamedia.com/artman2/publish/govt_politics/article_1947.shtml (accessed Apr 5 2010).

Portugal

As part of Interpol's Pangea II operation in November 2009, the Portuguese government raided the loading bays of Lisbon's airport as well as the capital's central post office and seized 48 suspicious consignments which contained over 1 million tablets believed to be counterfeit. As of 2009, no counterfeiting labs have been found in Portugal. General Deputy Director for Customs, Jose Pereira de Figueiredo, reported that customs officials seized around 28,000 counterfeit medicines in 2007. In 2008, seizures increased to 32,000 fake tablets, valued at USD 1.7 million.¹⁸⁵

Unlike in most developed economies, counterfeit medicines in Portugal have infiltrated formal markets. In February 2004, for example, Portuguese authorities seized thousands of counterfeit boxes of medication as part of an investigation into several illegal networks, which included registered doctors, nurses and pharmacy owners. Those involved in the networks were suspected of falsifying medical prescriptions, as well as bar codes on boxes of medicine, and then placing the medication, some of which had expired, into counterfeit boxes.¹⁸⁶

According to Infarmed, the drug regulatory body in Portugal, the most commonly counterfeited drugs in the country include growth hormones, weight loss pills, medicines to treat erectile dysfunction, and cardiovascular and oncology drugs.^{187,188} Most of the counterfeits in Portugal are imported; as of 2009, no counterfeiting labs had been found in Portugal.¹⁸⁹ Internet sites and online pharmacies also contribute to the proliferation of illegal medicines in the country.¹⁹⁰

In 2005, counterfeit medicines, including fake anabolic steroids, hormone-boosting substances, and cancer drugs, were imported into Portugal from Spain.¹⁹¹ In a separate incident, in November 2009, the Portuguese government raided the loading bays of the airport in Lisbon, the country's capital, as well as the central post office, and seized 48 suspicious consignments of medicines which contained over 1 million tablets believed to be counterfeit; this action on behalf of the government a part of Interpol's Pangea II operation.¹⁹²

¹⁸⁵ "Portugal Seizes Counterfeit Medicine as Part of International Operation." *BBC Monitoring Europe – Political* (Nov 24 2009), available through Lexis Nexis Academic (accessed Apr 2 2010).

¹⁸⁶ "Portuguese Police Smash Drug Networks Involving Doctors, Nurses, Pharmacists." *Agence France Presse* (Feb 12 2004), available through Lexis Nexis Academic (accessed Feb 11 2011).

¹⁸⁷ "Portugal Seizes Counterfeit Medicine as Part of International Operation." *BBC Monitoring Europe – Political* (Nov 24 2009), available through Lexis Nexis Academic (accessed Apr 2 2010).

¹⁸⁸ "Portugal Seizes Counterfeit Medicine as Part of International Operation." *BBC Monitoring Europe – Political* (Nov 24 2009), available through Lexis Nexis Academic (accessed Apr 2 2010).

¹⁸⁹ "Portugal Seizes Counterfeit Medicine as Part of International Operation." *BBC Monitoring Europe – Political* (Nov 24 2009), available through Lexis Nexis Academic (accessed Apr 2 2010).

¹⁹⁰ "Portugal Seizes Counterfeit Medicine as Part of International Operation." *BBC Monitoring Europe – Political* (Nov 24 2009), available through Lexis Nexis Academic (accessed Apr 2 2010).

¹⁹¹ "Counterfeit Drugs in Europe Factsheet." *The Partnership for Safe Medicines* (Jul 18 2005), available at <http://www.safemedicines.org/resources/europe.pdf> (accessed Apr 2 2010).

¹⁹² "Portugal Seizes Counterfeit Medicine as Part of International Operation." *BBC Monitoring Europe – Political* (Nov 24 2009), available through Lexis Nexis Academic (accessed Apr 2 2010).

Spain

According to a 2010 report sponsored by Pfizer, Spain accounts for 14.3% of Europe's fake drug market.¹⁹³ The report suggests that the value of counterfeit market in Spain in 2009 was around USD 2 billion, with more than 30% of the population using unauthorized channels (compared with Europe's average of 21%) to buy their medicines.¹⁹⁴ The study also revealed that most patients engaged in this type of activity in order to reduce spending (29%) and or due to time constraints (11%).¹⁹⁵

Counterfeits most commonly reported in Spain include anti-impotence drugs, in addition to anabolic steroids, birth control pills, and medicines for life-threatening disease such as cancer or AIDS. In 2009, Spanish police reported that, in their raids, they had also discovered a fake version of the anti-anxiety drug Xanax, Kamagra (one of the most common fake Viagras), and even a version of the wrinkle treatment Botox.¹⁹⁶

In March 2004, a police operation dubbed “Sledge Hammers,” resulted in the largest seizure of pharmaceuticals in Spain to date. Police detected illegal shipments of pharmaceuticals in the mail system, a raid on a supposed retailer of dietary products in Valencia led to the seizure of 500,000 dosage units of counterfeit and illegal medicines, worth roughly USD 8 million, in addition to 375,000 empty bottles, 160,000 inserts and 1.2 million counterfeit labels.¹⁹⁷ The fake drugs recovered included products meant to treat serious conditions such as AIDS and cancer. Criminal networks received supplies from Eastern Europe and the United States, and had been distributing its products countrywide.¹⁹⁸

In 2008, during an operation at Puerto Lumbreras, after discovering suspicious advertisements online, the Civil Guard recovered approximately 90,000 pills of counterfeit Viagra, Levitra and Cialis, which contained only 68% of the active ingredient; two arrests were also made, of a Dutch man and another from the United States, who faced charges of acting against public health and copyright.¹⁹⁹ In October 2009, another national police operation in Calpe led to the discovery of more than 160,000 fake Viagra pills, which reportedly came from India and China, and were brought into Spain using special courier companies; five were arrested. It is thought that the fake drugs would have been sold online.

¹⁹³ “Spain Pharmaceuticals and Healthcare Report Q2 2010.” *Business Monitor International* (Mar 2010), available through ProQuest Research Library (accessed Feb 11 2011).

¹⁹⁴ “Spain Pharmaceuticals and Healthcare Report Q2 2010.” *Business Monitor International* (Mar 2010), available through ProQuest Research Library (accessed Feb 11 2011).

¹⁹⁵ “Spain Pharmaceuticals and Healthcare Report Q2 2010.” *Business Monitor International* (Mar 2010), available through ProQuest Research Library (accessed Feb 11 2011).

¹⁹⁶ Kircz, Rupert. “Thousands of Counterfeit Viagra tablets seized in Spain.” *UK Medix* (Oct 31 2009), available at http://www.ukmedix.com/viagra/thousands_of_counterfeit_viagra_tablets_seized_in_spain5021.cfm (accessed Apr 2 2010).

¹⁹⁷ “Desarticulada una Red Dedicada a la Comercialización Ilegal de Anabolizantes,” *Guardia Civil* (Mar 18 2004), available at <http://www.guardiacivil.org/prensa/notas/noticia.jsp?idnoticia=1482> (accessed Feb 10 2011).

¹⁹⁸ “Desarticulada una Red Dedicada a la Comercialización Ilegal de Anabolizantes,” *Guardia Civil* (Mar 18 2004), available at <http://www.guardiacivil.org/prensa/notas/noticia.jsp?idnoticia=1482> (accessed Feb 10 2011).

¹⁹⁹ “90,000 Fake Viagra Pills Found in Murcia.” *Typically Spanish* (Nov 18 2008), available at http://www.typicallyspanish.com/news/publish/article_18911.shtml (accessed Apr 2 2010).

Unlike most of Southern Europe, Spain has a history of domestic counterfeit drug production. In the mid-1980s, an international group of drug traffickers based in the United States began importing, repacking, and distributing counterfeit birth control pills manufactured in Barcelona,²⁰⁰ the fakes were reportedly shipped from Spain to intermediary countries, smuggled into the United States and sold. Before the ring was busted, it made nearly USD 200,000 in profits, and six people were eventually indicted.^{201 202}

The problem with domestic counterfeiting is ongoing. In 2005, Spanish police raided six laboratories in the northeastern region of Catalonia and discovered a massive counterfeiting operation.²⁰³ The facility was capable of producing more than 20,000 doses of cancer medications, anabolic steroids, and hormone-boosting substances per hour.²⁰⁴ The counterfeit drugs came in various forms; packaging languages included Greek and Turkish, and the fake substances were distributed in vials, capsules, tablets and doses for injection.²⁰⁵ Police seized some 30 million doses and 10 tons of tablets, and arrested 70 individuals. Ingredients used in counterfeiting came from Mexico, Brazil, and Thailand, and the finished products seized were destined for distribution in various EU countries via lorries, the Internet, and health food stores run by one of the ring members.²⁰⁶ By the time the ring was busted, the products had already been exported to Italy, France, and Portugal.²⁰⁷

²⁰⁰ Maher, Patricia L. "The Importation of Bulk Counterfeit Pharmaceutical Products." *Statement before the Subcommittee of Oversight and Investigations of the Committee on Commerce, United States House of Representatives* (Oct 3 2000), available at <http://www.justice.gov/criminal/cybercrime/FDCAover.htm> (accessed Apr 20 2010).

²⁰¹ Maher, Patricia L. "The Importation of Bulk Counterfeit Pharmaceutical Products." *Statement before the Subcommittee of Oversight and Investigations of the Committee on Commerce, United States House of Representatives* (Oct 3 2000), available at <http://www.justice.gov/criminal/cybercrime/FDCAover.htm> (accessed Apr 20 2010).

²⁰² "Fake Birth Controls Lead to Indictment of 6." *The New York Times* (Feb 19 1987), available at <http://www.nytimes.com/1987/02/18/us/fake-birth-control-pills-lead-to-indictment-of-6.html> (accessed Apr 2 2010).

²⁰³ "Counterfeit Drugs in Europe Factsheet." *The Partnership for Safe Medicines* (Jul 18 2005), available at <http://www.safemedicines.org/resources/europe.pdf> (accessed Apr 2 2010).

²⁰⁴ "Counterfeit Drugs in Europe Factsheet." *The Partnership for Safe Medicines* (Jul 18 2005), available at <http://www.safemedicines.org/resources/europe.pdf> (accessed Apr 2 2010).

²⁰⁵ "Counterfeit Drugs in Europe Factsheet." *The Partnership for Safe Medicines* (Jul 18 2005), available at <http://www.safemedicines.org/resources/europe.pdf> (accessed Apr 2 2010).

²⁰⁶ "Counterfeit Drugs in Europe Factsheet." *The Partnership for Safe Medicines* (Jul 18 2005), available at <http://www.safemedicines.org/resources/europe.pdf> (accessed Apr 2 2010).

²⁰⁷ "Counterfeit Drugs in Europe Factsheet." *The Partnership for Safe Medicines* (Jul 18 2005), available at <http://www.safemedicines.org/resources/europe.pdf> (accessed Apr 2 2010).

II. Emerging Markets

Latin America

Counterfeit drugs are probably a major problem in Latin America, though the extent is difficult to quantify due to a general lack of data. What is known about counterfeits in Latin America is primarily based on enforcement seizures and reported incidents.

In 2008, the Caribbean Poison Information Network estimated the value of the counterfeit drug trade in Latin America and the Caribbean to be around USD 30.5 billion.²⁰⁸ According to the available data, drugs commonly counterfeited in Latin America include antibiotics, anti-impotence drugs, flu medications, anti-allergy pills, analgesics, and medicines such as Lipitor, used for the treatment of high cholesterol. Information on substandard drugs in the region is minimal, though substandard products—including expired and adulterated drugs—have been reported.

The counterfeit drug industry in Latin America has attracted the attention of organized criminal groups in the region, including Colombian cocaine traffickers and the Mexican mafia, particularly in environments of weak regulation and enforcement, where potential penalties are minimal compared with potential profits.

Many Latin American countries have strengthened efforts to detect, trace, and prosecute drug counterfeiting cases. In 2001, a survey conducted by Brazil's National Health Surveillance Agency (ANVISA) and the Pan American Health Organization (PAHO) revealed serious shortcomings in Latin American and Caribbean countries' abilities to fight drug counterfeiting. Problems included an absence of national standards for the distribution and dispensing of medicines, a lack of formal structures for preventing and fighting this type of crime, and a lack of public information about counterfeit drugs known to be in circulation.²⁰⁹ While many of the problems recorded in 2001 continue to exist, some progress has been made.

Police investigations, customs seizures, and health ministry efforts in various countries have developed a sizeable body of evidence regarding the prevalence of counterfeit and substandard drugs in Latin America. This section, organized by geographical region, provides a comprehensive overview of the available literature on fake medicines in Latin America and the Caribbean.

²⁰⁸Osbourne, Princess Thomas. "Counterfeit Medicines & Regulatory Systems in Place to Safeguard the Public." *Caribbean Poison Information Network Third Annual Scientific Conference* (May 31 2008), available at http://www.carpin.org/events08/3rdScConf/6-1_CounterfeitDrugsRegulatoryMechanism.pdf (accessed Feb 7 2011).

²⁰⁹"Deadly Imitations: Counterfeit Drugs Are A Growing Global Enterprise." *Pan American Health Organization* (Jan 1 2007), available at <http://www.thefreelibrary.com/Deadly+imitations:+counterfeit+drugs+are+a+growing+global+enterprise...-a0185654331> (accessed Feb 7 2011).

Central America

Belize

In July 2004, the US FDA discovered fake copies of Lipitor, Viagra, and Ambien (a sedative) from an online pharmacy listed as selling “Canadian generics.” The registered owners of the website were actually located in China and Belize.²¹⁰

In a similar case in 2006, 24 different types of drugs listed as “Canadian-made” were marketed by Hi-Tech Pharmaceuticals of Norcross, Georgia through unsolicited spam advertisements and e-mails—an investigation revealed that the pills were manufactured in substandard and unsanitary conditions in Belize, and had little or no medicinal value.²¹¹ Among the pills were counterfeit versions of steroids, Vioxx (to treat arthritis), Viagra, Cialis, Valium, Ambien, and Xanax.^{212,213} Federal authorities indicted 11 people in the United States and Belize on charges of selling counterfeit prescription drugs over the Internet; investigators suggested that the scam netted more than USD 19 million before it was shut down.²¹⁴

Costa Rica

In March 2005, investigators in Costa Rica discovered an international network manufacturing fake tablets of Lipitor that were reportedly intended to be sold in the United States for an estimated USD eight million.²¹⁵ In 2007, the US FDA estimated that as much as 85 percent of drugs promoted as Canadian actually came from other countries around the world, including Costa Rica, India, and Vanuatu.²¹⁶

El Salvador

In 2005, El Salvador’s Association of Pharmaceutical Companies reported widespread availability of counterfeit drugs on the domestic market.^{217,218} According to Gamma

²¹⁰Spake, Amanda. “Fake Drugs, Real Worries.” *U.S. News & World Report* (Sep 12 2004), available at <http://health.usnews.com/usnews/health/articles/040920/20internet.htm> (accessed Feb 24 2010).

²¹¹“Feds Charge 11 with Selling Fake Drugs.” *The Associated Press* (Sep 20 2006), available through Lexis Nexis Academic (accessed Mar 1 2010).

²¹²“Feds Charge 11 with Selling Fake Drugs.” *The Associated Press* (Sep 20 2006), available through Lexis Nexis Academic, (accessed Mar 1 2010).

²¹³Brunker, Mike. “Nutrition Firm or Herbal Cabal?” *MSNBC* (Apr 13 2007), available at <http://www.ergogenics.org/hitech.html> (accessed Mar 30 2010).

²¹⁴“Feds Charge 11 with Selling Fake Drugs.” *The Associated Press* (Sep 20 2006), available through Lexis Nexis Academic (accessed Mar 1 2010).

²¹⁵Loewy, Matías. “Deadly Imitations.” *Perspectives in Health (Pan American Health Organization)* 11:1 (2007), available at http://www.paho.org/English/DD/PIN/Number23_article3.htm (accessed Feb 24 2010).

²¹⁶Lutter, Randall W. “Policy Implications of Importing Drugs into the United States.” *Testimony Before the Subcommittee on Interstate Commerce, Trade, and Tourism Committee of the Commerce, Science, and Transportation Committee, U.S. Senate* (Mar 7 2007), available at <http://www.fda.gov/NewsEvents/Testimony/ucm154233.htm> (accessed Feb 7 2011).

²¹⁷“Fact Sheet – Counterfeit Medicines.” *World Health Organization* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Feb 24 2010).

Laboratorios, a local manufacturer, the commercialization of counterfeit medicines in El Salvador generated economic losses of around USD 40 million to the country's pharmaceutical industry in 2005.^{219,220}

Guatemala

In 2010, the Guatemalan police seized USD 308,000 worth of pseudoephedrine (a nasal and sinus decongestant), which is illegal in Guatemala. The counterfeits originated in Bangladesh.²²¹

In the mid-1980s counterfeiters successfully solicited a small company in Guatemala to make counterfeit birth control pills with no active ingredient. In August 1984, 12,000 cycles of the pill were shipped to the United States.²²² The US FDA learned of the counterfeit contraceptives several months later, and launched a government investigation that led to the conviction and imprisonment of six traffickers, all of whom resided in the United States.²²³

Honduras

In 2007, customs officials in the port of Le Havre, France seized almost 410,000 counterfeit medicines, valued at an estimated USD 7.8 million. The intercepted fakes were allegedly en route to Honduras from Syria.²²⁴

Mexico

Mexico's pharmaceutical industry, a USD 15.5 billion market, is plagued by widespread and complex problems, including counterfeit medicines, theft, and irregular sales practices. In 2009, illicit activity amounted to roughly USD 1.9 billion, or 12 percent, of the formal market, and counterfeiting represented 81 percent of the illicit market.²²⁵ Theft—ranging from pilferage to

²¹⁸ Loewy, Matías. "Deadly Imitations." *Perspectives in Health (Pan American Health Organization)* 11:1 (2007), available at http://www.paho.org/English/DD/PIN/Number23_article3.htm (accessed Feb 24 2010).

²¹⁹ "Fact Sheet – Counterfeit Medicines." *World Health Organization* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Feb 24 2010).

²²⁰ Loewy, Matías. "Deadly Imitations." *Perspectives in Health (Pan American Health Organization)* 11:1 (2007), available at http://www.paho.org/English/DD/PIN/Number23_article3.htm (accessed Feb 24 2010).

²²¹ "Counterfeit Medicines Seized." *Pharma and Healthcare Insight, Business Monitor International* (Feb 2010), available at <http://www.pharmaceuticalsinsight.com/file/86528/counterfeit-medicines-seized.html> (accessed Mar 8 2010).

²²² Maher, Patricia L. "The Importation of Bulk Counterfeit Pharmaceutical Products." (Oct 3 2000), available at <http://www.justice.gov/criminal/cybercrime/FDCAover.htm> (accessed Apr 7 2010).

²²³ Maher, Patricia L. "The Importation of Bulk Counterfeit Pharmaceutical Products." (Oct 3 2000), available at <http://www.justice.gov/criminal/cybercrime/FDCAover.htm> (accessed Apr 7 2010).

²²⁴ "Saisie de Près de 800 000 Faux Médicaments en 2007." *Emballage Digest* (Dec 17 2008), available at <http://www.emballagedigest.fr/blog.php?2008/12/17/8324-saisie-de-pres-de-800-000-faux-medicaments-en-2007> (accessed Feb 8 2011).

²²⁵ "A Glimpse Into Mexico's Shadow Pharmaceutical Market." *Global Fraud Report, KROLL* (Oct 9 2009), available at http://www.kroll.com/about/library/fraud/Oct2009/mexico_pharma.aspx (accessed Feb 24 2010).

stealing from pharmacies and warehouses —constituted 12 percent of the illicit market, while the illegal sale of drug samples accounted for 5 percent.²²⁶

In 2004, 20 percent of the drugs in Mexico were reported to be counterfeit or substandard.²²⁷ In 2005, one blog suggested that as many as 40 percent of all drugs distributed in the country were fake.²²⁸ In 2006, Mexico's drug counterfeiting sector was valued at USD 70 million, and by 2008, sales of fakes in the country exceeded USD 1.5 billion, equivalent to 10 percent of the total formal market.^{229, 230} Fake pharmaceuticals commonly found in Mexico include anti-impotence drugs, flu medications, and medicines that treat chronic illnesses such as high cholesterol.

In 2009, there were reports of a generic Tamiflu, for which no legitimate generic exists, being sold by vendors in Tijuana, the largest city in the Mexican state of Baja California.²³¹ In 2004, Mexican federal agents seized approximately 60 tons of stolen, expired and counterfeit pharmaceuticals in Sahuayo, in the western state of Michoacán, and Guadalajara, the capital city of the state of Jalisco.²³²

While counterfeits may be found all over the country, they are most prevalent in border towns frequented by Americans seeking cheaper medications. Such border towns, which often have more pharmacies than streets, are popular with US consumers, who spend more than USD one billion at Mexican pharmacies each year.^{233,234} For instance, in 2005, the US FDA warned American travelers to be aware of counterfeit versions of Lipitor, Viagra, and an unapproved product promoted as a generic form of Evista (used to treat and prevent osteoporosis) at pharmacies in Mexican border towns. The "generic Evista" was analyzed by FDA in coordination with the National Association of Boards of Pharmacy and was found to contain no active ingredient. The counterfeit Lipitor and counterfeit Viagra were analyzed by Pfizer, Inc.

²²⁶ "A Glimpse Into Mexico's Shadow Pharmaceutical Market." *Global Fraud Report, KROLL* (Oct 9 2009), available at http://www.kroll.com/about/library/fraud/Oct2009/mexico_pharma.aspx (accessed Feb 24 2010).

²²⁷ Doheny, Kathleen. "Think Twice Before Buying Prescription Drugs in Mexico." *Los Angeles Times* (Aug 8 2004), available at <http://www.latimes.com/features/health/medicine/la-tr-healthy8aug08.1.2053803.column> (accessed Mar 30 2010).

²²⁸ Pitts, Peter. "Counterfeit Drugs Deemed Threat in Europe." *Center for Medicine in the Public Interest Drug Wonks Blog* (Sep 23 2005), available at http://www.drugwonks.com/blog_post/show/4630 (accessed Feb 24 2010).

²²⁹ "Multinationals Urge Firm Action on Mexican Counterfeiting." *FDA News Daily International Pharma Alert* (Feb 14 2006), available at <http://www.fdanews.com/newsletter/article?articleId=84540&issueId=8981> (accessed Feb 24 2010).

²³⁰ "A Glimpse Into Mexico's Shadow Pharmaceutical Market." *Global Fraud Report, KROLL* (Oct 9 2009), available at http://www.kroll.com/about/library/fraud/Oct2009/mexico_pharma.aspx (accessed Feb 24 2010).

²³¹ "Doctor: Fake Flu Vaccine Being Sold in Mexico." *10 News* (Oct 30 2009), available at <http://www.10news.com/news/21482677/detail.html> (accessed Feb 24 2010).

²³² "Fact Sheet – Counterfeit Medicines." *World Health Organization* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Mar 30 2010).

²³³ Doheny, Kathleen. "Think Twice Before Buying Prescription Drugs in Mexico." *Los Angeles Times* (Aug 8 2004), available at <http://www.latimes.com/features/health/medicine/la-tr-healthy8aug08.1.2053803.column> (accessed Mar 30 2010).

²³⁴ Shetty, Raksha. "Mexico Eyes Fake Drugs on Border." *CBS News* (Aug 10 2004), available at <http://www.cbsnews.com/stories/2004/08/10/world/main635220.shtml> (accessed Feb 24 2010).

and were also found to contain no active ingredient.^{235,236} In July 2004, a fake of cholesterol drug, Zocor, was discovered to have been sold to American citizens in the Mexico-Arizona border town of Algodones (a ten-street hamlet with about 20 drug stores and 250 doctors).²³⁷ The incident prompted the US FDA to issue warnings about the fake Zocor, which contained no active ingredient, and also about the discovery of a very low level of active ingredient in substandard Carisoprodol (a muscle spasm medication).^{238,239}

The local production of counterfeit pharmaceuticals is a complex, lucrative, and significant clandestine industry in Mexico.²⁴⁰ Well-coordinated rings, often working closely with organized crime networks, shadow the industry and slip fake medication into the country's legitimate drug supply.²⁴¹ Counterfeiting in Mexico usually takes place in small laboratories, often located in residential buildings, supported by a network of suppliers and intermediaries. Sometimes legitimate business activities are used as a front, while in other cases fictitious corporations or ghost companies provide cover.²⁴²

The two most popular types of counterfeiting in the Mexican market are: (1) partial or total active product ingredient substitution, which can create drugs that are sub-potent and/or laced with hazardous materials, and (2) "recycling" of expired medications, in which organized crime rings repackage and redistribute drugs that have gone bad. This illicit practice is possible because Mexico lacks a formal waste management system for expired pharmaceuticals.²⁴³

Illicit online pharmacies are a major presence in the Mexican drug trade. In 2004, the US Drug Enforcement Administration detected over 200 online pharmacies operating along the US-

²³⁵ "Counterfeit Drugs Purchased in Mexico." *US Food and Drug Administration* (May 10 2005), available at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm151048.htm> (Accessed Feb 24 2010).

²³⁶ "Counterfeit Drugs Purchased in Mexico." *US Food and Drug Administration* (May 10 2005), available at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm151048.htm> (Accessed Feb 24 2010).

²³⁷ Shetty, Raksha. "Mexico Eyes Fake Drugs on Border." *CBS News* (Aug 10 2004), available at <http://www.cbsnews.com/stories/2004/08/10/world/main635220.shtml> (accessed Feb 24 2010).

²³⁸ Shetty, Raksha. "Mexico Eyes Fake Drugs on Border." *CBS News* (Aug 10 2004), available at <http://www.cbsnews.com/stories/2004/08/10/world/main635220.shtml> (accessed Feb 24 2010).

²³⁹ Shetty, Raksha. "Mexico Eyes Fake Drugs on Border." *CBS News* (Aug 10 2004), available at <http://www.cbsnews.com/stories/2004/08/10/world/main635220.shtml> (accessed Feb 24 2010).

²⁴⁰ Morris, Julian, and Stevens, Philip. "Counterfeit Medicines in Less Developed Countries." *International Policy Network* (2006), available at <http://counterfeiting.unicri.it/docs/Ctf%20medicines%20in%20less%20developed%20countries.pdf> (accessed Mar 30 2010).

²⁴¹ Morris, Julian, and Stevens, Philip. "Counterfeit Medicines in Less Developed Countries." *International Policy Network* (2006), available at <http://counterfeiting.unicri.it/docs/Ctf%20medicines%20in%20less%20developed%20countries.pdf> (accessed Mar 30 2010).

²⁴² Morris, Julian, and Stevens, Philip. "Counterfeit Medicines in Less Developed Countries." *International Policy Network* (2006), available at <http://counterfeiting.unicri.it/docs/Ctf%20medicines%20in%20less%20developed%20countries.pdf> (accessed Mar 30 2010).

²⁴³ "Mexico's Shadow Pharma Market." *Latin Business Chronicle* (Jan 11 2010), available at <http://www.latinbusinesschronicle.com/app/article.aspx?id=3905> (accessed Feb 1 2011).

Mexico border that delivered an estimated 11 million pills to US buyers from 2003 to 2008.²⁴⁴ In addition, over 2 percent of Mexico's 110 million inhabitants have purchased medications online. In an effort to thwart the trade of illicit drugs over the internet, Mexico's Federal Commission for Protection Against Health Risks banned all online pharmacies, including legitimate firms.²⁴⁵

In 2006, Mexico pledged to reform its health law to strengthen regulators' powers to crack down on the country's drug counterfeiting sector. Under the proposed reforms, counterfeiting would become a crime punishable by imprisonment.²⁴⁶ Suggested legal reforms include an increase of customs officers' authority to inspect and detain imported merchandise that infringes upon intellectual property rights.²⁴⁷ Another suggested reform would enable Mexican authorities to start investigations and perform raids without the need for intellectual property owners to file criminal complaints beforehand.²⁴⁸ As of 2011, none of these reforms had been enacted, despite growing pressure from legitimate business owners, industry coalitions and even some foreign governments.²⁴⁹

Nicaragua

Nicaraguan law outlaws the sale of medicines that have expired, punishable by fines of up to USD 600 and the closure of the establishment found to be selling those drugs.²⁵⁰ Furthermore, the importation, distribution, creation, promotion or commercial distribution of adulterated or counterfeit medicines is illegal in Nicaragua, with fines ranging from USD 400 to 600.²⁵¹

Panama

In 2006, Panama recorded that roughly 300 deaths had occurred as a result of consumption of fake drugs.²⁵² Of these, 115 deaths (and an additional 174 illnesses) are attributed to the mixture of toxic diethylene glycol syrup into government-made cough and anti-allergy syrups.²⁵³ Investigators traced the contaminated syrups to their origin in China, where a factory had sold 46

²⁴⁴ "Mexico's Shadow Pharma Market." *Latin Business Chronicle* (Jan 11 2010), available at <http://www.latinbusinesschronicle.com/app/article.aspx?id=3905> (accessed Feb 1 2011).

²⁴⁵ "Mexico's Shadow Pharma Market." *Latin Business Chronicle* (Jan 11 2010), available at <http://www.latinbusinesschronicle.com/app/article.aspx?id=3905> (accessed Feb 1 2011).

²⁴⁶ "Multinationals Urge Firm Action on Mexican Counterfeiting." *FDA News Daily International Pharma Alert* (Feb 14 2006), available at <http://www.fdanews.com/newsletter/article?articleId=84540&issueId=8981> (accessed Feb 24 2010).

²⁴⁷ Ramos-Zurita, Jose Luis. "Anti-counterfeiting in Mexico." *Legal 500*. (Aug 2008), available at <http://www.legal500.com/c/mexico/developments/4911> (accessed Apr 7 2010).

²⁴⁸ Ramos-Zurita, Jose Luis. "Anti-counterfeiting in Mexico." *Legal 500*. (Aug 2008), available at <http://www.legal500.com/c/mexico/developments/4911> (accessed Apr 7 2010).

²⁴⁹ Ramos-Zurita, Jose Luis. "Anti-counterfeiting in Mexico." *Legal 500*. (Aug 2008), available at <http://www.legal500.com/c/mexico/developments/4911> (accessed Apr 7 2010).

²⁵² Vidjningninou, Fiacre. "Africa's Fake Pharmaceuticals Problem." *Telegraph* (Oct 15 2009), available at <http://www.telegraph.co.uk/expat/expatnews/6335260/Africas-fake-pharmaceuticals-problem.html> (accessed Jan 25 2010).

²⁵³ Power, Mike. "Panama Mystery Illness Traced to Adulterated Drugs." *Reuters* (Oct 12 2006), available at <http://news.google.com/newspapers?nid=1241&dat=20061013&id=pFwPAAAAIIBAJ&sjid=VIYDAAAIBAJ&pg=6298.2062510> (accessed Feb 24 2010).

barrels of the toxic substance, labeled as “99.5% pure glycerin,” to a Chinese broker in Beijing. The syrup then travelled through brokers in Barcelona and Panama before it was sold to a Panamanian health service that unwittingly mixed the diethylene glycol into 260,000 bottles of cold medicine. Not one of the three trading companies on three continents had performed purity testing.²⁵⁴ Diethylene glycol was later detected in Chinese-made toothpaste sold in Panama, setting off a worldwide hunt for tainted toothpaste.^{255,256}

South America

Counterfeit pharmaceuticals are common in South America. In countries such as Argentina and Colombia, 40 percent of drugs in circulation have been reported as counterfeit.²⁵⁷

The local manufacture of fake medicine flourishes across the region, particularly in Brazil, Argentina and Venezuela.^{258,259} Counterfeits that are not made domestically are imported, most commonly from China. Worryingly, many of the fake medicines are for life threatening diseases such as asthma, cancer, or epilepsy. Other counterfeits include aspirins, pain killers, flu medicines, antibiotics, anti-impotence drugs, birth control pills, and diet pills.

Bolivia and Peru have taken legal measures to thwart counterfeit drug trade—both countries have banned the sale of drugs in informal markets, increased the legal penalties for counterfeiters, and strengthened enforcement activities. In Peru, for instance, a person found selling, storing, packaging or producing adulterated and faulty medicine may face up to ten years in prison.²⁶⁰

Argentina

An estimated 22,000 Argentines die each year as a result of consuming counterfeit and adulterated medicines, according to an official report of the Argentine Union of Pharmacists and

²⁵⁴ Bogdanich, Walt, and Hooker, Jake. “From China to Panama, a Trail of Poisoned Medicine.” *The New York Times* (May 6 2007), available at <http://www.nytimes.com/2007/05/06/world/06poison.html> (accessed Feb 24 2010).

²⁵⁵ Bogdanich, Walt. “Panama Releases Report on ’06 Poisoning.” *The New York Times* (Feb 14 2008), available at http://www.nytimes.com/2008/02/14/world/americas/14panama.html?_r=1 (accessed Feb 24 2010).

²⁵⁶ Hooker, Jake. “Chinese Company Linked to Deaths Wasn’t Licensed.” *The New York Times* (May 9 2007), available at <http://www.nytimes.com/2007/05/09/world/asia/09china.html?ex=1336363200&en=b6736b921242dfa6&ei=5088&partner=rssnyt&emc=rss> (accessed Feb 24 2010).

²⁵⁷ Young, Donna. “FDA Launches New Initiative to Combat Counterfeit Drugs.” *American Society of Health System Pharmacists* (Aug 20 2003), available at <http://www.ashp.org/import/news/HealthSystemPharmacyNews/newsarticle.aspx?id=1348> (Accessed Mar 3 2010).

²⁵⁸ Nevin, Tom. “The Deadly Scourge of Fake Drugs.” *The Free Library* (Oct 1 2006), available at <http://www.thefreelibrary.com/The+deadly+scourge+of+fake+drugs:+counterfeit+drugs,+which+are+not...-a0153007212> (accessed Apr 6 2010).

²⁵⁹ “The Economic Impact of Counterfeiting,” *Organization for Economic Co-operation and Development* (1998), available at <http://www.oecd.org/dataoecd/11/11/2090589.pdf> (accessed Mar 3 2010).

²⁶⁰ “Up to Ten Year Imprisonment for Drug Counterfeiters in Peru.” *The Med Guru* (Jun 2 2008), available at http://www.themedguru.com/articles/up_to_10_year_imprisonment_for_drug_counterfeiters_in_peru-7324138.html (accessed Mar 1 2010).

Biochemists.²⁶¹ The report also claims that 10 percent of drugs in Argentina are fakes, in contrast with the National Drug and Technology Agency (ANMAT) figure, which is less than one percent.²⁶² The report estimates the size of the industry to be approximately USD 320 million though another researcher claims it could be up to USD 735 million.²⁶³

The counterfeit drug trade in Argentina is a serious, systemic problem in which leaders in politics, business, and labor all participate. An official probe into counterfeit medicines in the Buenos Aires region began in 2007, when the recently appointed Minister of Health of the Nation, Graciela Ocaña, launched an investigation into more than 400 complaints from the State that had been collected since 1995 regarding reports of counterfeit drugs and forged documents found in various pharmacies.²⁶⁴

Most Argentines access healthcare—including doctors and prescription medicine—through their employment unions. Union healthcare providers receive refunds from the state-run Special Programs Administration (APE) to offset the cost of care for rare, high-complexity illnesses that require expensive treatment, such as cancer, hemophilia, and AIDS.²⁶⁵ Union leaders, drug distributors, and state officials have colluded to take advantage of the system by forging documents and disbursing fake drugs in order to get APE reimbursements. The leader of at least one union, Juan José Zanola of the Bank Clerks' Union, has been charged with defrauding the state in this way; he awaits trial in 2011.

Federal Judge Norberto Oyarbide ordered a number of raids and arrests in relation to the case. In November 2009, 155 establishments were raided and five arrests were made.²⁶⁶ In September 2010, a raid of the Bank Clerks' Union Hospital led to the seizure of expired medicines and evidence of counterfeit transactions among a number of other workers unions. In November 2010, Oyarbide ordered 42 raids in five Buenos Aires neighborhoods, and seized documents that show evidence of trade in counterfeit drugs for cancer, AIDS, and hemophilia.²⁶⁷ In December 2010, a raid was conducted at the APE offices in the Ministry of Health headquarters, and seized files indicating pharmaceutical providers had presented false vouchers and medicines to receive

²⁶¹ “Un Negocio Millonario que Mata el Miles de Personas el Año de al País.” *El Dia* (Sep 26 2010), available at <http://www.eldia.com.ar/edis/20100926/informaciongeneral0.htm> (accessed Feb 7 2011).

²⁶² “Un Negocio Millonario que Mata el Miles de Personas el Año de al País.” *El Dia* (Sep 26 2010), available at <http://www.eldia.com.ar/edis/20100926/informaciongeneral0.htm> (accessed Feb 7 2011).

²⁶³ “Un Negocio Millonario que Mata el Miles de Personas el Año de al País.” *El Dia* (Sep 26 2010), available at <http://www.eldia.com.ar/edis/20100926/informaciongeneral0.htm> (accessed Feb 7 2011).

²⁶⁴ “Un Negocio Millonario que Mata el Miles de Personas el Año de al País.” *El Dia* (Sep 26 2010), available at <http://www.eldia.com.ar/edis/20100926/informaciongeneral0.htm> (accessed Feb 7 2011).

²⁶⁵ “Argentina: The Healthcare Sector in Argentina.” *Human Development Department, Latin America and the Caribbean Region, World Bank Report No. 2144-AR* (Jul 21 2003), available at <http://siteresources.worldbank.org/INTDSRE/Resources/261440AR.pdf> (accessed Feb 9 2011).

²⁶⁶ “Medicines’ Mafia: 155 Raids and 5 Arrests.” *Momento 24* (Nov 4 2009), available at <http://m24digital.com/en/2009/11/04/medicines-mafia-155-raids-and-5-detainees/> (accessed Feb 9 2011).

²⁶⁷ “At Least 42 Police Raids on the Case of Counterfeit Drugs.” *Momento 24* (Nov 26 2010), available at <http://m24digital.com/en/2010/11/26/at-least-42-police-raids-on-the-case-of-counterfeit-drugs/> (accessed Feb 4 2011).

reimbursements.²⁶⁸ As of February 2011, over 50 workers unions, as well as a number of drug distributors and former politicians, are under investigation.²⁶⁹

In 2008, a pharmacy owner and entrepreneur Nestor Lorenzo was called to testify during the trial for a drug-related triple homicide in Buenos Aires.²⁷⁰ While the murders were allegedly attributed to a Mexican cartel over ephedrine trafficking, Lorenzo's testimony revealed that the three deceased traffickers had ties to the pharmaceutical industry as well. Lorenzo alleged that one of the dead, drug distributor Sebastián Forza, was responsible for selling a shipment of a counterfeit version of a hemophilia drug, Beriate, to ANMAT.²⁷¹ Lorenzo also admitted to being part of a drug consortium that included Forza and two others (including one known methamphetamine producer) that allegedly involved the disbursement of counterfeit medicines.²⁷²

The flawed healthcare system implicates not just labor and business leaders, but political leaders as well. In September 2009, an investigation into money laundering by two contributors (both linked to Nestor Lorenzo) to President Cristina Kirchner's 2007 campaign, led to a police raid, during which several people were caught trying to bury counterfeit medicines.²⁷³ The president's connection to the counterfeit medicine trade is strong—a disproportionate 20 to 30 percent of her campaign contributions came from drug industry leaders, and Hector Capaccioli, former Superintendent of Health Services is implicated in a scheme of enticing union distributors with the promise of increased business opportunities in exchange for an agreement to forge documents and distribute fake medicines through which money could be funneled through the APE to Kirchner's presidential campaign.^{274,275}

While the illicit activity of the Buenos Aires "medicines mafia" is indicative of the scope of Argentina's problem with drug counterfeiting, a number of probably unrelated cases have been reported throughout the country as well. In May 2000 for example, Argentinean authorities intercepted 200 truckloads of pharmaceuticals and raided 50 production plants in different parts of the country. ANMAT found evidence that up to 22.7 percent of total drug sales in Argentina

²⁶⁸ "Por Posibles Estafas al Estado, Oyarbide Allanó la Sede de APE." *La Nación* (Dec 8 2010), available at http://www.lanacion.com.ar/nota.asp?nota_id=1334672 (accessed Feb 7 2011).

²⁶⁹ "Medicines' Mafia: Over 50 Labor Union Health Services will be Investigated." *Momento 24* (Sep 24 2009), available at <http://m24digital.com/en/2009/09/24/medicines-mafia-over-50-labor-union-health-services-will-be-investigated/> (accessed Feb 4 2011).

²⁷⁰ "Triple Murder: Witness Nestor Lorenzo Testifies." *Momento 24* (Sep 16 2009), available at <http://m24digital.com/en/2009/09/16/triple-murder-witness-nestor-lorenzo-testifies/> (accessed Feb 4 2011).

²⁷¹ "Efedrina, Blanqueo de Dinero y Silencio Oficial." *Tribuna de Periodistas* (Dec 9 2008), available at <http://www.periodicotribuna.com.ar/4342-efedrina-blanqueo-de-dinero-y-silencio-oficial.html> (accessed Feb 4 2011).

²⁷² "Triple Murder: Witness Nestor Lorenzo Testifies." *Momento 24* (Sep 16 2009), available at <http://m24digital.com/en/2009/09/16/triple-murder-witness-nestor-lorenzo-testifies/> (accessed Feb 4 2011).

²⁷³ "Counterfeit Medicines: As the Investigation Moves Towards Money Laundering, the Police Find Loads of Expired Drugs." *Momento 24* (Sep 9 2009), available at <http://m24digital.com/en/2009/09/09/drug-phony-the-case-moves-to-money-laundering/> (accessed Feb 4 2011).

²⁷⁴ "Una Oscura Sombra se Cierne Sobre el Gobierno." *La Nacion* (Aug 19 2008), available at http://www.lanacion.com.ar/nota.asp?nota_id=1041120 (accessed Feb 7 2011).

²⁷⁵ "Tiemblan los K: Capaccioli Será Indagado Hoy en Causa Por medicamentos 'Truchos.'" *Tribuna de Periodistas* (Oct 5 2010), available at <http://www.periodicotribuna.com.ar/7485-tiemblan-los-k-capaccioli-sera-indagado-hoy-en-causa-por-medicamentos-truchos.html> (accessed Feb 7 2011).

were irregular: 9 percent were outdated products, 6 percent were smuggled (mainly from neighboring countries with less stringent controls), 4 percent had altered packaging, 2 percent were free samples intended for health professionals, and 1.7 percent were simply bogus.²⁷⁶

In 2004, fake medicines led to the deaths of multiple women who received iron injections to treat anemia.²⁷⁷ In 2007, Adrian Gimenez, one of Argentina's most experienced counterfeit drug investigators, reported that a group of counterfeiters were caught producing adulterated asthma medications inside a henhouse.²⁷⁸ He also reported two cases involving fake cancer medicines—in one case, no active ingredient was found, and in the other, the medicine had expired and been repackaged.²⁷⁹

In January 2010, Argentinean customs officials at the port of Buenos Aires seized a shipment that originated in China, allegedly carrying electric lamps; in reality, it was transporting 400,000 tablets of counterfeit medicines, most of which had been printed with the brand names Viagra and Cialis.²⁸⁰

In an effort to thwart the counterfeit drug trade, in November 2009 Argentinean lawmakers reformed the penal code to create Federal Law 26,524, which made drug counterfeiting a criminal offense punishable by a prison term of three to ten years and a monetary fine between approximately USD 3000 and 15,000.²⁸¹ In the same month, Article 1 of Pharmacy Law 17,565 was modified so that medicines previously available over-the-counter (OTC) now could only be sold by pharmacists or authorized dispensers in pharmacies.²⁸² Despite the new legislation, legal drawbacks remain—for instance, in Argentina it is not illegal to change the expiration date of a medicine unless it can be proven that doing so had damaged a person's health.²⁸³

The latest version of a drug traceability regulatory draft, which has been in circulation for over two years, was approved by the Senate in November 2010. However, due to the inclusion of

²⁷⁶ Iglesias-Rogers, Graciela. "Argentina to Crackdown on Pharmaceutical Black Market." *Lancet* (Jul 7 2001), accessed through Lexis Nexis Academic (Mar 1 2010).

²⁷⁷ "Fact Sheet – Counterfeit Medicines." *World Health Organization* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Feb 24 2010).

²⁷⁸ Loewy, Matías. "Deadly Imitations." *Perspectives in Health (Pan American Health Organization)* 11:1 (2007), available at http://www.paho.org/English/DD/PIN/Number23_article3.htm (accessed Feb 24 2010).

²⁷⁹ Loewy, Matías. "Deadly Imitations." *Perspectives in Health (Pan American Health Organization)* 11:1 (2007), available at http://www.paho.org/English/DD/PIN/Number23_article3.htm (accessed Feb 24 2010).

²⁸⁰ "Secuestran 400.000 Pastillas Falsas de Viagra en la Aduana." *La Nacion* (Jan 11 2010), available at http://www.lanacion.com.ar/nota.asp?nota_id=1220757 (accessed Mar 1 2010).

²⁸¹ "Amendment of Criminal Code to Include Counterfeiting of Medicines." *Moeller IP Advisors* (Jan 2010), available at http://www.moellerip.com/index.php?PN=news_detail&FX=1&EX=1&DX=54 (accessed Feb 9 2011).

²⁸² "The Pharmaceutical Market: Argentina." *ESPICOM* (Jan 27 2010), available at <http://www.pharmaceutical-market-research.info/research/PMAAADEY-Espicom-The-Pharmaceutical-Market--Argentina.shtml> (accessed Feb 2 2011).

²⁸³ Loewy, Matías. "Deadly Imitations." *Perspectives in Health (Pan American Health Organization)* 11:1 (2007), available at http://www.paho.org/English/DD/PIN/Number23_article3.htm (accessed Feb 24 2010).

some changes, the draft has been sent back to the Chamber of Deputies and final approval is expected in 2011.^{284,285}

Bolivia

Bolivian authorities seized more than 40 tons of counterfeit, expired and/or adulterated medicines between December 2009 and January 2010. Many of the drugs were seized from a local importer called Eske SRL had expired and were relabeled with new use-by dates.^{286,287} The head of Eske SRL, as well as the head of another company that was found to be producing counterfeits, faced prosecution for crimes against public health that carry a penalty of up to seven years jail.²⁸⁸ Following the seizures, 200 pharmacies were visited by authorities within a 48-hour period in January 2010; 26 were closed down and 74 set to be fined.²⁸⁹

Brazil

Some reports indicate that one-fifth of all branded medications in Brazil are counterfeit.²⁹⁰ Known counterfeits include anti-epileptic pills containing 25 percent of the labeled amount of active ingredient, fake penicillin, tetracycline, and prostate cancer drugs with no active ingredient.²⁹¹ Diet pills were found containing anything and everything from laxatives and diuretics to thyroid hormones and tranquilizers.²⁹²

²⁸⁴ “The Pharmaceutical Market: Argentina.” *ESPICOM* (Dec 10 2010), available at http://www.espicom.com/prodcat2.nsf/Product_ID_Lookup/00000327?OpenDocument (accessed Feb 2 2011).

²⁸⁵ “The Pharmaceutical Market: Argentina.” *ESPICOM* (Jan 27 2010), available at <http://www.pharmaceutical-market-research.info/research/PMAAADEY-Espicom-The-Pharmaceutical-Market--Argentina.shtml> (accessed Feb 2 2011).

²⁸⁶ “Bolivia Promises Tougher Stance on Fake Drugs.” *Securing Pharma* (Jan 15 2010), available at <http://www.securingspharma.com/40/articles/349.php> (accessed on Mar 1 2010).

²⁸⁷ “Bolivian Call For Tougher Sanctions on Counterfeit Drugs.” *The Pharmaletter* (Jan 12 2010), available at <http://www.thepharmaletter.com/file/3e7670ef71b518b9b566d88e4b8f98e7/bolivian-call-for-tougher-sanctions-on-counterfeit-drugs.html> (accessed Apr 7 2010).

²⁸⁸ “Bolivian Call For Tougher Sanctions on Counterfeit Drugs.” *The Pharmaletter* (Jan 12 2010), available at <http://www.thepharmaletter.com/file/3e7670ef71b518b9b566d88e4b8f98e7/bolivian-call-for-tougher-sanctions-on-counterfeit-drugs.html> (accessed Apr 7 2010).

²⁸⁹ “The Pharmaceutical Market: Argentina.” *ESPICOM* (Jan 27 2010), available at <http://www.pharmaceutical-market-research.info/research/PMAAADEY-Espicom-The-Pharmaceutical-Market--Argentina.shtml> (accessed Feb 2 2011).

²⁹⁰ “Counterfeiting and Piracy in Brazil: The Economic Impact.” *Brazil-U.S. Business Council*. (Jul 8 2008), available at http://www.iccwbo.org/uploadedFiles/BASCAP/Pages/Counterfeiting_and_Piracy_in_Brazil%5B1%5D.pdf (accessed Mar 3 2010).

²⁹¹ “Counterfeiting and Piracy in Brazil: The Economic Impact.” *Brazil-U.S. Business Council*. (Jul 8 2008), available at http://www.iccwbo.org/uploadedFiles/BASCAP/Pages/Counterfeiting_and_Piracy_in_Brazil%5B1%5D.pdf (accessed Mar 3 2010).

²⁹² “Counterfeiting and Piracy in Brazil: The Economic Impact.” *Brazil-U.S. Business Council*. (Jul 8 2008), available at http://www.iccwbo.org/uploadedFiles/BASCAP/Pages/Counterfeiting_and_Piracy_in_Brazil%5B1%5D.pdf (accessed Mar 3 2010).

In 1998, over two hundred women became pregnant after taking oral contraceptive pills made of nothing but wheat flour.²⁹³ In 2001, amidst public concern about confirmed cases of counterfeit birth control and Androcur, a medicine used to treat prostate cancer, Brazil introduced legislation that makes drug counterfeiting a crime on the level of kidnapping and terrorism, punishable by 10 to 15 years in jail and a fine.²⁹⁴

In March 2006, the US Joint Terrorism Task Force—an interagency initiative led by the FBI—charged 19 people with operating a counterfeit drug ring that traversed Lebanon, Canada, China, Brazil, Paraguay, and the United States; while there was no information available on what type of drugs were counterfeited, it was reported that the profits from the sales of these fakes were used to support the terrorist group Hezbollah.²⁹⁵

In 2008, Brazil's National Health Surveillance Agency (ANVISA) seized more than five tons of illegal medicines, both counterfeit and unregistered, from pharmacies in the state of Mato Grosso. Four tons of medicines were seized from a drug distribution establishment in Várzea Grande, after the drugs were found to be stored outside of regulation temperatures. 12 pharmacies were sampled in both Cáceres and Mirassol D'Oeste, leading to a total of ten pharmacies sealed and six owners arrested for selling counterfeit and substandard drugs. An estimated one ton of medicines were seized, many of them counterfeit anti-impotence drugs.²⁹⁶

In early 2009, ANVISA and the Ministry of Justice seized 170 tons of medicines, mostly because of parallel importation and the drugs were marketed without ANVISA's approval and registration.²⁹⁷ Of all the products seized, five percent were pirated, found mainly on the shelves of government-accredited pharmacies. The most commonly pirated medicines found were anti-impotence drugs, such as Viagra and Cialis.²⁹⁸

Colombia

In June 2001, the General Director of Colombia's National Institute for the Supervision of Medications & Foods (INVIMA), Dr. Miguel Rueda, estimated that 10 percent of the USD 1.2

²⁹³ Yankus, Wyatt. "Counterfeit Drugs: Coming to a Pharmacy Near You." *American Council on Science and Health* (Aug 24 2006), available at http://www.acsh.org/publications/pubID.1379/pub_detail.asp (accessed Feb 24 2010).

²⁹⁴ Capell, Kerry, and Timmons, Suzanne. "What's In That Pill?" *BusinessWeek* (Jun 18 2001), available at http://www.businessweek.com/magazine/content/01_25/b3737076.htm (accessed Feb 24 2010).

²⁹⁵ Liang, Bryan A. "Safety of Drug Supply: Tougher Laws Needed to Stem Counterfeit Drug Rings." *Daily Transcript* (May 4 2006), available at www.sddt.com/News/article.cfm?SourceCode=20060503crd (accessed Feb 24 2010).

²⁹⁶ "Operação Sallus Apreende 5 Toneladas de Medicamentos em MT." *TV Centro América* (Oct 2 2008), available at <http://rmtonline.globo.com/noticias.asp?em=2&n=410237&p=2> (accessed Feb 4 2011).

²⁹⁷ "Counterfeit and Parallel Importation of Medicines." *IP Tango* (May 14 2009), available at <http://iptango.blogspot.com/2009/05/counterfeit-and-parallel-importation-of.html> (accessed Mar 3 2010).

²⁹⁸ "Counterfeit and Parallel Importation of Medicines." *IP Tango* (May 14 2009), available at <http://iptango.blogspot.com/2009/05/counterfeit-and-parallel-importation-of.html> (accessed Mar 3 2010).

billion worth of Columbia's annual drug sales were counterfeit, though global drug makers suspected the share was closer to 30 percent.²⁹⁹

In 2003, the US FDA Counterfeit Drug Task Force Report estimated that roughly 40 percent of manufactured drugs in Colombia were counterfeit.³⁰⁰ By contrast, in 2004 the Association of Colombian Pharmaceutical Industries (ASINFAR) estimated that only 5 percent of the total annual market of medicines sold in Columbia were contraband, counterfeit or adulterated.^{301,302}

Between 2000 and 2001, in the span of just 18 months, INVIMA confiscated more than 18 tons of adulterated, relabeled, stolen, contraband, and counterfeit drugs.³⁰³ In May 2001, INVIMA discovered counterfeit manufacturing operations in the poor neighborhood of Bogotá, where each day workers were producing over 20,000 counterfeit pills of a flu drug, a generic aspirin and a popular painkiller every day.^{304,305}

According to INVIMA, in 2003 more than 1,000 tons of locally produced fake medicines were seized by authorities.³⁰⁶ In 2004, 38 illegal laboratories producing fake drugs were dismantled and INVIMA found fake medicines made of flour, sugar, boric acid and cement lime.³⁰⁷ In 2004, Pfizer reported a facility that manufactured counterfeit Viagra, in which authorities found bags of boric acid (a low-grade insecticide), used to make the fake pills.³⁰⁸

²⁹⁹ Capell, Kerry, and Timmons, Suzanne. "What's In That Pill?" *BusinessWeek* (Jun 18 2001), available at http://www.businessweek.com/magazine/content/01_25/b3737076.htm (accessed Feb 24 2010).

³⁰⁰ Young, Donna. "FDA Launches New Initiative to Combat Counterfeit Drugs." *American Society of Health System Pharmacists* (Aug 20 2003), available at <http://www.ashp.org/import/news/HealthSystemPharmacyNews/newsarticle.aspx?id=1348> (accessed Mar 3 2010).

³⁰¹ "Fact Sheet – Counterfeit Medicines." *World Health Organization* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Feb 24 2010).

³⁰² Loewy, Matías. "Deadly Imitations." *Perspectives in Health (Pan American Health Organization)* 11:1 (2007), available at http://www.paho.org/English/DD/PIN/Number23_article3.htm (accessed Feb 24 2010).

³⁰³ Loewy, Matías. "Deadly Imitations." *Perspectives in Health (Pan American Health Organization)* 11:1 (2007), available at http://www.paho.org/English/DD/PIN/Number23_article3.htm (accessed Feb 24 2010).

³⁰⁴ Capell, Kerry, and Timmons, Suzanne. "What's In That Pill?" *BusinessWeek* (Jun 18 2001), available at http://www.businessweek.com/magazine/content/01_25/b3737076.htm (accessed Feb 24 2010).

³⁰⁵ Capell, Kerry, and Timmons, Suzanne. "What's In That Pill?" *BusinessWeek* (Jun 18 2001), available at http://www.businessweek.com/magazine/content/01_25/b3737076.htm (accessed Feb 24 2010).

³⁰⁶ "Columbian Regulatory Agency Seizes 1,000 Tons of Fake Medicines." *SCRIP World Pharmaceutical News* (Oct 29 2004), available at <http://www.scripnews.com/home/news/Colombian-regulatory-agency-seizes-1000-tons-of-fake-medicines-75805> (accessed Feb 24 2010).

³⁰⁷ "Columbian Regulatory Agency Seizes 1,000 Tons of Fake Medicines." *SCRIP World Pharmaceutical News* (Oct 29 2004), available at <http://www.scripnews.com/home/news/Colombian-regulatory-agency-seizes-1000-tons-of-fake-medicines-75805> (accessed Feb 24 2010).

³⁰⁸ "Ex-FBI Man Warns of Counterfeit Threat." *SCRIP World Pharmaceutical News* (Jul 2 2004), available at <http://www.scripnews.com/home/news/Ex-FBI-man-warns-of-counterfeit-threat-77081> (accessed Feb 24 2010).

Many drugs that are nearing or past their sell-by date are bought in neighboring countries like Peru, Ecuador, and Venezuela, and are then repackaged in Colombia with a different expiry date and sold to illegal dealers.³⁰⁹

In 2001, INVIMA confiscated six million doses of a fake anti-arthritic drug from clandestine labs. The amount was far more than the Colombian market consumes annually, suggesting the drugs were probably slated for export elsewhere in the region; counterfeiters simply filled the vials with colored water to resemble Voltaren. Authorities suspect distributors are mixing counterfeits with genuine, expired, and stolen shipments of drugs”.³¹⁰

The penalties for trafficking narcotics are far higher than those for counterfeiting medicines. In 2001 the head of corporate security for Novartis, Jim Christian, commented: “If you get caught with a pound of cocaine, you can expect to do serious time. But if you are found with counterfeit medicines, you might do only six months.”³¹¹ Sometimes the arrested perpetrators are even free on bail within only a few days.³¹² These mild penalties, along with the nation’s weak regulatory and enforcement environment, have made the highly-profitable counterfeit drug industry attractive to organized Colombian cocaine traffickers.³¹³

Columbia has a known problem with not just counterfeits, but substandard medicines as well. In 2007, 43 lots of medicines, from analgesics to antidepressants, failed to meet quality standards and were destroyed.³¹⁴ 827 samples from 43 local and 17 multinational companies were analyzed. Of those samples, 2.3% failed because of storage or transportation problems which affected the medicines’ quality, and 4.1% failed because of non-compliance with manufacturing standards. In 2005, 7.8% of samples failed to comply with standards.³¹⁵

³⁰⁹ “Columbian Regulatory Agency Seizes 1,000 Tons of Fake Medicines.” *SCRIP World Pharmaceutical News* (Oct 29 2004), available at <http://www.scripnews.com/home/news/Colombian-regulatory-agency-seizes-1000-tons-of-fake-medicines-75805> (accessed Feb 24 2010).

³¹⁰ “Columbian Regulatory Agency Seizes 1,000 Tons of Fake Medicines.” *SCRIP World Pharmaceutical News* (Oct 29 2004), available at <http://www.scripnews.com/home/news/Colombian-regulatory-agency-seizes-1000-tons-of-fake-medicines-75805> (accessed Feb 24 2010).

³¹¹ Capell, Kerry, and Timmons, Suzanne. “What’s In That Pill?” *BusinessWeek* (Jun 18 2001), available at http://www.businessweek.com/magazine/content/01_25/b3737076.htm (accessed Feb 24 2010).

³¹² Capell, Kerry, and Timmons, Suzanne. “What’s In That Pill?” *BusinessWeek* (Jun 18 2001), available at http://www.businessweek.com/magazine/content/01_25/b3737076.htm (accessed Feb 24 2010).

³¹³ Yankus, Wyatt. “Counterfeit Drugs: Coming to a Pharmacy Near You.” *American Council on Science and Health* (Aug 24 2006), available at http://www.acsh.org/publications/pubID.1379/pub_detail.asp (accessed Feb 24 2010).

³¹⁴ “Products Pulled in Columbia for Failing Quality Standards.” *SCRIP World Pharmaceutical News* (Sep 14 2007), available at <http://www.scripnews.com/home/news/Products-pulled-in-Colombia-for-failing-quality-standards-36594> (accessed Feb 24 2010).

³¹⁵ “Products Pulled in Columbia for Failing Quality Standards.” *SCRIP World Pharmaceutical News* (Sep 14 2007), available at <http://www.scripnews.com/home/news/Products-pulled-in-Colombia-for-failing-quality-standards-36594> (accessed Feb 24 2010).

Guyana

In 2007, Minister of Health Dr. Leslie Ramsammy, reported that two counterfeit anti-malarial drugs had been discovered in the country within the last two years.³¹⁶ In 2008, the Ministry of Health announced it was establishing labs to carry out random testing.³¹⁷ According to the Director of the Food and Drugs department, local surveillance for counterfeit drugs entering Guyana currently lacks the collaboration necessary and the pharmaceutical vigilance to bring an end to the illegal practice.³¹⁸

Paraguay

In March 2006, the US Joint Terrorism Task Force—an interagency initiative led by the FBI—charged 19 people with operating a counterfeit drug ring that traversed Lebanon, Canada, China, Brazil, Paraguay, and the United States. While there was no information available on what type of drugs were counterfeited, it was reported that the profits from the sales of these fakes were used to support the terrorist group Hezbollah.³¹⁹

Peru

In 2002, counterfeit drug sales were estimated at USD 40 million, rising to USD 66 million by 2006, according to Peru's Association of Pharmaceutical Laboratories.³²⁰ In Lima alone, WHO reported the number of unauthorized pharmacies devoted to counterfeit medicines increased from an estimated 200 stores in 2002 to 1,800 in 2006.³²¹

In 2006 Peru's Ministry of Health estimated that the illegal sale of medicines accounted for 15 to 20 percent of the local market.³²² The Department of Health's General Directorate of Medicines, Supplies and Drugs (DIGEMID), impounded 28 tons of fake drugs in 2004, and another 460,000 adulterated and expired medicines the following year; it was reported that 43 percent of these intercepted products lacked the active ingredient advertised on the packaging.³²³ In 2005 there

³¹⁶ Seales, Iana. "More Vigilance, Training Needed to Curb Influx of Fake Drugs." *Stabroek News* (Aug 15 2007), available at <http://news.google.com/newspapers?nid=2516&dat=20070815&id=Ls81AAAAIBAJ&sjid=fiYMAAAAIBAJ&pg=2315,4918010> (accessed Feb 24 2010).

³¹⁹ Liang, Bryan A. "Safety of Drug Supply: Tougher Laws Needed to Stem Counterfeit Drug Rings." *Daily Transcript* (May 4 2006), available at <http://www.sddt.com/News/article.cfm?SourceCode=20060503crd> (accessed Feb 24 2010).

³²⁰ "Fact Sheet – Counterfeit Medicines." World Health Organization (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Feb 24 2010).

³²¹ "Fact Sheet – Counterfeit Medicines." World Health Organization (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Feb 24 2010).

³²² "Fact Sheet – Counterfeit Medicines." World Health Organization (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Feb 24 2010).

³²³ "Latin America Battles Counterfeit Drug Threat." *FDA News Daily International Pharma Alert* (Feb 27 2006), available at <http://www.fdanews.com/newsletter/article?articleId=84857&issueId=9017> (accessed Feb 26 2010).

were 42 separate instances of recorded counterfeiting in Peru.³²⁴

DIGEMID struggles to control the production, importation, and distribution of counterfeit pharmaceuticals.³²⁵ In 2008, in an attempt to crack down on the trade and discourage counterfeiters, Peru's Congressional Health Commission passed a bill that declared that any person found selling, storing, packaging or producing adulterated or faulty medicine will be imprisoned for up to ten years.³²⁶ 'Adulterated' medicines included any products which are contraband, expired, counterfeit, with altered or missing labels, and those stolen from the warehouses of the Ministry of Health, the armed forces, or the police.

Venezuela

In 2006 it was estimated that one in four pharmaceuticals in the country were counterfeit or failed to meet regulatory standards.³²⁷ ³²⁸ Penalties are low, and illegal local counterfeiting only results in a maximum fine of USD 12 and imprisonment of up to one year.³²⁹

While strict controls and clear norms and procedures, coupled with the use of a computerized drug regulation system, have made Venezuelan regulation more effective, a 2002 WHO study reported that staff shortages and a lack of financing continued to render implementation imperfect.³³⁰ As the Business Monitor says: "Venezuela appears on the Priority Watch List. According to the Special 301 Report, no patents have been issued in the country since 2005. With no progression made on improving the intellectual property environment since 2007, the inconsistent and erratic policies regarding counterfeiting are major deterrents for foreign pharmaceutical companies. In our view, the Venezuelan Patent Office's policies are inconsistent with the FTAs, which also conflicts with its Andean neighbors. BMI cautions that this could make Venezuela a more attractive location for counterfeiting activity, further propagating an already distinct problem."³³¹

³²⁴ Zarocostas, John. "WHO to Set Up International Task Force on Counterfeit Drugs." *Pub Med Central* (Feb 25 2006), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1382579/> (accessed Mar 3 2010).

³²⁷ "Latin America Battles Counterfeit Drug Threat." *FDA News Daily International Pharma Alert* (Feb 27 2006), available at <http://www.fdanews.com/newsletter/article?articleId=84857&issueId=9017> (accessed Feb 26 2010).

³²⁸ Nevin, Tom. "The Deadly Scourge of Fake Drugs." *The Free Library* (Oct 1 2006), available at <http://www.thefreelibrary.com/The+deadly+scourge+of+fake+drugs:+counterfeit+drugs,+which+are+not...-a0153007212> (accessed Apr 6 2010).

³²⁹ "Fake Pharmaceuticals: How They and Relevant Legislation or Lack Thereof Contribute to Consistently High and Increasing Drug Prices." *AllBusiness* (Jan 1 2003), available at <http://www.allbusiness.com/legal/3587468-1.html> (accessed Apr 7 2010).

³³⁰ Ratanawijitrasin, Sauwakon, and Wondemagegnehu, Eshetu. "Effective Drug Regulation: A Multicountry Study." *World Health Organization* (Jun 1 2002), available at <http://www.who.int/medicinedocs/collect/medicinedocs/pdf/s2300e/s2300e.pdf> (accessed Feb 26 2010).

³³¹ "Pharmaceutical Anti-Counterfeiting Efforts Strengthening." *Americas Pharma and Healthcare Insight, Business Monitor International* (Jan 1 2009), available through Lexis Nexis Academic (accessed Feb 26 2010).

The Caribbean

In Haiti, the rampant fake drug trade has caused hundreds of deaths. In the Dominican Republic, it is suggested that fakes represent as much as 10 percent of the total drug market.

The most commonly counterfeited drugs in the Caribbean include antibiotics, cold syrups, analgesics, tetanus vaccines, and medicines for life threatening conditions such as high cholesterol. Some nations, including Haiti and Cuba, have been implicated in local production of fakes, while others, including Barbados and the Bahamas, have been involved in international online drug rings.³³²

In order to discourage the trade, some Caribbean countries have introduced stiff penalties for counterfeiting pharmaceuticals. For instance, in Grenada, the punishment for counterfeiting medicines can be as much as a USD 250,000 fine and/or 20 years imprisonment.³³³ Other Caribbean locales, such the British Virgin Islands, Jamaica and St. Lucia, have initiated awareness and education campaigns against counterfeits in order to combat the trade.

Bahamas

According to the president of the Bahamas Pharmaceutical Association, as of June 2006 there had been zero documented cases of consumption or receipt of fake drugs in the Bahamas.³³⁴ However, the islands are a known entry point for fake drugs into the United States—in September 2007, a counterfeit drug bust in Dubai revealed a complex supply chain of fake drugs running from China through Hong Kong, the United Arab Emirates, Britain, and the Bahamas, ultimately ending up at an Internet pharmacy advertised as Canadian.^{335,336}

Barbados

In an April 2010 seminar entitled “Investigation and Detection of Counterfeit Pharmaceutical Drugs,” the Minister of Health stated that no counterfeit drugs had officially been confiscated in Barbados in recent years.³³⁷ However, the nation is a known link in international supply chains

³³² “OECS Secretariat Launches Proactive Mechanism Against Counterfeit Medicines.” *OECD News* (May 30 2008), available at <http://www.oecs.org/news-a-events/news-archive/224-oecs-secretariat-launches-proactive-mechanism-against-counterfeit-medicines> (accessed 8 Feb 2011).

³³³ Ramdhani, Darshan. “Legal Implications for the Prevention and Control of Illicit Traffic of Pharmaceutical Products and Other Drugs via the Internet in Grenada.” *Grenada Drug Information Network* (Dec 11 2008), available at http://www.gov.gd/egov/pdf/ncodc/docs/legal_implications_drugs_internet_11_12_2008.pdf (accessed Mar 1 2010).

³³⁴ Smith, Mike and Gray, Phillip. “The Growing Concern Over Counterfeit Medicine.” *Contact* (Jun 22 2006), available at <http://www.jonesbahamas.com/?c=135&a=9208> (accessed Feb 2 2011).

³³⁵ Bogdanich, Walt. “Panama Releases Report on ’06 Poisoning.” *The New York Times* (Feb 14 2008), available at http://www.nytimes.com/2008/02/14/world/americas/14panama.html?_r=1 (accessed Feb 24 2010).

³³⁶ Bogdanich, Walt. “Counterfeit Drugs’ Path Eased by Free Trade Zones.” *The New York Times* (Dec 17 2007), available at <http://www.nytimes.com/2007/12/17/world/middleeast/17freezone.html> (accessed Feb 8 2011).

³³⁷ Gill, Joy-Ann. “No Counterfeit Drugs Found Here.” *Barbados Government Information Service Media* (Apr 14 2010), available at http://www.gisbarbados.gov.bb/index.php?categoryid=13&p2_articleid=3589 (accessed Feb 2 2011).

of fakes sold by online pharmacies claiming to have Canadian origins.³³⁸ In a 2003 sampling of 45 “Canadian” Internet pharmacies, roughly one third were registered in other countries, including three in Barbados.³³⁹

Cuba

Fakes have been traced back to Cuba, suggesting the local manufacture of such drugs. For instance, Colombia's National Institute for the Supervision of Foods and Medications (INVIMA) has found counterfeit medicines in Colombia that originated in Cuba.³⁴⁰

Dominican Republic

In 2005, the Public Health Department reported that 50 percent of the country's pharmacies were operating illegally and that roughly 10 percent of imported medicines were fakes; some drugs confiscated by authorities were found to have expired over ten years before.^{341,342}

In August 2008, more than 50 customs and Public Health Ministry agents seized four truckloads of falsified, expired and relabelled medicines in the northern town of Moca.³⁴³ Further investigation led to five arrests, and several pharmacies were shut down.³⁴⁴

In February 2009, the Public Health Ministry launched a string of raids to crack down on the illegal drug trade in Moca, leading to the seizure of more than 500 sacks of expired or falsified medicine, hundreds of free samples that cannot be sold to the population and 36 units of anti-tetanus injections.³⁴⁵

³³⁸ “Canadian Prescription Drug Importation: Is There A Safety Issue?” *Hearing Before the Subcommittee on Human Rights and Wellness of the Committee on Government Reform of the House of Representatives* (Jun 12 2003), available at <http://www.access.gpo.gov/congress/house/pdf/108hr/89719.pdf> (accessed May 1 2010).

³³⁹ Tefft, Bruce. “An Analysis of Terrorist Threats to America’s Medicine Supply.” *GlobalOptions* (May 22 2003), available at <http://www.mail-archive.com/osint@yahoogroups.com/msg09778.html> (accessed Mar 1 2010).

³⁴⁰ “Counterfeit Pharmaceuticals: Current Status and Future: Magnitude of the Problem.” *Journal of the American Pharmacists Association* 43:6 (2003), available at http://www.medscape.com/viewarticle/465906_3 (accessed Mar 1 2010).

³⁴¹ “Fact Sheet – Counterfeit Medicines.” *World Health Organization* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Feb 24 2010).

³⁴² Loewy, Matías. “Deadly Imitations.” *Perspectives in Health (Pan American Health Organization)* 11:1 (2007), available at http://www.paho.org/English/DD/PIN/Number23_article3.htm (accessed Feb 24 2010).

³⁴³ “Dominican Customs Nabs 4 Trucks Full of Fake Medicines.” *Dominican Today* (Aug 5 2008), available at <http://www.dominicantoday.com/dr/local/2008/8/5/28930/Dominican-Customs-nabs-4-trucks-full-of-fake-medicines> (accessed Feb 2 2011).

³⁴⁴ “Dominican Customs Nabs 4 Trucks Full of Fake Medicines.” *Dominican Today* (Aug 5 2008), available at <http://www.dominicantoday.com/dr/local/2008/8/5/28930/Dominican-Customs-nabs-4-trucks-full-of-fake-medicines> (accessed Feb 2 2011).

³⁴⁵ “No More Fake Medicine Business, the Government Says.” *The Dominican Sun* (Feb 25 2009), available at <http://www.drsof.info/newsroom/index.php?a=send&id=25036&language=en> (accessed Feb 9 2011).

In May 2009, the Ministry of Public Health announced it had closed down four pharmacies for distributing illegal pharmaceuticals and filed charges against more than 50 others.³⁴⁶ The crackdown came just weeks after two people reportedly died after receiving fake tetanus shots.³⁴⁷

In 2010, two laboratories in Santo Domingo were raided by the Director General of Customs and the Ministry of Public Health, and both were discovered to be illegally manufacturing medicines such as Ampicillin (an antibiotic), Motrin (ibuprofen), and Diclofenac (a non-steroidal anti-inflammatory drug NSAID), among others. One arrest was made, and manufacturing equipment and materials were seized.³⁴⁸

Grenada

Punishment for counterfeiting medicines in Grenada can be as much as a USD 250,000 fine and/or 20 years imprisonment.³⁴⁹

Haiti

In 1995, 89 people died after consuming cough syrup contaminated with diethylene glycol.³⁵⁰ In a similar case in 2004, the Organization of Eastern Caribbean States' Pharmaceutical Procurement Service reported that scores of children were hospitalized after ingesting counterfeit cold syrup.³⁵¹

In March 2007, Robert Auguste, the Minister of Public Health in Haiti confirmed that anti-tuberculosis medicines stolen from Cap-Haiti, a city on the north coast of the country, had been confiscated at the main hospital in Port-au-Prince. The drugs were reported to be both expired and counterfeit, and were thought to have caused four deaths in the Artibonite region.³⁵²

In June 2007, a fake version of the analgesic Pentazocine caused one death in the northern city of Gonaives.³⁵³ One month later, a young woman died in Port-au-Prince seven minutes after being

³⁴⁶ "Illegal Pharmaceuticals – Two People Died After Receiving Fake Medicine." *Dominican Watchdog* (May 4 2010), available at http://www.dominicanwatchdog.org/dominican_news/page-Illegal_pharmaceuticals_two_people_died_after_receiving_fake_medicine (accessed Mar 1 2010).

³⁴⁷ "Illegal Pharmaceuticals – Two People Died After Receiving Fake Medicine." *Dominican Watchdog* (May 4 2010), available at http://www.dominicanwatchdog.org/dominican_news/page-Illegal_pharmaceuticals_two_people_died_after_receiving_fake_medicine (accessed Mar 1 2010).

³⁴⁸ "Media Reports on Medicine Quality: Focusing on USAID-Assisted Countries." *Promoting the Quality of Medicines Program, United States Pharmacopeia* (Jan 3 2011), available at http://www.usp.org/pdf/EN/dqi/Media_Reports-01_2011-final.pdf (accessed 9 Feb 2011).

³⁵⁰ "Médicaments Contrefaits: L'Epidémie Silencieuse." *Destination Sante Agence de Presse* (Jun 26 2006), available at <http://www.destinationsante.com/Medicaments-contrefaits-l-epidemie-silencieuse.15574.html> (accessed Mar 1 2010).

³⁵¹ "OECS Official Wants Tighter Control Over Sale of Drugs in the Caribbean." *CANANews* (Mar 28 2007), available at <http://www.cananews.net/news/127/ARTICLE/9064/2007-03-28.html> (accessed Mar 1 2010).

³⁵² "OECS Official Wants Tighter Control Over Sale of Drugs in the Caribbean." *CANANews* (Mar 28 2007), available at <http://www.cananews.net/news/127/ARTICLE/9064/2007-03-28.html> (accessed Mar 1 2010).

³⁵³ "Une Pharmacie Vendant un Médicament Contrefait est sous Scellés." *Metropole Haiti* (Jul 5 2007), available at http://www.metropolehaiti.com/metropole/full_une_fr.php?id=12800 (accessed Mar 3 2010).

injected with the same analgesic. In response, the Ministry of Health launched an investigation of counterfeit and substandard drug sales in the capital city, and vowed to close any pharmacy suspected of selling fakes.³⁵⁴

According to Senator Kelly Bastien, a member of the Haitian Senate Health Committee, many of the counterfeit medicines sold in Haiti are produced domestically; in addition some prominent legal enterprises, including hospitals, have been implicated in the sale of foreign-made fakes.³⁵⁵

Jamaica

In 2006, the Nurses Association of Jamaica, in conjunction the Ministry of Health (MOH) and a coalition of local doctors and pharmacists, launched a campaign to raise public awareness about counterfeit and substandard drugs under the theme: “Raising the alarm!”³⁵⁶ Also in 2006, the MOH launched PharmWatch, a program that aims to boost public participation in pharmacovigilance efforts. As part of this endeavor, the MOH, publishes a PharmWatch newsletter and maintains a pharmacovigilance website that notifies the public about the presence of counterfeit drugs, and pharmacists and consumers to use the site to report adverse reactions to drugs.³⁵⁷

Puerto Rico

In December 2003, federal officials in Florida charged a Miami-based network with selling USD 1 million worth of fake Lipitor, a drug used to treat high cholesterol. Investigators traced the drug shipments through a string of wholesalers, which included two Puerto Rican companies.³⁵⁸

³⁵⁴ “Une Pharmacie Vendant un Médicament Contrefait est sous Scellés.” *Metropole Haiti* (Jul 5 2007), available at http://www.metropolehaiti.com/metropole/full_une_fr.php?id=12800 (accessed Mar 3 2010).

³⁵⁵ Gilles, Claude. “La Commerce de la Mort!” *Le Nouvelliste* (Jul 12 2007), available at <http://www.lenouvelliste.com/article.php?PubID=1&ArticleID=46117&PubDate=2007-07-13> (accessed Mar 3 2010).

³⁵⁶ Wildes, Andrew. “Counterfeit Drugs Can Kill.” *Jamaica Gleaner* (Mar 12 2006), available at <http://www.jamaica-gleaner.com/gleaner/20060312/news/news3.html> (accessed Mar 3 2010).

³⁵⁷ “Pharmacovigilance.” *Government of Jamaica Ministry of Health* (Jan 15 2010), available at <http://www.moh.gov.jm/index.php/administrative/essential-medicine-list> (accessed Mar 3 2010).

³⁵⁸ Jaret, Peter. “Fake Drugs, Real Threat.” *Los Angeles Times* (Feb 9 2004), available at <http://biopsychiatry.com/pharmacy/fake-drugs.html> (accessed Mar 3 2010).

Sub-Saharan Africa

The problem of counterfeit drugs is especially severe in sub-Saharan Africa, but it is difficult to quantify penetration into markets due to a lack of data in many places. National estimates come from an amalgamation of case studies, reported incidents, and news articles. The number of unreported incidents is probably enormous.

WHO estimates that counterfeit drugs could represent up to a third of medicines in some African nations.³⁵⁹ Substandard drugs are just as prevalent. In 2008, the WHO estimated that 30 per cent of medicines in Africa may be substandard.³⁶⁰ In 2009, the President of West African Pharmaceuticals Manufacturers Association, Mazi Sam Ohuanbuwa, reported a high prevalence of counterfeit drugs in sub-Saharan Africa, ranging between 15% and 25% of all medicines.³⁶¹

According to WHO, drugs commonly counterfeited include antibiotics, antimalarials, hormones and steroids. Fake cancer medications and antiviral drugs have also been found in recent seizures.

Though a data vacuum persists, customs investigations, police seizures, and studies of samples collected from markets, kiosks, pharmacies, and hospitals in various countries have built a large body of evidence regarding the prevalence of counterfeit and substandard drugs throughout Africa.

West Africa

A range of counterfeit medications are now found in West Africa, including anti-malarial medicine, antibiotics, anti-tuberculosis drugs, and anti-retrovirals (ARVs).³⁶² Most of the existing literature on West Africa implies that the majority of fake pharmaceutical products in the region are imported, particularly from South and East Asia, India, in addition to the local pharmaceutical industry.³⁶³

Several small samplings estimated the prevalence of substandard drugs to be around 50 percent.^{364,365} Regional studies of antimalarial quality have revealed not only high failure rates

³⁵⁹ “Counterfeit Drugs Kill!” *IMPACT, WHO* (May 2008), available at <http://www.who.int/impact/FinalBrochureWHA2008a.pdf> (accessed Feb 2 2010).

³⁶⁰ “Counterfeit Drugs Kill!” *IMPACT, WHO* (May 2008), available at <http://www.who.int/impact/FinalBrochureWHA2008a.pdf> (accessed Feb 2 2010).

³⁶¹ Ollenu, Roberta. “Africa: Counterfeit Drugs on the Increase.” *Public Agenda (Accra)* (Nov 30 2009), available at <http://allafrica.com/stories/200912010946.html> (accessed Jan 29 2010).

³⁶² Bate, R.. “Making a Killing: The deadly implications of the counterfeit drug trade.” *The American Enterprise Institute Press* (2008), 16, Washington DC.

³⁶³ “Fake Medicines in West Africa a Health Risk for All.” *United Nations Office on Drugs and Crime* (Jul 8 2009), available at <http://www.unodc.org/unodc/en/frontpage/2009/Jul/fake-medicines-pose-health-risk-in-west-africa.html> (accessed Jan 20 2010).

³⁶⁴ “Transnational Trafficking and the Rule of Law in West Africa.” *United Nations Office of Drugs and Crime* (Jul 2009), available at http://www.unodc.org/documents/data-and-analysis/Studies/West_Africa_Report_2009.pdf (accessed 20 Jan 2010).

among this class of drugs, but also the pervasiveness of such counterfeits, from district hospitals to local vendors to households.³⁶⁶

UNODC projects that if half of the estimated 83 million malaria cases treated in the private sector annually were treated with counterfeits, fake antimalarials would singlehandedly represent a market worth just under a half billion dollars in West Africa.³⁶⁷ Clearly, the size and value of the total market for fake drugs in West Africa has the potential to be enormous.³⁶⁸

Nigeria

A study by the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) in 2002 found that nearly 41 percent of pharmaceuticals in the country were counterfeit,^{369,370} and as many as 70 percent were unregistered.³⁷¹ At one point, a study estimated that fake antimalarials in Nigeria comprised 85 percent of the total market.³⁷²

Between 2001 and 2006, Nigerian officials destroyed between USD 109-169 million worth of counterfeit and substandard products.^{373,374} Combative efforts by NAFDAC have significantly decreased the prevalence of substandard drugs since 2002, but it is still dangerously high. In 2006, officials estimated that counterfeits made up 16.7 percent of total market,³⁷⁵ and 19 percent of the drugs in the market are still unregistered.³⁷⁶

Fake, expired, and unregistered drugs can be found all over Nigeria. Authorities suspect that most come from India and China, though some come from the local pharmaceutical industry as

³⁶⁵ Maponga, C. and Ondari, C. "The Quality of Antimalarials: A Study in Selected African Countries." *World Health Organization* (2003), available at http://whqlibdoc.who.int/hq/2003/WHO_EDM_PAR_2003.4.pdf (accessed Feb 1 2010).

³⁶⁶ Maponga, C. and Ondari, C. "The Quality of Antimalarials: A Study in Selected African Countries." *World Health Organization* (2003), available at http://whqlibdoc.who.int/hq/2003/WHO_EDM_PAR_2003.4.pdf (accessed Feb 1 2010).

³⁶⁷ Ibid.

³⁶⁸ "Transnational Trafficking and the Rule of Law in West Africa." *United Nations Office of Drugs and Crime* (Jul 2009), available at http://www.unodc.org/documents/data-and-analysis/Studies/West_Africa_Report_2009.pdf (accessed Jan 20 2010).

³⁶⁹ Edike, T. and Obinwanne, C. "NAFDAC Destroys N14bn Fake Drugs." *Vanguard* (Nov 7 2006), available at <http://allafrica.com/stories/200611070673.html> (accessed Jan 20 2010).

³⁷⁰ Taylor, R.B., Shakoor, O., Everard, M. et al, "Pharmacopoeial Quality of Drugs Supplied by Nigerian Pharmacies." *The Lancet* (Jun 16 2001) 357: 9272, available at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(00\)05065-0/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(00)05065-0/fulltext) (accessed Jan 25 2010).

³⁷¹ "Nigeria Fights Corruption." *SCRIP World Pharmaceutical News* (Jul 7 2004), available at <http://www.scripnews.com/home/news/Nigeria-fights-corruption-77125> (accessed Jan 20 2010).

³⁷² Yankus, W. "Counterfeit Drugs: Coming to a Pharmacy Near You." *American Council on Science and Health* (2006) 3, available at www.acsh.org/publications/pubID.1379/pub_detail.asp (accessed Jan 20 2010).

³⁷³ Akunyili, D. "IMPACT – a New Force in Global Anti-Counterfeiting." *Proceedings of the 3rd Global Forum on Pharmaceutical Anti-counterfeiting* (Mar 13-15 2007), Prague, Czech Republic.

³⁷⁴ Agabi, C. "NAFDAC Destroys Fake Drugs Worth N20bn." *Daily Trust* (31 Oct 2007), available at <http://allafrica.com/stories/200710310418.html> (accessed 1 Feb 2010).

³⁷⁵ Edike, T. and Obinwanne, C. "NAFDAC Destroys N14bn Fake Drugs." *Vanguard* (Nov 7 2006), available at <http://allafrica.com/stories/200611070673.html> (accessed Jan 20 2010).

³⁷⁶ Edike, T. and Obinwanne, C. "NAFDAC Destroys N14bn Fake Drugs." *Vanguard* (Nov 7 2006), available at <http://allafrica.com/stories/200611070673.html> (accessed Jan 20 2010).

well.³⁷⁷ In March 2011, India announced plans to introduce a mandatory life imprisonment sentence to Indian nationals caught producing or supplying counterfeit drugs to Nigeria.³⁷⁸ This development is the result of a Memorandum of Understanding (MoU) signed by India's Joint Secretary in the Department of Pharmaceuticals, Arun Jha, and Nigeria's Director General of National Agency for Food and Drug Administration and Control (NAFDAC), Dr. Paul Orhii.³⁷⁹ According to the MoU, India may also introduce measures to compensate whistleblowers, provide training and assistance to NAFDAC, mandate seizure of manufacturing equipment used in illegal operations, and provide funding for Nigerian investigations of counterfeit operations with links to India.³⁸⁰

Unsurprisingly, the most common fakes are those that are in the highest demand, including antimalarials, blood pressure medications, and commonly used drugs that treat infection. In September 2006, Nigerian authorities discovered USD 25,000 worth of fake antimalarial and blood pressure medicines hidden in a shipment of purses coming from China.³⁸¹ In May 2009, NAFDAC seized \$675,000 worth of counterfeit medicines at a Lagos airport that included fake antimalarials, diabetes medicines, heart medicines, anti-anxiety drugs, and a variety of antibiotics such as amoxicillin, ciprofloxacin, and ampicillin.³⁸² In January 2010, NAFDAC intercepted a large consignment of fake Lonart-DS antimalarial tablets, valued at \$66,530, in a shed near the Lagos airport.³⁸³

Substandard drugs are also a problem in Nigeria. In 2008, 84 children died after using a teething formula called My Pikin made by a Lagos-based pharmaceutical firm, which was tainted with diethylene glycol.^{384,385} In March of the following year, this firm and five other manufacturing depots were shut down after the director of the Pharmaceutical Council of Nigeria (PCN) expressed concern over an increase in substandard drugs produced by the companies.³⁸⁶ In the first week of June 2009, 28 illegal pharmaceutical companies and patent medicine stores were shut down in Lagos for offenses including the sale of unregistered, counterfeit, or substandard

³⁷⁷ "Transnational Trafficking and the Rule of Law in West Africa." *United Nations Office of Drugs and Crime* (Jul 2009), available at http://www.unodc.org/documents/data-and-analysis/Studies/West_Africa_Report_2009.pdf (accessed Jan 20 2010).

³⁷⁸ Edomarusse, Collins. "Life Imprisonment for Indians Shipping Fake Drugs to Nigeria." *This Day Live* (Mar 30 2011), available at <http://www.thisdaylive.com/articles/life-imprisonment-for-indians-shipping-fake-drugs-to-nigeria/88697/> (accessed May 9 2011).

³⁷⁹ Ibid.

³⁸⁰ Ibid.

³⁸¹ McNeil Jr., D. "A Growing Epidemic of Fake Medications in Asia." *International Herald Tribune* (Feb 20 2007), available at http://www.nytimes.com/2007/02/20/health/20iht-drugs.4656560.html?_r=1 (accessed Jan 20 2010).

³⁸² Milissa, "Matrix of Drug Quality Reports Affecting USAID-assisted Countries." *U.S. Pharmacopeia Drug Quality and Information Program* (Nov 6 2009), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 1 2010).

³⁸³ Udoh, F. "Nigeria: NAFDAC Impounds N10 Million Fake Malaria Drugs." *Daily Champion* (Jan 21 2010), available at <http://allafrica.com/stories/201001210140.html> (accessed Jan 22 2010).

³⁸⁴ Mbachu, D. "Nigeria Tainted Syrup Kills 84 Children; Drug Still Selling." *Bloomberg Press* (Feb 6 2009), available at <http://www.bloomberg.com/apps/news?pid=20601116&sid=aQXgfk2SqeDU&refer=africa> (accessed Jan 20 2010).

³⁸⁵ "Nigeria Bans Teething Drug After 25 Children Die." *CBS News* (Nov 26 2008), available at <http://www.cbsnews.com/stories/2008/11/26/ap/world/main4635309.shtml> (accessed 20 Jan 2010).

³⁸⁶ Muhammad, A. "Five drug firms shut in Kano." *Vanguard* (Apr 24 2009), available at <http://allafrica.com/stories/200904240155.html> (accessed Jan 20 2010).

drugs.³⁸⁷ In October, seven more patent medical stores were closed down, and \$394,000 worth of counterfeit products was destroyed.³⁸⁸ When NAFDAC shut down a single market in Lagos, officials discovered 17 truckloads of fakes, adulterated drugs, and other pharmaceutical materials.³⁸⁹

Ghana

In July 2009, the government announced a mass recall of two batches of counterfeit Coartem, an antimalarial drug manufactured by the Swiss pharmaceutical company Novartis, as it was found they contained no active-ingredients. This was the first, and so far only reported instance of Coartem being counterfeited.

Earlier, in 2002, another antimalarial, Halfan, was faked in unknown quantities.³⁹⁰

Recognizing the extent of the problem, Ghana has implemented innovative strategies to fight counterfeits which focus on consumer awareness. In 2008, the government introduced a medication verification system that allows consumers who purchase medicines to SMS a special number found on the medicine label to the drug manufacturer, and receive a reply within seconds which verifies the drug's authenticity.³⁹¹

Substandard drugs are also prevalent in Ghana, one report suggests up to 50 percent.³⁹² In 2008, researchers at the Kwame Nkrumah University of Science and Technology (KNUST) tested a selection of artesunate tablets sold in pharmacies in Kumasi, the second-largest city in the country, and found that 82 percent of the drugs did not meet European pharmacopeia guidelines.³⁹³ In November 2009, the Chief Executive of Ghana's Food and Drugs board acknowledged these quality issues and ordered the withdrawal of 22 batches of anti-malaria medicines from the Ghanaian drug market due to quality defects.³⁹⁴

³⁸⁷ Ugbodaga, K. "28 Pharmacies Shut In Lagos." *The PM News* (Jun 9 2009), available at <http://thepmnews.com/2009/06/09/28-pharmacies-shut-in-lagos> (accessed Jan 20 2010).

³⁸⁸ Akoni, O. "Lagos Shuts 7 Illegal Medicine Stores." *Vanguard* (20 Oct 2009), available at <http://www.vanguardngr.com/2009/10/20/lagos-shuts-7-illegal-medicine-stores/> (accessed Jan 20 2010).

³⁸⁹ Anyanwu, G. "17 Lorry-Load Of Banned Drugs Recovered from Onitsha Market." *The Daily Sun* (Mar 16 2007), available at www.sunnewsonline.com/webpages/news/national/2007/mar/16/national-16-03-2007-09.htm (accessed Jan 20 2010).

³⁹⁰ Cockburn, R., Newton, P.N., Agyarko, E.K., Akunyili, D., and White, N., "The Global Threat Of Counterfeit Drugs: Why Industry And Governments Must Communicate The Dangers." *Public Library of Science Medicine* (2005) 2:4, available at <http://counterfeiting.unicri.it/docs/The%20global%20threat%20of%20ctf%20drugs.pdf> (accessed Jan 20 2010).

³⁹¹ "Ghana: Defeating Drug Counterfeiters With SMS." *UN Integrated Regional Information Networks* (Mar 10 2009), available at <http://www.irinnews.org/Report.aspx?ReportId=83555> (accessed Jan 22 2010).

³⁹² "Ghana; Counterfeit Drugs Kill Over 700,000 People Every Year." *Public Agenda* (May 22 2009), available at <http://allafrica.com/stories/200905220732.html> (accessed Jan 20 2010).

³⁹³ Ofori-Kawakye, K., Asantewaa, Y., and Gaye, O. "Quality of Artesunate Tablets Sold In Pharmacies In Kumasi, Ghana." *Tropical Journal of Pharmaceutical Research* (2008) 7:4, 1179-1184, available at <http://ajol.info/index.php/tjpr/article/viewFile/14704/32237> (accessed Jan 20 2010).

³⁹⁴ Opuni, Dr. S. K., "Press Rerelease: Food And Drugs Board Orders Product Recall." *Ghanaian Food and Drug Board* (Nov 2009), available at <http://www.fdbghana.gov.gh/press%20release%20nov.pdf> (accessed 20 Jan 2010).

Burkina Faso

In 2008, 20 percent of medicines in the capital city of Ouagadougou were estimated to be counterfeit and sold without a prescription or expiration date.³⁹⁵ According to the National Committee of Drug Control (CNLD), these counterfeits cost the economy \$4.7 million dollars a year.³⁹⁶ Since 2007, the government has seized a total of 23.6 tons of fake medicines circulating around Ouagadougou.³⁹⁷ Substandard drugs are also a problem in both the licensed and illicit markets. In 2008, a study which tested 77 anti-malarial samples in northwestern Burkina Faso found that 42 percent were substandard. Within this group, there was a notable discrepancy between licensed sellers, who were selling 10.6 percent substandard products, unlicensed sellers, who sold a shocking 90 percent substandard drugs.^{398,399}

Senegal

In Senegal, the black market for medicines was estimated to be worth \$11.4-15.2 million in 2005.⁴⁰⁰ In 2005, President Abdoulaye Wade allocated USD\$48,000 for the 2006 budget to tackle this black market, to promote generic medicines, and to strengthen inspections on the illegal market.⁴⁰¹ In 2005, an information campaign was launched with such slogans as “Street medicines kill” and “every time you buy drugs on the street, you buy death” in an attempt to raise public awareness of the issues.⁴⁰²

Studies have found various substandard antimalarial and antibacterial drugs, like Mefloquine and ampicillin respectively,⁴⁰³ around the country.⁴⁰⁴ A 2002 study found that twenty-one of twenty-two samples of ampicillin (95%) contained flour and no active pharmaceutical ingredients.⁴⁰⁵ In another case, 90% of ampicillin tablets contained no active ingredient.⁴⁰⁶

³⁹⁵ “Government Inaction Spurs Consumption Of Counterfeit Drugs.” *UN Integrated Regional Information Networks* (Feb 20 2008), available at <http://allafrica.com/stories/200802200689.html> (accessed Jan 20 2010).

³⁹⁶ Ibid.

³⁹⁷ Ibid.

³⁹⁸ Tipke M., Diallo, S., et al., “Substandard Anti-Malarial Drugs In Burkina Faso.” *Malaria Journal* (2008) 7:95, available at <https://www.malariajournal.com/content/7/1/95> (accessed Jan 20 2010).

³⁹⁹ Harris, J., Stevens, P., Morris, J., “Keeping it Real: Combating the Spread Of Fake Drugs in Developing Countries.” *International Policy Network* (2009), available at http://www.policynetwork.net/sites/default/files/keeping_it_real_2009.pdf (accessed Jan 22 2010).

⁴⁰⁰ “Senegal tackling counterfeits.” *SCRIP World Pharmaceutical News* (Sep 21 2005), available at <http://www.scripnews.com/home/news/Senegal-tackling-counterfeits-74291> (accessed 20 Jan 2010).

⁴⁰¹ Ibid.

⁴⁰² Ibid.

⁴⁰³ Reidenberg, M.M., Conner, B.A., “Counterfeit and Substandard Drugs.” *Clinical Pharmacology and Therapeutics* (2001) 69:189–93, available at <http://www.nature.com/clpt/journal/v69/n4/full/clpt200125a.html> (accessed Jan 20 2010).

⁴⁰⁴ Sow, P.S., Gueye, T.S.N., Sy, E., Toure, L., Ba, C., and Badiane, M., “Drugs in the Parallel Market for the Treatment of Urethral Discharge in Dakar: Epidemiological Investigation Physicochemical Tests.” *International Journal of Infectious Diseases* (2002) 6:2, 108–12.

⁴⁰⁵ Ibid.

⁴⁰⁶ “Transnational Trafficking and the Rule of Law in West Africa.” *United Nations Office of Drugs and Crime* (Jul 2009), available at http://www.unodc.org/documents/data-and-analysis/Studies/West_Africa_Report_2009.pdf (accessed 20 Jan 2010).

The first case of legal action against counterfeits in Senegal occurred in September of 2009. Two men from Touba, Senegal's holy city, were caught with creams and fake pills that were worth nearly \$8,650.⁴⁰⁷ The two counterfeit drug dealers were condemned to four months in prison and a fine of \$1,675.⁴⁰⁸

According to Dr Aboubakrine Sarr, president of the Syndicate of private pharmacists of Senegal, the importation and resale of drugs on the streets and in markets represent close to \$17 million.⁴⁰⁹ But in July 2009 bandits attacked a pharmacy in Dakar and killed two people who resisted them. A public outcry ensued, leading the authorities to release a statement outlawing the resale of medicine in the streets. Until then, this law had never been enforced.⁴¹⁰

The United States Pharmacopeia Drug Quality and Information (USP DQI) Program, funded by USAID, has been assisting Senegal in strengthening quality control and quality assurance since 2002.⁴¹¹ PMI's Planned Obligations for FY08 included \$100,000 for "maintaining the system of drug quality assurance".⁴¹² In the same year, the Senegal Mission budgeted \$50,000 for post-marketing surveillance of HIV/AIDS medicines and \$43,000 for TB medicines.⁴¹³

Sierra Leone

A media report from January 2009 stated that the most common counterfeits in Sierra Leone were painkillers, antibiotics and other everyday products.⁴¹⁴

In order to monitor the growing threat, the Pharmacy Board commissioned the National Drug Safety Monitoring Programme in 2006. The Board lost no time in attacking the problem; by the end of the year, it had destroyed \$168,000 worth of counterfeit and substandard drugs.⁴¹⁵ In the first half of 2007, the Board destroyed illegally imported, substandard, and counterfeit drugs worth an additional USD 1.33 million.⁴¹⁶

In June of 2008, the Pharmacy Board issued a recall of nine different batches of drugs which included counterfeit amoxicillin, ampicillin, ibuprofen, cimetidine, and cough syrup.⁴¹⁷

⁴⁰⁷ "Sénégal : Les Vendeurs de rue de Médicaments se Font Discrets." *News Sénégal* (Oct 12 2009), available at <http://www.en-afrique.info/?senegal-les-vendeurs-de-rue-de> (accessed Jan 20 2010).

⁴⁰⁸ Ibid.

⁴⁰⁹ Ibid.

⁴¹⁰ Ibid.

⁴¹¹ "DQI Proposed Work Plan: Senegal Oct 1, 2008 – Sep 30, 2009." *President's Malaria Initiative* (2009), available at http://www.fightingmalaria.gov/funding/contracts/uspdqi_senegal09.pdf (accessed Jan 20 2010).

⁴¹² Ibid.

⁴¹³ Ibid.

⁴¹⁴ Horner, R. and Hallam, B., "Sierra Leone: Porous Borders Hinder Fight Against Fake Drugs." *Concord Times* (Jan 19 2009), available at <http://allafrica.com/stories/200901191358.html> (accessed Jan 20 2010).

⁴¹⁵ Massaquoi, M., "Pharmacy Board Destroys Le 9 Million Drugs." *Concord Times* (Jun 6 2007), available at <http://allafrica.com/stories/200706060852.html> (accessed 20 Jan 2010).

⁴¹⁶ Turay, A., "Pharmacy Board Discloses Plans of Operations in Sierra Leone." *Awareness Times* (Jan 17 2008), available at http://www.news.sl/drwebsite/publish/article_20057398.shtml (accessed Jan 20 2010).

⁴¹⁷ "Pharmacy Board Warning of Counterfeit Drugs in Sierra Leone." *Awareness Times* (4 Jun 2008), available at http://www.news.sl/drwebsite/publish/article_20058721.shtml (accessed 20 Jan 2010).

The following month, the Ministry of Health and Sanitation publicly announced that it would destroy all counterfeit pharmaceutical products imported into the Sierra Leone; a 20ft container holding 650 cartons of substandard toothpaste contaminated with diethylene glycol was the first to be destroyed.⁴¹⁸ The Ministry publicly burned \$10,600 worth of fake antibiotics at Kenema Government Hospital, and \$ 21,000 worth of other expired, substandard, and counterfeit drugs in the Kono District.⁴¹⁹ On one day in December 2008, the Pharmacy Board publicly burned \$336,000 worth of substandard, fake, and expired medicines,⁴²⁰ bringing the total value of drugs burned in 2008 to \$492,000.⁴²¹

Along with counterfeit drugs, expired drugs that remain on the shelves of pharmacies pose a serious threat in Sierra Leone. A study in 2007 revealed that a meager 27 percent of health practitioners in the country stated categorically that expired products should not be used; all others believed that expired medications were medically useful.⁴²² In April 2009, a large consignment of expired antimalarials was destroyed in Freetown, the country's capital.⁴²³ November of the same year, the Deputy Health and Sanitation Minister, Mohamed Koroma, and the Pharmacy Board cancelled the licenses of over twenty-one pharmaceutical outlets which were selling counterfeit and expired medicines.⁴²⁴

In February 2009, an investigation by Sierra Leonean journalist Sorious Samura, uncovered a black market stocked with donated drugs. Sorious, reporting for the BBC, discovered that drugs donated by UNICEF⁴²⁵ were being sold in a pharmacy which was owned by an ex-registrar of the Pharmacy Board.⁴²⁶

In December 2009, a Pharmacy Board representative said "99 percent of drugs that are peddled come from insecure border crossings and 99 percent of the border remains open to such

⁴¹⁸ James, B., "Deadly drugs to be destroyed: health minister to start with 20ft container of deadly toothpaste." *Awareness Times* (17 Jul 2008), available at http://www.news.sl/drwebsite/publish/article_20059160.shtml (accessed 21 Jan 2010).

⁴¹⁹ "Pharmacy Board Destroys 65M Drugs." *Concord Times (Freetown)* (Jun 17 2008), available at <http://allafrica.com> (accessed Feb 2 2010).

⁴²⁰ Turay, A., "Pharmacy Board Destroys Le.1.20 Billion Worth of Drugs in Sierra Leone." *Awareness Times* (Dec 11 2008) available at http://www.news.sl/drwebsite/publish/article_200510633.shtml (accessed Jan 20 2010).

⁴²¹ Horner, R. and Hallam, B., "Sierra Leone: Porous Borders Hinder Fight Against Fake Drugs." *Concord Times* (Jan 19 2009) available at <http://allafrica.com/stories/200901191358.html> (accessed Jan 20 2010).

⁴²² Amin, A.A. and Kokwaro, G.O., "Antimalarial Drug Quality in Africa." *Journal of Clinical Pharmacy and Therapeutics* (2007) 32:5, 429-440, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2653781/> (accessed Jan 20 2010).

⁴²³ McGinnis, Milissa, "Matrix of Drug Quality Reports Affecting USAID-assisted Countries." *U.S. Pharmacopeia Drug Quality and Information Program* (Nov 6 2009), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 1 2010).

⁴²⁴ Fonti, A. "In Sierra Leone, Pharmacies Licenses Cancelled." *Awareness Times* (Nov 13 2009), available at http://www.news.sl/drwebsite/publish/article_200513643.shtml (accessed Feb 1 2010).

⁴²⁵ Alarminglly, some of the donated medications seized from this pharmacy were also fakes. This demonstrates that counterfeiters in Africa are even able to infiltrate international donors supply chains.

⁴²⁶ Harris, J., Stevens, P., Morris, J., "Keeping it Real: Combating the Spread of Fake Drugs in Developing Countries." *International Policy Network* (2009), available at http://www.policynetwork.net/sites/default/files/keeping_it_real_2009.pdf (accessed Jan 22 2010).

smugglings that supply the black market in Sierra Leone.”⁴²⁷ The Pharmacy Board has reported that there are still more than 1000 border crossing points in the country that are unmanned by customs officials, making drug inspections nearly impossible. In 2009, the Ministry of Health increased the Pharmacy Board’s budget to allow them to hire 15 more inspectors, but borders are still porous.⁴²⁸

According to Sierra Leone’s Director of Drugs and Medical Supplies, Dr. Bassey Turay, most of the fake drugs come from China and are circulated by Chinese living in the country.⁴²⁹

Mali

In June of 2009, Malian authorities burned more than 100 tons of fake pharmaceuticals to mark the International fight against drug use and commerce day.⁴³⁰

Substandard drugs are also common. A 2003 WHO study on the quality of antimalarials in African countries revealed that 66.7 percent of the chloroquine syrups and 47.3 percent of tablets sampled from Mali had content failures. The study also discovered that 91.1 percent of the sulphadoxine/pyrimethamine tablets failed quality tests.⁴³¹

Cote d’Ivoire

Officials estimate that the legitimate pharmaceutical market provides only 48 percent of the drugs that are available in the country.⁴³² The black market consists of both donated and counterfeit drugs sold on the streets.⁴³³ The counterfeits are mainly believed to come from Ghana, Nigeria and India, although the presence of fake Chinese drugs in the Ivory Coast has also recently been documented.⁴³⁴

In a 2006 survey of the packaging and drug quality of 293 oral anti-infective and paracetamol products in the Ivory Coast, 49 (17%) were deemed substandard.⁴³⁵ A separate study of the antimalarial chloroquine, revealed that there was too much (113.2%) of the stated active

⁴²⁷ “Government Vows 2010—No Fake Drugs.” *Sierra Express Media* (Dec 22 2009), available at <http://www.sierraexpressmedia.com/archives/4661> (accessed Jan 20 2010).

⁴²⁸ Horner, R. and Hallam, B., “Sierra Leone: Porous Borders Hinder Fight Against Fake Drugs.” *Concord Times* (Jan 19 2009), available at <http://allafrica.com/stories/200901191358.html> (accessed Jan 20 2010).

⁴²⁹ “Sierra Leone: The Lure of Fake Pharmaceuticals.” *Medilinks* (Jun 22 2007), available at <http://medilinkz.org/news/news2.asp?NewsID=20810> (accessed Jan 20 2010).

⁴³⁰ Wague, S., “Drogues et Médicaments Contrefaits: Une Destruction Par le Feu Pour Marquer Les Esprits.” *Malikounda* (Jun 29 2009), available at http://www.malikounda.com/nouvelle_voir.php?idNouvelle=21876 (accessed Jan 20 2010).

⁴³¹ Maponga, C. and Ondari, C., “The Quality of Antimalarials: A Study in Selected African Countries.” *World Health Organization* (2003), available at http://whqlibdoc.who.int/hq/2003/WHO_EDM_PAR_2003.4.pdf (accessed Feb 2 2010).

⁴³² Legris, C., “Étude Pilote Menée sur le Maré Illicite des Médicaments en Côte d’Ivoire.” *Réseau Médicaments et Développement* (1997), available at <http://www.remed.org/candice3.pdf> (accessed 20 Jan, 2010).

⁴³³ Ibid.

⁴³⁴ Ibid.

⁴³⁵ Legris C., “La Détection des Médicaments Contrefaits par Investigation de leur Authenticité. Étude Pilote sur le Maré Pharmaceutique Illicite de Côte d’Ivoire.” *Réseau Médicaments et Développement* (2005), available at http://www.remed.org/these_legris (accessed Jan 20 2010).

ingredient in half of the samples.⁴³⁶ Similar smaller studies found variable active ingredients in other antimalarials, in addition to false information on the origin of the drugs.⁴³⁷ Other studies found counterfeit SP tablets.⁴³⁸

Mauritania

Officials seized and destroyed approximately 36,000 bottles of counterfeit drugs in 2007, which they believe were manufactured in China, Syria, Nigeria, and Hong Kong.⁴³⁹

Benin

On October 12, 2009, six African leaders met with former French President Jacques Chirac in Benin to campaign against the trade in fake medicines.⁴⁴⁰ At the meeting, Benin's President Yaya Boni reported that the fake drug market in Benin led to annual losses of around \$67.41 million in legal pharmaceutical sales, and caused the government lose out on roughly \$11 million in taxes.⁴⁴¹ The head of the state health protection agency, Laurent Assogbathe, reported that approximately 85 percent of the population relied on fake drugs, which they bought from more than 10,000 traders in the informal sector market.⁴⁴² These drugs come from neighboring nations like Gabon and Nigeria, or from large scale producers from Asia, Europe and North America. This market is often controlled by travelling sales persons who have no pharmaceutical training.⁴⁴³

Counterfeit drugs were found in Benin's formal health sector as well. At a hospital in Cotonou, largest city and economic capital of Benin, some estimate that at least one patient dies every day due to counterfeit drugs.⁴⁴⁴

In 2006, the national laboratory of medicinal quality control tested hundreds of drugs taken from stalls at a popular market in Cotonou, and found that 70 percent of the drugs contained

⁴³⁶ "Transnational Trafficking and the Rule of Law in West Africa." *United Nations Office of Drugs and Crime* (Jul 2009), available at http://www.unodc.org/documents/data-and-analysis/Studies/West_Africa_Report_2009.pdf (accessed Jan 20 2010).

⁴³⁷ Ibid.

⁴³⁸ Ibid.

⁴³⁹ Tran, P., "Counterfeit Drug Sales in Africa Strong, Threaten Public Health." *Voice of America News* (Oct 19 2007), available at <http://www1.voanews.com/english/news/a-13-2007-10-19-voa8-66800082.html> (accessed Jan 20 2010).

⁴⁴⁰ "African leaders, Chirac Attack Fake Drug Trade." *Reuters* (Oct 12 2009), available at <http://www.reuters.com/article/idUSLC417804> (accessed Jan 25 2010).

⁴⁴¹ Ibid.

⁴⁴² Ibid.

⁴⁴³ "Global Trends." *The National Agency for Food, Drug Administration & Control (NAFDAC), Nigeria* (2009), available at <http://www.nafdacnigeria.org/globaltrends.htm> (accessed Jan 25 2010).

⁴⁴⁴ "Benin Declares War on Fake Medicine." *France 24* (Oct 12 2009), available at <http://www.france24.com/en/20091012-focus-benin-war-fake-drugs-medication-cotonou-hospital> (accessed Jan 25 2010).

inadequate amounts of active ingredients.⁴⁴⁵ Between April 2007 and June 2008, 250 deaths and 340 cases of chronic illnesses were linked to adulterated drugs.⁴⁴⁶

The Gambia

In The Gambia, there are no systems which monitor either the medicine quality or regulate pharmacy operations,⁴⁴⁷ and counterfeit drugs are as prevalent as authentic products.⁴⁴⁸ Chalk has been reportedly sold as aspirin, paracetamol, or as anti-malarials.⁴⁴⁹ Many of these deceptive drugs are thought to imported from China, India or Nigeria by Lebanese-owned firms and distributed through chains of four main pharmacies.⁴⁵⁰

Equatorial Guinea

In March 2009, the military government in Guinea arrested several people for the alleged manufacture and sale of counterfeit medicines and prohibited the sales of drugs outside of pharmacies.⁴⁵¹ The drug regulators' success was short-lived, however: only a few months after the military government cracked down on unregulated drug sales, there were reports of dubious medicines were re-emerging in the markets and streets of Conakry, the country's capital.⁴⁵²

In June 2009, the health and public hygiene ministry's chief of staff, Mohamed Lamine Yansané, reported that the fight against counterfeit drugs in Guinea was a difficult one given the severe shortage of medicines in public hospitals and health centers.⁴⁵³ The military government has done little to date to alleviate this problem.⁴⁵⁴ The United Nations Office on Drugs and Crime, stated in August 2009 that it had found equipment and a laboratory for the production of counterfeit antibiotics.⁴⁵⁵

⁴⁴⁵ Ouellet, D., "2008 Awardee Profiles: Daphnée Dion-Viens." *The International Development Research Center* (2008), available at http://www.idrc.ca/awards/ev-132672-201-1-DO_TOPIC.html (accessed Jan 25 2010).

⁴⁴⁶ Ibid.

⁴⁴⁷ "African Union and Interpol." *The Gambia Journal* (May 2 2009), available at <http://www.thegambiajournal.com/Top-News-and-Analyses/331.html> (accessed Jan 25 2010).

⁴⁴⁸ Ibid.

⁴⁴⁹ Ibid.

⁴⁵⁰ Ibid.

⁴⁵¹ "Guinea: Black Market Medicines Reemerge." *UN Integrated Regional Information Networks* (Jun 1 2009), available at <http://www.irinnews.org/Report.aspx?ReportId=84644> (accessed Jan 25 2010).

⁴⁵² Ibid.

⁴⁵³ Ibid.

⁴⁵⁴ Ibid.

⁴⁵⁵ "Evidence of Clandestine Drugs Manufacturing in Guinea Concerns UN." *UN News Centre* (Aug 5 2009), available at <http://www.un.org/apps/news/story.asp?NewsID=31690&Cr=unodc&Cr1=west+afrika> (accessed Jan 25 2010).

Liberia

The problem of counterfeit drugs increased in Liberia after the country's second civil war, which concluded in 2003.⁴⁵⁶ Medicines are scarce, and many are counterfeit or distributed beyond their expiration date.^{457,458}

Since 2005, President Ellen Johnson Sirleaf has installed new quality control mechanisms to crack down on both fake and outdated drug dealers.⁴⁵⁹ In June 2006, the Pharmaceutical Board's inspection team confiscated several cartons of alleged fake drugs.⁴⁶⁰

Despite increased regulation, porous borders allow smugglers from neighboring countries in the Mano River union basin to continue to infiltrate Liberian pharmaceutical markets. In 2009, the Liberian government, with the help of the United Nations Development Programme (UNDP), established a laboratory for testing imported medicines. The National Drugs Services (NDS), in collaboration with the International Drugs services (IDS) and the Ministry of Health, has dispatched 11 pharmacists throughout the country to provide monitoring and oversight for all new drug imports.⁴⁶¹

Niger

In 1995, 50,000 people received a fake meningitis vaccine which directly led to 2,500 deaths.^{462,463} According to the WHO, this documents one of the most fatal cases of counterfeited products which is directly provable. Other large-scale counterfeiting schemes exist which have undoubtedly caused many deaths, but it is more difficult prove direct causality.⁴⁶⁴

Togo

In October 2008, customs officers at Brussels airport seized more than two million counterfeit pills made in India and destined for two companies in Togo. Blister packs of the pills including

⁴⁵⁶ "WHO Situation Report: 16 Mar – 30 Apr 2002." *Office of the WHO Representative For Liberia* (2002), available at www.who.int/disasters/repo/8095.doc (accessed Jan 27 2010).

⁴⁵⁷ "Liberia 2009 Crime and Safety Report." *Overseas Security Advisory Council* (Jan 27 2009), available at <https://www.osac.gov/Reports/report.cfm?contentID=96512> (accessed Jan 27 2010).

⁴⁵⁸ "WHO Situation Report: 16 Mar – 30 Apr 2002." *Office of the WHO Representative For Liberia* (2002), available at www.who.int/disasters/repo/8095.doc (accessed Jan 27 2010).

⁴⁵⁹ Karnaga Jr., M., "Liberia: Health Ministry Confiscates Fake Drugs." *The Analyst* (Jun 8 2006), available at <http://allafrica.com/stories/200606080762.html> (accessed Jan 25 2010).

⁴⁶⁰ Ibid.

⁴⁶¹ Conteh, A., "Liberia: Govt Traces Fake Drugs to Border Points." *Concord Times* (Jun 2 2009), available at <http://allafrica.com/stories/200906030895.html> (accessed Jan 25 2010).

⁴⁶² Ibid.

⁴⁶³ Nsimba, S., "Problems Associated with Substandard and Counterfeit Drugs in Developing Countries: A Review Article on Global Implications of Counterfeit Drugs in the Era of Anti-retroviral (ARVs) Drugs in a Free Market Economy." *East African Journal of Public Health*, (Dec 2008) 5:3, available at <http://www.bioline.org.br/request?lp08038> (accessed Jan 25 2010).

⁴⁶⁴ Ibid.

counterfeit painkillers and antimalarials were found.⁴⁶⁵ The two companies which purchased the drugs used Togo as a commercial base for the interregional trade of high end counterfeits worth around \$2 million dollars.⁴⁶⁶

East Africa

Fake drugs commonly found across the region include cancer medications, antimalarial and antiretroviral medications, antibiotics, analgesics, anti-virals, and erectile dysfunction drugs.⁴⁶⁷

One of the major challenges facing the region is that a large volume of legal medications are diverted from public health facilities and sold on illegal markets. In Somalia and Ethiopia, stolen drugs originally donated to the Kenyan Government and marked ‘Not for Sale’ are sold openly in private chemist shops.⁴⁶⁸ During 2009 investigations conducted by a Nairobi newspaper *The Standard*, the Crime Courts and Investigation team found eight clinics in the town of Suftu along the Ethiopian border and seven in the Somalia border town of BullaHawa openly selling such drugs.⁴⁶⁹ “In Somalia, drugs can be purchased on either side of the border from drug peddlers who call themselves ‘Dhakhaatiirta aan Xuduuda Lahyn’ (Doctors Without Borders). The peddlers also administer drugs to patients, sometimes with fatal consequences. In early 2010, an eight-year-old boy in Olla location in Rhamu Division died after an Ethiopian peddler gave him an injection of an adulterated drug.⁴⁷⁰ In an effort to tackle corruption, the government has begun stationing police officers at some hospitals to deter public health workers from stealing drugs.⁴⁷¹

Burundi

Nearly half of the drugs sold in the informal market in Burundi were substandard, according to a recent report.⁴⁷² An analysis of antimalarials from Angola, Burundi, and the Democratic Republic of Congo in 2006 discovered that 46 percent of drugs had been incorrectly formulated. More than half of the time the drugs were sold without the original packaging, the name of the active ingredient, the pill’s strength, or the expiry date. In some cases, the only identification on

⁴⁶⁵ Tagliabue, J., “Belgium: Shipments of Fake Pills Seized.” *The New York Times* (Oct 2 2008), available at http://www.nytimes.com/2008/10/03/world/europe/03briefs-SHIPMENTSOFF_BRF.html?_r=1 (accessed Jan 25 2010).

⁴⁶⁶ “Togo: Deux Sociétés Togolaises Impliquées dans un Trafic de Faux Médicaments.” *République Togolaise* (Oct 3 2008), available at <http://fr.allafrica.com/stories/200810030761.html> (accessed Jan 25 2010).

⁴⁶⁷ “Operation Mamba (IMPACT)—Targeting Counterfeits in Tanzania and Uganda.” *INTERPOL* (Oct 29 2009), available at <http://www.interpol.int/public/news/2008/mamba20081029.asp> (accessed Jan 10 2010).

⁴⁶⁸ Jubat, A. and Onger, B., “Exposed: Sale of Government Drugs in Foreign Lands.” *The Standard Kenya* (Jul 29 2009), available at <http://www.standardmedia.co.ke/mag/InsidePage.php?id=1144020470&cid=459&> (accessed Jan 27 2010). BROKEN LINK I think this may no longer be available via the standard online

⁴⁶⁹ Ibid.

⁴⁷⁰ Ibid.

⁴⁷¹ Ibid.

⁴⁷² Harris, J., Stevens, P., Morris, J., “Keeping it Real: Combating the Spread of Fake Drugs in Developing Countries.” *International Policy Network* (2009), available at http://www.policynetwork.net/sites/default/files/keeping_it_real_2009.pdf (accessed Jan 22 2010).

the pill was the producer's name and country scrawled in pen, providing a ready opportunity for counterfeiters.⁴⁷³

Ethiopia

In 2003, the general manager of Ethiopia's Drug Administration and Control Authority (DACA), Haileselassie Bihon, reported that smugglers in Ethiopia were passing off illegally imported concoctions of unauthorized quality and unpredictable effects as antiretroviral drugs (ARVs) countrywide.⁴⁷⁴ In 2004, the Ethiopian Ministry began to stress the need for Ethiopia to start locally mass-producing ARVs; according to the ministry and the HIV/AIDS Prevention and Control Office, nation-wide drug shortages encourage those desperate for medical help to buy any products available.⁴⁷⁵

In 2008, The Federal Drug Authority of Ethiopia withdrew the import licenses of 60 generic manufacturers from India because of extensive evidence that they were providing sub-standard products.⁴⁷⁶ They banned a further 120 Asian importing companies which were supplying counterfeit or substandard medications.⁴⁷⁷

The nationally owned airline, Ethiopian Airlines, was accused in 2002 of transporting fake drugs to Nigeria.⁴⁷⁸

Kenya

In 2008, the Kenyan Association of Pharmaceutical Industry (KAPI) estimated that counterfeit medicines worth US\$130 million were sold in the country every year.⁴⁷⁹ In 2005, a random survey by the National Quality Control Laboratories (NQCL) and the Pharmacy and Poisons Board found that almost 30 percent of the drugs in Kenya were counterfeit. In 2008, the Medical Services Minister put the number of fakes in the country to be as high as 80 percent of the total market, with some being no more than chalk and water.^{480,481,482}

⁴⁷³ Gaudiano, M.C., Di Maggio, A., Cocchieri, E., Antoniella, E., Bertocchi, P., Alimonti, S., and Valvo, L., "Medicines Informal Market in Congo, Burundi and Angola: Counterfeit and Sub-Standard Antimalarials." *Malaria Journal* (Feb 2007) 6:22, available at www.malariajournal.com/content/6/1/22 (accessed Jan 13 2010).

⁴⁷⁴ "Ethiopia: Black Market Bogus AIDS Drugs." *Addis Tribune* (Oct 10 2003), available at <http://allafrica.com/stories/200310100530.html> (accessed Jan 27 2010).

⁴⁷⁵ "Ethiopia: Focus on Local Manufacture of Anti-Retroviral Drugs." *UN Integrated Regional Information Networks* (Mar 10 2004), available at <http://www.irinnews.org/report.aspx?reportid=48995> (accessed Jan 28 2010).

⁴⁷⁶ "Weakened Patent Protection Impacts Pharmaceutical Product Safety." *Patients and Patents* (2008), available at http://www.patientsandpatents.com/us/resources/discussion/weakened_patent_protection_impacts_pharmaceutical_product_safety (accessed Jan 27 2010).

⁴⁷⁷ "Rx for Africa, Inc. to Benefit from New Ethiopian Government Policy on Pharma Industry." *Drug Week* (Feb 15 2008), available at www.newsr.com (accessed Jan 27 2010).

⁴⁷⁸ "Nigeria Accuses Ethiopian of Importation of Fake Drugs." *EthioNews* (Sep 4 2002), available at <http://lists.sn.apc.org/pipermail/pol.ethiopia/2002-Sep/012274.html> (accessed Jan 27 2010).

⁴⁷⁹ McGinnis, Milissa, "Matrix of Drug Quality Reports Affecting USAID-assisted Countries." *U.S. Pharmacopeia Drug Quality and Information Program* (Nov 6 2009), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 1 2010).

⁴⁸⁰ Ibid.

In 2008, it was estimated that Kenyans spend about USD \$64.5 million on fake medicines every year.⁴⁸³ The counterfeiters themselves, however, only face up to USD \$80 in fines if convicted of this crime.⁴⁸⁴ The most commonly counterfeited drugs include antimalarials, pain relievers, and antibiotics. In May 2008, a nationwide survey conducted by the Pharmacy and Poisons Board revealed that 16 percent of the antimalarial medications in the country were counterfeit.⁴⁸⁵ In December 2008, over USD \$64,000 worth of fake Panadol—a pain reliever and fever reducer—was discovered by authorities and destroyed.⁴⁸⁶ In December 2009, the Pharmacy and Poisons Board destroyed 40 tons of counterfeit drugs worth USD \$223,686.⁴⁸⁷

The Pharmacy and Poisons Board has begun cracking down on illegal distribution outlets in the capital city, Nairobi, and in seven other provinces. 225 outlets have been shut down so far.⁴⁸⁸

Along with counterfeit products, expired and substandard drugs are also prevalent in Kenya. Although drug regulatory legislation exists in Kenya, poor enforcement and a shortage of well-trained regulatory staff render it ineffective. In 2004, for instance, Kenya's Drug Inspectorate Unit had just ten inspectors for the entire country,⁴⁸⁹ the Pharmaceutical Inspectorate Unit at the Pharmacy and Poisons Board had only five staff members (all pharmacists), and the board itself only seven members.⁴⁹⁰ Tasked with carrying out inspection, regulation, and quality-control functions, these board members tend to be desperately overcommitted.⁴⁹¹ One raid conducted by the Pharmacy and Poisons Board in August of 2009 resulted in the confiscation and destruction of both counterfeit and expired products, some of which had been banned for safety reasons and others which had expired nearly ten years earlier.⁴⁹²

⁴⁸¹ "WHO Raises Fears Over High Levels Of Counterfeit Drugs In Kenya." *APA News* (Sep 4 2008), available at <http://www.apanews.net/apa.php?article74365> (accessed Jan 15 2010).

⁴⁸² "WHO Factsheet" *World Health Organization* (Nov 2006), available at http://74.125.93.132/search?q=cache:oHIMD7WrGUMJ:www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc+value+of+fake+drug+market+in+russia&cd=10&hl=en&ct=clnk&gl=us&client=safari (accessed Jan 21 2010).

⁴⁸³ Mbogo, S., "Why We Are Losing The War Against Fake Drugs." *Business Daily* (May 1 2008), available at <http://allafrica.com/stories/200805010751.html> (accessed 15 Jan 2010).

⁴⁸⁴ Ibid.

⁴⁸⁵ McGinnis, Milissa, "Matrix of Drug Quality Reports Affecting USAID-assisted Countries." *U.S. Pharmacopeia Drug Quality and Information Program* (Nov 6 2009), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 1 2010).

⁴⁸⁶ Mathenge, O., "Fake drugs destroyed." *Daily Nation* (17 Dec 2008) available at <http://www.nation.co.ke/News/-/1056/503478/-/u0mg6l/-/index.html> accessed 15 Jan 2010

⁴⁸⁷ Mwai, E., "40 tonnes of counterfeit drugs burnt." *The Standard* (8 Dec 2009) available at <http://www.standardmedia.co.ke/InsidePage.php?id=1144021310&cid=159&story=40%20tonnes%20of%20counterfeit%20drugs%20burnt> accessed 22 Jan 2010

⁴⁸⁸ Maina, J., "Pharmacy Board cracks the whip." *Kenya Broadcasting Corporation* (28 Jul 2008) available at <http://www.kbc.co.ke/story.asp?ID=51514> accessed 15 Jan 2010

⁴⁸⁹ Kimani, D., "Illegally Imported, Fake Drugs Flood Kenya." *East African* (10 May 2004) available at <http://www.theeastafrican.co.ke/magazine/-/434746/243284/-/13yj6ql/-/index.html> accessed 15 Jan 2010

⁴⁹⁰ McGinnis, Milissa, "Matrix of Drug Quality Reports Affecting USAID-assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (6 Nov 2009) available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> accessed 1 Feb 2010

⁴⁹¹ Ibid.

⁴⁹² Bii, B., "Fake and expired drugs seized." *Daily Nation* (31 Jul 2009) available at <http://www.nation.co.ke/News/-/1056/632954/-/ulj85i/-/index.html> accessed 15 Jan 2010

There are also reports of a black market in donated drugs in Kenya, most notably for antiretroviral medications, which can be purchased without a prescription at a quarter of the normal price.⁴⁹³ An INTERPOL/IMPACT operation in October 2009, called Operation Mamba II, revealed that medicines donated to the Kenyan government and marked 'Not for sale' were found in private supply chains, as well as Government-provided medicines for public hospital distribution only.⁴⁹⁴

Substandard drugs are also a problem. In a 2007 study, 9 out of 24 batches (38%) of antimalarial drugs sampled from pharmacies in Nairobi, Kenya and DR Congo did not contain enough API to meet European pharmaceutical requirements;⁴⁹⁵ seven batches were underdosed, and two contain too much API.⁴⁹⁶ While most of the under-dosed drugs were manufactured in China and India, one of the overdosed dry powder suspensions was manufactured in Kenya.⁴⁹⁷ All of the 16 drugs analyzed from Kenya were brands registered by the Kenya Drug Regulatory Agency which had broken no packaging rules, yet half (8) failed to meet API standards.⁴⁹⁸ This led researchers to believe that the poor quality of drugs here was likely the result of poor manufacturing practices, poor storage conditions, or insufficient quality assurance.⁴⁹⁹ Another study in 2005 revealed that over 40 percent of antimalarials in the Kenyan retail sector failed to meet quality standards.⁵⁰⁰

Mauritius

In 2007, Steve Allen, a senior investigator for Pfizer, said his current concern regarding fake drugs involved counterfeit shipments passing through Jordan and Mauritius, an island east of Africa.⁵⁰¹ Mauritius is a major transit point for Asian pharmaceuticals en route to Africa. In July 2007, authorities in Dubai said a consignment of fake drugs from Mauritius had been seized at a free zone next to the Dubai airport, containing more than half a million pills of counterfeit Plavix, a blood-thinning drug made by the French company Sanofi-Aventis.⁵⁰² Though Dubai health authorities do not know who made the drugs, some of the pills contained only cement powder.⁵⁰³

⁴⁹³ Siringi S., "AIDS drugs being sold illegally on market stalls in Kenya." *Lancet* 2004: 363(377) available at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(04\)15479-2/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)15479-2/fulltext) accessed 15 Jan 2010

⁴⁹⁴ "East African countries crack down on counterfeiters in INTERPOL/IMPACT supported Operation Mamba II." *INTERPOL Report* (9 Oct 2009) available at

<http://www.interpol.int/Public/News/2009/OperationMambaII20091002.asp> accessed 13 Jan 2010

⁴⁹⁵ Atemnkeng, M., De Cock, K., and Plaizier-Vercammen, J., "Quality control of active ingredients in artemisinin-derivative antimalarials within Kenya and DR Congo." *Tropical Medicine and International Health* 2007: 12(1) accessed 8 Jan 2010

⁴⁹⁶ Ibid

⁴⁹⁷ Ibid.

⁴⁹⁸ Ibid.

⁴⁹⁹ Ibid.

⁵⁰⁰ Amin, A.A., Snow, R.W., Kokwaro, G.O., "The quality of sulphadoxine-pyrimethamine and amodiaquine products in the Kenyan retail sector." *Journal of Clinical Pharmacological Therapy* 2005: 30 accessed 20 Jan 2010

⁵⁰¹ Bogdanich, W., "Counterfeit Drugs' path eased by free trade zones." *New York Times* (17 Dec 2007) available at <http://www.nytimes.com/2007/12/17/world/africa/17iht-17freezone.8775156.html> accessed 9 Jan 2010

⁵⁰² Ibid.

⁵⁰³ Ibid.

In October 2009, officials from the Mauritius Anti-Drug and Smuggling Unit (ADSU) raided a pharmacy in Curepipe and seized approximately 10,000 pills of a painkiller.⁵⁰⁴

Somalia

The president of Somaliland (self-declared republic in northern Somalia), Dahir Riyale Kahin, reported that expired and counterfeit drugs are imported into Somaliland and asked the World Health Organization (WHO) for help in tackling the problem.⁵⁰⁵

Tanzania

In 2008, the Confederation of Tanzania Industries (CTI) estimated that 60 percent of the medicines imported into Tanzania are counterfeit.⁵⁰⁶ In 2009 the CTI claimed Tanzania was a 'dumping ground' for fake drugs from China, India, Europe and the USA, which used the country as a gateway into Africa.⁵⁰⁷

In October 2008, government authorities seized several tons of expired, unregistered, and counterfeit medicines including antibiotics, pain killers, antimalarials and vitamins.⁵⁰⁸ Counterfeit antimalarials discovered in January 2009 contained only wheat flour.⁵⁰⁹ In 2009, the fake anti-malarial drug, Metakelfin, (for which Pfizer has the licence) was discovered in 40 pharmacies, suggesting that counterfeit drugs in Tanzania have not only infiltrated the informal health sector but the official health sector as well.⁵¹⁰

In April 2009, the Tanzania Food and Drug Authority (TFDA) suspended the importation, distribution, sale, and use of the antimalarial Metakelfin because TFDA carried out an inspection of 40 pharmacies and discovered several batches of Metakelfin that were imported without TFDA approval or had low percentages of active pharmaceutical ingredient (some as low as

⁵⁰⁴ "Mauritius Police Force seize suspected counterfeit drugs." *Net News Publisher* (19 Oct, 2009) available at <http://www.netnewspublisher.com/mauritius-police-force-seize-suspected-counterfeit-drugs/> accessed 11 Jan 2010

⁵⁰⁵ "UN to establish laboratories in Somaliland to check food, counterfeit drugs." *Hiraan Online* (22 Nov 2009) available at http://toolkit.dialog.com/intranet/cgi/present?STYLE=739318018&PRESENT=DB=985_AN=290300247_FM=9_SEARCH=MD.GenericSearch accessed 27 Jan 2010

⁵⁰⁶ McGinnis, Milissa, "Matrix of Drug Quality Reports Affecting USAID-assisted Countries." *U.S. Pharmacopeia Drug Quality and Information Program* (Nov 6 2009), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 1 2010).

⁵⁰⁷ "Tanzania: Counterfeit Drugs Put Lives At Risk." *UN Integrated Regional Information Networks* (Jan 19 2009), available at <http://allafrica.com/stories/200901150798.html> (accessed Jan 15 2010).

⁵⁰⁸ McGinnis, Milissa, "Matrix of Drug Quality Reports Affecting USAID-assisted Countries." *U.S. Pharmacopeia Drug Quality and Information Program* (Nov 6 2009), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 1 2010).

⁵⁰⁹ "Tanzania: Counterfeit Drugs Put Lives At Risk." *UN Integrated Regional Information Networks* (Jan 19 2009), available at <http://allafrica.com/stories/200901150798.html> (accessed Jan 15 2010).

⁵¹⁰ "World Pharma: A Potential Massacre." *The Economist Intelligence Unit* (Dec 14 2009), available at http://viewswire.eiu.com/index.asp?layout=ib3Article&article_id=1685058953&pubtypeid=1152462500&country_id=1510000351&IBNL=true&rf=0 (accessed Jan 21 2010).

0.4%).⁵¹¹ In September 2009, police and TFDA joined forces in a major crackdown on fake and expired drugs.⁵¹²

In 2008, the first WHO supported INTERPOL/IMPACT operation conducted in Africa, “Operation Mamba,” took place in Tanzania.⁵¹³ During “Operation Mamba,” INTERPOL, the WHO and local officials tested drugs sold in over 191 locations in Tanzania, including pharmacies, warehouses, and illicit markets.⁵¹⁴ Officials confiscated more than 100 types of fake medical products, including anti-malarial, cardiac, anti-fungal, multivitamin, hormonal and skin medicines.⁵¹⁵ Four pharmacies and 18 drug shops that were in breach of the law were closed, and the police initiated 44 new investigations.⁵¹⁶

One year later, “Operation Mamba II” was expanded to include Kenya, Tanzania and Uganda. More than 270 pharmacies, hospitals, warehouses and shops across these three countries were targeted for investigation. The operation focused on medicines for life threatening diseases, as well as other common counterfeits including Viagra, anti-malarial, antibiotics, and anti-viral medications.⁵¹⁷ The operation resulted in 83 new police cases several prosecutions. In Tanzania, Operation Mamba II resulted in the seizure of around 319 brands of antimalarial drugs and antibiotics, worth an estimated USD \$7,097.⁵¹⁸

Uganda

Counterfeit ARVs, anti-bacterial medications, and anti-malarials are found in a broad range of locations including National Medical Stores, informal outdoor markets, and street vendors’ carts.^{519,520,521} In 2006, senior NMS officials were suspended on charges of hoarding ARVs and causing them to expire.⁵²² In 2008, a raid undertaken by the Ugandan National Drug Authority

⁵¹¹ Shekighenda, L., “TFDA Halts Sale, Use of Metakelfin.” *IPP Media* (Apr 1 2009), available at www.ippmedia.com (accessed Jan 15 2010).

⁵¹² Mnyanyika, V., “Tanzania: Beware of Counterfeit Antibiotics.” *UN Integrated Regional Information Networks* (Sep 8 2009), available at <http://allafrica.com/stories/200909080984.html> (accessed 15 Jan 2010).

⁵¹³ “Tanzania: Counterfeit Drugs Put Lives At Risk.” *UN Integrated Regional Information Networks* (Jan 19 2009), available at <http://allafrica.com/stories/200901150798.html> (accessed Jan 15 2010).

⁵¹⁴ “Operation Mamba (IMPACT)—Targeting Counterfeits in Tanzania and Uganda.” *INTERPOL* (Oct 29 2009), available at <http://www.interpol.int/public/news/2008/mamba20081029.asp> (accessed Jan 15 2010).

⁵¹⁵ *Ibid.*

⁵¹⁶ “Tanzania: Counterfeit Drugs Put Lives At Risk.” *UN Integrated Regional Information Networks* (Jan 19 2009), available at <http://allafrica.com/stories/200901150798.html> (accessed Jan 15 2010).

⁵¹⁷ “Operation Mamba (IMPACT)—Targeting Counterfeits in Tanzania and Uganda.” *INTERPOL* (Oct 29 2009), available at <http://www.interpol.int/public/news/2008/mamba20081029.asp> (accessed Jan 15 2010).

⁵¹⁸ Mnyanyika, V., “Tanzania: Beware of Counterfeit Antibiotics.” *UN Integrated Regional Information Networks* (Sep 8 2009), available at <http://allafrica.com/stories/200909080984.html> (accessed 15 Jan 2010).

⁵¹⁹ Richey, L. and Haakonsson, S., “Access to ARV Treatment: Aid, Trade, and Governance in Uganda.” *Danish Institute for International Studies Working Paper* (2004), available at <http://www.ciaonet.org/wps/ri101/ri101.pdf> (accessed Jan 22 2010).

⁵²⁰ Nyakairu, F. and Nakabugo, Z., “Fake drugs smuggled from DR Congo.” *The Monitor* (Oct 1 2005) available at <http://allafrica.com/stories/200509300689.html> (accessed Jan 15 2010).

⁵²¹ Bogere, H. and Nafula, J., “Fake Quinine on Market.” *Daily Monitor* (May 10 2007), available at <http://www.monitor.co.ug/news/news05102.php> (accessed Jan 13 2010).

⁵²² McGinnis, Milissa, “Matrix of Drug Quality Reports Affecting USAID-assisted Countries.” *U.S. Pharmacopeia Drug Quality and Information Program* (Nov 6 2009), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 1 2010).

(NDA) and the Ugandan police led to the discovery of counterfeit drugs in thirty-eight of the forty pharmacies investigated.⁵²³ In 2009, a joint operation carried out by INTERPOL/IMPACT and the NDA, Operation Mamba II, discovered five tons of fake drugs in central and eastern districts of the country. It also found medicines donated to the Ugandan government marked ‘Not for sale’ in private supply chains, as well as government-provided medicines for public hospital distribution only, including chloroquine and quinine.^{524,525} One container labeled “Quinine” actually contained chloroquine, which is typically sold at a lower price.⁵²⁶ A large quantity of the antimalarial Amodiaquine seized during the operation was deemed fake when investigators observed that all the pills had the same batch number, but different expiry dates.⁵²⁷

Muhammad Lukwago, the NDA drug inspector, asserts that most of the containers’ labels do not reflect the actual contents or the container – many drugs contained none of the stated active ingredient, expired drugs, or different chemicals.⁵²⁸ Other anti-malarial drugs failed laboratory tests: including Metakelfin and quinine.⁵²⁹ Many drugs found that had been stolen from public stores in Kenya and Tanzania.⁵³⁰

The boss of Interpol Uganda, Fred Kiyaga, said that following Mamba II in 2009, five people were convicted and fined USD \$520 each for illegal possession of counterfeit drugs, while 38 other cases awaiting court decisions.⁵³¹

Rwanda

A 2007 study on the quality of essential antimicrobial and antimalarial drugs marketed in Rwanda found some products were substandard.⁵³² Of the 13 formulations sampled, all passed initial assay testing for drug content at the time of purchase. However, two formulations (one sulfamethoxazole/trimethoprim and one quinine) failed tests after being stored in simulated tropical conditions for six months.⁵³³ In addition, two samples had unsatisfactory dissolution properties at time of purchase (one sulfamethoxazole/trimethoprim and one

⁵²³ Wandera, A. and Bagala, A., “Police Impound Fake Drugs, Cosmetics.” *Daily Monitor* (Oct 6 2008), available at <http://allafrica.com/stories/200810070704.html> (accessed Jan 13 2010).

⁵²⁴ “East African Countries Crack Down On Counterfeiters in INTERPOL/IMPACT Supported Operation Mamba II.” *INTERPOL Report* (Oct 9 2009), available at <http://www.interpol.int/Public/News/2009/OperationMambaII20091002.asp> (accessed Jan 13 2010).

⁵²⁵ McGinnis, Milissa, “Matrix of Drug Quality Reports Affecting USAID-assisted Countries.” *U.S. Pharmacopeia Drug Quality and Information Program* (Nov 6 2009), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 1 2010).

⁵²⁶ Mugabe, D., “Fake Drugs Hit Ugandan Market.” *The New Vision* (Sep 9 2009), available at <http://www.newvision.co.ug/D/8/220/693713> (accessed Jan 13 2010).

⁵²⁷ Ibid.

⁵²⁸ Ibid.

⁵²⁹ Ibid.

⁵³⁰ Ibid.

⁵³¹ Ibid.

⁵³² Kayumba PC, et al. “The Quality of Essential Antimicrobial and Antimalarial Drugs Marketed in Rwanda and Tanzania: Influence of Tropical Storage Conditions on In Vitro Dissolution.” *Journal of Clinical Pharmacy and Therapeutics* 29: 331-8 (2004), available at <http://www.ncbi.nlm.nih.gov/pubmed/15271100> (accessed May 9 2011).

⁵³³ Ibid.

sulphadoxine/pyrimethamine).⁵³⁴ In total, 31 percent of the sampled formulations (4/13) failed quality tests.

Seychelles

There is very little data on the size of the counterfeit trade in the Seychelles, but companies in the Seychelles are heavily involved in the internet drug market.⁵³⁵ The World Customs Organization reported that, in 2008, seizures of substandard drugs in 27 countries were valued at more than 126 million dollars and that these fake medicines came from India first and foremost, followed by China and the Seychelles.⁵³⁶

Central Africa

Some of the most popularly counterfeited drugs are antimalarial and antiretroviral treatments. Many of the known cases of bad drugs in this region of the continent also revolve around ineffective, substandard drugs.

Angola

According to the National Department of Intellectual Copyright Crime of the Economic Police, approximately 70 percent of the medicines used by the Angolan population in 2004 were counterfeits.⁵³⁷

A 2007 study of antimalarial tablets in the capital cities of Angola (Luanda), Burundi (Bujumbura), and the Congo (Kinshasa), found that 46 percent of the drugs being sold in the informal market were substandard.⁵³⁸ The results obtained from the analyzed samples revealed three different kinds of problems: (i) the presence of a low quantity of active substance, observed in one sample; (ii) the substitution of an active substance by a different one, observed in one sample, and (iii) the out of specification (OOS) results concerning the dissolution profile, a parameter that correlates with bioavailability.⁵³⁹ Moreover, the high Relative Standard Deviation values observed in some dissolution tests indicate a large variability in the production process, implying that most drugs are not produced with "Good Manufacturing Practices".⁵⁴⁰

⁵³⁴ Ibid.

⁵³⁵ "Santé: Loterie Sur Le Net." *Association des Médecins du canton de Genève* (Mar 26 2009), available at <http://www.amge.ch/2009/03/26/sante-loterie-sur-le-net/> (accessed Jan 27 2010).

⁵³⁶ "Dossier De Presse A L'initiative Du Président Jacques Chirac." *Fondation Chirac* (Oct 12 2009), available at <http://www.fondationchirac.eu/wp-content/uploads/2009/10/dossier-de-presse-appel-de-cotonou-leger.pdf> (accessed Jan 27 2010).

⁵³⁷ "WHO Factsheet" *World Health Organization* (Nov 2006), available at http://74.125.93.132/search?q=cache:oHIMD7WrGUMJ:www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc+value+of+fake+drug+market+in+russia&cd=10&hl=en&ct=clnk&gl=us&client=safari (accessed Jan 21 2010).

⁵³⁸ Gaudiano, M. C., Di Maggio, A., Cocchieri, E., Antoniella, E., Bertocchi, P., Alimonti, S., Valvo, L. "Medicines Informal Market in Congo, Burundi and Angola: Counterfeit and Sub-Standard Antimalarials" *Malaria Journal* (2007) 6:22, available at <http://www.malariajournal.com/content/6/1/22> (accessed Feb 2 2010).

⁵³⁹ Ibid.

⁵⁴⁰ Ibid.

Due to problems with counterfeit and substandard products, the Provincial Government of Luanda banned the sale of medicines, surgical tools, and hospital equipment in municipal markets.⁵⁴¹ According to an official press release, “products were being sold without the meticulous observance of hygienic technical and scientific conditions.”⁵⁴²

Cameroon

A 2004 study assessed the quality of 284 samples of antimalarial drugs from 132 different vendors in sixteen villages and cities throughout the country. The study found that 38 percent of the sampled chloroquine, 52 percent of the quinine, and 12 percent of the sulphadoxine-pyrimethamine samples had either no API, insufficient API, incorrect ingredients, or unknown ingredients.⁵⁴³ In total, 39 percent of the samples failed quality tests. Some of the fake quinine contained chloroquine.⁵⁴⁴ Of drugs used for self-medication by 15 malaria-infected patients, six “chloroquine” samples contained no active ingredient, one contained a lower than expected chloroquine content, and two “quinine” samples contained the less costly drug chloroquine.⁵⁴⁵

Democratic Republic of the Congo

Counterfeit drugs are largely uncontrolled throughout the DRC. In 2003, fake antiretroviral medications were found in Lubumbashi, the country’s second largest city. Counterfeiters have targeted health prescribers and patients to buy these cheap fake ARVs.⁵⁴⁶

In 2004, Médecins Sans Frontières (MSF) discovered counterfeit ARVs on the market in the Democratic Republic of Congo that contained an antidepressant and a muscle relaxant, and were labeled as either “Triomune” or “Duovir”, the two commonly prescribed antiretroviral brands that are manufactured by Indian pharmaceutical company Cipla.^{547,548}

In a 2007 study of East African pharmacies, including pharmacies in Bukavu, 9 out of 24 samples failed European pharmacopeial requirements for API content (95-105%). Two samples

⁵⁴¹ “Luanda Government Bans Medicines Sale at Markets” *Agencia Angola Press*. (May 16 2009), available at www.portalangop.co.ao (accessed Feb 2 2010).

⁵⁴² *Ibid.*

⁵⁴³ Basco LK. “Molecular Epidemiology of Malaria in Cameroon.” *The American Journal of Tropical Medicine and Hygiene* (2004) 70: 245–50, available at <http://www.ajtmh.org/cgi/content/full/70/3/245> (accessed May 9 2011).

⁵⁴⁴ *Ibid.*

⁵⁴⁵ *Ibid.*

⁵⁴⁶ Ravinetto R, “Counterfeit ARVs in DRC.” *EDRUG* (Feb 11 2004), available at <http://www.essentialdrugs.org/edrug/archive/200402/msg00028.php> (accessed Feb 1 2010).

⁵⁴⁷ “Antidepressants are Sold as Antiretrovirals in DR Congo.” *The Lancet* (2004) 363: 713, available at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(04\)15670-5/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)15670-5/fulltext) (accessed Feb 1 2010).

⁵⁴⁸ “Antidepressants are Sold as Antiretrovirals in DR Congo.” *The Lancet* (2004) 363: 713, available at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(04\)15670-5/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)15670-5/fulltext) (accessed Feb 1 2010).

had slight overdoses, while 7 were underdosed.⁵⁴⁹ Another 2007 study of antimalarial tablets in Goma found that 46 percent of the drugs being sold in the informal market were substandard.⁵⁵⁰

Gabon

Substandard antimalarials have reportedly been a problem in Gabon, like in much of Central Africa. A 2003 WHO study on the quality of antimalarials in Africa countries revealed that 29 percent of the chloroquine tablets tested from Gabon failed quality tests.⁵⁵¹

Republic of the Congo

Counterfeit and substandard products proliferate due to a combination of self-medication and poor diagnosis by unauthorized medical practitioners.⁵⁵² For instance, according to official 2000 figures approximately 60 percent of people in Brazzaville, the capital and the country's largest city, use antimalarial medicines purchased from illegal street vendors to treat malaria over the recommended, and more expensive treatment (ACTs).⁵⁵³ Many of the drugs available on the street are fakes which were manufactured illegally in China or India and brought into the Congo via the neighboring Democratic Republic of Congo.⁵⁵⁴

Many products are transported at incorrect temperatures or stored poorly, which contributes to the proliferation of degraded products in informal markets.⁵⁵⁵

Sudan

In 2006, a study on eight types of antimalarials across six Sudanese states revealed serious quality issues among malaria treatments throughout the country.⁵⁵⁶ The National Drug Quality Control Laboratory reported percentage failures of samples based on physical appearance that ranged from 27 percent for chloroquine syrups to 100 percent for quinine injections.⁵⁵⁷ Failures in both the public (33%) and private (13%) supply systems were also significant.⁵⁵⁸ While eight

⁵⁴⁹ Atemnkeng, M., De Cock, K., and Plaizier- Vercammen J. "Quality Control of Active Ingredients in Artemisinin-Derivative Antimalarials within Kenya and DR Congo." *Tropical Medicine and International Health* (Jan 2007) 12: 1, 68-74.

⁵⁵⁰ Gaudiano, M.C., et. al. "Medicines Informal Market in Congo, Burundi and Angola: Counterfeit and Sub-Standard Antimalarials." *Malaria Journal* (Feb 2007) 6:22, available at www.malariajournal.com/content/6/1/22 (accessed Jan 13 2010).

⁵⁵¹ Maponga, C. and Ondari, C. "The Quality of Antimalarials: A Study in Selected African Countries." *World Health Organization* (2003), available at http://whqlibdoc.who.int/hq/2003/WHO_EDM_PAR_2003.4.pdf (accessed Feb 1 2010).

⁵⁵² "Backstreet Remedies Hinder Anti-Malaria Fight." *IRIN* (Jan 14 2009), available at <http://www.irinnews.org/Report.aspx?ReportId=82353> (accessed Jan 20 2010).

⁵⁵³ Ibid.

⁵⁵⁴ Ibid.

⁵⁵⁵ Ibid.

⁵⁵⁶ Alfadel, et al "Quality of Antimalarial Drugs in Sudan." *Sudanese Journal of Public Health*: (Apr 2006) 1:2, available at <http://indexmedicus.afro.who.int/iah/fulltext/quality-antimalarial.pdf> (accessed Jan 14 2010).

⁵⁵⁷ Ibid.

⁵⁵⁸ Ibid.

percent of the total drug failures in the study were due to low active ingredients, 80 percent were due to changes in the physical characteristics of the drugs, leading researchers to suggest that transport and storage conditions in Sudan affected product quality. But the samples from Khartoum, where the drugs were tested, had failure rates similar to other states (23%) meaning that the extent to which transportation factors caused the drugs to be substandard was not clear.⁵⁵⁹

A 2003 WHO study of antimalarials revealed that 26.6 percent of the chloroquine syrup and 5.2 percent of the chloroquine tablets sampled from Sudan failed content standards, while 80 percent of the Sulphadoxine/pyrimethamine tablets tested were also found substandard.

Southern Africa

Botswana

WHO studies have found that 31 percent of antituberculosis drugs in Botswana are substandard.⁵⁶⁰ While all samples contained the correct API, 15 percent had too low API, 8 percent had excessive API, and 8 percent had excess amounts of a different API.⁵⁶¹

Lesotho

In June 2009, a five day police operation against counterfeit medical products in Lesotho called “Operation Fiela,” (means ‘clean up’), supported by INTERPOL, led to the seizure of repackaged medicines sold on the streets.⁵⁶² Working together with Drug Regulatory Authorities and Customs, Lesotho police inspected more than 50 suspected premises, including pharmacies and supermarkets, in the capital city Maseru and two other regions, Mefeteng in the South and Leribe in the North. Cleanup efforts resulted in the closure of eight outlets.⁵⁶³ Among the illegal products seized during the inspections were illegal steroids, antifungals, oral contraceptives, and antibiotics.⁵⁶⁴

Malawi

In 2009, unregistered and illegally sold medical and cosmetic products worth thousands of dollars were seized in a series of operations across Malawi, Swaziland, Zambia and Zimbabwe coordinated by INTERPOL. During Operation Zambezi, which ran from 12 October to 6

⁵⁵⁹ Ibid.

⁵⁶⁰ Zarocostas, J. “WHO to Set Up International Task Force On Counterfeit Drugs.” *British Medical Journal* (Feb 25 2006) 332: 7539, available at <http://www.bmj.com/cgi/content/extract/332/7539/444-d> (accessed Jan 25 2010).

⁵⁶¹ Kenyon TA, Kenyon AS, Kgarebe BV, et al. “Detection Of Substandard Fixed-Dose Combination Tuberculosis Drugs Using Thin Layer Chromatography.” *Int J. Tuberc Lung Dis* (1999) 3:11, S347-S350, available at <http://www.ingentaconnect.com/content/ijatld/ijtd/1999/00000003/a00311s3/art00015> (accessed Feb 1 2010).

⁵⁶² “Counterfeit Medical Products Seized In Lesotho Interpol-Supported Operation.” *INTERPOL Media Release* (Jul 29 2009), available at <http://www.interpol.int/public/ICPO/PressReleases/PR2009/PR200973.asp> (accessed Jan 23 2010).

⁵⁶³ Ibid.

⁵⁶⁴ Ilston, G. “Interpol Support Leads To Counterfeit Seizure.” *Police Professional* (Aug 6 2009), available at <http://www.policeprofessional.com/news.aspx?id=9173> (accessed Jan 22 2010).

November, investigators visited 263 pharmacies, surgeries, wholesalers and supermarkets, and subsequently initiated 25 cases to pursue possible international links.⁵⁶⁵ Among the 19 premises closed down was an unauthorized private clinic in Malawi which was discovered to be re-using disposable material and dispensing illegally obtained government-owned medicines.⁵⁶⁶

Madagascar

In 2003, USAID Drug, Quality, and Information Program (USP DQI) set up a partnership with the government in Madagascar and helped them to set up the l'Agence de Médicament de Madagascar (AMM) to help improve drug quality.⁵⁶⁷ They found that out of the 46 drugs fully tested from the public, private, and informal sectors, 22 percent were found to be substandard⁵⁶⁸ Since 2004, the drug quality monitoring program has analyzed more than 1,600 samples in two rounds of testing nationwide and the AMM has recalled three essential drugs from the market nationwide, closed two pharmacies, and withdrawn 16 lots of medicines.⁵⁶⁹

South Africa

In 2009, the spokesman for the Medical Controls Council in South Africa, Griffiths Molewa, reported that counterfeit medicines accounted for between 2 and 10 percent of the market in South Africa, and 10 cases had been reported to South African authorities that year.⁵⁷⁰ Molewa also reported that most of the counterfeit medicines smuggled originated from China, India, or Pakistan, with distribution being done from the US through the internet, and the finance operations based in the Caribbean tax havens, notorious for money laundering.⁵⁷¹

In 2003, South Africa's Medicines Control Council (MCC) blocked generic antiretroviral drugs imports from Swaziland's SwaziPharm because the company was under suspicion of exporting counterfeit drugs.⁵⁷²

⁵⁶⁵ Counterfeit Medical Products Seized In Lesotho Interpol-Supported Operation." *INTERPOL Media Release* (Jul 29 2009), available at <http://www.interpol.int/public/ICPO/PressReleases/PR2009/PR200973.asp> (accessed Jan 23 2010).

⁵⁶⁶ Counterfeit Medical Products Seized In Lesotho Interpol-Supported Operation." *INTERPOL Media Release* (Jul 29 2009), available at <http://www.interpol.int/public/ICPO/PressReleases/PR2009/PR200973.asp> (accessed Jan 23 2010).

⁵⁶⁷ Foster, M.L. and Phanouvong, S., "The Hunt for Inferior Drugs." *Pharmaceutical Formulation & Quality* (Dec/Jan 2009), available at <http://www.pharmaquality.com/ME2/Audiences/dirmod.asp?sid=325598564E8C4B3EB736C7159241312D&nm=&type=Publishing&mod=Publications%3A%3AArticle&mid=D3E3C719D8D44216836DCA4F4144BEC4&tier=4&id=BC62A79068BB4D75BB4386CE15B53375&AudID=5648A5C28C97462DBBDB309539B820EF> (accessed Jan 25 2010).

⁵⁶⁸ Ibid.

⁵⁶⁹ Ibid.

⁵⁷⁰ Mtyala, Q., "Trade in Fake Goods Costing SA R2bn." *Business Report* (May 14 2009), available at <http://www.busrep.co.za/index.php?fSectionId=561&fArticleId=4980219> (accessed Jan 25 2010).

⁵⁷¹ Ibid.

⁵⁷² Smart, T., "Medicines Control Council Blocks Generic Anti-Hiv Drugs Imports From Swaziland Into South Africa." *AIDSMAP* (Apr 24 2003), available at <http://www.aidsmap.com/en/news/4292756A-DA63-4682-BAAE-6B05928E2937.asp> (accessed Jan 25 2010).

In 2008, South African Health Minister, Manto Tshabalala-Msimang, announced the withdrawal of two generic drugs used to treat tuberculosis from the market due to quality concerns, after initial tests at the local WHO laboratory found that the two combination drugs did not contain the appropriate levels of active pharmaceutical ingredients.^{573,574}

Swaziland

In 2009, inspections of 49 pharmacies and supermarkets that sold pharmaceutical products in Manzini, Matsapha, Ezulwini and Mbabane led to the seizure of counterfeit and illicit medicines, prescription medications which were available without a prescription, the arrest of at least 32 people, and the closure of five pharmacies that were found operating illegally or selling counterfeit medicines.^{575,576,577}

In 2003, South Africa's Medicines Control Council (MCC) blocked antiretroviral drugs imports from SwaziPharm, a domestic generic manufacturer, into South Africa because the company was under suspicion of exporting counterfeit drugs.⁵⁷⁸

Zambia

Substandard and counterfeit pharmaceuticals are prevalent.⁵⁷⁹ Since 2004, the Pharmaceutical Regulatory Authority of Zambia (PRA) has intensified its supervision of the medical industry and promulgated laws and regulations to standardize the operation of both local and foreign drug companies.⁵⁸⁰ At the end of 2008, the Government launched a task force aimed at checking the proliferation of counterfeit drugs in order to safeguard people's health,⁵⁸¹ and tightened the existing regulatory structures governing pharmaceutical products.

⁵⁷³ Sidley, P., "South Africa Withdraws TB Drugs Because Of Quality Concerns." *British Medical Journal* (20 Aug 2008) 337:7667, available at http://www.bmj.com/cgi/content/extract/337/aug20_1/a1385 (accessed 25 Jan 2010)

⁵⁷⁴ Kniaz, S., "Le Raison de Résistance: Substandard TB Drugs Found in South Africa." *Center for Global Development Global Health Policy Blog* (Aug 18 2009), available at <http://blogs.cgdev.org/globalhealth/2008/08/le-raison-de-resistance-substa.php> (accessed Jan 25 2010).

⁵⁷⁵ "Counterfeit Medical Products Seized In Lesotho Interpol-Supported Operation." *INTERPOL Media Release* (Jul 29 2009), available at <http://www.interpol.int/public/ICPO/PressReleases/PR2009/PR200973.asp> (accessed Jan 23 2010).

⁵⁷⁶ Ibid.

⁵⁷⁷ Ngubane, S., "Local Chemists Selling Illegal Drugs." *Times of Swaziland* (Dec 13 2009), available at http://www.swazilive.com/Swaziland_News/Swaziland_News_Stories.asp?News_id=1069 (accessed Jan 25 2010).

⁵⁷⁸ Smart, T., "Medicines Control Council Blocks Generic Anti-Hiv Drugs Imports From Swaziland Into South Africa." *AIDSMAP* (Apr 24 2003), available at <http://www.aidsmap.com/en/news/4292756A-DA63-4682-BAAE-6B05928E2937.asp> (accessed Jan 25 2010).

⁵⁷⁹ "Zambia." available at <http://www.notofakes.com/Resources/TravelAdvisory/Africa/Zambia/tabid/356/Default.aspx> (accessed 24 Jan 2010).

⁵⁸⁰ Lian, Liu. "Tasly Zambia Attended PRA Press Conference." *Tasly Online* (Apr 22 2009), available at <http://www.taslyint.com/show.aspx?id=321&cid=6> (accessed Jan 25 2010).

⁵⁸¹ "Zambia: State Acts to Curb Counterfeit Drugs." *The Times of Zambia* (Nov 12 2008), available at <http://allafrica.com/stories/200811120648.html> (accessed Jan 22 2010).

Zimbabwe

In 2006, a Zimbabwean health professional warned that the country's deteriorating health services had made room for a thriving parallel market for drugs, many of them counterfeit.⁵⁸² According to Dr. Paul Chimedza, the president of the Zimbabwe Medical Association (ZIMA), the sale of genuine as well as fake medicines on the streets is a "big, booming business."⁵⁸³ In the parallel, informal market, Zimbabweans pay much less for drugs than they do at a registered pharmacy, often between five to eight times less. In the informal market, a month's course of antiretroviral medication could cost anywhere from US\$200 to \$400, while this same amount would cost almost \$1,200 from a legitimate source.⁵⁸⁴ But the low prices come with high risk, as there is no quality control for drugs obtained in the parallel market. Buying drugs off the street can be dangerous, even where the drugs are genuine, because they are often not stored under prescribed conditions and can cause side effects to consumers.⁵⁸⁵

According to health officials, the high cost of antiretroviral (ARV) drugs and inadequate control mechanisms in Zimbabwe drive a flourishing trade in fake ARVs by unlicensed dealers.⁵⁸⁶ In September 2007, the Medicines Control Authority of Zimbabwe (MCAZ) issued a statement to warn the public that contaminated, diluted, and counterfeit antiretrovirals were being imported and sold in both flea markets and hairdressing salons throughout the country in the face of growing shortages in clinics linked to Zimbabwe's economic crisis.^{587 588}

In 2009, Zimbabwean police launched an operation called "Operation Zambezi," targeting pharmacies, surgeries, clinics and open market shops operating illegally or dealing in counterfeit drugs.⁵⁸⁹ This operation led to the arrest of 51 people, including six doctors, for allegedly dispensing expired and unregistered drugs.⁵⁹⁰

Chief Superintendent Oliver Mandipaka reported that during the operation it was discovered that some doctors were dispensing medicines, including expired and unregistered drugs, without

⁵⁸² "Zimbabwe: Sick Economy Fuels Growth Of Fake Drug Market." *UN Integrated Regional Information Networks (IRIN)* (Dec 11 2006), available at <http://www.irinnews.org/report.aspx?reportid=62413> (accessed Jan 25 2010).

⁵⁸³ "Zimbabwe: Sick Economy Fuels Growth Of Fake Drug Market." *UN Integrated Regional Information Networks (IRIN)* (Dec 11 2006), available at <http://www.irinnews.org/report.aspx?reportid=62413> (accessed Jan 25 2010).

⁵⁸⁴ Ibid.

⁵⁸⁵ Ibid.

⁵⁸⁶ "Zimbabwe: Sick Economy Fuels Growth Of Fake Drug Market." *UN Integrated Regional Information Networks (IRIN)* (Dec 11 2006), available at <http://www.irinnews.org/report.aspx?reportid=62413> (accessed Jan 25 2010).

⁵⁸⁷ Ibid.

⁵⁸⁸ "Fake AIDS Drugs Flood Stricken Zimbabwe." *The Associated Press* (Sep 11 2007), available at <http://www.msnbc.msn.com/id/20716622/> (accessed Jan 25 2010).

⁵⁸⁹ "Many Arrested for Selling Expired, Fake Medicine in Zimbabwe." *Harare Tribune* (Nov 9 2009), available at <http://www.hararetribune.com/health-a-science/public-policy/537-many-arrested-for-selling-expired-fake-medicine-in-zimbabwe-.html> (accessed Jan 25 2010).

⁵⁹⁰ "51 Arrested in Police Raids." *The Herald* (Nov 7 2009), available at <http://allafrica.com/stories/200911090056.html> (accessed Feb 1 2010).

proper licenses.⁵⁹¹ In some pharmacies, police discovered unqualified personnel dispensing medicines and unregistered drugs.⁵⁹²

⁵⁹¹ Ibid.

⁵⁹² Ibid.

Middle East and North Africa

Middle East

According to WHO figures, fakes account for as much as 35 percent of the drug market in the region. Available data suggests that Viagra, antibiotics, psychotropic drugs, and oncology heart and liver medicines are most commonly counterfeited.

Disturbingly, fake drugs appear to have penetrated both the informal and formal sectors in Western Asia. Free trade zones—specially designated areas with no tariffs and minimal regulatory oversight to encourage trade — undermine the safety of supply chains and encourage illicit activity. In 2008, EU customs officials reported that a third of the medicines they confiscated along its borders originated from the UAE, which has several free trade zones.⁵⁹³

Other factors which contribute to the prevalence of counterfeits include a lack of appropriate legislation, weak regulatory authorities, poor enforcement, corruption, and the sheer sophistication of the illegal drug manufacturing industry.^{594,595}

In many of the former Soviet republics fake drugs represent roughly a fifth of the market.⁵⁹⁶

Azerbaijan

Although data is limited, existing numbers indicate Azerbaijan has a thriving counterfeit drug market. In 2006, the Azerbaijan Ministry of Health inspected more than 230 pharmacies in Baku, the country's capital and largest city, and found that 33 brands of pharmaceuticals were substandard. The government took swift action, closing 12 pharmacies and withdrawing all affiliated drugs from pharmacy shelves.⁵⁹⁷

Iraq

Sayed Kathem Khawasiya, inspector general for the Ministry of Health (MOH), reported in 2008 approximately 20 percent of medicines in the Iraqi market were outright fakes.⁵⁹⁸ Substandard, unregistered and expired drugs are also a problem in the country. According to Adil Muhsin-Generalin, the Iraqi Health Ministry Director, approximately 70 percent of the medicines in Iraq

⁵⁹³ Bogdanich, W., "Counterfeit Drugs' Path Eased by Free Trade Zones." *The New York Times* (Dec 17 2007), available at <http://www.nytimes.com/2007/12/17/world/middleeast/17freezone.html> (accessed Feb 24 2010).

⁵⁹⁴ Ibid.

⁵⁹⁵ Faucon, B., "No Cure For Fake Drugs." *The Wall Street Journal* (Feb 16 2010), available at <http://online.wsj.com/article/SB10001424052748704533204575047282075703998.html> (accessed Feb 22 2010).

⁵⁹⁶ "Counterfeit Medicine Factsheet," *World Health Organization* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Feb 19 2010).

⁵⁹⁷ "Measles/Rubella Vaccination Funded in Azerbaijan." *SCRIP News* (Mar 29 2006), available at <http://www.scripnews.com/home/news/Measlesrubella-vaccination-funded-in-Azerbaijan-62292> (accessed Jan 29 2010).

⁵⁹⁸ Levinson, C., "Iraq Returns To Its Alternative Medicine Roots." *USA Today* (Nov 2 2008), available at http://www.usatoday.com/news/world/iraq/2008-11-02-herbalmeds_N.htm (accessed Jan 28 2010).

in 2008 were expired or imported illegally.⁵⁹⁹ Many of the illegitimate drugs enter Iraq from Syria.⁶⁰⁰

According to the MOH, 90 percent of medicines are imported by companies which are not registered in Iraq. And many importers and local companies have not tested the products properly. Due to poor regulation, pharmacies and stores are filled with counterfeit or substandard products. According to Adel Mohsin, the Health Ministry's inspector general, the Ministry collected 100 samples in 2009 from local pharmacies. All samples failed quality tests, and some even contained poisonous substances.⁶⁰¹

In September 2008, the Iraqi government committed itself to enforcing existing international drug regulations. Under enhanced enforcement measures, one sample from each incoming shipment is to be tested for efficacy, and the shipment is to be held until the sample passes all requisite tests. Teams of inspectors will perform spot checks of pharmacies and drug warehouses, and have already stepped up investigations and raids on markets where counterfeit dealers operate.⁶⁰² From September to November, the government raided 120 illegal pharmacies.⁶⁰³

New enforcement measures, however, have been fraught with corruption. Local residents and pharmacies owners complained in 2009 that corrupt soldiers and law enforcement officials from the Iraqi Army and National Guard often burglarize local businesses rather than cracking down on fraudulent pharmacies.⁶⁰⁴

Every Iraqi physician surveyed in a 2009 study expressed dissatisfaction with the increase in counterfeit drugs circulation in Iraq; all urged the National Drug Quality Control Laboratory and the Ministry of Health to solve this problem and prevent distribution and usage of these drugs.⁶⁰⁵

⁵⁹⁹ "Iraq: Fake Drugs A Danger To Public Health, Says Un Official." *Adnkronos International* (Aug 25 2008), available at <http://www.adnkronos.com/AKI/English/Security/?id=1.0.2435160516> (accessed Jan 28 2010).

⁶⁰⁰ "Iraq Pharmaceuticals and Healthcare Report." *Business Monitor International* (Jul 2010), available at <http://www.reportlinker.com/p0240012/Iraq-Pharmaceuticals-and-Healthcare-Report-Q3.html>. (accessed Feb 4 2011).

⁶⁰¹ "Trade in Counterfeit Drugs in Jordan Drops." *AME Info* (Jun 8, 2009), available at http://www.newstin.com/related.a?edition=us&group_id=en-010-014988648&similarFilter=ALL. (accessed Jan 28 2010).

⁶⁰² Susman, T. and Ahmad, C., "Iraq Takes On Fake Drugs," *Los Angeles Times* (Aug 30 2008), available at <http://articles.latimes.com/2008/aug/30/world/fg-iraqdrugs30> (accessed Feb 11 2010).

⁶⁰³ Levinson, C., "Iraq Returns To Its Alternative Medicine Roots," *USA Today* (Nov 2 2008), available at http://www.usatoday.com/news/world/iraq/2008-11-02-herbalmeds_N.htm (accessed Jan 28 2010).

⁶⁰⁴ "Fake Pharmacies Plague Iraq," *Alive in Baghdad* (Jan 27 2009), available at <http://www.aliveinbaghdad.org/2009/01/27/fake-pharmacies-plague-iraq/> (accessed Feb 11 2010).

⁶⁰⁵ Sharrad, A.K., Hassali, M.A. and Shafie, A.A., "Generic Medicines: Perceptions of Physicians in Basrah, Iraq." *Australasian Medical Journal* (2009), 1:8, available at [http://www.amj.net.au/index.php?journal=AMJ&page=article&op=viewFile&path\[\]=82&path\[\]=295](http://www.amj.net.au/index.php?journal=AMJ&page=article&op=viewFile&path[]=82&path[]=295) (accessed Feb 11 2010).

While the problem is acute, government officials are hopeful that recent legislation passed in Syria will help curb the influx of substandard medications to Iraq.⁶⁰⁶

Israel

In 2007, according to the Manufacturers Association of Israel (MAI), sales of out-of-date, counterfeit, and stolen medicine for human and veterinary use reached between USD 28-37 million.⁶⁰⁷ In 2009, the Pharmaceutical Security Institute reported 52 instances of counterfeit drugs seized/discovered in Israel, making it the 9th highest ranking country in the world.⁶⁰⁸ That same year, the Israeli Health Ministry estimated that more than 50 percent of prescription medications advertised in Israel's print media are counterfeit.⁶⁰⁹

Cases of counterfeit drugs are widely reported in Israel, and commonly involve anti-impotence drugs and general antibiotics. In 2007, the Israeli Customs Authority seized a shipment of counterfeit drugs from a container ship from China which included 11,820 fake Viagra pills, 800 fake Cialis pills, and several hundred other unidentified pills.⁶¹⁰ A 2008 raid led to the seizure of a leukemia treatment that contained no active ingredients.⁶¹¹ That same year, inspectors from the Israeli police and Health Ministry found 6,000 suspected counterfeit pills in Tel Aviv, Haifa, and Jerusalem, including anti-impotence drugs, anti-narcolepsy drugs, contraceptives, antibiotics, and psychotropic drugs.⁶¹² The following year, the Health Ministry shut down Neve Avivim Pharmacy in Ramat Aviv, which was selling counterfeit and unregistered medicines.⁶¹³ In December 2009, the Tel Aviv Public Prosecution successfully tried a ring of counterfeiters, who had been distributing anti-impotence pills through the internet, under the Criminal Code. Two of the defendants were sentenced to 16 months in prison and fined USD 14,000.⁶¹⁴

⁶⁰⁶ "Iraq Pharmaceuticals and Health Report." *Business Monitor International* (Jul 2010), available at <http://www.reportlinker.com/p0240012/Iraq-Pharmaceuticals-and-Healthcare-Report-Q3.html>. (accessed Feb 4 2011).

⁶⁰⁷ "MAI: Sale of Counterfeit and Out of Date Pharmaceuticals in 2007 was NIS100-130 Million." *Port 2 Port* (Apr 14 2008), available at <http://www.port2port.com/Index.asp?CategoryID=46&ArticleID=1707> (accessed Jan 22 2010).

⁶⁰⁸ Widup Jr., Richard. "Pharma Fights Back: How to Combat Counterfeit Drugs Online." *MarkMonitor Webinar* (Mar 24 2011), available at

⁶⁰⁹ Siegel-Itzkovich, J., "Israel Joins World Effort To Halt Counterfeit Drug Sales." *The Jerusalem Post* (Nov 16 2008), available at <http://www.highbeam.com/doc/1P1-158297879.html> (accessed Jan 21 2010).

⁶¹⁰ "Ashod Customs Seizes Nis 1 Million Counterfeit Viagra Pills." *Port 2 Port*. (Mar 5 2007), available at <http://www.port2port.com/Index.asp?CategoryID=43&ArticleID=1258> (accessed Mar 10 2010).

⁶¹¹ Faucon, B., "In Developing World, Police Investigate Drug Counterfeiting." *Dow Jones Newswires* (Apr 29 2009), available at http://forexdaily.org.ru/Dow_Jones/page.htm?id=553622 (accessed May 11 2011).

⁶¹² Siegel-Itzkovich, J., "Israel Joins World Effort to Halt Counterfeit Drug Sales." *The Jerusalem Post* (Nov 16 2008), available at <http://www.highbeam.com/doc/1P1-158297879.html> (accessed Jan 21 2010).

⁶¹³ Rozenberg, R., "Fake Drugs May Bring You Fake Health." *Haaretz*. (Nov 29 2009), available at <http://www.resourcing.uk.com/news/pharmacy-news/-fake-drugs-may-bring-you-fake-health.aspx> (accessed Jan 20 2010).

⁶¹⁴ Factor, M., "Israel Court Issues Stiff Sentence to Fake Viagra Distributors." *The IP Factor* (Dec 31 2009), available at <http://blog.ipfactor.co.il/2009/12/31/israel-court-issues-stiff-sentence-to-fake-viagra-distributors/> (accessed Feb 5 2010).

Mickey Arieli, the director of the pharmaceutical crime unit at Israel's Ministry of Health, asserts that the majority of the medical counterfeits found in Israel were made in China.⁶¹⁵ Even fake drugs with Hebrew packaging are more likely to be made in China than in Israel.⁶¹⁶

In order to stem the rising tide of counterfeit imports, the Health Ministry established the Pharmaceutical Crime Unit (PCU) in 2007. As of November 2009, it only had three employees—a lab technician, a former head of police, and an inspector with a Ph.D. in Pharmacy. Despite its small staff, the PCU has uncovered multiple smuggling rings. It has confiscated **counterfeit** Tamiflu, exposed an illegal trading ring selling Ritalin which causes non-ADHD patients to get "high," and intercepted ping-pongs balls containing the raw material used for producing Viagra at Ben-Gurion airport.⁶¹⁷

As of 2009, the punishment for counterfeiting pharmaceuticals in Israel is six months in jail and a USD 3,227 fine.⁶¹⁸

Jordan

In 2007, the head of Jordan Pharmacists Association (JPA), Taher Shakhshsheer, reported that approximately USD 16.9 million worth of counterfeit medicines were confiscated by Jordanian officials that year. Most of these drugs had been imported from China and India.⁶¹⁹

According to Leila Jarrar, head of the Jordan Food and Drug Administration, most of the fake drugs seized in Jordan came from China, and were illegally transported through free trade zones in Dubai or the Jordanian port of Aqaba. Many were on their way to Iraq.⁶²⁰

Counterfeits in Jordan are found in both the formal and informal sectors. In 2007, the Jordan Food and Drug Administration (JFDA) closed 150 of the country's 1700 pharmacies which had proven links to counterfeit traders.⁶²¹ The following year, another 431 pharmacies were discovered to be in violation of current pharmaceutical regulation, and the 14 with proven links to the counterfeit industry were closed. Of the remaining pharmacies in violation, 346 had no

⁶¹⁵ Faucon, B., "In Developing World, Police Investigate Drug Counterfeiting." *Dow Jones Newswires* (Apr 29 2009), available at http://forexdaily.org.ru/Dow_Jones/page.htm?id=553622 (accessed May 11 2011).

⁶¹⁶ Faucon, B., "In Developing World, Police Investigate Drug Counterfeiting." *Dow Jones Newswires* (Apr 29 2009), available at <http://www.zawya.com/printstory.cfm?storyid=ZW20090429000166&l=152446090429#ZW20090429000166> (accessed Mar 16 2010).

⁶¹⁷ Siegel-Itzkovich, J., "Psst! Wanna Buy Some Pills?" *The Jerusalem Post* (Nov 29 2009), available at <http://bx.businessweek.com/pharmaceutical-manufacturing/psst-wanna-buy-some-pills/13996189214420269076-ec45a4904fa5eb697cdcc3546e75b06/> (accessed Feb 5 2010).

⁶¹⁸ Ibid.

⁶¹⁹ Halteh, S., "Unified Efforts Needed To Combat Counterfeited Medicines In Jordan – Experts Say." *AG-IP News* (Apr 15 2008), available at http://www.ag-ip-news.com/getArticle.asp?Art_ID=5736&lang=en (accessed Jan 28 2010).

⁶²⁰ Faucon, B., "In Developing World, Police Investigate Drug Counterfeiting." *Dow Jones Newswires* (Apr 29 2009), available at http://forexdaily.org.ru/Dow_Jones/page.htm?id=553622 (accessed May 11 2011).

⁶²¹ Halteh, S., "Unified Efforts Needed To Combat Counterfeited Medicines In Jordan – Experts Say." *AG-IP News* (Apr 15 2008), available at http://www.ag-ip-news.com/getArticle.asp?Art_ID=5736&lang=en (accessed Jan 28 2010).

licensed pharmacists on staff, 57 were selling free medical samples, 34 were purchasing smuggled drugs, and 45 stocked medications which were either untraceable or unregistered.⁶²² The JFDA increased the number of investigations conducted again in 2009, and closed an additional 75 pharmacies out of the 304 found to be in violation of drug laws.⁶²³ The number of forced closures spiked in 2009 when the JFDA ordered the closure of pharmacies operating without a licensed pharmacist and selling smuggled medications, in addition to the pharmacies dealing with counterfeit traders.⁶²⁴

The JFDA has made major strides in decreasing the Jordanian trade in counterfeit and smuggled drugs through a variety of avenues.⁶²⁵ In both 2008 and 2009, the administration ramped up the number of inspections, hired new drug inspectors and began to regularly inspect beauty and fitness centers, printing presses, and herbal shops.⁶²⁶ New laws increased the severity of punishment for those selling counterfeit drugs, and fines for counterfeiting doubled from USD 7,500 to USD 15,000.⁶²⁷ Furthermore, the jail term for drug counterfeiting increased from six months to between three to five years.⁶²⁸ Experts agree the new JFDA restrictions are slowly but effectively attacking the counterfeit industry.⁶²⁹

Kuwait

During a series of raids conducted in 2009 by Food and Drug Control Administration (FDCA) in Gujarat, India, officials seized USD 131,868 worth of fake drugs from a transport company, which were destined for Kuwait, Saudi Arabia, Yemen, and South Africa.⁶³⁰⁶³¹ Medicines called

⁶²²“Report: Hundreds of pharmacies in Jordan violated the law in 2008.” *Jordan Times* (12 Dec 2009) available at http://www.menafn.com/qn_news_story_s.asp?storyid=1093288415 (accessed 28 Mar 2010)

⁶²³ “Jordan Pharmacy Closures On The Up.” *SecuringPharma* (Jan 15 2010), available at <http://www.securingspharma.com/40/articles/350.php> (accessed Feb 5 2010).

⁶²⁴ “Jordan Pharmacy Closures On The Up.” *SecuringPharma* (Jan 15 2010), available at <http://www.securingspharma.com/40/articles/350.php> (accessed Feb 5 2010).

⁶²⁵ “Trade in Counterfeit Drugs in Jordan Drops,” *AME Info* (Jun 8 2009), available at http://www.newstin.com/related.a?edition=us&group_id=en-010-014988648&similarFilter=ALL (accessed Jan 28 2010).

⁶²⁶ “Trade in Counterfeit Drugs in Jordan Drops,” *AME Info* (Jun 8 2009), available at http://www.newstin.com/related.a?edition=us&group_id=en-010-014988648&similarFilter=ALL (accessed Jan 28 2010).

⁶²⁷ *Ibid.*

⁶²⁸ Faucon, B., “In Developing World, Police Investigate Drug Counterfeiting.” *Dow Jones Newswires* (Apr 29 2009), available at http://forexdaily.org.ru/Dow_Jones/page.htm?id=553622 (accessed May 11 2011).

⁶²⁹ “Trade in Counterfeit Drugs in Jordan Drops,” *AME Info* (Jun 8 2009), available at http://www.newstin.com/related.a?edition=us&group_id=en-010-014988648&similarFilter=ALL (accessed Jan 28 2010).

⁶³⁰ “Fake Sex Drugs for Saudi, Kuwait, seized in Gujarat,” *Q8NRI* (Aug 10 2009), available at <http://www.q8nri.com/home/2009/08/10/fake-sex-drugs-for-saudi-kuwait-siezed-in-gujarat/> (accessed Mar 12 2010).

⁶³¹ “Fake Sex Drugs for Saudi, Kuwait, seized in Gujarat,” *Q8NRI* (Aug 10 2009), available at <http://www.q8nri.com/home/2009/08/10/fake-sex-drugs-for-saudi-kuwait-siezed-in-gujarat/> (accessed Mar 12 2010).

‘Ramagra’ and ‘Kamagra,’ fake versions of Viagra, are commonly found in Kuwait, and often come from India.⁶³²

Lebanon

In 2004, a report by Lebanon’s National Health Commission (NHC) estimated that roughly 35 percent of pharmaceuticals available in the Lebanese market were counterfeit.⁶³³ In 2007, the Lebanese minister of health, Mohammed Khalifa, reported that the attorney general was investigating 43 pharmacies and individual pharmacists for the sale of counterfeit drugs.⁶³⁴ Commonly counterfeited medicines include anti-impotence drugs, common painkillers, and antidepressants.⁶³⁵

In August 2008, Lebanon's Ministry of Health launched a public awareness campaign to clamp down on counterfeit drug trade, following a rise in cases of adverse reactions reported by healthcare workers.⁶³⁶ In 2009, the Health ministry, in collaboration with pharmaceutical companies, launched a televised awareness campaign aimed at the broader public.

Thanks to a new marking system, patients can now check the medicine’s authenticity by calling a national helpline. All legitimate drugs entering the country since March 2010 have been marked with a sticker which reads "Living Proof," and contains a unique alphanumeric code. The code can be revealed by scratching a gray panel on the box, and verified via cellular phone. Once the code has been verified, it cannot be reused.⁶³⁷

While this campaign has been met with support, anti-counterfeiting campaigners insist many more changes must be made. Advocates argue for increased policy support, a coherent national drug policy, a drug testing laboratory to maintain national quality control, and a change the legal status of counterfeiting under Lebanese law. The production and sale of counterfeit medicines is considered an intellectual property violation, punishable by a fine of USD 6,000–30,000 and a jail sentence of 1–3 years. Sentences can become harsher if evidence of harm is presented, but judges often ignore this stipulation. Proponents of a new law argue the punishments should be

⁶³² “Fake Sex Drugs for Saudi, Kuwait, seized in Gujarat,” *Q8NRI* (Aug 10 2009), available at <http://www.q8nri.com/home/2009/08/10/fake-sex-drugs-for-saudi-kuwait-siezed-in-gujarat/> (accessed Mar 12 2010).

⁶³³ “Fake Sex Drugs for Saudi, Kuwait, seized in Gujarat,” *Q8NRI* (Aug 10 2009), available at <http://www.q8nri.com/home/2009/08/10/fake-sex-drugs-for-saudi-kuwait-siezed-in-gujarat/> (accessed Mar 12 2010).

⁶³⁴ Ghosn, Z., “Lebanon Launches Campaign To Counter Fake Drugs,” *SciDev.Net* (Aug 28 2008), available at <http://www.scidev.net/en/china/news/lebanon-launches-campaign-to-counter-fake-drugs.html> (accessed Mar 1 2010).

⁶³⁵ Ghosn, Z., “Lebanon Launches Campaign To Counter Fake Drugs,” *SciDev.Net* (Aug 28 2008), available at <http://www.scidev.net/en/china/news/lebanon-launches-campaign-to-counter-fake-drugs.html> (accessed Mar 1 2010).

⁶³⁶ Ghosn, Z., “Lebanon Launches Campaign To Counter Fake Drugs,” *SciDev.Net* (Aug 28 2008), available at <http://www.scidev.net/en/china/news/lebanon-launches-campaign-to-counter-fake-drugs.html> (accessed Mar 1 2010).

⁶³⁷ Hall, R., “New Coded Stickers To Help Consumers Identify Counterfeit Medicine,” *The Daily Star* (Mar 20 2010), available at <http://dailynews.com/story/2010032000000666/coded-stickers-consumers-identify-counterfeit-medicine.html> (accessed Mar 29 2010).

harsher, citing a 2007 case where the owner of a hospital and five employees were jailed for a single month after substituting water for a USD 2,000 cancer drug.⁶³⁸

In 2010, 12 pharmacies and four medical supplies warehouses were closed by the Ministry of Health for smuggling and selling counterfeit drugs.⁶³⁹ The head of the Parliamentary Health Committee, Atef Majdalani, warned that counterfeit drugs still posed a danger to hundreds of Lebanese each year. He is currently attempting to pass a draft law banning the advertisement of counterfeit or imitation drugs, thereby establishing the country's first laws prosecuting counterfeit sales.⁶⁴⁰

Palestine

In August 2007, the Palestinian Ministry of Health implemented new standards to prevent stolen and counterfeit medicines from reaching pharmacy shelves. The Ministry committed to monitoring drug manufacturers and ensuring that pharmacists only buy drugs from licensed companies.⁶⁴¹

In March 2008, four tons of counterfeit medicines were seized in al-Ram, while an estimated USD 2 million worth of counterfeit drugs (sixteen different types, including cancer treatments) were seized in Nablus.⁶⁴² In May 2008, three people were arrested in conjunction with a government seizure of large quantities of expired medicines from three unlicensed stores and warehouses in the West Bank city of Hebron.⁶⁴³

Over the past two years, Palestinian authorities have discovered multiple dangerous counterfeiting rings. In December 2008, Palestinian police uncovered a network of smugglers and local manufacturers of dangerous placebo pills intended for sale in Palestine and elsewhere

⁶³⁸ Ghosn, Z., "Lebanon Launches Campaign To Counter Fake Drugs," *SciDev.Net* (Aug 28 2008), available at <http://www.scidev.net/en/china/news/lebanon-launches-campaign-to-counter-fake-drugs.html> (accessed Mar 1 2010).

⁶³⁹ Hall, R., "New Coded Stickers To Help Consumers Identify Counterfeit Medicine," *The Daily Star* (Mar 20 2010), available at <http://dailyme.com/story/2010032000000666/coded-stickers-consumers-identify-counterfeit-medicine.html> (accessed Mar 29 2010).

⁶⁴⁰ "Officials Urge Crackdown On Counterfeit Drugs." *The Daily Star* (Jan 18 2010) available at: [http://investing.businessweek.com/research/stocks/news/article.asp?docKey=600-201001180052KRTRIB_BUSNEWS_28668-309F9VSVF7Q4A8M829U94NIGA9¶ms=timestamp||01/18/2010\)percent2012:52 percent20AM percent20ET||headline||Officials percent20urge percent20crackdown percent20on percent20counterfeit percent20drugs percent3A percent20MP percent20calls percent20on percent20Parliament percent20committee percent20to percent20consider percent20Draft percent20law percent20to percent20ban percent20fake percent20medicine percent20|The percent20Daily percent20Star percent20C percent20Beirut percent20C percent20Lebanon||docSource||The percent20McClatchy percent20Company||provider||ACQUIREMEDIA&ticker=ABT:US](http://investing.businessweek.com/research/stocks/news/article.asp?docKey=600-201001180052KRTRIB_BUSNEWS_28668-309F9VSVF7Q4A8M829U94NIGA9¶ms=timestamp||01/18/2010)percent2012:52 percent20AM percent20ET||headline||Officials percent20urge percent20crackdown percent20on percent20counterfeit percent20drugs percent3A percent20MP percent20calls percent20on percent20Parliament percent20committee percent20to percent20consider percent20Draft percent20law percent20to percent20ban percent20fake percent20medicine percent20|The percent20Daily percent20Star percent20C percent20Beirut percent20C percent20Lebanon||docSource||The percent20McClatchy percent20Company||provider||ACQUIREMEDIA&ticker=ABT:US) (accessed Mar 1 2010).

⁶⁴¹ "Palestinian Health Ministry To Introduce New Drug Standards." *Maan News Agency* (Aug 30 2007), available at <http://www.maannews.net/eng/ViewDetails.aspx?ID=198601> (accessed 22 Feb 2010)

⁶⁴² "Palestinian Health Minister: Investigations Continuing Into Counterfeit Medicines." *Maan News Agency* (Mar 21 2008) available at <http://www.maannews.net/eng/ViewDetails.aspx?ID=201743> (accessed Feb 22 2010).

⁶⁴³ "Expired Medicine Seized in Hebron," *Maan News Agency* (May 19 2008), available at <http://www.maannews.net/eng/ViewDetails.aspx?ID=202666> (accessed Feb 22 2010).

in the Middle East.⁶⁴⁴ Days earlier, police in Nablus had seized several boxes of fake medicines from China hidden inside large containers. Most of the drugs were for heart and other chronic diseases, and contained no active chemicals; the medicines were to be sold at a discount of 20-50 percent.⁶⁴⁵ In November 2009, police seized the contents of five cosmetic and medical factories, confiscating raw materials and medicines. These five factories, which had been in operation since 2004, had been manufacturing counterfeit products and relabeling expired drugs, then selling their products to local markets.⁶⁴⁶ Fersan Bani Jaber, head of the Customs Office, claimed that the factories had obtained their materials from illegal Israeli settlements in the West Bank.⁶⁴⁷

One million pills were confiscated by Palestinian authorities in 2009.^{648 649}

Palestinian Authority Health Minister Fathi Abu-Moghli believes that the chaos following the eruption of the second Intifada in 2000 increases the risk that counterfeits enter the West Bank supply chains.⁶⁵⁰ Others assert that corruption has played a role in the proliferation of counterfeits in Palestinian territories. In an attempt to address this problem, the head of the Palestinian Union of Pharmacists, Mahmoud Salaymah, was arrested in March 2008 and detained at the request of the Palestinian attorney general for further interrogation concerning expired and counterfeit medicines.⁶⁵¹

Qatar

Qatar has recently faced an influx of fake diet pills from neighboring countries. Despite strict warnings from the Drugs Control Department at the Supreme Council of Health, these pills continue to slip into the country.⁶⁵² Most appear to have originated in China, and many contain a

⁶⁴⁴ "Counterfeit Medicine Smuggling Ring Discovered In Nablus." *Maan News Agency* (Dec 3 2008), available at <http://www.maannews.net/eng/ViewDetails.aspx?ID=201618> (accessed Feb 22 2010).

⁶⁴⁵ "Counterfeit Medicine Smuggling Ring Discovered In Nablus." *Maan News Agency* (Dec 3 2008), available at <http://www.maannews.net/eng/ViewDetails.aspx?ID=201618> (accessed Feb 22 2010).

⁶⁴⁶ "Palestinian Police Continue Seizure of Expired and Counterfeit Cosmetics, Drugs and Detergents," *Maan News Agency* (Apr 11 2009), available at <http://www.maannews.net/eng/ViewDetails.aspx?ID=209799> (accessed Feb 22 2010).

⁶⁴⁷ "Palestinian Police Continue Seizure of Expired and Counterfeit Cosmetics, Drugs and Detergents," *Maan News Agency* (Apr 11 2009), available at <http://www.maannews.net/eng/ViewDetails.aspx?ID=209799> (accessed Feb 22 2010).

⁶⁴⁸ "Egypt Seizes Large Amount Of Suspected Fake Drugs," *Dow Jones* (May 1 2009), available at <http://www.easybourse.com/bourse/actualite/egypt-seizes-large-amount-of-suspectedfake-661006> (accessed Feb 22 2010).

⁶⁴⁹ "Police Seize Expired Milk, Counterfeit Pills at Hebron Dairy," *Maan News Agency* (Feb 16 2010), available at <http://www.maannews.net/eng/ViewDetails.aspx?ID=261826> (accessed Feb 22 2010).

⁶⁵⁰ Faucon, B., "In Developing World, Police Investigate Drug Counterfeiting," *Dow Jones Newswires* (Apr 29 2009), available at http://forexdaily.org.ru/Dow_Jones/page.htm?id=553622 (accessed May 11 2011).

⁶⁵¹ "Pharmacists' Union Head Still Being Questioned," *Maan News Agency* (Mar 27 2008), available at <http://www.maannews.net/eng/ViewDetails.aspx?ID=201858> (accessed Feb 22 2010).

⁶⁵² "Qatar: SCH Cautions Against Use Of Slimming Pills." *MENAFN* (Mar 10 2010), available at http://www.menafn.com/qn_news_story_s.asp?storyid=1093312615 (accessed Mar 10 2010).

dangerous chemical, not listed in the ingredients, which is internationally banned because of its dangerous side effects.⁶⁵³

Saudi Arabia

In October 2008, the director of a pharmaceutical manufacturing company, Abdullah Al-Abdelgader, estimated that around 30-40 percent of the medicines sold at pharmacies and hospitals in the Kingdom were counterfeit.⁶⁵⁴ In 2009, it was estimated that roughly 14 percent of the medicines sold in the Kingdom were fake.⁶⁵⁵

In 2009, several raids led Saudi police to seize nearly 4 million anti-depressant treatments and arrested several drug traffickers.⁶⁵⁶ Authorities shut down an unlicensed clinic for weight loss pills, and seized a large quantity of fake medications during the raid.⁶⁵⁷

In 2009, the government formed the Saudi Food and Drug Authority (SFDA) to monitor and stop counterfeit medicines. Ibrahim Alshowaier, an SFDA Consultant, offered the following insight: “[The counterfeit drug trade is] not big in Saudi Arabia, but this doesn’t mean we’re immune from the problem. We’re working closely with pharmaceutical companies...customs...the police to tackle this issue and maintain vigilance... We’re actively taking measures to block the traffic of counterfeit drugs. For example, we advise customs and the police about what to specifically look for, and we’ll have SFDA personnel operating at border controls and working with the customs officials there.” He added that the government’s preventative approach promised to be more effective than identifying fakes already in the country.⁶⁵⁸

Syrian Arab Republic

Syria is a regional hub for the counterfeit drug trade. Syrian companies import, manufacture, and export illegal medications throughout Europe and the Middle East. The European Commission revealed that 37 percent of the fake drugs seized at EU borders during 2008 came from Syria.⁶⁵⁹

⁶⁵³ “Qatar: SCH Cautions Against Use Of Slimming Pills.” *MENAFN* (Mar 10 2010), available at http://www.menafn.com/qn_news_story_s.asp?storyid=1093312615 (accessed Mar 10 2010).

⁶⁵⁴ Al-Iryani, A. and Ba-Swaid, H., “Some 30-40 Percent of Medicines Sold Locally ‘are Counterfeit.” *Saudi Gazette* (Oct 22 2008), available at <http://www.saudigazette.com.sa/index.cfm?method=home.regcon&contentID=2008102219824> (accessed Feb 19 2010).

⁶⁵⁵ Al-Ghamdi, M., “Shoura Members Want Curbs On Fake Medicines.” *Saudi Gazette* (May 10 2009), available at <http://www.saudigazette.com.sa/index.cfm?method=home.regcon&contentID=2009051037546> (accessed Feb 19 2010).

⁶⁵⁶ Ghafour, P.K.A., “Drug Networks Busted,” *Arab News* (Mar 9 2009) available at <http://www.arabnews.com/?page=1§ion=0&article=120059&d=9&m=3&y=2009> (accessed Feb 19 2010).

⁶⁵⁷ Al-Barakati, S., “Clinic with Bogus TV Ads Shuts Down,” *Saudi Gazette* (Mar 22 2009), available at <http://saudigazette.com.sa/index.cfm?method=home.regcon&contentID=2009032232902> (accessed Feb 19 2010).

⁶⁵⁸ “No Country Immune To Counterfeit Drugs.” *Secure Pharma Chain* (Apr 30 2009), available at http://securepharmachain.blogspot.com/2009_04_01_archive.html (accessed Feb 19 2010).

⁶⁵⁹ “Report on EU Customs Enforcement of Intellectual Property Rights: Results at the European Border 2008.” *European Commission Taxation and Customs Union* (2008), available at http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/2009_statistics_for_2008_full_report_en.pdf (accessed Feb 5 2010).

In November 2008, French officials found 350,000 tablet copies of impotence drugs in plastic buckets bound for Honduras; the drugs originated in **Syria**.⁶⁶⁰ In 2009, a Syrian company producing fake Viagra and Lipitor was exposed.⁶⁶¹ In May 2009, Egypt's anti-fraud office released details of a massive seizure of fake diabetes and cancer drugs that were suspected to have come from China via Syria.⁶⁶²

In February 2010, Syrian authorities seized a large amount of counterfeit medicines and busted a vast ring responsible for them. Various raids between April and October of 2009 led to the detainment of 65 people (including smugglers and pharmacists) and netted millions of dollars worth of breast cancer and leukemia medicines, along with tens of thousands of anticoagulant pills; all were fakes with no medicinal value.⁶⁶³

The February 2010 bust, which also seized equipment used to make and package fake drugs, apparently put an end to counterfeit networks of an enormous scale, ending the ring's lucrative trade of counterfeits to Iraq, Turkey, Lebanon, Iran and Egypt. Distribution networks were enormous and far-reaching; this particular ring sold large quantities to private pharmacies, but had also managed to infiltrate public health-care systems as well, penetrating hospitals in Iraq. According to reports, the Iraqi health ministry logo was emblazoned across hundreds of boxes of medication for mouth ulcers which were found in huge plastic bags seized in Damascus.⁶⁶⁴

Syrian Health Minister Reda Saed explains that the counterfeit manufacturers began as a smuggling ring, importing counterfeit drugs from China. Sometime around 2007, however, the ring began to manufacture its own fakes, using Chinese technology and raw materials.⁶⁶⁵

In response to increasing criticism from the international community, the Syrian government recently passed legislation increasing penalties for counterfeiting. Smugglers and illegal manufacturers may now face criminal charges and up to twenty years of hard labour.⁶⁶⁶

Turkey

Turkey has more than 24,000 pharmacies, many of which operate at the high standards of Northern European or U.S. pharmacies. However, there are hundreds, possibly thousands, of

⁶⁶⁰ "Major Fake Drugs Hauls in France, Seized In Transit." *Pharma Marketletter* (Nov 21 2008).

⁶⁶¹ "Egypt Seizes Large Amount Of Suspected Fake Drugs," *Secure Pharma Chain* (May 4 2009), available at <http://securepharmachain.blogspot.com/2009/05/egypt-seizes-large-amount-of-suspected.html> (accessed Jan 28 2010).

⁶⁶² Harris, J., "Swinish Profit From Fever." *The Daily News Egypt* (May 7 2009), available at <http://www.thedailynewsegypt.com/article.aspx?ArticleID=21531> (accessed Feb 5 2010).

⁶⁶³ Faucon, B., "No Cure For Fake Drugs." *The Wall Street Journal* (Feb 16 2010), available at <http://online.wsj.com/article/SB10001424052748704533204575047282075703998.html> (accessed Feb 22 2010).

⁶⁶⁴ Faucon, B., "No Cure For Fake Drugs." *The Wall Street Journal* (Feb 16 2010), available at <http://online.wsj.com/article/SB10001424052748704533204575047282075703998.html> (accessed Feb 22 2010).

⁶⁶⁵ Faucon, B., "No Cure For Fake Drugs." *The Wall Street Journal* (Feb 16 2010), available at <http://online.wsj.com/article/SB10001424052748704533204575047282075703998.html> (accessed Feb 22 2010).

⁶⁶⁶ "Iraq Pharmaceuticals and Health Report." *Business Monitor International* (Jul 2010), available at <http://www.reportlinker.com/p0240012/Iraq-Pharmaceuticals-and-Healthcare-Report-Q3.html> (accessed Feb 4 2011).

small ‘hole-in-the-wall’ pharmacies with little quality control over what they dispense. Turkish businesses benefit from more than a dozen free trade zones throughout the country, which allow for a low tax environment to boost exports and earn foreign currency.⁶⁶⁷ Although the light regulation in these zones certainly increases trade, free-trade areas also often act as transit points for fake drugs. According to Cengiz Gumustus, a private investigator working for the pharmaceutical industry, at least three of Turkey’s free trade zones, a southern Turkey zone known as Mersin and two zones close to Istanbul, are involved in smuggling counterfeit drugs.⁶⁶⁸

In 2008, Turkish authorities arrested counterfeiters on 68 separate occasions; only China, South Korea, and Brazil made more arrests than Turkey that year, according to the Pharmaceutical Security Institute.⁶⁶⁹

On October 19, 2008, the Istanbul Financial Crimes Department raided suspected purveyors of counterfeit drugs in Istanbul. They arrested seventy-seven people involved in all aspects of the counterfeit drug trade. The counterfeit ring included importers, local manufacturers, wholesale distributors who were repackaging fake or expired medicines, and publishers printing packaging for the manufacturers. Further investigations revealed that pharmacists, doctors, and nurses were also involved in the scam. These investigations led to the seizure of four truck loads of substandard pharmaceuticals, and over three dozen arrests in other parts of Turkey.⁶⁷⁰

United Arab Emirates

According to the European Commission’s 2006 report, 31 percent of fake medicines imported into the EU originated from the United Arab Emirates.⁶⁷¹ One media report from 2008 says that “inspectors from the Department of Economic Development seized huge quantities of herbal medicine sold by shops claiming to treat diabetes. The authorities sent samples of the medication for analysis and the Medical District reported that it never issued any approval for this particular herbal medication to circulate in the emirate”⁶⁷²

In 2007, Dubai customs inspectors infiltrated a complex counterfeiting supply chain, which ran through China, Hong Kong, the United Arab Emirates, Britain, and the Bahamas. These counterfeiters marketed the drugs to American consumers via an online pharmacy purportedly

⁶⁶⁷ Bate, R., “Fighting a Bitter Prescription,” *The American* (Jul 30 2009), available at <http://www.american.com/archive/2009/july/fighting-a-bitter-prescription/> (accessed Mar 10 2010).

⁶⁶⁸ Bate, R., “Fighting a Bitter Prescription,” *The American* (Jul 30 2009), available at <http://www.american.com/archive/2009/july/fighting-a-bitter-prescription/> (accessed Mar 10 2010).

⁶⁶⁹ Bate, R., “Fighting a Bitter Prescription,” *The American* (Jul 30 2009), available at <http://www.american.com/archive/2009/july/fighting-a-bitter-prescription/> (accessed Mar 10 2010).

⁶⁷⁰ Bate, R., “Fighting a Bitter Prescription,” *The American* (Jul 30 2009), available at <http://www.american.com/archive/2009/july/fighting-a-bitter-prescription/> (accessed Mar 10 2010).

⁶⁷¹ “Summary of Community Customs Activities on Counterfeit and Piracy.” *European Commission Taxation and Customs Union* (2006), available at http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2006_en.pdf (accessed Mar 10 2010).

⁶⁷² Fake Herbal Medicine for Diabetes Cure Seized,” *Gulf News*, (January 3, 2008) Available at: <http://gulfnews.com/news/gulf/uae/government/fake-herbal-medicine-for-diabetes-cure-seized-1.76020> Accessed on March 10, 2010

operating out of Canada.^{673 674} Customs officials in the UEA confiscated roughly five million counterfeit sexual stimulant tablets and sedative drugs, which were worth more than USD 5.4 million, from a company warehouse operating in Jebel Ali Free Zone Area (JAFZA).^{675 676} Other seizures included counterfeit cholesterol-lowering medicine and antibiotics. Dubai Customs has destroyed illicit drugs under controlled environmental conditions.⁶⁷⁷

The 2007 operation highlights two major challenges in combating counterfeit drug trafficking. First of all, many counterfeiting rings operate across national boundaries, and thrive in countries with poor regulation. Even though the UAE officials were able to disrupt the supply chain, the global reach of the network prohibited UAE officials from shutting the ring down. Secondly, counterfeiters often take advantage of light regulation in free trade zones to conduct illicit activity. Ilisa Bernstein, director of pharmacy affairs at the United States Food and Drug Administration, argues that, "[f]ree trade zones allow counterfeiters to evade the laws of the country because often times the regulations are lax in these zones."⁶⁷⁸

Dubai is particularly attractive to counterfeiters because of its strategic position. Located in the Persian Gulf, Dubai lies on a major trading route which connects Asia, Europe and Africa by both land and sea. Nearly a third of all counterfeit drugs confiscated in Europe in 2008 passed through the UAE.⁶⁷⁹

Dr Mohammed Abuelkhair, the head of the authority's drug-control department, argues that the more serious criminals in UAE are entering the counterfeit drugs because of potential for massive profit.⁶⁸⁰ The UAE is currently considering legislation to counteract these incentives. The maximum penalty for the manufacture or distribution of counterfeit medicines in 2008 was USD 2,722 or three years in jail. Under a proposed new law, however, criminals may be fined up to USD 272,294, or jailed for a maximum of 10 years.⁶⁸¹

Some health officials argue that the UAE needs to use newer technology to track and control the domestic pharmaceutical supply. To counter the menace of fake drugs, health authorities have

⁶⁷³ According to interviews with regulators and drug company investigators in six countries.

⁶⁷⁴ Bogdanich, W., "Free Trade Zones Ease Passage of Fake Drugs." *The New York Times*. (Dec 17 2007), available at http://www.nytimes.com/2007/12/17/world/africa/17iht-17freezone.8775156.html?_r=1 (accessed Mar 10 2010).

⁶⁷⁵ Landais, E., "Fake Sex Stimulants and Sedatives Worth Dh 20 Million Seized in Jebel Ali Raid." *Gulf News* (Sep 12 2007), available at <http://gulfnews.com/news/gulf/uae/general/fake-sex-stimulants-and-sedatives-worth-dh20m-seized-in-jebel-ali-raid-1.200589> (accessed Mar 10 2010).

⁶⁷⁶ Landais, E., "Fake Sex Stimulants and Sedatives Worth Dh 20 Million Seized in Jebel Ali Raid." *Gulf News* (Sep 12 2007), available at <http://gulfnews.com/news/gulf/uae/general/fake-sex-stimulants-and-sedatives-worth-dh20m-seized-in-jebel-ali-raid-1.200589> (accessed Mar 10 2010).

⁶⁷⁷ Landais, E., "Fake Sex Stimulants and Sedatives Worth Dh 20 Million Seized in Jebel Ali Raid." *Gulf News* (Sep 12 2007), available at <http://gulfnews.com/news/gulf/uae/general/fake-sex-stimulants-and-sedatives-worth-dh20m-seized-in-jebel-ali-raid-1.200589> (accessed Mar 10 2010).

⁶⁷⁸ Bogdanich, W., "Free Trade Zones Ease Passage of Fake Drugs." *The New York Times*. (Dec 17 2007), available at http://www.nytimes.com/2007/12/17/world/africa/17iht-17freezone.8775156.html?_r=1 (accessed Mar 10 2010).

⁶⁷⁹ Bogdanich, W., "Free Trade Zones Ease Passage of Fake Drugs." *The New York Times*. (Dec 17 2007), available at http://www.nytimes.com/2007/12/17/world/africa/17iht-17freezone.8775156.html?_r=1 (accessed Mar 10 2010).

⁶⁸⁰ "Jail Threat for Counterfeit Medicine." *The National* (May 30 2008), available at <http://www.thenational.ae/article/20080529/NATIONAL/573216782/1001&profile=1001> (accessed Mar 10 2010).

⁶⁸¹ "New Federal UAE Agency to Fight Counterfeit Medicines." *Business Intelligence Middle East* (Jan 7 2008), available at <http://www.bi-me.com/main.php?id=16230&t=1&c=33&cg=4> (accessed Mar 10 2010).

begun screening drugs at the ports of entry using high-end technology, and equipping pharmacists with technological tools to maintain quality control. A coding system has already been established in Abu Dhabi to identify each medical product, and inspectors are using forensic analysis of suspicious drug samples to verifying the drug's authenticity and trace its origin.⁶⁸²

Yemen

In July 2006, local authorities seized and destroyed 15 tons of fake and smuggled medicines, according to Adel Humaid, head of the Drug Monitoring Department at the Ministry of Health's Higher Authority for Medicine.⁶⁸³ In August 2007, Yemeni officials destroyed one million counterfeit tablets of the painkiller Panadol, whose packages bore the word "Pandadole" and an oval design which made the fake nearly indistinguishable from the real product.⁶⁸⁴

Dr. Ali Al-Zabaidi, the head of the Customs Authority in Yemen, said that "Every month the Customs Authority reveals a number of seizures of smuggled counterfeit and adulterated medicines."⁶⁸⁵ A news story in 2008 reported that the counterfeit medicines had become a key source of income for many smuggling operations, leading to the proliferation of fake and substandard drugs in the country.⁶⁸⁶ In November 2009, security authorities in Northern Hodiedah, a city in Western Yemen, uncovered a large drug smuggling operation near Al-Oahaia and Midi, the largest ports for smuggling medicines from Yemen to neighboring countries.⁶⁸⁷ That same month, the Court of Irregularities seized a more than 50 different types of counterfeited, smuggled or expired medicines.⁶⁸⁸

Yemen faces serious challenges to overcoming the problem of counterfeit drugs, as a complex web of factors contributes to the problem. Yemen lacks of a strong national drug regulatory authority, its enforcement of existing legislation is generally weak, corrupt legislators fail to act due to conflicts of interests, and countries from which counterfeits are exported routinely fail to

⁶⁸² Zain, A.A., "UAE- Efforts to curb entry of counterfeit drugs." *MENAFN* (Dec 19 2009), available at http://www.menafn.com/qn_news_story_s.asp?StoryId=1093289697&src=MOEN (accessed Mar 10 2010).

⁶⁸³ McGinnis, M, "Matrix of Drug Quality Reports Affecting USAID-assisted Countries," *U.S. Pharmacopeia Drug Quality and Information Program* (Jan 12, 2010) available at: <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19, 2010).

⁶⁸⁴ "A Review of Intellectual Property-Related News and Developments in the Middle East and North Africa." *Saba & Co. Intellectual Property Bulletin* (Sep 2007), available at <http://www.sabaip.com/NewsLetter/Attachments/Bulletin-0907.pdf> (accessed Feb 19 2010).

⁶⁸⁵ "Flood of counterfeit goods hurting Yemen's economy." *Business Intelligence Middle East* (Jun 29 2008), available at <http://www.bi-me.com/main.php?id=21909&t=1> (accessed Feb 19 2010).

⁶⁸⁶ For instance, in May 2006, a woman was arrested entering Yemen with 80 packets of medicine valued at USD 4,061;⁶⁸⁶ According to the article, the woman had not kept the drugs at carefully controlled temperatures, which made them potentially dangerous. See McGinnis, M, "Matrix of Drug Quality Reports Affecting USAID-assisted Countries," *U.S. Pharmacopeia Drug Quality and Information Program* (Jan 12, 2010) available at: <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19, 2010).

⁶⁸⁷ "Security Authorities Seized Drugs, Counterfeit Currency Dealers and Expired Medicines." *Yemen Post* (Nov 12 2009), available at <http://www.yemenpost.net/Detail123456789.aspx?ID=100&SubID=1561&MainCat=3> (accessed Feb 19 2010).

⁶⁸⁸ *Ibid.*

adequately regulate their drug industries or cooperate with countries like Yemen. Furthermore, counterfeiters are increasingly difficult to track: they use intermediaries to dilute transactions, and sophisticated technology to render many fakes virtually indistinguishable from legitimate medications to the poorly equipped Yemeni inspectors.⁶⁸⁹ The trade is also extremely lucrative, because demand and price of legitimate medications is high. A 2006 USAID Report stated that some of the private drug companies in Yemen may be knowingly involved in the developing the market for fake pharmaceuticals, many of which are manufactured in India.⁶⁹⁰

Yemen also faces a growing trade in unregistered and expired medicines. According to the Supreme Board for Drugs and Medical Appliances, only 80 percent of medicines found in the Yemeni pharmacies in 2008 were registered with the board. Others say that as many as 70 percent of the drugs in Yemen are contraband.⁶⁹¹ A recent study in 2008 discovered that illegal imports included huge quantities of expired or ineffective drugs. It suggested that roughly 37 to 50 percent of all medicines sold in Yemen had been smuggled into the country; most of the medications had been smuggled from the Horn of Africa, India or China.⁶⁹²

In June 2008, the Ministry of Public Health and Population in Yemen performed raids on 178 pharmacies in the Capital Secretariat, Aden, Ibb, Hodeidah and al-Baidha governorates, and seized huge quantities of smuggled, fake, and expired drugs. The Ministry found smuggled drugs in 111 pharmacies (57 of which were selling drugs diverted from governmental medical facilities), counterfeit drugs in 30 facilities, and expired medicines in 38 stores. In total, officials seized more than 932 kinds of illegal and counterfeit medicine and 9,000 ready-made labels used to mask expired medicines.⁶⁹³ One small counterfeiting factory was also discovered in the city of Sana'a.⁶⁹⁴

Substandard antimalarial drugs have also been discovered in Yemen. In 2005, the percentage failure of samples based on ingredient content was 6.7 percent for chloroquine based syrup (CQS) and 20 percent for chloroquine phosphate (CQT). In the same study, dissolution test failure rates were 8 percent for CQT and 70 percent for sulfadoxine/pyrimethamine (SPT).⁶⁹⁵

North Africa

The majority of reported cases of fake and substandard drugs in Northern Africa revolve less around fake antimalarials and antibiotics (though those certainly exist) and more around

⁶⁸⁹ Ibid.

⁶⁹⁰ "Yemen Corruption Assessment." *United States Agency for International Development* (Sep 25 2006), available at <http://yemen.usembassy.gov/root/pdfs/reports/yemen-corruption-assessment.pdf> (accessed Feb 19 2010).

⁶⁹¹ "When the Cure Becomes the Killer." *Yemen Observer* (Jun 3 2008), available at <http://www.yobserver.com/sports-health-and-lifestyle/10014371.html> (accessed Feb 19 2010).

⁶⁹² "Raids Underline Size Of Counterfeit Medicine Market." *International Chamber of Commerce* (Jul 1 2008), available at <http://www.icc-ccs.co.uk/bascap/article.php?articleid=780> (accessed Mar 3 2010).

⁶⁹³ "Raids Underline Size Of Counterfeit Medicine Market." *International Chamber of Commerce* (Jul 1 2008), available at <http://www.icc-ccs.co.uk/bascap/article.php?articleid=780> (accessed Mar 3 2010).

⁶⁹⁴ "When the Cure Becomes the Killer." *Yemen Observer* (Jun 3 2008), available at <http://www.yobserver.com/sports-health-and-lifestyle/10014371.html> (accessed Feb 19 2010).

⁶⁹⁵ Abdo-Rabbo, A., Bassili, A. and Atta, H., "The Quality Of Antimalarials Available in Yemen." *Malaria Journal* (2005) 4:28, available at <http://www.malariajournal.com/content/4/1/28> (accessed Feb 19 2010).

counterfeit lifestyle products, such as Viagra. Similar to other parts of the Middle East, Egypt, Algeria, and Morocco serve as an important link in the global counterfeit trade.

Algeria

According to Faouzi Mohamed, President of the Pharmacists Union in Oujda, on the north-east border of Algeria and Morocco, drug markets sell a selection of illegal products that often come from Spain, Eastern European countries, Libya and Egypt.⁶⁹⁶ One counterfeit product frequently found in these markets is a drug called “Vegra,” a play off of the brand Viagra.⁶⁹⁷ In Algeria and Morocco, the famous “souk al fellah” (“peasants’ markets”) are inundated with fake Viagra; other commonly counterfeited drugs include neuroleptic medicines, antiseptic dressings and anti-inflammatory products.⁶⁹⁸

In 2008, Algeria was added to the US Trade Representative watch list due to America’s concern that Algeria’s health and patent authorities were issuing marketing approvals for unauthorized copies of patented pharmaceutical products.^{699,700}

Egypt

In 2009, the Ministry of Health and Population estimated that 10 percent of pharmaceutical products sold in Egypt were counterfeit.⁷⁰¹ In April and May of 2009, six combined warehouse raids led to the seizure of nearly a dozen containers in Egypt holding hundreds of thousands of counterfeit medicines, all bound for the Middle East.⁷⁰² According to authorities, the drugs originated in China and passed through Syria before arriving in Egypt.⁷⁰³ Three of the containers seized were confiscated by Egyptian customs in the Suez Canal, and another 3,300 bottles of counterfeit pharmaceuticals were seized at the airport in Cairo.⁷⁰⁴ Among the shipments confiscated were medications for life-threatening diseases like cancer, diabetes, high cholesterol, heart disease, and epilepsy, as well as erectile dysfunction medications, schizophrenia prescriptions, and products intended for organ-transplant patients.⁷⁰⁵

⁶⁹⁶ “Counterfeit Medicine: the Silent Epidemic.” *Destination Santé*. (Jun 7 2006), available at <http://www.destinationsante.com/Counterfeit-medicine-the-silent-epidemic.html> (accessed Jan 7 2010).

⁶⁹⁷ Ibid.

⁶⁹⁸ Ibid.

⁶⁹⁹ “US Trade Representative Watchlist,” *Office of the USTR*, available at http://www.ustr.gov/sites/default/files/asset_upload_file193_14872.pdf (accessed Jan 18 2010).

⁷⁰⁰ Ibid.

⁷⁰¹ “The Ministry of Health and Population Targets Counterfeit Drugs In Pharmacies.” *Egypt Today* (Jun 15 2009), available at <http://www.egypttoday.com/printerfriendly.aspx?ArticleID=8532> (accessed Jan 19 2010).

⁷⁰² “Arrests and Major Seizure of Counterfeit Medicines Across Egypt Follow International Co-Operation with INTERPOL and IMPACT Stake-Holders” *Interpol* (May 29 2009), available at <http://www.interpol.int/Public/news/2009/CounterfeitMedecine20090529.asp> (accessed Feb 1 2010).

⁷⁰³ “Egypt Seizes Large Amount Of Suspected Fake Drugs.” *CNN Money* (May 1 2009), available at www.money.cnn.com (accessed Feb 1 2010).

⁷⁰⁴ “Arrests and Major Seizure of Counterfeit Medicines Across Egypt Follow International Co-Operation with INTERPOL and IMPACT Stake-Holders” *Interpol* (May 29 2009), available at <http://www.interpol.int/Public/news/2009/CounterfeitMedecine20090529.asp> (accessed Feb 1 2010).

⁷⁰⁵ Ibid.

A 2008 report supervised by the European Federation of Pharmaceutical Industries and Associations found that nearly 10% of the Egyptians annual drug spending, USD \$187 million per year, is squandered on counterfeit drugs.⁷⁰⁶ In 2009, the General Administration of the Pharmaceuticals Inspection Department (GAPID), affiliated with the Ministry of Health, recorded 807 police reports against entities accused of producing, distributing, or selling fake medicines. Seventy five of these entities were shut down.⁷⁰⁷

According to evidence presented by the US and other countries, Egypt is a manufacturing and packaging base for counterfeiters.⁷⁰⁸ The Organisation for Economic Co-operation and Development (OECD) estimates that Egypt supplies around 7% of all global pharmaceutical counterfeits.⁷⁰⁹ While Egypt's counterfeit drug profile is significantly smaller than that of other major producers like India (which may supply up to 75% of the world's fake drugs), the figures still demonstrate that Egypt's poor regulation poses a major threat to global health.⁷¹⁰

Under current (2009) Egyptian laws, a person found guilty of involvement in the trade of counterfeit medicine can receive a seven-year jail sentence.⁷¹¹

Libya

According to the Director General M. Hatem Hachicha, of Pfizer's Libya and Tunisia Department, 80 percent of Viagra sold in Libyan pharmacies in 2009 were counterfeit.⁷¹²

Morocco

According to the President of the Casablanca Pharmacists' Union, Redouane Al Menjira Saady, the illegal drug distribution networks that exist between local laboratories and local markets allow fake drug traffickers in Morocco to operate on an industrial scale.⁷¹³ Morocco's 18.3 percent tariff on imported medicines increases prices and encourages smuggling and a pervasive market for fake drugs, and the illegal trade of both real and fake medicines is rampant in the country's capital, Rabat.^{714, 715} To combat the fake drug trade, in November 2010 the Ministry of

⁷⁰⁶ "Egypt." *No To Fakes* (2009) available at <http://www.notofakes.com/Resources/TravelAdvisory/Africa/Egypt/tabid/495/Default.aspx> (accessed Jan 29 2010).

⁷⁰⁷ Ghazala, A. "Not what the doctor ordered." *Al-Ahram Weekly*. Jul 19, 2010. available at www.weekly.ahram.org.eg (accessed Jul 19, 2010)

⁷⁰⁸ "Egypt." *No To Fakes* (2009) available at <http://www.notofakes.com/Resources/TravelAdvisory/Africa/Egypt/tabid/495/Default.aspx> (accessed Jan 29 2010).

⁷⁰⁹ "Economic Impact of Counterfeiting and Piracy." *OECD Report*. (2008), available at http://www.oecd.org/document/4/0,3343,en_2649_34173_40876868_1_1_1_1,00.html (accessed Feb 2 2010).

⁷¹⁰ "Economic Impact of Counterfeiting and Piracy." *OECD Report*. (2008), available at http://www.oecd.org/document/4/0,3343,en_2649_34173_40876868_1_1_1_1,00.html (accessed Feb 2 2010).

⁷¹¹ "Large Amount Of Suspected Fake Drugs Confiscated." *MyAuthentic* (Jun 24 2009), available at <http://myauthentic.com/large-amount-of-suspected-fake-drugs-seized-in-egypt> (accessed Jan 20 2010).

⁷¹² "Pfizer et Wyeth : Fusion Pharmaceutique De 160 Milliards De Dollars." *Realities Online* (March 11 2009), available at http://41.226.15.227/realites/home/lire_article.asp?id=1128016&t (accessed Feb 1 2010).

⁷¹³ *Ibid.*

⁷¹⁴ "High tariffs on drugs breeds counterfeit medicines." Ghana News Agency (Jul 27 2006)

⁷¹⁵ "The Casablanca Grocery Store Drug Scandal." *Destination Sante Health News Agency* (Jul 20 2007), available at http://www.destinationsante.com/en_depeche.php?id_rubrique=26&id_article=22351&cat=1 (accessed Jan 20 2010).

Health announced it would work with the fraud prevention departments in the Ministries of Agriculture and Internal Affairs to increase inspections at drug outlets.⁷¹⁶

In 2007, Moroccan officials seized 50,000 boxes of counterfeit Aspro (aspirin) and Claradol (a paracetamol-based drug), both manufactured by Bayer Laboratories.⁷¹⁷ The drugs were stored in Casablanca and destined for distribution in Rabat. Investigations revealed a complex criminal network was behind the operation, including several Bayer laboratory workers, grocers, retail traders, pharmacists, transport companies, and two Mauritanian enterprises. Over the course of two years, the network had traded more than 7.5 million bottles of medicine in the black market.⁷¹⁸

In 2004, the US signed a Free Trade Agreement with Morocco which was supposed to herald an age of tougher IPR enforcement, including stricter penalties for piracy and counterfeiting.^{719,720} The Agreement requires Morocco to provide stronger deterrents by criminalizing end-user piracy, making it a crime to purchase as well as sell counterfeit items. Piracy has also recently become punishable by a jail term (of between six months and four years) and fines that can reach USD 68,000.⁷²¹

⁷¹⁶ Ari, Siham. "Contraband Medicines: Risky Solution for Impoverished Moroccans." *Magharebia* (Dec 28 2010), available at http://www.magharebia.com/cocoon/awi/xhtml1/en_GB/features/awi/features/2010/12/28/feature-02 (accessed May 10 2011).

⁷¹⁷ "The Casablanca Grocery Store Drug Scandal." *Destination Sante* (Jul 20 2007), available at http://www.destinationsante.com/The-Casablanca-grocery-store-drug-scandal.html?debut_articles_recents=20 (accessed May 10 2011).

⁷¹⁸ "Maroc: Bayer Accuse De Vente De Medicaments Au Noir." *Jeune Marocain* (Dec 17 2007), available at <http://www.jeunemarocain.com/modules/news/article.php?storyid=1429> (accessed Jan 29 2010).

⁷¹⁹ "Morocco" *No to fakes*, available at www.notofakes.com/Resources/TravelAdvisory/Africa/Morocco/tabid/496/Default.aspx (accessed Jan 20 2010).

⁷²⁰ Aloui, O., "Intellectual Property Rights." *Peterson Institute for International Economics* (Sep 2009), available at http://www.piie.com/publications/chapters_preview/4334/07iie4334.pdf (accessed Jan 29 2010).

⁷²¹ Ibid.

Asia

Asia is widely considered to be the fake drug factory of the world. India and China, which both having thriving legitimate domestic pharmaceutical manufacturing industries, are also the source of most substandard active pharmaceutical ingredients and counterfeit drugs found around the world. Insufficient regulation, porous borders, and lack of enforcement mechanisms in Pakistan, Iran, and the Mekong River Valley countries (Cambodia, Laos, Thailand, and Vietnam) have enabled Asia's myriad, unregulated small producers to market fake and substandard drugs to Asia, Europe, Africa and even the Western Hemisphere.

As the production hub for counterfeit and substandard drugs, the threat that insufficient regulation and poor manufacturing in Asia presents to consumers in other countries is enormous.⁷²² This danger ought to be particularly alarming for western nations like the United States, since roughly 20 percent of generic drugs and 40 percent of the active pharmaceutical ingredients (APIs) in all medications in the US are produced in either India or China. Within fifteen years, these two countries may be producing 80 percent of the US' APIs.⁷²³

Investigators hired by drug manufacturers assert that fakes consume between 5 and 30 percent of Asian pharmaceutical markets.⁷²⁴ However, local governments deny such high numbers. The Indian government estimates that "spurious" drugs, as fakes are known in India, comprise less than 1 percent of the national market, and substandard drugs less than 10 percent.⁷²⁵ China's research and development-based pharmaceutical association has estimated that about 8 percent of over-the-counter drugs sold in China are counterfeit.⁷²⁶

Eastern Asia

Most counterfeits sold in Eastern Asia are manufactured in China, India and North Korea.⁷²⁷ Counterfeit drugs sales flourish in informal flea markets and illegitimate shops, but are increasingly infiltrating legitimate shops and pharmacies where they are sold alongside regulated medicines.

⁷²² "Summary of Community Customs Activities on Counterfeit and Piracy." *European Commission Taxation and Customs Union* (2006), available at http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2006_en.pdf (accessed Mar 5 2010).

⁷²³ Kaufman, Marc. "FDA Scrutiny Scant in India, China as Drugs Pour into U.S." *Washington Post* (Jun 17 2007), available at <http://www.washingtonpost.com/wp-dyn/content/article/2007/06/16/AR2007061601295.html> (accessed Mar 5 2010).

⁷²⁴ Personal communication with Suresh Sati, a consultant who investigates abuses of intellectual property rights on behalf of private companies and Dr. Uday Shankar (pharmacist at the Indian Government Hospital) (16-17 Jan 2008)

⁷²⁵ "A Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs." *Ministry of Health and Family Welfare, Government of India* (Nov 2003), available at http://cdsco.nic.in/html/Final_percent20Report_percent20mashelkar.pdf (accessed Mar 9 2010).

⁷²⁶ "Counterfeit Medicines: an Update on Estimates." *International Medical Products Anti-Counterfeiting Taskforce* (Nov 16 2006), available at http://www.ifpma.org/fileadmin/templates/ifpmaissues/pdfs/IMPACT_counterfeit_estimate_15Nov06.pdf (accessed Feb 15 2010).

⁷²⁷ "World Macro Regions and Components." *United Nations Online* (2000), available at <http://www.un.org/depts/dhl/maplib/worldregions.htm> (accessed Mar 11 2010).

One of the most commonly counterfeited drugs is Viagra; other commonly produced fake medications include remedies for heart disease and diabetes; bladder, liver, and gastric disorders; and common antibiotics, painkillers, dietary supplements, and vaccines.

Counterfeit drug prevalence generally reflects the ability of the domestic government to control their borders. In well-regulated nations such as Japan and South Korea, very few fakes are sold, and the illegal drugs which do arrive are generally sold over the black market. In China and Mongolia, however, porous borders allow counterfeiters easy access to both legitimate and illegitimate drug markets.

Japan

Japan's robust domestic pharmaceutical market, the third largest in the world, presents a lucrative opportunity for drug counterfeiters.⁷²⁸ A Japanese newspaper reported that the number of illicit imports has been increasing since 2006, and substandard medications represent a growing problem for Japanese citizens.⁷²⁹ In June 2006, the arrest of three Japanese men in Osaka led to the discovery of a major counterfeiting operation which had already sold roughly 60,000 tablets of fake Viagra in the country.⁷³⁰ In 2007, a total of 96,591 counterfeit drugs were seized at Japan's customs, almost a 23-fold surge from the 4,213 the previous year. Eighty percent of these drugs were fake Viagra pills, and most came from China.⁷³¹

While counterfeit drugs are not known to have infiltrated official health channels, Japan routinely struggles to control the sale of fakes in the informal market. During the recent nuclear meltdown following the Japanese earthquake on March 10, 2011, two Japanese dealers sold "Premium Zeolite" online, claiming that it would protect people living near the damaged Fukushima Daiichi nuclear power plant by absorbing the radiation both within the body and in the environment. The two criminals were charged with unlicensed drug sales.⁷³²

Most illegally imported medications are brought into Japan for personal use. In September 2002, five women in Japan and Singapore died and 60 more became sick after taking counterfeit diet pills, which had apparently been manufactured in China.⁷³³ In 2008, Nagoya Customs arrested

⁷²⁸ "Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation, and Public Health." *Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization* (2006), available at <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> (accessed Feb 22 2010).

⁷²⁹ "Japan Awash in Fake Medicines." *Japan Today* (Nov 12 2006), available at <http://www.japantoday.com/category/kuchikomi/view/japan-awash-in-fake-medicines> (accessed Feb 19 2010).

⁷³⁰ "Japan Awash in Fake Medicines." *Japan Today* (Nov 12 2006), available at <http://www.japantoday.com/category/kuchikomi/view/japan-awash-in-fake-medicines> (accessed Feb 19 2010).

⁷³¹ "Fake Viagra Haul Ups '07 Counterfeit Import Seizures 16%." *The Japan Times Online* (Mar 7 2008), available at <http://search.japantimes.co.jp/cgi-bin/nb20080307a5.html> (accessed Mar 1 2010).

⁷³² Imber, S. "Online Snake Oil Salesmen Exploit Japanese Radiation Fears." *SafeMedicines.org* (Apr 14 2011), available at <http://www.safemedicines.org/2011/04/online-snake-oil-salesmen-exploit-japanese-radiation-fears-215.html> (accessed May 23 2011).

⁷³³ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 15 2010).

Japanese men for attempting to smuggle 5,000 fake pills that had been smuggled from China using the Express Mail service.⁷³⁴

In 2006 and 2007, multinational pharmaceutical manufacturers including Pfizer, Bayer and Eli Lilly asked Japanese customs to try to reduce importation of counterfeit virility drugs. According to Pfizer, since its request in May 2006 more than 123,000 fake Viagra pills have been seized in 169 cases.⁷³⁵ Though Viagra appears to dominate the counterfeit market, other fakes, including a variety of fake anti-Alzheimer's drugs, have been found in illegitimate pharmacies.⁷³⁶ Since 2002, the country has worked to streamline and strengthen its regulatory system by amending its Pharmaceutical Affairs Law (PAL). The law now includes a risk-based classification for products, revised manufacturing controls and quality assurance standards, and increased postmarketing surveillance.⁷³⁷ Those caught in violation of the ban on counterfeit drugs are subject to no more than three years imprisonment and/or no more than USD 25,000 in fines.⁷³⁸

In April 2005, the government established a separate entity, the Pharmaceuticals and Medical Devices Agency (PMDA), to promote a more efficient and transparent drug review and approval process.⁷³⁹ In accordance with PAL, PMDA must conduct GMP inspections at Japan's international pharmaceutical suppliers' manufacturing sites. To fulfill this requirement, PMDA has hired inspectors, and trained them with assistance from the pharmaceutical industry.⁷⁴⁰

Democratic People's Republic of Korea (North Korea)

It is widely believed that North Korean officials are involved in large-scale production of expertly packaged pharmaceuticals, including knock-off erectile enhancement drugs like Viagra and Cialis. Due to rigid press controls in North Korea, public source data on such alleged activity is sketchy. However, knock-off Viagra and Cialis are widely available just across the Chinese border, leading to speculation that these drugs are manufactured by the North Korean Regime (Democratic People's Republic of Korea - DPRK) and exported to China. Proof of domestic

⁷³⁴ "IPR Protection: The Role of Japan Customs." *Customs and Tariff Bureau, Ministry of Finance, Japan* (2009), available at http://www.customs.go.jp/mizuguiwa/chiteki/ipr_p.pdf (accessed May 10 2011).

⁷³⁵ Akasaka, Tatsuya. "Pharmaceutical Firms Trying to Combat Spread of Fake Drugs." *Japan Today* (May 16 2008), available at <https://www.japantoday.com/category/features/view/pharmaceutical-firms-trying-to-combat-spread-of-fake-drugs> (accessed May 10 2011).

⁷³⁶ "Japan Awash in Fake Medicines." *Japan Today* (Nov 12 2006), available at <http://www.japantoday.com/category/kuchikomi/view/japan-awash-in-fake-medicines> (accessed Feb 19 2010).

⁷³⁷ Bate, Roger. "Making a Killing: The Deadly Implications of the Counterfeit Drug Trade." *The American Enterprise Institute Press* (2008), available at http://www.aei.org/docLib/20080520_MakingaKillingnew.pdf (accessed 14 Feb 2011).

⁷³⁸ Kimura, Kazuko. "Counterfeit Medicines & Japan." *ASEAN-CHINA Conference on Combating Counterfeit Medical Product* (Nov 13 2007), available at www.who.int/entity/impact/activities/Japan_JAKARTA_Conf.ppt (accessed May 10 2011).

⁷³⁹ D'Eramo, Paul. "Japan's Pharmaceutical Affairs Law (PAL): Opportunities and Challenges." (Feb 2007), available at http://www.ispe.org/cs/regulatory_review_archive/february_2007_japans_pharmaceutical_affairs_law_pal_opportunities_and_challenges (accessed Feb 22 2010).

⁷⁴⁰ Bate, Roger. "Making a Killing: The Deadly Implications of the Counterfeit Drug Trade." *The American Enterprise Institute Press* (2008), available at http://www.aei.org/docLib/20080520_MakingaKillingnew.pdf (accessed 14 Feb 2011).

manufacture of counterfeit drugs in China also exists.⁷⁴¹ At issue, however, is not the existence of the knock-off drugs, but whether the North Korean regime is indeed the manufacturer, with some speculating that China may be the most common source of production. No data regarding domestic consumption of fake pharmaceuticals exists.

Republic of Korea (South Korea)

As *In-PharmaTechnologist* reports “In April 2009, South Korean drug regulators ordered the recall of 1,222 medical products and pharmaceuticals that may have contained asbestos-tainted talcum powder imported from China by Ansan headquartered Duksan Pure Chemicals and may have been used in the production of pharmaceuticals by more than 120 drug makers. According to a report in the *JoonAngDaily* newspaper, Duksan, which imports around 20 percent of the talcum sold in South Korea each year, posted an official apology on its website on April 2 and initiated a recall of the affected batch.”⁷⁴²

In March 2008, three men were arrested for smuggling fake high blood pressure medicine into South Korea from China. The men apparently partnered with an unlicensed supplier in Shandong Province in northeastern China, who shipped the first batch of 1.2 million pills (out of a total order of 10 million fakes) in January 2008. The pills, which contained less than 10 percent of the required levels of active ingredients, were to be repackaged in Seoul by the smugglers and each bottle of 500 tablets was to be sold at a 25 percent discount.⁷⁴³

“In 2008, two people were also arrested for allegedly smuggling 300,000 tablets of counterfeit Cialis and Viagra from China into South Korea. The pills, valued at USD 4.5 million, were smuggled on passenger ships over the previous three years, advertised in free community newspapers, and distributed through home delivery services; the pills were over dosed and caused various negative side effects, some were life-threatening.”⁷⁴⁴

Illegal import traders selling anti-impotence drugs pose a huge threat to South Korea. A police raid in December of 2009 led to the seizure of anti-impotence drugs from 103 sex shops, which are not licensed for pharmaceutical sales. Over the previous months, police raids yielded more than 3,604 impotence samples. Drug inspections revealed that all the medications seized in 2009

⁷⁴¹ Note that “knock-off” Viagra and Cialis are readily available in China, notably in Dandong on the DPRK border. For allegations/reports linking the DPRK in the past to such activity, see Statement of David L. Asher before the Subcommittee on Federal Financial Management, Government Information, and International Security of the Senate Homeland Security and Government Affairs Committee, Apr 25, 2006. See also, *U.S. News and World Report*, White House Week, May 30, 2005.

⁷⁴² “South Korea pulls 1000 asbestos tainted drugs from its shelves,” *In pharma-technologist*. (09 April 2009) Available at: <http://www.in-pharmatechnologist.com/On-your-radar/Globalisation/South-Korea-pulls-1-000-asbestos-tainted-drugs-from-shelves> Accessed 15 February 2010

⁷⁴³ “Three Arrested For Smuggling Fake Medicine From China.” *Yonhap News Agency* (Mar 18, 2008) available at <http://english.yonhapnews.co.kr/national/2008/03/18/67/0301000000AEN20080318005900315F.HTML> (accessed Jan 28 2010).

⁷⁴⁴ “Three Arrested for Smuggling Fake Medicine from China.” *Yonhap News Agency* (Mar 18 2008) available at <http://english.yonhapnews.co.kr/national/2008/03/18/67/0301000000AEN20080318005900315F.HTML> (accessed Jan 28 2010).

were fakes.⁷⁴⁵ While most Cialis pills did not contain sufficient amounts of the active ingredients, some of the fake Viagra pills contained twice the expected dose, and others contained none.⁷⁴⁶

China

Counterfeit drugs are a major problem in China, with a long and extensive history.

Counterfeit drugs cause thousands of deaths in China every year.^{747,748} Counterfeit drugs cause thousands of deaths in China every year.^{749,750} A report from the International Policy Network (IPN), estimates the death toll from substandard medicines in China is between 200,000 and 300,000 each year.⁷⁵¹

Specific examples, although they contain much smaller numbers, are illustrative of the widespread problem. In 2005, it was reported that about 50 babies died in Anhui Province and more than 100 became gravely malnourished after being fed with fake milk formula, some of which contained only 6 percent of the required vitamins, minerals, and proteins.⁷⁵² In May, 2006, 11 people died after taking antibiotics contaminated with diethylene glycol. In February 2009, two died and nine were hospitalized in Xinjiang Uygur Autonomous Region of NW China, due to a counterfeit diabetes drug that had six times the normal dose of the chemical glibenclamide, used to lower blood sugar.⁷⁵³

Fake drugs have clearly penetrated both the public and the private health sectors. In 2007, a Shanghai-based drug investigator reported that 22 of the 32 drugstores investigated in Nanjing were selling counterfeit drugs, and 4 of the 15 drugstores supported by public medical insurance

⁷⁴⁵ “Crackdown on Fake Viagra, Cialis.” *The Korea Times* (Dec 21 2009), available at http://www.koreatimes.co.kr/www/news/nation/2009/12/117_57714.html (accessed Feb 15 2010).

⁷⁴⁶ “Crackdown on Fake Viagra, Cialis.” *The Korea Times* (Dec 21 2009), available at http://www.koreatimes.co.kr/www/news/nation/2009/12/117_57714.html (accessed Feb 15 2010).

⁷⁴⁷ “Three Arrested for Smuggling Fake Medicine from China.” *Yonhap News Agency* (Mar 18 2008) available at <http://english.yonhapnews.co.kr/national/2008/03/18/67/0301000000AEN20080318005900315F.HTML> (accessed Jan 28 2010).

⁷⁴⁸ “Nigeria Criticizes China over Counterfeit Threat.” *FDA News, Daily International Pharma Alert* 2:283 (Feb 14 2006), available at <http://www.fdanews.com/newsletter/article?articleId=84541&issueId=8981> (accessed Jan 27 2010).

⁷⁴⁹ “Three Arrested for Smuggling Fake Medicine from China.” *Yonhap News Agency* (Mar 18 2008) available at <http://english.yonhapnews.co.kr/national/2008/03/18/67/0301000000AEN20080318005900315F.HTML> (accessed Jan 28 2010).

⁷⁵⁰ “Nigeria Criticizes China over Counterfeit Threat.” *FDA News, Daily International Pharma Alert* 2:283 (Feb 14 2006), available at <http://www.fdanews.com/newsletter/article?articleId=84541&issueId=8981> (accessed Jan 27 2010).

⁷⁵¹ Jia, Hepeng. “China’s Battle with Fake Drugs.” *Royal Society of Chemistry* (May 18 2007), available at <http://www.rsc.org/chemistryworld/News/2007/May/18050701.asp> (accessed Jan 26 2010).

⁷⁵² Watts Jonathan. “China Drug Pirates Leave Death in their Wake.” *The Guardian* (Dec 4 2006), available at <http://www.guardian.co.uk/business/2006/dec/04/china.internationalnews/2006/12/06/2003339298> (accessed Jan 24 2010).

⁷⁵³ “Deadly Fake Diabetes Drug Found in Sichuan.” *China Daily* (Feb 5 2009), available at http://www.chinadaily.com.cn/china/2009-02/05/content_7447081.htm (accessed Jan 27 2010).

also carried counterfeit drugs.⁷⁵⁴

Corrupt public officials in China may be involved in the illicit drug trade. In September 2008, Gao Jindge, celebrated in the Chinese media for his relentless campaign to eliminate counterfeit medicines from Chinese pharmacies, reported that approximately 66 percent of drug stores in China sold counterfeit medicine.⁷⁵⁵ From 2004 to 2008, Gao conducted grassroots investigations of drug stores and hospitals and discovered counterfeit medicines in 289 stores, 87 of which were located in Nanjing.⁷⁵⁶ After completing an investigation of Nanfang University Medical Center hospital in 2008, Gao, who has suffered from the adverse effects of unwittingly using counterfeit medications in the past, was brutally attacked by four men. He believes the attackers were hired by hospital authorities to stop him from exposing the hospital's corrupt deals with counterfeiters.

Chinese police confiscated 440,000 fake impotence pills in 2005⁷⁵⁷ and found a further 1,781,000 pills in 2006 in workshops in the Zhejiang Province along the eastern coast.⁷⁵⁸ That same year, Chinese authorities shut down a factory producing both fake Viagra and birth control pills which contained starch, glucose, and toxic substances.⁷⁵⁹

Vaccines and other lifesaving medications, including heart medication, diabetes drugs, and antimalarials are also frequently counterfeited in China. In 2005, police discovered 40,000 boxes of fake rabies vaccines.⁷⁶⁰ In 2007, Chinese officials discovered that a drug-gang had sold counterfeit rabies vaccines, made with a combination of distilled water and starch, to 227 people in the Heilongjiang Province. During the raid which led to the arrest of the gang's 17 members, Chinese authorities reportedly found a massive stash of counterfeits which included 10,000 doses of the rabies vaccine, 20,250 bottles of cardiovascular disease medication, and 211 bottles of blood protein. Authorities confiscated a total of 67 types of pharmaceutical drugs produced by 53 different companies.⁷⁶¹

During another series of raids in 2007, Chinese police seized one tonne of fake Viagra pills, along with fake Tamiflu and antimalarials.⁷⁶² In 2007, the SFDA discovered several thousand

⁷⁵⁴ Jia, Hepeng. "China's Battle with Fake Drugs." *Royal Society of Chemistry* (May 18 2007), available at <http://www.rsc.org/chemistryworld/News/2007/May/18050701.asp> (accessed Jan 26 2010).

⁷⁵⁵ Qi, Qiao. "Two-Thirds of Chinese Drug Stores Sell Counterfeit Medicine, Says Investigator." *The Epoch Times* (Sep 29 2008), available at <http://www.theepochtimes.com/n2/content/view/4973/> (accessed Jan 28 2010).

⁷⁵⁶ Qi, Qiao. "Two-Thirds of Chinese Drug Stores Sell Counterfeit Medicine, Says Investigator." *The Epoch Times* (Sep 29 2008), available at <http://www.theepochtimes.com/n2/content/view/4973/> (accessed Jan 28 2010).

⁷⁵⁷ "China, US Jointly Seize 440,000 Pills of Counterfeit Viagra." *People's Daily Online* (Sep 9 2005), available at http://english.peopledaily.com.cn/200509/09/eng20050909_207454.html (accessed Jan 28 2010).

⁷⁵⁸ Shao, Xiaoyi. "Fake Viagra Maker Given 10-Year Prison Term." *China Daily* (May 10 2006), available at http://www2.chinadaily.com.cn/china/2006-05/10/content_585862.htm (accessed Jan 28 2010).

⁷⁵⁹ "China Arrests One over Fake, Toxic Birth-Control Pills." *BD News 24* (Dec 18 2006), available at <http://www.bdnews24.com/details.php?id=46268&cid=1> (accessed Feb 14 2011).

⁷⁶⁰ "China Arrests One over Fake, Toxic Birth-Control Pills." *BD News 24* (Dec 18 2006), available at <http://www.bdnews24.com/details.php?id=46268&cid=1> (accessed Feb 14 2011).

⁷⁶¹ Hu, Yinan. "17 Nabbed for Fake Rabies Vaccine." *China Daily* (Aug 3 2007), available at http://www.chinadaily.com.cn/china/2007-08/03/content_5447768.htm (accessed Jan 28 2010).

⁷⁶² "China Seizes Viagra in Crackdown on Fake Drugs." *China Daily* (Jul 25 2007), available at http://www.chinadaily.com.cn/china/2007-07/25/content_5443310.htm (accessed Jan 27 2010).

packs of fake human albumin, a protein found in blood plasma, circulating in eight Chinese provinces.⁷⁶³

In 2006, the EU trade commissioner reported seizures by European customs officers of fake birth control pills and ARVs that came from China, while the U.S. FDA seized 51 separate shipments of Tamiflu coming from China that same year. In 2007 John Newton, a senior investigator with Interpol, reported that transnational Chinese gangs are responsible for the counterfeit antimalarial drug trade in Southeast Asia. In 2007, counterfeit versions of at-home diabetes tests, used to measure blood sugar levels, were discovered by Johnson & Johnson, the maker of the tests. Court filings disclose that China was the source of around one million fake test strips that were found in 35 of the United States as well as in Canada, Greece, India, Pakistan, the Philippines, Saudi Arabia, and Turkey. In 2007, in Milan, Italy, at the world's largest trade show for pharmaceutical ingredients, approximately 82 Chinese chemical companies claimed to make and export pharmaceutical ingredients; yet records showed that none were certified by the SFDA.

In a crackdown on the sale of counterfeit drugs to treat impotence in April 2005, Hong Kong Customs and Department of Health officers arrested eight people and seized 236 suspected counterfeit tablets worth about USD 22,000.⁷⁶⁴

In 2007, Hong Kong customs officers arrested a man believed to be the mastermind behind a massive international fake pharmaceutical drug-smuggling syndicate distributing fake drugs to Europe, the US, Australia, and India. The crackdown resulted in the seizure of approximately 470,000 counterfeit tablets (valued at approximately USD 2.44 million) intended for heart disease, male impotence, avian influenza, and weight loss. Analysis revealed that the drugs did not contain harmful substances, but also did not include any genuine active ingredients either.⁷⁶⁵

Legal action against counterfeits

Chinese courts have increasingly cracked down on counterfeiters over the past few years. In 2004, the head of the litigation department of Chinese legal firm Rouse and Co reported that criminal prosecutions against illegal pharmaceutical manufactures had achieved progress in curbing the actions of large criminal networks. China has been tackling counterfeiting through administrative raids carried out by China's State FDA and civil and criminal cases initiated in court.⁷⁶⁶ Below are some reported cases.

- In 2006, Xi Yongli was sentenced to eight years in prison for producing over 60 tons of fake Viagra pills without a license or the permission of the patent holder, Pfizer. By the time he was arrested, Xi and his company had sold approximately USD 2.7 million worth of products.⁷⁶⁷

⁷⁶³ "China Uncovers More Fake Blood Products." *SCRIP News* 3272, 17 (Jun 29 2007)

⁷⁶⁴ "Hong Kong authorities seize fake Viagra, Cialis pills." *The Star* (May 1 2005), available at <http://thestar.com.my/news/story.asp?file=/2005/5/1/latest/20050501132401&sec=Latest> (accessed May 9 2011).

⁷⁶⁵ "Hong Kong Customs Seizes 19 million HKD worth of Counterfeit Drugs." *People's Daily Online* (Jan 29 2007), available at http://english.peopledaily.com.cn/200701/26/eng20070126_345135.html (accessed May 9 2011).

⁷⁶⁶ *Scrip World Pharmaceutical News* (Jun 11, 2004) Issue 2960; London, UK. PJB Publications Ltd: p. 17.

⁷⁶⁷ Watts Jonathan. "China Drug Pirates Leave Death in their Wake." *The Guardian* (Dec 4 2006), available at <http://www.guardian.co.uk/business/2006/dec/04/china.internationalnews/2006/12/06/2003339298>

- In April 2006, 65 patients received treatments contaminated with diethylene glycol instead of propylene glycol, at a hospital in Guangzhou, the capital of southern China's Guangdong Province. Fourteen of these patients died from kidney failure.⁷⁶⁸ The Chinese court ordered three pharmaceutical companies and one hospital to pay a combined USD 510,000 in compensation to the 11 plaintiffs, the highest possible amount under existing law.⁷⁶⁹
- In 2007, a court in Beijing ordered three Chinese drug makers to pay a USD 38,000 fine, publicly apologize, and cease producing counterfeit Viagra.⁷⁷⁰ In 2008, five employees of Qiqihar No 2 Pharmaceutical Co Ltd. were sentenced to jail terms ranging from 4 to 7 years for producing and manufacturing counterfeit medicines.⁷⁷¹
- The most severe ruling by the Chinese courts against counterfeiting occurred in July 2007. Zheng Xiaoyu, the head of the SFDA from 1997 to 2006, was executed for approving the use of six fake medicines in exchange for cash during his tenure at the SFDA.⁷⁷²

On November 29, 2007, China's SFDA released the draft judicial interpretation of new anti-drug counterfeiting laws. Under the new laws, anyone convicted of manufacturing or selling counterfeit drugs which could cause serious injury or death may face the death penalty.⁷⁷³ If drug use causes serious deformities or bodily harm to more than 3 people, or slight injury to more than 10, convicted counterfeiters could face life imprisonment.⁷⁷⁴ Hospitals that buy, store, or use medicines which they know to be fake or substandard will now face criminal charges as well.^{775,776}

The Chinese State Food and Drug Administration (SFDA) Increases Efforts

In recent years, the Chinese government has shown real increases in their efforts to curb and combat the counterfeit drug trade in the country. In 2005, China ranked second in the number of counterfeit drugs seized or destroyed, with a total of 87 seizures.⁷⁷⁷ In 2005, Chinese authorities

(accessed Jan 24 2010).

⁷⁶⁸ "Death Toll from Contaminated Drug Rises to 14 in S China." *Xinhua News Agency* (Jan 24 2008), available at http://news.xinhuanet.com/english/2008-01/24/content_7482979.htm (accessed Jan 28 2010).

⁷⁶⁹ Liang, Qiwen. "Hospital, Firms Made to Pay for Deadly Drug." *China Daily* (Jun 26 2008), available at http://www.chinadaily.com.cn/china/2008-06/27/content_6799568.htm (accessed Jan 28 2010).

⁷⁷⁰ "Pfizer Wins Viagra Ruling in China." *China.org* (Dec 28 2006), available at http://china.org.cn/business/2006-12/28/content_1194201.htm (accessed Jan 28 2010).

⁷⁷¹ Qiu, Quanlin. "5 Jailed for Sale of Illegal Drugs." *China Daily* (Apr 30 2008), available at http://www.chinadaily.com.cn/china/2008-04/30/content_6652996.htm (accessed Jan 28 2010).

⁷⁷² "China Food Safety Head Executed." *BBC News* (Jul 10 2007) available at <http://news.bbc.co.uk/2/hi/6286698.stm> (accessed Jan 28 2010).

⁷⁷³ Ying, Huang. "China State FDA Recommends Death Penalty for Drug Counterfeiters." *PharmAsia News* (Dec 10 2007), available at <http://fdcalerts.typepad.com/asia/2007/12/china-state-fda.html> (accessed Jan 29 2010).

⁷⁷⁴ Ying, Huang. "China State FDA Recommends Death Penalty for Drug Counterfeiters." *PharmAsia News* (Dec 10 2007), available at <http://fdcalerts.typepad.com/asia/2007/12/china-state-fda.html> (accessed Jan 29 2010).

⁷⁷⁵ Ying, Huang. "China State FDA Recommends Death Penalty for Drug Counterfeiters." *PharmAsia News* (Dec 10 2007), available at <http://fdcalerts.typepad.com/asia/2007/12/china-state-fda.html> (accessed Jan 29 2010).

⁷⁷⁶ "Global Legal Monitor." *Law Library of Congress* (Aug 2007), available at http://www.loc.gov/law/news/global-monitor/2007_glm_08.pdf (accessed Mar 26 2010).

⁷⁷⁷ Gibson, Liza. "Drug Regulators Study Global Treaty to Tackle Counterfeit Drugs." *British Medical Journal* 328:7438, 486 (Feb 28 2004), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1125287> (accessed Jan 28 2010).

also investigated 310,000 reports of counterfeit drugs, and destroyed 530 factories.⁷⁷⁸

In 2006, the Chinese State Food and Drug Association (SFDA) announced that the budget for Food and Drug Supervision for 2006-2007 would be approximately USD 500 million, more than the total funding from 1998 through 2005 combined. According to Administration Head, Shao Mingli, the extra spending provided the SFDA with equipment for 90 percent of the provincial drug departments (60 percent of those at city level), allowing them to conduct full-scale drug testing nationwide.⁷⁷⁹ In early 2007 China also overhauled its Food and Drug Safety Regulations, placing new controls on imports and exports of food and drugs, stepping up random testing on drugs, and having inspection information for 90percent of food products in the country.⁷⁸⁰

Recent changes culminated in sweeping legislative reforms following investigations of corruption in the nation's regulatory body, the State Food and Drug Administration (SFDA). As previously mentioned, the former SFDA director was tried and subsequently executed in 2006 for taking over USD 850,000 in bribes in the form of cash and gifts for approving hundreds of drugs and medical devices, some of which proved to be fake.^{781,782} Recent reforms in the SFDA have begun to assuage fears over high levels of corruption. Drug safety inspections across the country have been stepped up, and SFDA officials have been ordered to divest themselves of the 3.5 million shares they held in pharmaceutical companies.⁷⁸³ SFDA's anti-corruption campaign also introduced eight rules which are intended to prevent its officials from engaging in corrupt activities, and combat corruption and crime in the global pharmaceutical market.⁷⁸⁴

Since this budgetary increase and regulation reforms, the capacity of the SFDA to conduct quality tests has significantly increased. From March to August in 2006, the SFDA supported the screening of 110,426 batches of drugs from nine provinces in China, out of which 3,122 batches were found to contain counterfeit or substandard drugs.⁷⁸⁵

Between July 2006 and December 2007, Vice Premier Wu Yi stated that the SFDA destroyed

⁷⁷⁸ Watts Jonathan. "China Drug Pirates Leave Death in their Wake." *The Guardian* (Dec 4 2006), available at <http://www.guardian.co.uk/business/2006/dec/04/china.internationalnews/2006/12/06/2003339298> (accessed Jan 24 2010).

⁷⁷⁹ "China's Budget for Food, Drug Supervision Hits Record." *Xinhua News Agency* (Feb 5 2008) available at <http://english.sina.com/china/1/2008/0131/144370.html> (accessed Jan 28 2010).

⁷⁸⁰ Barboza, David. "China Tightens Food Safety Regulations." *The New York Times* (Jun 6 2007), available at <http://www.nytimes.com/2007/06/06/business/worldbusiness/06iht-food.4.6028767.html> (accessed Jan 28 2010).

⁷⁸¹ "Health and Education." *Asia-Pacific Human Development Network* (2007), available at [http://www3.undprcc.lk/ext/crhdr/pdf/Health percent20and percent20education.pdf](http://www3.undprcc.lk/ext/crhdr/pdf/Health%20and%20education.pdf) (accessed Jan 27 2010).

⁷⁸² Barboza, David. "China Sentences Former Drug Regulator to Death." *The New York Times* (May 29 2007), available at <http://www.nytimes.com/2007/05/29/world/asia/29cnd-drug.html> (accessed Jan 28 2010).

⁷⁸³ Barboza, David. "China Sentences Former Drug Regulator to Death." *The New York Times* (May 29 2007), available at <http://www.nytimes.com/2007/05/29/world/asia/29cnd-drug.html> (accessed Jan 28 2010).

⁷⁸⁴ Barboza, David. "China Sentences Former Drug Regulator to Death." *The New York Times* (May 29 2007), available at <http://www.nytimes.com/2007/05/29/world/asia/29cnd-drug.html> (accessed Jan 28 2010).

⁷⁸⁵ Jin, Shaohong. "Mobile Labs Developed in China for Detection of Counterfeit Drugs." *National Institute for the Control of Pharmaceutical and Biological Products, Proceedings of the 3rd Global Forum on Pharmaceutical Anticounterfeiting* (Mar 13-15 2007), cited by McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 22 2010).

more than 900 counterfeit drug operations and criminally charged 279 people.⁷⁸⁶ In 2008, the SFDA investigated 300,000 cases of illegal activities related to medicine and medical products, shutdown 363 producers of fake drugs and charged 94 people on counts of counterfeiting.⁷⁸⁷ In 2009, local drug authorities in Shanghai took action in 165 cases involving counterfeit or illegal medicines. These cases led to 11 sentences, and 29 criminal case referrals to other provinces for further investigation. Authorities in Shanghai spearheaded the largest of recent cases in December of 2009, when they arrested a ring of three family members who were caught with 129 packages of fake medicines and medical appliances worth an estimated USD 410,000.⁷⁸⁸

Cracking down on Internet Sales of Fakes

In 2006, Shanghai police seized 900 pounds of counterfeit Tamiflu, an antiviral drug, and arrested 13 suspects who had been selling the drugs to Chinese citizens over the internet.⁷⁸⁹ In 2008, the SFDA shut down 23 websites because the sites either sold counterfeit drugs or published “false, exaggerated, or misleading information” about medicines or cures for various ailments, often pretending to be affiliated with hospitals or other medical institutions.⁷⁹⁰ In 2008, thirteen Chinese citizens and a Greek national were arrested on charges related to selling counterfeit prescription drugs through internet pharmacies; Chinese officials seized 880 pounds of counterfeit Tamiflu and about 40 tons of raw chemical materials.⁷⁹¹

In 2009, Chinese authorities blocked more than 75 websites with connections to the global counterfeit drug trade. The SFDA blacklisted 25 websites for selling fake medicines, and China's State Administration of Traditional Chinese Medicine (SATCM) blacklisted 46 websites for selling fake herbal medicines.^{792,793} Director of State Food and Drug Administration, Shao Mingli, also reported that year that 36,000 illegal drug advertisements were handed over for investigations and that 231 suspects involved in major cases were arrested.⁷⁹⁴ In January 2010,

⁷⁸⁶ Bogdanich, Walt, and Hooker, Jake. “Agreement with China to Regulate Some Drugs.” *The New York Times* (Dec 12 2007), available at <http://www.nytimes.com/2007/12/12/business/worldbusiness/12safety.html> (accessed Jan 28 2010).

⁷⁸⁷ “China’s Ministries Work Together to Bust Online Counterfeit Drug Dealers.” *China Daily* (May 15 2009), available at http://www2.chinadaily.com.cn/bizchina/2009-05/16/content_7784217.htm (accessed Jan 26 2010).

⁷⁸⁸ Wenjun, C. “Local FDA Cracks Down on 165 Cases of Unqualified Meds.” *Shanghai Daily* (Dec 15 2009) available at http://www.yanhai.net.cn/html/Coastal_News/shanghai/2009/1215/137032.html (accessed Jan 28 2010).

⁷⁸⁹ “Chinese Police Seize Fake Tamiflu Sold on Internet.” *The New York Times* (Aug 31 2006), available at <http://query.nytimes.com/gst/fullpage.html?res=9C01EFDD1E3EF932A0575BC0A9609C8B63> (accessed Jan 28 2010).

⁷⁹⁰ “China Shuts Down 23 Websites for Illegal Drug Sales.” *Xinhua News Agency* (Mar 29 2008) available at http://news.xinhuanet.com/english/2008-03/29/content_7878440.htm (accessed Jan 28 2010).

⁷⁹¹ Gandy, Sara. “Greek National Arrested for Reportedly Selling Counterfeit Drugs Online.” *9 News* (Apr 4 2008), available at <http://www.9news.com/news/local/article.aspx?storyid=89359> (accessed Jan 28 2010).

⁷⁹² “China Shuts Down 23 Websites for Illegal Drug Sales.” *Xinhua News Agency* (Mar 29 2008) available at http://news.xinhuanet.com/english/2008-03/29/content_7878440.htm (accessed Jan 28 2010).

⁷⁹³ “China Blacklists 46 Website for Selling Fake TCM.” *Xinhua News Agency* (Mar 24 2009), available at http://www.china.org.cn/health/2009-03/24/content_17490156.htm (accessed Jan 28 2010).

⁷⁹⁴ “China Shuts Down 558 Websites.” *New Straits Times* (Jan 19 2010), available at <http://www.nst.com.my/articles/20100119104313/Article/index.html> (accessed Jan 28 2010).

the SFDA shut down another 558 websites for releasing false drug information.⁷⁹⁵

Domestic Production/Regulation

In 2006, the EU trade commissioner reported that European customs officers had seized fake birth control pills and ARVs that came from China, and the U.S. FDA seized 51 shipments of fake Tamiflu also coming from China.⁷⁹⁶

In 2007, numerous drug busts showed clear links to Chinese firms. John Newton, a senior investigator with INTERPOL, reported that transnational Chinese gangs were responsible for the counterfeit trade in antimalarial drugs Southeast Asia.⁷⁹⁷ Counterfeit versions of at-home diabetes tests, used to measure blood sugar levels, were discovered by Johnson & Johnson, the legal manufacturer of diabetes tests. Court records disclose that the 1 million fake test strips were manufactured by Chinese firms, and marketed in Canada, Greece, India, Pakistan, the Philippines, Saudi Arabia, Turkey, and 35 out of 50 states in the United States.⁷⁹⁸ In Milan, Italy, at the world's largest trade show for pharmaceutical ingredients, approximately 82 Chinese chemical companies claimed to make and export pharmaceutical ingredients, but records revealed that none were certified by the SFDA.⁷⁹⁹

Chinese and American regulators signed an agreement to strengthen the regulation of medicines and medical devices exported from China to the U.S. Chinese officials acknowledged that gaps in the system allow chemical companies to sell chemical ingredients, which might be substandard and dangerous, as pharmaceutical ingredients. Under the agreement, Chinese companies that make certain medicines for export to the U.S. must register with Chinese regulators. U.S. officials stated that the agreement was limited, but that it represented an important step in assisting the government of China to regulate such companies.⁸⁰⁰

Substandard Products

In 2004, during a program monitoring the quality of antimalarials in the Mekong region, Yunnan Province, about 6 percent of the samples failed basic quality tests⁸⁰¹, 3 percent had no API, and

⁷⁹⁵ "China Shuts Down 558 Websites." *New Straits Times* (Jan 19 2010), available at

<http://www.nst.com.my/articles/20100119104313/Article/index.html> (accessed Jan 28 2010).

⁷⁹⁶ Watts Jonathan. "China Drug Pirates Leave Death in their Wake." *The Guardian* (Dec 4 2006), available at <http://www.guardian.co.uk/business/2006/dec/04/china.internationalnews/2006/12/06/2003339298> (accessed Jan 24 2010).

⁷⁹⁷ McGivering, Jill. "Chinese Gangs 'Behind Fake Drugs'." *BBC News* (Jun 4 2007), available at <http://news.bbc.co.uk/2/hi/asia-pacific/6718645.stm> (accessed Jan 28 2010).

⁷⁹⁸ Frank, Allan Dodds, and Rapaport, Lisa. "China Counterfeit Diabetes Tests Tracked by J&J." *Bloomberg* (Aug 16 2007), available at <http://www.bloomberg.com/apps/news?pid=20601103&sid=a5XA7.yplw9k> (accessed Jan 28 2010).

⁷⁹⁹ Bogdanich, Walt, and Hooker, Jake. "Agreement with China to Regulate Some Drugs." *The New York Times* (Dec 12 2007), available at <http://www.nytimes.com/2007/12/12/business/worldbusiness/12safety.html> (accessed Jan 28 2010).

⁸⁰⁰ Bogdanich, Walt, and Hooker, Jake. "Agreement with China to Regulate Some Drugs." *The New York Times* (Dec 12 2007), available at <http://www.nytimes.com/2007/12/12/business/worldbusiness/12safety.html> (accessed Jan 28 2010).

⁸⁰¹ "Fake Antimalarials Found in Yunnan Province, China." *USP Drug Quality and Information program* (2004),

more than half (53 percent) of samples did not identify the manufacturing or expiration date, important quality indicators.⁸⁰²

After 200 Chinese cancer patients were paralyzed or otherwise harmed in 2007 by contaminated leukemia drugs, the SFDA shut down Shanghai Hualian, the maker of methotrexate.⁸⁰³ Problems with the drug first came to light in summer 2007 after patients receiving the drug experienced leg pain or even paralysis, but after cytarabin hydrochloride (another cancer drug manufactured by Shanghai Hualian) began to cause adverse reactions, officials suspected contamination and found that the two drugs had indeed been contaminated with vincristine sulfate, also a cancer drug.⁸⁰⁴ After 6 people died at No 2 Hospital at Nanchang University in Jiangxi province in May of 2008, the SFDA suspended the sale and use of all immune globulin products labeled from Jiangxi Boya Bio-Pharmaceutical Co.⁸⁰⁵ After testing some of the 500 units of the medicine purchased by the hospital, the SFDA reported that irregularities in some samples had been found.⁸⁰⁶ In October 2008, following the death of a 9-day-old infant, the Ministry of Health ordered hospitals to discontinue use of Yinzhihuang, a herbal drug used to treat jaundice and liver disease. After three other newborns treated with the drug also experienced adverse effects, Taihang Pharmaceuticals, the maker of the drug, recalled the batch.⁸⁰⁷ In 2008, the Consumer' Foundation tested 167 samples of Chinese herbal medicines and found that 22 were adulterated with Western medicines ingredients, 71 contained lead, 61 contained mercury, and 40 contained cadmium.⁸⁰⁸

Hong Kong (Special Administrative Region of China)

Although Hong Kong is modern with western style health regulations and consumer safeguards, the presence of counterfeits in Hong Kong is a reality, in both shops and pharmacies throughout the region. In 2006, Hong Kong customs seized USD 17,800 worth of counterfeit drugs across 19 cases. In 2007, the Hong Kong Customs and Excise Department seized approximately USD 2.64 million worth of counterfeits in 28 cases.⁸⁰⁹

available at <http://www.usp.org/pdf/EN/dqi/yunnanTesting.pdf> (accessed Jan 28 2010).

⁸⁰² "Fake Antimalarials Found in Yunnan Province, China." *USP Drug Quality and Information program* (2004), available at <http://www.usp.org/pdf/EN/dqi/yunnanTesting.pdf> (accessed Jan 28 2010).

⁸⁰³ Bogdanich, Walt, and Hooker, Jake. "Tainted Drugs Tied to Maker of Abortion Pill." *The New York Times* (Jan 31 2008), available at <http://www.nytimes.com/2008/01/31/world/asia/31pharma.html> (accessed Jan 28 2010).

⁸⁰⁴ Bogdanich, Walt, and Hooker, Jake. "Tainted Drugs Tied to Maker of Abortion Pill." *The New York Times* (Jan 31 2008), available at <http://www.nytimes.com/2008/01/31/world/asia/31pharma.html> (accessed Jan 28 2010).

⁸⁰⁵ Shan, Juan. "Irregularities Found in Samples of Lethal Drug." *China Daily* (Jun 3 2008), available at http://www.chinadaily.com.cn/china/2008-06/03/content_6729905.htm (accessed Jan 28 2010).

⁸⁰⁶ Shan, Juan. "Irregularities Found in Samples of Lethal Drug." *China Daily* (Jun 3 2008), available at http://www.chinadaily.com.cn/china/2008-06/03/content_6729905.htm (accessed Jan 28 2010).

⁸⁰⁷ "Tainted Medicine Suspected in China Baby Death." *USA Today* (Oct 20 2008), available at http://www.usatoday.com/news/world/2008-10-20-3831070611_x.htm (accessed Jan 28 2010).

⁸⁰⁸ "Chinese Herbal Medicines Contain West Ingredients." *The China Post* (Feb 6 2009), available at <http://www.chinapost.com.tw/taiwan/national/national-news/2009/02/06/194872/Chinese-herbal.htm> (accessed Jan 28 2010).

⁸⁰⁹ Moy, Patsy. "HK at Center of Global Drugs Scam." *The Standard* (Feb 11 2008), available at http://www.thestandard.com.hk/news_detail.asp?pp_cat=12&art_id=61319&sid=17539318&con_type=1 (accessed Jan 28 2010).

Unlike in much of sub-Saharan Africa, and many other parts of Asia, counterfeit medicines in Hong Kong are not being peddled to consumers through informal markets. Instead, they are more often sold in regular legitimate shops, alongside legitimate Chinese and Western medicines, and are well packaged fakes, sometimes covered with special “anti-counterfeiting” tapes and stickers.⁸¹⁰

In September 2003, a fake painkiller was discovered in stores across Hong Kong.⁸¹¹ In November 2005, Hong Kong Customs and Department of Health officers arrested nine people and seized 300 suspected counterfeit tablets worth about USD 22,000.⁸¹² In 2006, Hong Kong customs officers, in conjunction with the US Food and Drug Administration, arrested a suspect believed to be the mastermind behind a massive international fake pharmaceutical drug-smuggling syndicate distributing fake drugs to Europe, the US and Southeast Asia; four tablets of fake Cialis and 24 tablets of fake Viagra were seized.⁸¹³ In 2008, during a much larger undercover operation called “King Fisher,” Hong Kong customs officials seized about 470,000 counterfeit tablets with no API meant to treat heart disease, impotence, and avian influenza, as well as supposed diet pills.^{814 815}

According to the data from the Hong Kong Association of the Pharmaceutical Industry (HKAPI), from 2004 to 2007, the penalty for cases ending in conviction for counterfeiting pharmaceuticals generally resulted in fines of only 4,000 to 20,000 Hong Kong dollars (\$500 to \$2,500).⁸¹⁶ In 2007, after the death of 1 man from taking counterfeit Viagra and the hospitalization of eleven others, the HKAPI urged the government to increase the penalty for counterfeiting or even to introduce a new law to specifically increase the penalty for drug counterfeiters who put the public’s safety at risk, which would act as a greater deterrent for criminals.^{817,818}

⁸¹⁰ Flank, Sharon. “Anticounterfeiting and NIR: A Hong Kong Diary.” *Pharmaceutical Manufacturing* (May 21 2008), available at <http://www.pharmamanufacturing.com/articles/2008/068.html> (accessed Feb 11 2010).

⁸¹¹ Adler, Carlye. “Which is Safe to Take?” *Time* (May 31 2004), available at <http://www.time.com/time/magazine/article/0,9171,644218,00.html#ixzz0eIqhbB6I> (accessed Feb 1 2010).

⁸¹² “USD 22,000 Worth of Counterfeit Drugs Seized.” *IPR Strategic Business Information Database* (Nov 19 2005), available at <http://www.highbeam.com/doc/1G1-138917227.html> (accessed Feb 11 2010).

⁸¹³ Wong, Albert. “‘Key Player’ in Fake-Drugs Ring Busted.” *The Standard* (Sep 23 2006), available at http://www.thestandard.com.hk/news_detail.asp?pp_cat=11&art_id=27927&sid=10061575&con_type=1 (accessed Feb 11 2010).

⁸¹⁴ “Hong Kong Customs Seizes 19 Million HKD Worth of Counterfeit Drugs.” *People’s Daily Online* (Jan 26 2007), available at http://english.peopledaily.com.cn/200701/26/eng20070126_345135.html (accessed Jan 28 2010).

⁸¹⁵ “Hong Kong Customs Seizes 19 Million HKD Worth of Counterfeit Drugs.” *People’s Daily Online* (Jan 26 2007), available at http://english.peopledaily.com.cn/200701/26/eng20070126_345135.html (accessed Jan 28 2010).

⁸¹⁶ “The Pharmaceutical Industry Strongly Condemns the Selling of Counterfeit Drugs and Urges the Government to Increase Penalty for Counterfeiting.” *Press Release, The Hong Kong Association of the Pharmaceutical Industry* (Feb 20 2008), available at http://www.hkapi.hk/images/newsletter/Press_release_04022008_revised.pdf (accessed Feb 1 2010).

⁸¹⁷ “HK Customs Smashes International Ring of Counterfeit Medicines.” *Hong Kong Special Administrative Region Government Press Releases* (Jan 26 2007), available at <http://www.info.gov.hk/gia/general/200701/26/P200701260269.htm> (accessed Feb 14 2011).

⁸¹⁸ “The Pharmaceutical Industry Strongly Condemns the Selling of Counterfeit Drugs and Urges the Government to Increase Penalty for Counterfeiting.” *Press Release, The Hong Kong Association of the Pharmaceutical Industry* (Feb 20 2008), available at http://www.hkapi.hk/images/newsletter/Press_release_04022008_revised.pdf (accessed Feb 1 2010).

Taiwan

In 2005, the Department of Health estimated that the fake drug trade in Taiwan is worth USUSD 300 million per year. The Department of Health's Bureau of Pharmaceutical Affairs routinely checks pharmacies, and 2 to 3 percent turn up counterfeits. Companies hire private investigators to locate counterfeits in the market by making routine purchases of drugs and testing them for authenticity. Private investigators, like the DOH, suspect they are merely scratching the surface of the issue since the identification of fakes is so difficult.⁸¹⁹

In 2009, there were 102 fake medicine cases processed, 283 cases punished, and 6,947 advertisements for fake drugs were fined a total of about USD 3.8 million.⁸²⁰ It was also estimated that about one percent of drugs in the country were counterfeits. Taiwan introduced new near-infrared spectrography (NIR) to further protect their consumers against any remaining counterfeit drugs in, or trying to enter, the domestic market.⁸²¹

Despite increased regulatory and enforcement efforts since 2003, Taiwanese officials continue to discover a high number of fakes produced domestically, suggesting a far greater problem. In December 2005, the Criminal Investigation Bureau (CIB) in Taiwan arrested the largest underground-drug manufacturing ring and seized 550,000 counterfeit pills.⁸²² During the raid, police seized 20,000 Zantac (antacid), 50,000 Reductil (slimming pill), 70,000 Stinox (sedative), 50,000 Viagra, 70,000 Cialis, 120,000 flu drug pills, and 210,000 unknown drug pills.⁸²³ The primary suspect in the case confessed to police that seven out of ten pharmacies in north Taiwan were channeling partners of the ring. He said that the drug ingredients were imported from mainland China due to their lax regulations, and were manufactured and packaged in Taiwan.⁸²⁴

An investigative report in 2006 revealed that Taiwan is also fighting an influx of foreign counterfeit drugs.⁸²⁵ Months later, in May 2006, Taiwan's Criminal Investigation Bureau (the CIB) announced that roughly USD 9 million worth of counterfeit drugs were seized in Taipei.⁸²⁶ During a raid in 2007, Taiwanese police officers found more than 2 million counterfeit

⁸¹⁹ Courtenay, Philip. "Taking the Lead Against Counterfeit Medicines." *Taiwan Today* (Mar 20 2008), available at <http://www.taiwantoday.tw/ct.asp?xItem=30694&CtNode=426> (accessed Feb 19 2010).

⁸²⁰ "Gov't Determined to Fight Fake Medicine." *The China Post* (Mar 26 2010), available at <http://www.chinapost.com.tw/taiwan/national/national-news/2010/03/26/249899/Govt-determined.htm> (accessed Mar 29 2010).

⁸²¹ Harris, Julian, and Stevens, Philip. "Fake Drugs and Failed Governance." *The China Post* (Jan 16 2009), available at <http://www.chinapost.com.tw/commentary/the-china-post/special-to-the-china-post/2009/01/16/192286/p2/Fake-drugs.htm> (accessed Feb 1 2010).

⁸²² "Counterfeit Medicine Ring Busted by CIB." *The China Post* (Dec 9 2005), available at <http://www.chinapost.com.tw/taiwan/detail.asp?ID=73318&GRP=B> (accessed Jan 28 2010).

⁸²³ "Counterfeit Medicine Ring Busted by CIB." *The China Post* (Dec 9 2005), available at <http://www.chinapost.com.tw/taiwan/detail.asp?ID=73318&GRP=B> (accessed Jan 28 2010).

⁸²⁴ "Counterfeit Medicine Ring Busted by CIB." *The China Post* (Dec 9 2005), available at <http://www.chinapost.com.tw/taiwan/detail.asp?ID=73318&GRP=B> (accessed Jan 28 2010).

⁸²⁵ Courtenay, Philip. "Taking the Lead Against Counterfeit Medicines." *Taiwan Today* (Mar 20 2008), available at <http://www.taiwantoday.tw/ct.asp?xItem=30694&CtNode=426> (accessed Feb 19 2010).

⁸²⁶ Pitts, Peter. "Counterfeit Drugs and China." *Center for Medicine in the Public Interest* (May 31 2006), available at <http://www.cmpi.org/in-the-news/testimony/counterfeit-drugs-and-china-new/> (accessed Feb 19 2010).

medicines, including various dietary supplements and ointments.⁸²⁷ According to reports, the fakes had been imported in bulk from China and were in the process of being repackaged for sale in Taiwan.⁸²⁸

In 2008 the Taiwan Medical Product Anti-Counterfeit Task Force sent 501 surveys to pharmacies,⁸²⁹ and found 8 percent of surveyed pharmacies sold counterfeit products in their stores.⁸³⁰

In 2003, the DOH set up an anti-counterfeit drugs inter-agency working group to coordinate counterfeit-drug inspections.⁸³¹ In 2004 Taiwanese officials also introduced significantly increased penalties for making and distributing counterfeit drugs, hoping to deter counterfeiters further from the act.⁸³² In May 2005, the DOH also launched a pharmaceutical Web site to assist medical personnel and the general public in fighting counterfeits by providing guidance on the identification of 5,200 different types of medicines, along with 18 images of the most commonly found counterfeit drugs.⁸³³ The DOH also provided a toll-free hotline and an informant box in the form of an e-mail address for the public to report on cases involving counterfeit drugs, and created workshops for the inspection of counterfeit drugs for its enforcement officers.⁸³⁴ Most recently, in March 2010, Taiwan set up a special task force to fight fake and illegal medicine.

The task force consists of members from the Department of Health (DOH), Ministry of Justice, National Communications Commission and National Police Agency.^{835,836}

Mongolia (this colour is somewhat fabricated – I coloured it yellow but figures are somewhat inconclusive).

In 2006, the Ministry of Health in Mongolia estimated that about 85 percent of medicines in the country were imported. Mongolian officials admit that there are 14 permanent entry points and 7 seasonal entry points along Mongolia's Russian and Chinese borders at which they are unable to

⁸²⁷ Oung, Angelica. "DOH Issues Fake Drugs Warning." *Taipei Times* (Dec 18 2007), available at <http://www.taipeitimes.com/News/taiwan/archives/2007/12/18/2003392998> (accessed Feb 14 2011).

⁸²⁸ Oung, Angelica. "DOH Issues Fake Drugs Warning." *Taipei Times* (Dec 18 2007), available at <http://www.taipeitimes.com/News/taiwan/archives/2007/12/18/2003392998> (accessed Feb 14 2011).

⁸²⁹ "Lots of Fake Viagra, Viartril-S, and Reductil Emerge." *The China Post* (Mar 28 2009), available at <http://www.chinapost.com.tw/health/medicine/2009/03/28/201948/Lots-of.htm> (accessed Jan 28 2010).

⁸³⁰ "Lots of Fake Viagra, Viartril-S, and Reductil Emerge." *The China Post* (Mar 28 2009), available at <http://www.chinapost.com.tw/health/medicine/2009/03/28/201948/Lots-of.htm> (accessed Jan 28 2010).

⁸³¹ Courtenay, Philip. "Taking the Lead Against Counterfeit Medicines." *Taiwan Today* (Mar 20 2008), available at <http://www.taiwantoday.tw/ct.asp?xItem=30694&CtNode=426> (accessed Feb 19 2010).

⁸³² Courtenay, Philip. "Taking the Lead Against Counterfeit Medicines." *Taiwan Today* (Mar 20 2008), available at <http://www.taiwantoday.tw/ct.asp?xItem=30694&CtNode=426> (accessed Feb 19 2010).

⁸³³ Courtenay, Philip. "Taking the Lead Against Counterfeit Medicines." *Taiwan Today* (Mar 20 2008), available at <http://www.taiwantoday.tw/ct.asp?xItem=30694&CtNode=426> (accessed Feb 19 2010).

⁸³⁴ Courtenay, Philip. "Taking the Lead Against Counterfeit Medicines." *Taiwan Today* (Mar 20 2008), available at <http://www.taiwantoday.tw/ct.asp?xItem=30694&CtNode=426> (accessed Feb 19 2010).

⁸³⁵ "Gov't Determined to Fight Fake Medicine." *The China Post* (Mar 26 2010), available at <http://www.chinapost.com.tw/taiwan/national/national-news/2010/03/26/249899/Govt-determined.htm> (accessed Mar 29 2010).

⁸³⁶ "Executive Yuan Chief Vows to End Sales of Bogus Drugs." *China Daily* (Mar 26 2010), available at http://www.chinadaily.com.cn/hkedition/2010-03/26/content_9644257.htm (accessed Mar 29 2010).

sufficiently regulate medicine imports.⁸³⁷ The National Quality Control Laboratory in Mongolia is too centralized to reach outlying border towns through which imports are sourced, and has too little technical and human resource capacities to effectively monitor the large number of counterfeit and substandard drugs which routinely pass through its borders. During a 2006 study by the Ministry of Health on counterfeit medicines in the country, 55 suspicious samples were chosen after visual inspection and found that 16 out of the 55 (29 percent) samples were inconsistent with quality standards, while 8 (14.5 percent) were counterfeit.⁸³⁸

Due to the general lack of knowledge and awareness regarding the problem of counterfeit drugs in the country, the penalties for counterfeiting medicines are weak in Mongolia.⁸³⁹

South-Central Asia

Even compared with Eastern Asia, South Central Asia suffers from an exceedingly high prevalence of fake drugs. Countries in this region either do not have regulatory bodies to regulate the flow of medicines or, if these bodies exist, their effectiveness is severely strained. Low government capacity, lack of enforcement capabilities, a lack of funds, and porous borders, often result in a series of unprotected distribution networks easily subject to infiltration by fakes.

Most counterfeit and substandard drugs in South-Central Asia come from India, Pakistan, China, and Iran. Smuggling and illegal imports provide the necessary routes for the conduit of the fakes, while illegal pharmacies in the region act as distribution centers for a variety of counterfeit and substandard products including common antibiotics, syringes, saline fluids, birth control, anti-depressants, and insulin, among other medicines.

Afghanistan

Counterfeit pharmaceuticals are a major problem in Afghanistan. Between mid-2006 to 2008, Afghanistan's Pharmacy Affairs Department (PAD) reportedly seized approximately 200 tons of counterfeit medicine across the country.⁸⁴⁰

⁸³⁷ "Report of Intensified Surveillance on Counterfeit Medicines in Mongolia." *Ministry of Health, Mongolia* (Aug 2 2006), available at http://moh.mn/moh_percent20db/HealthReports.nsf/ecb18f03b32fae434825768500144b6e/a85f8ce2676c2376c825712600245fbc/USD_FILE/Report.counterfiet.08.02.06.pdf (accessed Feb 19 2010).

⁸³⁸ "Report of Intensified Surveillance on Counterfeit Medicines in Mongolia." *Ministry of Health, Mongolia* (Aug 2 2006), available at http://moh.mn/moh_percent20db/HealthReports.nsf/ecb18f03b32fae434825768500144b6e/a85f8ce2676c2376c825712600245fbc/USD_FILE/Report.counterfiet.08.02.06.pdf (accessed Feb 19 2010).

⁸³⁹ "Report of Intensified Surveillance on Counterfeit Medicines in Mongolia." *Ministry of Health, Mongolia* (Aug 2 2006), available at http://moh.mn/moh_percent20db/HealthReports.nsf/ecb18f03b32fae434825768500144b6e/a85f8ce2676c2376c825712600245fbc/USD_FILE/Report.counterfiet.08.02.06.pdf (accessed Feb 19 2010).

⁸⁴⁰ "Fake Medicine Floods Market – Ministry." *Quqnoos.com* (Nov 5 2008), cited by McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 22 2010).

The sale of substandard and expired medicines is also a major issue. According to official statistics, Afghanistan has about 5,640 doctors for about 28 million people, or one doctor for roughly 4,964 people. Most trained health care workers are based in cities, so the task of dispensing medicines in rural villages often falls on untrained health workers.

Health ministry officials claim that they test about 80 percent of all medicines legally imported into the country, but only about 30 percent of the medicines in the country are legally imported.⁸⁴¹ Seventy percent of the medicines available in the country are smuggled across Afghanistan's borders, or imported by companies without appropriate legal permits.⁸⁴² Since so many imports are unregistered, rural health workers, who received little to no pharmaceutical training, are dealing with poor quality or expired drugs.⁸⁴³ In 2006, the Health Ministry officials reported that at least 18 people were killed by fake and expired medicines between May and March of 2007.⁸⁴⁴ Due to poor reporting mechanisms, they believe the actual number of deaths to be much higher.⁸⁴⁵

Most of the poor quality medicines originate in Pakistan, Iran, China, or India.⁸⁴⁶ Though the pharmaceutical department carries out surprise checks on drug stores and attempts to control imports at some border check points, it is largely unequipped and unable to control the spread of fake, expired, or substandard medicines in Afghanistan.

Bangladesh

Poor government vigilance and supervision over drug manufacturers and sellers allows the market for fakes to flourish in Bangladesh, and the government itself has admitted that it has limited manpower and facilities to cope with the country's rapidly expanding supply of pharmaceuticals.⁸⁴⁷

⁸⁴¹ "Sale Of Expired, Spurious Drugs on Rise in Afghanistan." *Pak Tribune* (Jan 15 2007), available at <http://www.rawa.org/temp/runews/2007/01/15/sale-of-expired-spurious-drugs-on-rise-in-afghanistan.html> (accessed Jan 22 2010).

⁸⁴² "Sale Of Expired, Spurious Drugs on Rise in Afghanistan." *Pak Tribune* (Jan 15 2007), available at <http://www.rawa.org/temp/runews/2007/01/15/sale-of-expired-spurious-drugs-on-rise-in-afghanistan.html> (accessed Jan 22 2010).

⁸⁴³ "Sale Of Expired, Spurious Drugs on Rise in Afghanistan." *Pak Tribune* (Jan 15 2007), available at <http://www.rawa.org/temp/runews/2007/01/15/sale-of-expired-spurious-drugs-on-rise-in-afghanistan.html> (accessed Jan 22 2010).

⁸⁴⁴ "Sale Of Expired, Spurious Drugs on Rise in Afghanistan." *Pak Tribune* (Jan 15 2007), available at <http://www.rawa.org/temp/runews/2007/01/15/sale-of-expired-spurious-drugs-on-rise-in-afghanistan.html> (accessed Jan 22 2010).

⁸⁴⁵ "Sale Of Expired, Spurious Drugs on Rise in Afghanistan." *Pak Tribune* (Jan 15 2007), available at <http://www.rawa.org/temp/runews/2007/01/15/sale-of-expired-spurious-drugs-on-rise-in-afghanistan.html> (accessed Jan 22 2010).

⁸⁴⁶ "Sale Of Expired, Spurious Drugs on Rise in Afghanistan." *Pak Tribune* (Jan 15 2007), available at <http://www.rawa.org/temp/runews/2007/01/15/sale-of-expired-spurious-drugs-on-rise-in-afghanistan.html> (accessed Jan 22 2010).

⁸⁴⁷ Islam, Mohammad Saidul. "Therapeutic Drug Use in Bangladesh: Policy Versus Practice." *Indian Journal of Medical Ethics* 5:1, 24-25 (2008), available at <http://www.ncbi.nlm.nih.gov/pubmed/18630250> (accessed Feb 22 2010).

Some 2004 reports estimate that prevalence rates of fake or substandard versions of life-saving drugs in Bangladesh may be as high as 70 to 80 percent.⁸⁴⁸

In 2004, the general secretary of the Bangladesh Pharmaceutical Industries Association estimated that between USD 100 to USD 150 million worth of counterfeit drugs were present in Bangladesh, and that there were approximately 80,000 unlicensed drugstores in the country.^{849,850} He and others maintain that most fake or substandard drugs in the country are made in Bangladesh, India, Pakistan, China and Thailand.⁸⁵¹ Dozens of unauthorized pharmaceutical establishments have mushroomed on the Bangladesh border and smuggled drugs into the country.⁸⁵² Many companies manufacture fake post-operative antibiotics like Cephadrine and Hydrocortisone, while fungus-coated saline fluids and used syringes are also commonly found.⁸⁵³ In 2009, at least 20 infants died of kidney failure in Bangladesh; the children were all aged between 11 months and three years and doctors suspected that they had all taken cough syrup containing diethylene glycol.⁸⁵⁴

Bangladesh's local pharmaceutical producers also struggle with quality issues, which compound the country's substandard drug issue. A 2008 study revealed that of the 300 pharmaceutical companies in Bangladesh, only 20 to 25 of the best companies produce drugs which meet international quality standards. Numerous smaller and less reputable companies market substandard drugs in the country.⁸⁵⁵ A 2008 report noted that 69 percent of paracetamol tablets and 80 percent of ampicillin capsules produced by small domestic companies were substandard.⁸⁵⁶

In a survey conducted between 1988-91, 66 of the 198 licensed manufacturers in Bangladesh were producing substandard medications. These manufacturers produced between 1-16 brands of substandard prescription drugs (49 percent OTC drugs and 6.3 percent injectables, the remainder

⁸⁴⁸ Islam, Mohammad Saidul. "A Review on the Policy and Practices of Therapeutic Drug Uses in Bangladesh." *Calicut Medical Journal* 4:4 (2006), available at <http://www.calicutmedicaljournal.org/2006/4/4/e2.pdf> (accessed Feb 22 2010).

⁸⁴⁹ Khan, Sharier. "Fake Drugs Flood Bangladesh." *SOS-Arsenic.net* (2003), available at <http://www.sos-arsenic.net/english/environment/fake-med.html> (accessed Feb 22 2010).

⁸⁵⁰ "Fake Drugs Flood Bangladesh." *Pharmabiz Chronicle* (Oct 28 2004), available at <http://www.pharmabiz.com/NewsDetails.aspx?aid=24463&sid=21> (accessed Feb 14 2011).

⁸⁵¹ Khan, Sharier. "Fake Drugs Flood Bangladesh." *SOS-Arsenic.net* (2003), available at <http://www.sos-arsenic.net/english/environment/fake-med.html> (accessed Feb 22 2010).

⁸⁵² Khan, Sharier. "Fake Drugs Flood Bangladesh." *SOS-Arsenic.net* (2003), available at <http://www.sos-arsenic.net/english/environment/fake-med.html> (accessed Feb 22 2010).

⁸⁵³ Khan, Sharier. "Fake Drugs Flood Bangladesh." *SOS-Arsenic.net* (2003), available at <http://www.sos-arsenic.net/english/environment/fake-med.html> (accessed Feb 22 2010).

⁸⁵⁴ "Counterfeiting." *United Nations Interregional Crime and Justice Research Institute* (2009), available at http://counterfeiting.unicri.it/risks.php?c_ =4 (accessed Feb 22 2010).

⁸⁵⁵ Islam, Mohammad Saidul. "Therapeutic Drug Use in Bangladesh: Policy Versus Practice." *Indian Journal of Medical Ethics* 5:1, 24-25 (2008), available at <http://www.ncbi.nlm.nih.gov/pubmed/18630250> (accessed Feb 22 2010)..

⁸⁵⁶ Islam, Mohammad Saidul. "Therapeutic Drug Use in Bangladesh: Policy Versus Practice." *Indian Journal of Medical Ethics* 5:1, 24-25 (2008), available at <http://www.ncbi.nlm.nih.gov/pubmed/18630250> (accessed Feb 22 2010).

being non-injectable prescription drugs). The content of the active ingredients was found to be insufficient.⁸⁵⁷

In 1992, a total of 137 brand samples were obtained from retail shops in various parts of the country and analyzed for level of content of the active ingredients as well as the disintegration of tablets. Results showed 37 samples were substandard, all manufactured by small companies. All products produced by 13 of the top 15 companies in Bangladesh met the required standards.⁸⁵⁸

In 2004, during an annual testing of 5,000 drug samples, the Public Health and Drug Testing Laboratory (PHDTL) detected 300 of the drug samples were either counterfeit or substandard, many of which included popular antibiotics and lifesaving drugs.^{859,860} In 2004, another study conducted on the quality of antibiotics in the country found that⁸⁶¹ seven of the ten drugs were substandard.⁸⁶² Another 2004 study conducted by the USP found 69 percent paracetamol tablets and 80 percent ampicillin capsules tested were substandard.⁸⁶³ A 2006 study of 15 brands of ciprofloxacin, showed that 47 percent of the collected samples were underdosed.⁸⁶⁴

In November 2007, fake medicine, and other items worth USD 30,000 were seized when smuggled to Bangladesh.⁸⁶⁵

The small, independent pharmacies and manufacturers which make up Bangladesh's drug distribution marketplace are exceedingly difficult to regulate. The country's already weak oversight system enables Bangladesh's numerous firms to trade low-quality drugs at higher prices, which partly explains why the quality of available drugs varies significantly.⁸⁶⁶

⁸⁵⁷ Roy, J. "The Menace of Substandard Drugs." *World Health Forum* 15:4, 406-407 (1994), available at <http://www.ncbi.nlm.nih.gov/pubmed/7999239> (accessed Feb 22 2010).

⁸⁵⁸ Roy, J. "The Menace of Substandard Drugs." *World Health Forum* 15:4, 406-407 (1994), available at <http://www.ncbi.nlm.nih.gov/pubmed/7999239> (accessed Feb 22 2010).

⁸⁵⁹ Khan, Sharier. "Fake Drugs Flood Bangladesh." *SOS-Arsenic.net* (2003), available at <http://www.sos-arsenic.net/english/environment/fake-med.html> (accessed Feb 22 2010).

⁸⁶⁰ Islam, Mohammad Saidul. "Therapeutic Drug Use in Bangladesh: Policy Versus Practice." *Indian Journal of Medical Ethics* 5:1, 24-25 (2008), available at <http://www.ncbi.nlm.nih.gov/pubmed/18630250> (accessed Feb 22 2010).

⁸⁶¹ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 22 2010).

⁸⁶² McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 22 2010).

⁸⁶³ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 15 2010).

⁸⁶⁴ Islam, Mohammad Saidul. "A Review on the Policy and Practices of Therapeutic Drug Uses in Bangladesh." *Calicut Medical Journal* 4:4 (2006), available at <http://www.calicutmedicaljournal.org/2006/4/4/e2.pdf> (accessed Feb 22 2010).

⁸⁶⁵ "Economy Chronology – 2007." *Alternative ASEAN Network on Burma* (2008), available at <http://www.altsean.org/Chronology/Chronology2007/EconomyChronology2007.htm> (accessed Feb 22 2010).

⁸⁶⁶ "Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh." *Bangladesh Development Series Paper No. 23, Human Development Unit, South Asia Region, The World Bank* (Mar 2008),

The International Centre for Diarrheal Disease Research, Bangladesh (ICDDR, B) tested content in zinc-syrup formulations purchased from local pharmacies in Dhaka, the capital. Only 10 percent contained zinc concentrations within 5 percent of the stated content. This problem could have resulted from either poor manufacturing or poor product handling in the distribution channel, since zinc degrades when exposed to light.⁸⁶⁷

Although there are approximately 200,000 private pharmacies in Bangladesh, the government lists officially only 76,000 pharmacies. The remaining 124,000 have no legal license or accredited pharmacist on staff. Even accredited pharmacists have varying education levels, and many lack adequate training.⁸⁶⁸

Bhutan

There is virtually no information available on the counterfeit and substandard drug trade in Bhutan. In August 2003, the country passed the “Medicines Act of the Kingdom of Bhutan,” setting up the country’s Drug Regulatory Authority and Medicines Board, which set rules and regulations for the quality of medicines and oversee enforcement of these rules.⁸⁶⁹ Although this suggests that Bhutan does indeed face a public health crisis, there is no data available to substantiate these claims.

India

In 2002, India’s pharmaceutical companies suggested that in India’s major cities, 20 percent of medicines sold were fake, causing the drug companies to lose between 4 and 5 percent of their annual revenue.⁸⁷⁰ From 2002 to 2003, fake drugs were estimated to represent 13–30 percent of the pharmaceutical market.⁸⁷¹ In 2008, according to the Associated Chambers of Commerce and Industry of India (ASSOCHAM), 20 percent of medicines sold in India were fakes.⁸⁷² Of those, 60 percent did not have active ingredients, 19 percent had incorrect ingredients, and 16 percent

available at <http://siteresources.worldbank.org/INTBANGLADESH/Resources/pharmaceutical.pdf> (accessed Feb 22 2010).

⁸⁶⁷ “Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh.” *Bangladesh Development Series Paper No. 23, Human Development Unit, South Asia Region, The World Bank* (Mar 2008), available at <http://siteresources.worldbank.org/INTBANGLADESH/Resources/pharmaceutical.pdf> (accessed Feb 22 2010).

⁸⁶⁸ “Public and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh.” *Bangladesh Development Series Paper No. 23, Human Development Unit, South Asia Region, The World Bank* (Mar 2008), available at <http://siteresources.worldbank.org/INTBANGLADESH/Resources/pharmaceutical.pdf> (accessed Feb 22 2010).

⁸⁶⁹ “Essential Drugs in Brief.” *Department of Essential Drugs and Medicines Policy, World Health Organization* (Jun 2004), available at <http://apps.who.int/medicinedocs/pdf/s6167e/s6167e.pdf> (accessed Mar 10 2010).

⁸⁷⁰ “Around the World: Reports of Counterfeit Medicines.” *World Health Organization* (2006), available at http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html (accessed Mar 8 2010).

⁸⁷¹ “Counterfeit Medicine Factsheet.” *World Health Organization* (Nov 14 2006), available at http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html (accessed Feb 19 2010).

⁸⁷² “Fake Drugs Growing at 20-25%: ASSOCHAM.” *Business Standard* (Feb 11 2008), available at <http://www.business-standard.com/india/news/fake-drugs-growing-at-20-25-assochem/313278/> (accessed Feb 14 2011).

had either harmful or inappropriate ingredients, like talcum powder.⁸⁷³ ASSOCHAM also reported in 2008 that counterfeits had penetrated both the formal and informal health sector, estimating that approximately 38 percent of medicines in government hospitals were counterfeit.⁸⁷⁴ The Indian Health Ministry, however, refuted the claims made by ASSOCHAM by claiming that only 5 percent of drugs in India are counterfeit while 0.3 percent are spurious. Health secretary Naresh Dayal said, "The counterfeit drug market in India, which we believe is still not that large, has the potential to become extremely threatening. We need to know its actual size in order to combat it."⁸⁷⁵ According to ASSOCHAM, the market for fake and spurious drugs in India is growing at a rate of 10-25 percent annually.⁸⁷⁶ Furthermore, in 2008, the Organization for Economic Cooperation and Development (OECD) reported that 75 percent of fake drugs worldwide have origins in India.^{877,878}

Each year, state drug inspectors collect around 40,000 samples for regular testing. Over the past fifteen years, an average of 0.3-0.4 percent are found to have no active content and are defined locally as spurious, and 8 percent are substandard.⁸⁷⁹⁸⁸⁰ However, government figures may belie a problem much larger in reality. In some independent surveys from 2007, more than 90 percent of the medicines were found to be fakes.⁸⁸¹ In one significant study conducted in 2007, 10,743 samples from 243 retail outlets in 15 states were collected and 20 percent of the samples were sent for testing at government labs; the study found 3.1 percent to be counterfeit.⁸⁸² In 2009, a controversial survey conducted by the Central Drugs Standard Control Organization (CDSCO), collected and tested 24,136 samples of medicines, and reported that the prevalence of spurious drugs was a meager 0.046 percent.⁸⁸³

In 2004, the Delhi government carried out 618 inspections of chemists and manufacturing units,

⁸⁷³ "Fake Drugs Growing at 20-25%: ASSOCHAM." *Business Standard* (Feb 11 2008), available at <http://www.business-standard.com/india/news/fake-drugs-growing-at-20-25-assochem/313278/> (accessed Feb 14 2011).

⁸⁷⁴ "Fake Drugs Growing at 20-25%: ASSOCHAM." *Business Standard* (Feb 11 2008), available at <http://www.business-standard.com/india/news/fake-drugs-growing-at-20-25-assochem/313278/> (accessed Feb 14 2011).

⁸⁷⁵ Sinha, Kounteya, "20 Percent of Drugs Sold in India are Fake, Fear Experts." *The Times of India* (May 14 2008), available at <http://timesofindia.indiatimes.com/articleshow/msid-3037664,prtpage-1.cms> (accessed Jan 19 2010).

⁸⁷⁶ "Fake Drugs Market Growing at Alarming Rate: ASSOCHAM." *The Economic Times* (Feb 11 2008), available at <http://economictimes.indiatimes.com/articleshow/msid-2771350.cms> (accessed Feb 19 2010).

⁸⁷⁷ Lal, Neeta. "Fake Drugs Need Better Pill for India." *Asia Times Online* (Jun 7 2008), available at http://www.atimes.com/atimes/South_Asia/JF07Df01.html (accessed Jan 21 2010).

⁸⁷⁸ Swaminath, G. "Faking It II—Countering and Preventing Counterfeiting of Drugs." *Indian Journal of Psychiatry* 51:1, 9-11 (2009), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2738397/> (accessed Feb 19 2010).

⁸⁷⁹ Sinha, Kounteya, "20 Percent of Drugs Sold in India are Fake, Fear Experts." *The Times of India* (May 14 2008), available at <http://timesofindia.indiatimes.com/articleshow/msid-3037664,prtpage-1.cms> (accessed Jan 19 2010).

⁸⁸⁰ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 22 2010).

⁸⁸¹ "Counterfeit Medicines on the Rise in India." *Huliq* (May 17 2007), available at <http://www.huliq.com/?q=21813/counterfeit-medicines-on-the-rise-in-india> (accessed Feb 19 2010).

⁸⁸² Datta, P.T. Jyothi. "Fake Drugs Across the Price Spectrum: WHO Study." *Hindu Business Line* (Dec 22 2007), available at <http://www.thehindubusinessline.com/2007/12/23/stories/2007122351390100.htm> (accessed Feb 19 2010).

⁸⁸³ Pandeya, Radhieka. "Supply of Fake Drugs Grossly Overstated." *Live Mint* (Nov 26 2009), available at <http://www.livemint.com/2009/11/27010916/Supply-of-fake-drugs-grossly-o.html> (accessed Feb 19 2010).

suspending 112 chemist licenses and three manufacturing licenses due to violations of the Drugs and Cosmetics Law. According to Delhi health minister, the testing laboratory of the government collected 132 drugs and cosmetics samples, eight of which were substandard. Chemists and manufacturers found in violation were prosecuted following the study's publication.⁸⁸⁴ Other raids in January 2007 led the arrest of a single person for possession and sale of fake thyroid hormone supplements.⁸⁸⁵

In 2007, approximately USD 509,000 of fake drugs were seized in Orissa's Bolangir district.⁸⁸⁶ In 2008, the Indian police found more than 700,000 counterfeit tablets of the brand name analgesic, Saridon.⁸⁸⁷ In 2009, Ghaziabad police arrested four people and confiscating machinery, packaging, and cartons of fake medicine.⁸⁸⁸ Rajasthan police raided a house in Rajpura and arrested a factory owner on charges of manufacturing fake drugs, seizing 35 boxes of amoxicillin during the raid.⁸⁸⁹ In Rajasthan, the state Drug Control Organization seized 15 fake immune disorder treatments in August 2009.⁸⁹⁰ In November 2009, raids conducted by Uttar Pradesh authorities resulted in approximately USD 222,000 worth of fake and substandard medicines being seized.⁸⁹¹

In 2009, fake antidepressants, painkillers, and insulin were found at Danapur Railway Hospital, many of which had only 11-12 percent of the active pharmaceutical ingredient.⁸⁹² Fake anesthetics were also found at Osmania General Hospital in Hyderabad. One patient woke up after 30 minutes when they should have been unconscious for two hours.⁸⁹³ In March 2010, Sewree region raids led to seizure of fakes used to treat cancer and AIDS patients.⁸⁹⁴ Officials

⁸⁸⁴ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

⁸⁸⁵ "FDA Raids Fake Thyroid Drug Makers in Mumbai." *The Economic Times* (Mar 20 2007), available at <http://economictimes.indiatimes.com/articleshow/msid-1780951.cms> (accessed Feb 19 2010).

⁸⁸⁶ "Fake Medicine Factory Busted in Orissa." *India eNews* (Jul 21 2007), available at <http://www.indiaenews.com/health/20070721/61808.htm> (accessed Feb 19 2010).

⁸⁸⁷ "Fake Antibiotic Pills Worth Rs 20L Seized." *The Times of India* (Aug 27 2008), available at <http://vlex.in/vid/65198200> (accessed Feb 19 2010).

⁸⁸⁸ "Fake Drug Racket Busted." *Indian Express* (Dec 24 2009), available at <http://www.indianexpress.com/news/fake-drugs-racket-busted-one-arrested/558472/> (accessed Feb 19 2010).

⁸⁸⁹ "Spurious Drugs: Factory Owner Held." *The Times of India* (May 31 2009), available at <http://timesofindia.indiatimes.com/city/chandigarh/Spurious-drugs-Factory-owner-held/articleshow/4599209.cms> (accessed Feb 19 2010).

⁸⁹⁰ "Ignoring Bills Aids Fake Drug Biz." *The Times of India* (Aug 24 2009), available at <http://timesofindia.indiatimes.com/articleshow/msid-4926002.prtpage-1.cms> (accessed Feb 19 2010).

⁸⁹¹ "Uttar Pradesh Authorities Seize Counterfeit Meds." *Securing Pharma* (Dec 30 2009), available at <http://www.securingspharma.com/40/articles/340.php> (accessed Feb 19 2010).

⁸⁹² Bate, Roger. "Nursing India's Drug Market Back to Health." *The American* (Apr 16 2009), available at <http://www.american.com/archive/2009/april-2009/nursing-india2019s-drug-market-back-to-health> (accessed Feb 19 2010).

⁸⁹³ Bate, Roger. "Nursing India's Drug Market Back to Health." *The American* (Apr 16 2009), available at <http://www.american.com/archive/2009/april-2009/nursing-india2019s-drug-market-back-to-health> (accessed Feb 19 2010).

⁸⁹⁴ Singh, Virat A. "FDA Busts Case of Fake Drug for AIDS, Cancer." *Mumbai Mirror* (Mar 15 2010), available at <http://www.mumbaimirror.com/index.aspx?page=article§id=2&contentid=201003152010031503234204805313e7> (accessed Mar 29 2010).

seized 324 bottles of the injection, which were found to resemble the chemical properties of another, cheaper brand also used to treat terminally ill patients, leading officials to believe that fake labels were printed and placed on bottles of the cheaper injection for resale.⁸⁹⁵

In March 2010, after a round of quality testing revealed that one out of four drug samples tested were spurious, the Maharashtra Food and Drug Administration (FDA) launched a statewide drive against fake drugs. The officials of the FDA amended their strategy from picking samples from the retailers, wholesalers and manufacturing units on a routine basis, to conducting raids using specific intelligence input in order to increase efficiency.⁸⁹⁶ Raids were launched in 30 districts and 207 samples were collected.⁸⁹⁷ A raid carried out in July 2010 by the drug inspector of Lucknow, Uttar Pradesh, seized USD 10,800 worth of fake medications at an unlicensed retailer in Aminabad market.⁸⁹⁸

Most of the 15,000 generics manufacturers who operate in India are legitimate, but a small and dangerous minority does not comply with proper standards. Most of the domestic market, around 70 percent, is supplied by 20 companies which regularly pass inspections from visiting international regulators, so quality is generally good.⁸⁹⁹

In March 2010, the Public Analyst Laboratory (PAL) of Lucknow stated that a majority of poor quality drugs come from 'kasbas' (small towns).⁹⁰⁰ On the basis of this report, the Uttar Pradesh FDA launched an investigation in 38 districts across the state and subsequently cancelled the licenses of 25 pharmaceutical companies, suspended 44 others and warned 65 companies and drug wholesalers.⁹⁰¹

One 2002 study by government officials demonstrated that approximately 9 per cent of all drugs tested in India were substandard.⁹⁰² A study conducted in two cities in India in 2009 revealed that 12 percent of drug samples from Delhi failed either one or both tests used (thin-layer chromatography and disintegration), while 5 percent of drug samples from Chennai failed one or

⁸⁹⁵ Singh, Virat A. "FDA Busts Case of Fake Drug for AIDS, Cancer." *Mumbai Mirror* (Mar 15 2010), available at <http://www.mumbaimirror.com/index.aspx?page=article§id=2&contentid=201003152010031503234204805313e7> (accessed Mar 29 2010).

⁸⁹⁶ Singh, Kumar Rajesh. "Drive Against Fake Drugs Launched." *Hindustan Times* (Mar 27 2010), available at <http://www.hindustantimes.com/Drive-against-fake-drugs-launched/Article1-523548.aspx> (accessed Feb 14 2011).

⁸⁹⁷ Singh, Kumar Rajesh. "Drive Against Fake Drugs Launched." *Hindustan Times* (Mar 27 2010), available at <http://www.hindustantimes.com/Drive-against-fake-drugs-launched/Article1-523548.aspx> (accessed Feb 14 2011).

⁸⁹⁸ "Fake medicines Worth Rs5 Lakh Recovered from Shop in Lucknow." *Daily News and Analysis* (Jul 3 2010), available at http://www.dnaindia.com/india/report_fake-medicines-worth-rs5-lakh-recovered-from-shop-in-lucknow_1404689 (accessed Jul 12 2010).

⁸⁹⁹ Morris, Julian, and Stevens, Philip. "Counterfeit Medicines In Less Developed Countries: Problems and Solutions." *International Policy Network* (2006), available at http://www.fightingdiseases.org/pdf/IPN_Counterfeits.pdf (accessed Feb 15 2010).

⁹⁰⁰ Singh, Kumar Rajesh. "Drive Against Fake Drugs Launched." *Hindustan Times* (Mar 27 2010), available at <http://www.hindustantimes.com/Drive-against-fake-drugs-launched/Article1-523548.aspx> (accessed Feb 14 2011).

⁹⁰¹ Singh, Kumar Rajesh. "Drive Against Fake Drugs Launched." *Hindustan Times* (Mar 27 2010), available at <http://www.hindustantimes.com/Drive-against-fake-drugs-launched/Article1-523548.aspx> (accessed Feb 14 2011).

⁹⁰² "Interim Report of the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs." *Ministry of Health and Family Welfare, Government of India* (Aug 2003), available at <http://cdsco.nic.in/html/interim%20report.htm#extent> (accessed May 11 2011).

both of the tests.⁹⁰³

Legal Actions

In January 2008, a man found guilty of manufacturing fakes and passing them off as brand name products was fined and sentenced to 15 years in jail.⁹⁰⁴ In August 2009, the Indian Health Minister, Ghulam Nabi Azad, announced the passing of a new law that allows courts to sentence those who manufacture and sell spurious drugs to life terms.⁹⁰⁵

In March 2011, India announced plans to introduce a mandatory life imprisonment sentence to Indian nationals caught producing or supplying counterfeit drugs to Nigeria.⁹⁰⁶ This development is the result of a Memorandum of Understanding (MoU) signed by India's Joint Secretary in the Department of Pharmaceuticals, Arun Jha, and Nigeria's Director General of National Agency for Food and Drug Administration and Control (NAFDAC), Dr. Paul Orhii.⁹⁰⁷ According to the MoU, India may also introduce measures to compensate whistleblowers, provide training and assistance to NAFDAC, mandate seizure of manufacturing equipment used in illegal operations, and provide funding for Nigerian investigations of counterfeit operations with links to India.⁹⁰⁸

Kazakhstan

In 2002, an independent survey revealed that the Kazakhstan was a producer of fake drugs.⁹⁰⁹ Increasing numbers of counterfeits found between 2002 and 2005 prompted the Kazakhstani Association of Representatives of foreign pharmaceutical companies to pass legislation in 2006 which included the following provisions: 1. increasing the severity of punishment for producing and trading counterfeits; 2. establishing well-equipped laboratories to analyze samples more quickly; 3. improving the collaboration between manufacturers and state quality control organizations; and 4. labeling all drugs in Kazakh (the state language).⁹¹⁰

⁹⁰³ Bate, Roger, et al. "Pilot Study of Essential Drug Quality in Two Major Cities in India." *PLoS One* 4:6 (Jun 23 2009), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2695555/> (accessed Feb 19 2010).

⁹⁰⁴ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

⁹⁰⁵ "Life Term for Spurious Drug Peddlers: Government." *Thaindian News* (Aug 7 2009), available at http://www.thaindian.com/newsportal/business/life-term-for-spurious-drug-peddlers-government_100228905.html (accessed Feb 19 2010).

⁹⁰⁶ Edomaruse, Collins. "Life Imprisonment for Indians Shipping Fake Drugs to Nigeria." *This Day Live* (Mar 30 2011), available at <http://www.thisdaylive.com/articles/life-imprisonment-for-indians-shipping-fake-drugs-to-nigeria/88697/> (accessed May 9 2011).

⁹⁰⁷ Ibid.

⁹⁰⁸ Ibid.

⁹⁰⁹ "Counterfeit Medicines Rise to 12 Percent of Total Russian Market; Cost to Pharmaceutical Manufacturers Totals USD 250 Million Annually; Industry Calls for Tough Prison and Financial Punishments to Fit the Seriousness of Counterfeiting Crimes." *PR Newswire* (Apr 25 2002), available through Lexis Nexis (accessed Mar 10 2010).

⁹¹⁰ "Kazakhstani Association Proposes New Anti-Counterfeiting Measures." *SCRIP News* (Nov 3 2006), available at <http://www.scripnews.com/home/news/Kazakhstani-association-proposes-new-anti-counterfeiting-measures-59264> (accessed Feb 3 2010).

Kyrgyzstan

While there is a general lack of hard data regarding what percentage counterfeits make up of Kyrgyzstan's drug market, a regional comparative analysis completed in 2009 suggests that the share is between the ranges of 20-30 percent.⁹¹¹

Fake pharmaceutical purchases abound, and have been increasing annually.⁹¹² In 2006, 44.7 percent of Kyrgyz respondents to a World Intellectual Property Organization (WIPO) survey claimed to have knowingly purchased counterfeit "pharmaceuticals or medicines, not generics" within the past year.⁹¹³

In 2009, the Ministry of Health reported that up to 70 percent of pharmaceuticals for sale in the capital, Bishkek, could be counterfeit. Rustam Kurmanov, director of the pharmaceutical supply department at Kyrgyzstan's Ministry of Health, believes that most fakes in the country are antibiotics.⁹¹⁴ High tariffs drive up the price of officially imported medicines, and patients often resort to purchasing cheaper drugs on the streets, where fake and poor quality medicines abound.⁹¹⁵

In 2009, 5 percent of pharmaceutical deliveries that passed through Kyrgyzstan customs were identified as counterfeit or low-quality products.⁹¹⁶ Medicines Transparency Alliance reported in 2009 that 80 percent of medicines that entered the country through official channels were withdrawn due to poor quality.⁹¹⁷

The government faces difficulty in stemming the flow of both counterfeit and substandard drugs partly because the mountainous terrain makes border control difficult, and partly because there are few facilities which are able to adequately differentiate between counterfeit and genuine drugs. As of 2009, the drug information system in the country was also under-developed.⁹¹⁸ To address these problems, Kyrgyzstan's Prime Minister Igor Chudinov signed legislation in April 2010 reaffirming Kyrgyzstan's commitment to the fight against fakes as part of the Commonwealth of Independent States Agreement. The Ministry of Health and the State Customs

⁹¹¹ "Combating the Spread of Fake Drugs in Kyrgyzstan." *The Central Asian Free Market Institute* (2009), available at <http://freemarket.kg/en/publications/fakedrugs2009> (accessed Mar 10 2010).

⁹¹² "Combating the Spread of Fake Drugs in Kyrgyzstan." *The Central Asian Free Market Institute* (2009), available at <http://freemarket.kg/en/publications/fakedrugs2009> (accessed Mar 10 2010).

⁹¹³ "IP Outreach Research." *World Intellectual Property Organization* (Jan 20 2009), available at <http://www.wipo.int/ip-outreach/en/tools/research/details.jsp?id=774> (accessed Mar 10 2010).

⁹¹⁴ "Combating the Spread of Fake Drugs in Kyrgyzstan." *The Central Asian Free Market Institute* (2009), available at <http://freemarket.kg/en/publications/fakedrugs2009> (accessed Mar 10 2010).

⁹¹⁵ "Counterfeit Drugs Spreading in Kyrgyzstan." *SCRIP News* (Apr 9 2009), available at <http://www.scripnews.com/home/news/Counterfeit-drugs-spreading-in-Kyrgyzstan-78454> (accessed Feb 3 2010).

⁹¹⁶ "Counterfeit Drugs Spreading in Kyrgyzstan." *SCRIP News* (Apr 9 2009), available at <http://www.scripnews.com/home/news/Counterfeit-drugs-spreading-in-Kyrgyzstan-78454> (accessed Feb 3 2010).

⁹¹⁷ "Kyrgyzstan." *Medicines Transparency Alliance*, available at <http://www.medicinestransparency.org/meta-countries/kyrgyzstan/> (accessed Mar 10 2010).

⁹¹⁸ "Kyrgyzstan." *Medicines Transparency Alliance*, available at <http://www.medicinestransparency.org/meta-countries/kyrgyzstan/> (accessed Mar 10 2010).

Committee are responsible for implementing the changes this legislation introduces.⁹¹⁹ The ministry also proposed an amendment to the country's Criminal Code which would enable prosecutors to file criminal charges against counterfeiters.⁹²⁰

Nepal

In 2004, 70 percent of Nepal's annual pharmaceutical consumption came from Indian imports, 27 percent from domestic production accounts, and the remaining 3 percent were imported from other countries. Failures in India's domestic regulation system pose a huge threat to Nepal.⁹²¹

In February 2004, the Department of Drug Administration (DDA) seized 1,200 capsules of counterfeit amoxicillin from three pharmacies in Rupendehi district that contained no active ingredient.⁹²² The listed manufacturer was Adip Labs of Kalol in India, but inquiries revealed that no such company exists. Eight DDA inspectors in 2004 estimated that up to 20 percent of the drugs in the market were substandard. In a batch of spot tests in 2004, 96 out of 359 (27 percent) samples of medicines were found to be substandard.⁹²³

Consumer groups and doctors in Nepal say the only reason the DDA has found so few cases of counterfeit drugs in Nepal is because of poor and irregular monitoring. Traders can therefore easily buy fake drugs from smugglers and make huge profits.⁹²⁴ In principle, only companies certified by WHO's Good Manufacturing Practice (GMP) can import medicines into Nepal, Only two Chinese manufacturers are registered with the DDA, and higher demand for Indian drugs leads to fewer cases of Chinese fakes infiltrating the pharmaceutical market.⁹²⁵

Pakistan

Counterfeit drugs are easily available all over Pakistan, thanks to gaps in the process of drug registration, weak institutions, and loose enforcement.⁹²⁶ In 2004, the WHO estimated that 40-50

⁹¹⁹ "Combating the Spread of Fake Drugs in Kyrgyzstan." *The Central Asian Free Market Institute* (2009), available at <http://freemarket.kg/en/publications/fakedrugs2009> (accessed Mar 10 2010).

⁹²⁰ "Counterfeit Drugs Spreading in Kyrgyzstan." *SCRIP News* (Apr 9 2009), available at <http://www.scripnews.com/home/news/Counterfeit-drugs-spreading-in-Kyrgyzstan-78454> (accessed Feb 3 2010).

⁹²¹ Rai, Dewan. "Which is Real, and Which is Fake?" *Nepali Times* (Mar 19-25 2004), available at <http://www.nepalitimes.com/issue/2004/03/19/Nation/3765> (accessed Feb 8 2010).

⁹²² Rai, Dewan. "Which is Real, and Which is Fake?" *Nepali Times* (Mar 19-25 2004), available at <http://www.nepalitimes.com/issue/2004/03/19/Nation/3765> (accessed Feb 8 2010).

⁹²³ Rai, Dewan. "Which is Real, and Which is Fake?" *Nepali Times* (Mar 19-25 2004), available at <http://www.nepalitimes.com/issue/2004/03/19/Nation/3765> (accessed Feb 8 2010).

⁹²⁴ Rai, Dewan. "Which is Real, and Which is Fake?" *Nepali Times* (Mar 19-25 2004), available at <http://www.nepalitimes.com/issue/2004/03/19/Nation/3765> (accessed Feb 8 2010).

⁹²⁵ Rai, Dewan. "Which is Real, and Which is Fake?" *Nepali Times* (Mar 19-25 2004), available at <http://www.nepalitimes.com/issue/2004/03/19/Nation/3765> (accessed Feb 8 2010).

⁹²⁶ Nishtar, S. "Pharmaceuticals—Strategic Considerations in Health Reforms in Pakistan." *Journal of the Pakistan Medical Association* 56:12, 100-111 (Dec 2006), available at <http://www.ncbi.nlm.nih.gov/pubmed/17595837> (accessed Feb 22 2010).

percent of drugs consumed in Pakistan were counterfeit,^{927,928} and in 2006 the country was ranked 13th (presumably by PSI) in the world for the production and sale of fake medicines.⁹²⁹

In 2006, provincial authorities seized 495 samples of locally produced substandard, fake or illegal medicines in the Punjab province; 64 (13 percent) of the samples were discovered to be fake.⁹³⁰ In 2008, reports of fake drugs were made to the Danish Medicines Agency.⁹³¹ The counterfeit medicine was found not to contain the same active substance as the real drug, but traces of other active substances were found.⁹³² In 2009, Medsafe, a medicines safety authority, reported that 65 websites running out of Pakistan were selling fraudulent herbal products.⁹³³

In September 2008, the Federal Investigation Agency (FIA) reportedly recovered USD 191,000 worth of counterfeit copies of life-saving drugs in Karachi.⁹³⁴ In November 2008, Mir Zubair Mehmood, the Director of the Federal Investigation Agency (FIA), reported that in 15 raids, the organization had seized five truckloads of medicines worth approximately USD 745,800; according to Mehmood these raids were the first time in 10 years that the FIA had taken action against fake drugs.⁹³⁵

In early 2009, the Federal Investigation Agency seized more counterfeit and unregistered drugs in 13 separate raids.⁹³⁶

In 2008, Representatives of the Islamabad Capital Territory (ICT) conducted a check of medical stores in Peshawar Mor and Sihala area which resulted in the closure of four illegal clinics which were selling fake or unregistered medicines; all their medications were seized.⁹³⁷

⁹²⁷ “Multinationals Urge Pakistan to Raise Drug Prices.” *FDA News, Daily International Pharma Alert* 2:271 (Jan 27 2006), available at <http://www.fdanews.com/newsletter/article?articleId=84111&issueId=8933> (accessed Feb 19 2010).

⁹²⁸ “40-50pc Medicines in Market ‘Counterfeit’.” *The Dawn* (Apr 26 2008), available at <http://archives.dawn.com/2008/04/26/top9.htm> (accessed Feb 19 2010).

⁹²⁹ “40% of All Medicines in Pakistan are Fake.” *Daily Times* (Mar 9 2006), available at http://www.dailytimes.com.pk/default.asp?page=2006\03\09\story_9-3-2006_pg7_60 (accessed Feb 19 2010).

⁹³⁰ Waqar, Ali. “Sale of Homeopathic and Herbal ‘Viagra’ Rampant.” *Daily Times* (Apr 6 2006), available at http://www.dailytimes.com.pk/default.asp?page=2006\04\06\story_6-4-2006_pg7_20 (accessed Feb 19 2010).

⁹³¹ “Warning: Counterfeit packages of Cipralax Found in Pakistan.” *Danish Medicines Agency* (Apr 30 2008), available at <http://laegemiddelstyrelsen.dk/en/service-menu/news/warnings/warning-counterfeit-packages-of-cipralax---pakistan-> (accessed Feb 19 2010).

⁹³² “Warning: Counterfeit packages of Cipralax Found in Pakistan.” *Danish Medicines Agency* (Apr 30 2008), available at <http://laegemiddelstyrelsen.dk/en/service-menu/news/warnings/warning-counterfeit-packages-of-cipralax---pakistan-> (accessed Feb 19 2010).

⁹³³ “Fake Internet Herbal Drugs Claim to be from NZ.” *Radio New Zealand News* (Nov 24 2009), available at <http://www.radionz.co.nz/news/stories/2009/11/24/1245d450888e> (accessed Feb 19 2010).

⁹³⁴ “Rs 15m in Fake Drugs Found.” *Daily Times* (Sep 11 2008), available at http://www.dailytimes.com.pk/default.asp?page=2008\09\11\story_11-9-2008_pg12_5 (accessed Feb 19 2010).

⁹³⁵ “Punishment for Sale of Counterfeit Drugs.” *Apna Karachi* (Nov 6 2008), available at <http://www.apnakarachi.com/Punishment-for-sale-of-counterfeit-drugs.html> (accessed Feb 19 2010).

⁹³⁶ Ali, Imtiaz. “Counterfeit Drugs Add to Woes of Patients.” *The News* (Jan 3 2009), available at http://health.dir.groups.yahoo.com/group/social_pharmacy_usm/message/1605 (accessed Feb 19 2010).

⁹³⁷ McGinnis, Milissa. “Matrix of Drug Quality Reports Affecting USAID-Assisted Countries.” *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

In January 2010, Pakistan's Interior Minister, Rehman Malik, told the National Assembly that the sale of substandard life-saving drugs for children was booming.⁹³⁸ Malik also reported that 50 percent of the medicines available in the country were substandard and fake.⁹³⁹

Karachi serves as a regional trading hub for unregistered medicines from India, China, Saudi Arabia, and the United Arab Emirates.⁹⁴⁰ In the first half of 2004, Pakistani officials seized more than 100,000 doses of various drugs during smuggling attempts by commercial air shipments from India.⁹⁴¹

Legal

Pakistan faces a major substandard and counterfeit drug crisis, but lacks the political will to alter the status quo. In 2006, the Pakistani government established a national Drug Regulatory Authority (DRA) to focus on drug quality and registration. Though Pakistan's health secretary, Syed Anwar Mahmood, said the DRA would be autonomous, some consumer rights proponents believe it is only furthering the interests of drug companies.⁹⁴²

While there are laws aimed at curtailing counterfeit medicines and unapproved remedies, non-implementation of these laws and corruption among many drug inspectors limit their effectiveness. For instance, in June 2008, the Provincial Drug Inspector in Karachi raided a house where several Pakistanis were found refilling used syringes in unhygienic conditions and with incorrect ingredients. Unfortunately, this did not lead to any convictions as the Sindh Higher Court overturned the ruling of a lower court, stating that the evidence "did not contain the details of the recovered drugs, their date, time and place of recovery."⁹⁴³

Complacency and negligence of the Quality Control Board (QCB) give too much leeway to those accused, a drug inspector named Abdul Raheem Abbasi, claimed in January 2010. "Piles of cases have been filed in the Sindh Drugs Court, but all of it seems in vain as the court is busy dealing with cases that had been registered nine or 10 years ago."⁹⁴⁴

In recent years the Supreme Court has spurred the government to demand warranties to accompany drugs through the supply chain from manufacturers to retailers, and retailers will be

⁹³⁸ "50 Percent Medicines in Country Substandard, Spurious: Malik." *Daily Times* (Jan 20 2010), available at http://www.dailytimes.com.pk/default.asp?page=2010\01\20\story_20-1-2010_pg7_4 (accessed Jan 21 2010).

⁹³⁹ "50 Percent Medicines in Country Substandard, Spurious: Malik." *Daily Times* (Jan 20 2010), available at http://www.dailytimes.com.pk/default.asp?page=2010\01\20\story_20-1-2010_pg7_4 (accessed Jan 21 2010).

⁹⁴⁰ Qasim, M., "Unregistered Drugs Being Smuggled from China and India." *The News* (Aug 21 2009), available at http://www.thenews.com.pk/daily_detail.asp?id=194125 (accessed Feb 19 2010).

⁹⁴¹ "Operation of the International Drug Control System." *Report of the International Narcotics Control Board* (2004), available at http://www.incb.org/pdf/e/ar/2004/incb_report_2004_2.pdf (accessed Feb 19 2010).

⁹⁴² "Pakistan: Mixed Reaction to Proposed Drug Authority." *Integrated Regional Information Network* (Nov 3 2006), available at <http://www.irinnews.org/report.aspx?reportid=61778> (accessed Feb 19 2010).

⁹⁴³ Bano, Shamim. "Acquittal in Spurious Drug Case." *The News International* (Nov 16 2009), available at http://www.thenews.com.pk/daily_detail.asp?id=208756 (accessed Mar 10 2010).

⁹⁴⁴ Baloch, S. "Complacency Delays Cases Against Spurious Drugs." *The News* (Jan 23 2010) available at http://www.thenews.com.pk/daily_detail.asp?id=220256 (accessed Feb 19 2010).

held legally responsible for products that do not have a warranty.⁹⁴⁵ According to a 2006 Supreme Court ruling, Under the Drug Act-1976, the maximum punishment for counterfeiting is 10 years imprisonment and a fine, depending on the nature of the crime, but this sentence has yet to be awarded, there have been no convictions yet.⁹⁴⁶

Sri Lanka

Doctors allege that, in 2009, as much as 30 percent of the country's drug supply was fake.⁹⁴⁷

In 2009, after a death occurred following an injection of the Rubella vaccine and "particles" in drug vials and saline bottles were discovered, the Healthcare and Nutrition Ministry of Sri Lanka decided to launch a "full-scale probe" into the matter, which resulted in the questioning of six Indian companies and their local representatives.⁹⁴⁸ Despite government promises, no significant action was taken due to pressure from health sector trade unions. Four pharmaceutical companies were banned for two years for selling substandard and adulterated drugs (some of which contained glass or plastic), but no domestic prosecutions of criminal traders occurred.⁹⁴⁹

Uzbekistan

In 2009, the Federation of Societies of Consumer Protection surveyed 1,214 pharmacies across the country. Tests of the sampled drugs revealed that 35 percent of pharmacies sell counterfeit drugs, 50 percent sell drugs that are boxed without any instructions, and 122 types of unlicensed drugs are for sale in the country.⁹⁵⁰

South-Eastern Asia

Counterfeit drugs have been a serious and persistent problem across Southeast Asia. Estimates from 2009 suggest that as much as 15 percent of drugs in the region are fakes.⁹⁵¹ Commonly faked drugs found in Southeast Asia include antimalarials, anti-tuberculosis drugs, anti-

⁹⁴⁵ "Clampdown on Fake Drugs in Pakistan." *SCRIP News* (May 26 2006), available at <http://www.scripnews.com/home/news/Clampdown-on-fake-drugs-in-Pakistan-63608> (accessed Feb 19 2010).

⁹⁴⁶ Baloch, S. "Complacency Delays Cases Against Spurious Drugs." *The News* (Jan 23 2010) available at http://www.thenews.com.pk/daily_detail.asp?id=220256 (accessed Feb 19 2010).

⁹⁴⁷ Wijewardene, R. "Pirated Pills." *The Sunday Leader* 15:40 (Apr 12 2009), available at <http://www.thesundayleader.lk/archive/20090412/probe.htm> (accessed Feb 3 2010).

⁹⁴⁸ "Contaminated Medicine: 'Show Cause' on Six Indian Companies." *Daily News* (Oct 30 2009), available at <http://www.dailynews.lk/2009/10/30/news31.asp> (accessed Feb 3 2010).

⁹⁴⁹ Balachandran, P.K. "Lanka Bans Four Indian Drug Companies." *Express Buzz* (Nov 10 2009), available at <http://www.expressbuzz.com/edition/story.aspx?Title=Lanka+bans+four+Indian+drug+companies&artid=GyzhkBYyZtg=&SectionID=XT7e3Zkr/lw=&MainSectionID=XT7e3Zkr/lw=&SectionName=HFdYSiSflu29kcfsAfeq==&SEQ> (accessed Feb 8 2010).

⁹⁵⁰ "Uzbekistan: Fake Drugs Are Prevalent In Central Asian State." *EurasiaNet News Briefs* (Feb 12 2009), available at <http://www.eurasianet.org/departments/news/articles/eav021309c.shtml> (accessed Feb 3 2010).

⁹⁵¹ "Cambodia Campaigns Against Counterfeit Medicines With Aid from USP Drug Quality and Information Program." *Partnership for safe medicines.org* (Oct 2009), available at <http://www.safemedicines.org/2009/10/cambodia-campaigns-against-counterfeit-medicines-with-aid-from-usp-drug-quality-and-information-program.html> (accessed Mar 26 2010).

infectives, and common antibiotics. Unlike other parts of Asia, reports of counterfeit Viagra in the region were minimal.

Due to the high prevalence of malaria in the region, anti-malarial drugs are the most commonly faked drugs in Southeast Asia; convenience surveys in 2000–01 and 2002–03, revealed that 38 percent and 53 percent, respectively, of artesunate blisterpacks obtained from pharmacies and shops in Southeast Asia were counterfeit.⁹⁵²

Increasingly, counterfeit artesunate drugs that contain some active ingredient (but in insufficient quantities to kill the parasite) are emerging on shelves in kiosks and pharmacies in Southeast Asia as well. In fact, a study in 2006 found that more than two thirds (68 percent) of artesunate drugs in Laos, Myanmar, Cambodia and Vietnam contained insufficient active ingredients.^{953,954} In Burma, counterfeit artesunate samples collected in 2006 were found to have between 3.5 and 12.1 mg of artesunate per tablet, less than one fifth the amount in a standard, authentic tablet (50mg). Such counterfeits have not only caused unnecessary loss of life, as they left sick individuals essentially untreated, but they have also made the parasite more resistant to the once-effective drug, spread resistance in the region, and led to a loss of confidence in artesunate-based medicines in the region.⁹⁵⁵

Drug laws either absent or poorly enforced, which prevents the penetration of fakes across borders.⁹⁵⁶ The few successful prosecutions of manufacturers/traders of fakes in the region have mostly involved cases with medicines used by the relatively wealthy, such as Viagra, as opposed to antimalarials.⁹⁵⁷

Fortunately, countries like Malaysia are beginning to take measures to combat the problem of counterfeit drugs by equipping consumers and pharmacists to differentiate authentic from fake products.⁹⁵⁸ For instance, in 2005, Malaysian officials introduced its Meditag program, which required all products registered with the Malaysian Drug Control Authority to bear a holographic security device, allowing pharmacists and consumers to check the authenticity of a drug's assigned Meditag using decoder units available at pharmacies.

⁹⁵²Day, N.P.J., et al. "Counterfeit Anti-Infective Drugs." *Lancet Infectious Diseases* 6:9, 602-613 (2006), available at <http://www.ncbi.nlm.nih.gov/pubmed/16931411> (accessed Feb 19 2010).

⁹⁵³Morris, Julian, and Stevens, Philip. "Counterfeit Medicines In Less Developed Countries: Problems and Solutions." *International Policy Network* (2006), available at http://www.fightingdiseases.org/pdf/IPN_Counterfeits.pdf (accessed Feb 8 2010).

⁹⁵⁴Alter Hall, Krystn, et al. "Characterization Of Counterfeit Artesunate Antimalarial Tablets From Southeast Asia." *American Journal of Tropical Medicine and Hygiene* 75:5, 804–11 (2006), available at <http://www.ajtmh.org/cgi/content/full/75/5/804> (accessed 15 Feb 2011).

⁹⁵⁵Bojang, Kalifa, et al. "Manslaughter By Fake Artesunate In Asia—Will Africa Be Next?" *PLoS Medicine* 3:6 (Jun 13 2006), available at <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030197> (accessed Mar 9 2010).

⁹⁵⁶"Editorial: The Scourge Of Fake Medicine," *Bangkok Post* (Feb 9 2008), available at <http://www.aegis.org/news/bp/2008/BP080204.html> (accessed Mar 9 2010).

⁹⁵⁷Saywell, T., McManus, J. "What's In That Pill?" *Far Eastern Economic Review* 34-40 (Feb 21 2002).

⁹⁵⁸Bate, Roger. "Making a Killing: The Deadly Implications of the Counterfeit Drug Trade." *The American Enterprise Institute Press* (2008), available at http://www.aei.org/docLib/20080520_MakingaKillingnew.pdf (accessed 14 Feb 2011).

INTERPOL's "Operation Storm," a five-month investigation in 2008 which involved 200 raids across Cambodia, China, Laos, Burma, Singapore, Thailand and Vietnam, led to the seizure of more than USD 6.65 million worth of counterfeit medicines and to the arrest of 27 people.⁹⁵⁹ Of the 16 million pills that police seized during Operation Storm, most were for the treatment of malaria, HIV/AIDS, tuberculosis and other common infections in Southeast Asia, including fake antibiotics for pneumonia and child-related illnesses.⁹⁶⁰

A second major INTERPOL investigation, "Operation Storm II," led to the seizure of USD 12 million of counterfeit drugs, USD 8 million substandard medications, more than 30 arrests, and the closure of over 100 pharmacies.⁹⁶¹

Cambodia

In 2002, a survey conducted by the Cambodian Health Ministry revealed that 13 percent of the drugs on the domestic market in Cambodia were counterfeit or substandard, including a variety of both antimalarial drugs and antibiotics.⁹⁶² Cambodia was party to the 2010 Operation Storm II, co-ordinated by Interpol, which covered eight countries in the region; international investigators applauded local efforts to disband regional trade in counterfeits.⁹⁶³

Counterfeit mefloquine and artesunate were first noticed in Cambodia in 1998 when suspiciously inexpensive tablets were found; the cheaper "artesunate" contained 6 percent chloroquine but no artesunate, and the cheaper "mefloquine" contained sulphadoxine-pyrimethamine but no mefloquine. In 1999, most of the antimalarial samples from Cambodia were fakes.⁹⁶⁴ A follow up survey at the end of 1999 found that 71 percent of drug vendors and pharmacies were selling fake artesunate, and 60 percent sold fake mefloquine.⁹⁶⁵ Another survey found that 25 percent of artesunate tablets in Cambodia were substandard.⁹⁶⁶

⁹⁵⁹ "Fake Drugs Worth More Than £4m Seized By Interpol." *The Telegraph* (Nov 17 2008), available at <http://www.telegraph.co.uk/news/worldnews/asia/cambodia/3474591/Fake-drugs-worth-more-than-4m-seized-by-Interpol.html> (accessed Jan 22 2010).

⁹⁶⁰ "Global Interagency Efforts Stem Counterfeit Drugs In Greater Mekong Asia." *Alliance for Case Studies for Global Health* (Oct 2009), available at http://www.casestudiesforglobalhealth.org/case_study_PDFs/GHCS_6_MekongDrugs.pdf (accessed Mar 9 2010).

⁹⁶¹ "\$12 Million In Counterfeit Drugs Seized In Southeast Asia." *The Partnership for Safe Medicines* (Jan 28 2010), available at <http://www.safemedicines.org/2010/02/12m-in-counterfeit-drugs-seized-in-southeast-asia.html> (accessed Feb 4 2011).

⁹⁶² "Counterfeit Medicines." *World Health Organization Factsheet* (Nov 2006), available at http://www.wipo.int/export/sites/www/enforcement/en/global_congress/docs/valerio_reggi/impact_who.doc (accessed Feb 19 2010).

⁹⁶³ "INTERPOL Applauds Southeast Asia Operation Storm II's Success In Disrupting Trade Of Counterfeit Medical Products." *INTERPOL Media Release* (Jan 27 2010), available at <http://www.interpol.int/Public/ICPO/PressReleases/PR2010/PR007.asp> (accessed Feb 4 2011).

⁹⁶⁴ Rozendaal, J. "Fake Antimalaria Drugs In Cambodia." *Lancet* 358:9282, 666-667 (2001), available at <http://www.ncbi.nlm.nih.gov/pubmed/11265991> (accessed Feb 19 2010).

⁹⁶⁵ Rozendaal, J., "Fake Antimalaria Drugs In Cambodia." *Lancet* 358:9282, 666-667 (2001), available at <http://www.ncbi.nlm.nih.gov/pubmed/11265991> (accessed Feb 19 2010).

⁹⁶⁶ Chotivanich, K., et al. "Fake Artesunate In Southeast Asia." *Lancet* 357, 1948-1949 (2001), available at <http://www.ncbi.nlm.nih.gov/pubmed/11425421> (accessed Feb 19 2010).

In 2002, data obtained from the USP DQI antimalarial drug quality monitoring project in the Mekong region showed the presence of both fake and substandard antimalarial drugs throughout the country.⁹⁶⁷ In 2003, another study conducted by USP DQI found that 27 percent of 451 antimalarial samples tested were counterfeit.⁹⁶⁸

Most of the counterfeits in Cambodia are found at informal, unlicensed outlets. In 1999, the Ministry of Health set up an Inter-Ministerial Committee to try to combat the pharmaceutical chaos by strengthening the management of the licensed pharmacies and eliminating illegal outlets. These efforts, however, were largely unsuccessful owing to the lack of collaboration among concerned regulatory agencies.⁹⁶⁹

In 2000, the Committee for Research and Study on Counterfeit, funded by the WHO, conducted a survey on counterfeit and substandard drugs and collected 230 random sample products from Phnom Penh markets and the five provinces of Kampong Cham, Kampong Chhnang, Takeo, Kampong Speu, and Kandal. Of the 230 samples, 30 (13.04 percent) failed quality testing, 24 (10.43 percent) were considered counterfeit (failed the test and not registered), and 6 (2.61 percent) were considered substandard (failed the test but registered). The results showed that even in genuine products, as claimed by the manufacturers, 3 of 49 still failed quality tests. Among the 115 registered samples, only six (5.21 percent) failed the test; 24 samples (20.86 percent) of 115 unregistered also samples failed the test. Although the study showed that the prevalence of counterfeit drugs was only 13.04 percent, it is believed that the figure could be higher because people who lived in the remote areas choose to buy their medicine from small illegal drug outlets that flourish around the country (2800 unlicensed outlets).⁹⁷⁰

The problem of fake drugs is fueled by the vast number of informal pharmacies and merchants who do not have proper pharmacy training. Unregistered pharmacies and medicines present a challenge; in 2009, 9 illegal pharmacies were shut down for selling counterfeit medicines, and 100 more faced closure.⁹⁷¹ In 2008 only half of the country's 2,000 pharmacies were registered with the Ministry of Health. Even after an inspection of the pharmacies registered with the MOH, Dr. Yim Yann, President of the Pharmacists Association of Cambodia (PAC), reported

⁹⁶⁷ Phanouvong, S. "Antimalarial Drug Quality Monitoring Project In The Mekong Sub-region." *United States Pharmacopeia Drug Quality and Information Program* (2004), available at http://www.who.int/prequal/trainingresources/pq_pres/workshop_Thailand/uspdqiQAandGMP.ppt (accessed Jan 28 2010).

⁹⁶⁸ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

⁹⁶⁹ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

⁹⁷⁰ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

⁹⁷¹ Leakhana, Khoun. "Pharmacy Crackdown." *The Phnom Penh Post* (Nov 23 2009) available at <http://khmernz.blogspot.com/2009/11/pharmacy-crackdown.html> (accessed Feb 15 2011).

that approximately 20-40 percent of medicines even within those pharmacies were unregistered with the Ministry of Health.⁹⁷²

According to a study in 2005, the drug laws enacted are weakly enforced due to a number of complicating factors including a poor awareness of the problem; the general poverty throughout the country; a lack of trained drug inspectors and an inadequate budget to implement regular inspections; common corruption among authorities; and a lack of political will and cooperation.⁹⁷³

Commonly found substandard drugs include anti-infective drugs, antibiotics (such as amoxicillin, penicillin, tetracycline, and erythromycin), anti-tuberculosis medicines, and especially antimalarial drugs.⁹⁷⁴ For instance, a study conducted in 1997 showed 36 of 128 (28 percent) anti-infective drugs tested for quality were substandard, and six actually had no active ingredient at all.⁹⁷⁵ In a 2001 case study, a total of 132 samples of 14 different drugs showed that 13 percent of medicines from public facilities were substandard, while 7.7 percent from nongovernmental organizations (NGOs)/mission facilities and 9.6 percent from private retail outlets were also substandard.⁹⁷⁶ Other studies show slightly better results.⁹⁷⁷

Reports on substandard anti-malarials in Cambodia are rife. One study in 2004 on 39 samples of quinine sulfate tablets collected in the four provinces of Cambodia revealed an average failure rate of 77 percent of all quinine samples collected.⁹⁷⁸ Another study in 2006, found that 68 percent of anti-malaria drugs found in Laos, Myanmar, Vietnam and Cambodia did not contain

⁹⁷² Sovan, N., and Yin, C. "Bad Medicine Floods Countryside." *The Phnom Penh Post* (Jul 25 2008), cited by McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

⁹⁷³ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 19 2010).

⁹⁷⁴ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 19 2010).

⁹⁷⁵ Bruneton, C., Gimenez, F., and Narong, Rith D.Y. "Etude de la Qualite des Medicaments Vendus et Dispenses au Cambodge." *Médecine et Maladies Infectieuses* 27, 541-4 (1997), available at <http://cat.inist.fr/?aModele=afficheN&cpsid=2715190> (accessed Feb 19 2010).

⁹⁷⁶ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 15 2010).

⁹⁷⁷ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 15 2010).

⁹⁷⁸ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

⁹⁷⁹ Results attained through conducting TLC testing using GPHF Minilab on all the samples.

the correct amount of active ingredient.⁹⁸⁰ A separate study in June 2009 found that out of 205 samples tested, 9 failed laboratory tests.⁹⁸¹

The proliferation of such drugs leads to many deaths directly following treatment, and increased drug resistance to current antimalarial treatments in the long run.⁹⁸² Chloroquine and sulphadoxine-pyrimethamine which are cheap and common, are already ineffective in this area. In 2006, the director of the nation's Malaria Control Program reported that people's unwitting use of substandard drugs from China and Thailand continues to increase resistance to common antimalarials.⁹⁸³

According to Veng Thai, the Director of the Phnom Penh Municipal Department of Health, rural areas in Cambodia have a much higher rate of substandard medicines than urban areas. In 2008 Veng Thai estimated that only 2-3 percent of medicines sold in the capital city were expired or fake.⁹⁸⁴

Indonesia

The International Pharmaceutical Manufacturers Group (IPMG) in Indonesia estimated that before 2006, fake drugs constituted 25 percent of Indonesia's USD 2 billion pharmaceutical market. By 2008, the IPMG estimated that the number had risen to 40 percent.^{985,986}

Popularly targeted drugs include common antimalarials, antibiotics, and analgesics. In May 2003, The Indonesian Drug and Food Control Agency (BPOM) seized 55 counterfeit medications, including substandard amoxicillin, in a local market.⁹⁸⁷ In 2007 eleven men were arrested in the capital city of Jakarta for refilling syringes with water, forging new expiration

⁹⁸⁰ Miller, Talea. "Fake And Substandard Drugs Threaten Malaria Treatment In Cambodia." *PBS News Hour* (Jul 24 2009), available at http://www.pbs.org/newshour/updates/health/july-dec09/malaria_0724.html (accessed Feb 5 2010).

⁹⁸¹ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

⁹⁸² Miller, Talea. "Fake And Substandard Drugs Threaten Malaria Treatment In Cambodia." *PBS News Hour* (Jul 24 2009), available at http://www.pbs.org/newshour/updates/health/july-dec09/malaria_0724.html (accessed Feb 5 2010).

⁹⁸³ Miller, Talea. "Fake And Substandard Drugs Threaten Malaria Treatment In Cambodia." *PBS News Hour* (Jul 24 2009), available at http://www.pbs.org/newshour/updates/health/july-dec09/malaria_0724.html (accessed Feb 5 2010).

⁹⁸⁴ Sovan, N., and Yin, C. "Bad Medicine Floods Countryside." *The Phnom Penh Post* (Jul 25 2008), cited by McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

⁹⁸⁵ Rulistia, Novia D. "40 Percent Of All Drugs In RI May Be Fake." *The Jakarta Post* (Jul 17 2008), available at <http://www.thejakartapost.com/news/2008/07/17/40-all-drugs-ri-may-be-fake.html> (accessed Feb 19 2010).

⁹⁸⁶ "Counterfeit Medicines: An Update On Estimates." *International Medical Products Anti-Counterfeiting Taskforce* (Nov 15 2006), available at http://www.ifpma.org/fileadmin/templates/ifpmaissues/pdfs/IMPACT_counterfeit_estimate_15Nov06.pdf (accessed Feb 15 2010).

⁹⁸⁷ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 19 2010).

dates, repackaging the product, and passing the syringes off as legitimate drugs.⁹⁸⁸ Police raids in 2009 led to the discovery of several fake medicines on the islands of Java and Sumatra following a three-month investigation.⁹⁸⁹ In July 2009, more police raids led to the confiscation of millions of fake pills at a fake drug factory in Penjaringan, North Jakarta.⁹⁹⁰

The Indonesian Drug and Food Control Agency (BPOM) claims weak law enforcement contributes to counterfeit drug problems. BPOM suspects corruption in the judicial system may be contributing to the lenient sentences usually handed to counterfeiters.⁹⁹¹ Recognizing major failures in the Indonesian justice and enforcement systems, INTERPOL officials conducted training for these departments in Jakarta in 2010.⁹⁹²

In July 2007, Jakarta police confiscated approximately 160,000 drugs that lacked distribution permits during a raid of two drug shops and arrested their owners.⁹⁹³ Among the medicines confiscated were products containing high levels of mercury.⁹⁹⁴

Lao People's Democratic Republic

In 2004, a study on the knowledge and perception of drug quality among consumers and sellers in the country revealed that 63 percent of drug sellers believed “all drugs [are] of good quality,” 8 percent of urban consumers, and 96 percent of rural consumers, were unaware of the dangers

⁹⁸⁸ McGinnis, Milissa. “Matrix of Drug Quality Reports Affecting USAID-Assisted Countries.” *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

⁹⁸⁹ Rachman, Anita, and Sagita, Dessy. “Raids Uncover Counterfeit Drugs.” *Jakarta Globe* (Mar 17 2009), available at <http://www.safemedicines.org/2009/03/raids-uncover-counterfeit-drugs-jakarta-indonesia.html> (accessed Jan 22 2010).

⁹⁹⁰ “Police Raid Counterfeit Drug Factory.” *The Jakarta Post* (Jul 17 2009), available at <http://www.thejakartapost.com/news/2009/07/17/police-raid-counterfeit-drug-factory.html> (accessed Jan 22 2010).

⁹⁹¹ Primo-Carpenter, Joyce. “A Review of Drug Quality in Asia with Focus on Anti-Infectives.” *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 19 2010).

⁹⁹² “\$12 Million In Counterfeit Drugs Seized In Southeast Asia.” *The Partnership for Safe Medicines* (Jan 28 2010), available at <http://www.safemedicines.org/2010/02/12m-in-counterfeit-drugs-seized-in-southeast-asia.html> (accessed Feb 4 2011).

⁹⁹³ “Pharmacy Owners Arrested For Selling Illegal Drugs.” *The Jakarta Post* (Jul 25 2007), available at <http://www.thejakartapost.com/news/2007/07/25/pharmacy-owners-arrested-selling-illegal-drugs.html> (accessed Jan 22 2010).

⁹⁹⁴ “Pharmacy Owners Arrested For Selling Illegal Drugs.” *The Jakarta Post* (Jul 25 2007), available at <http://www.thejakartapost.com/news/2007/07/25/pharmacy-owners-arrested-selling-illegal-drugs.html> (accessed Jan 22 2010).

posed by counterfeit drugs.^{995, 996} INTERPOL, however, argues that Laos has the largest domestic market for counterfeit medications in the entire region.⁹⁹⁷

According to WHO, there were roughly 2,100 illegal medicine sellers active in Laos in 2003. Of the 2,000 licensed private pharmacies, a subsequent study revealed that 60 percent bought drugs from illegal sources.^{998,999}

The most popularly faked medicines in Laos are antimalarials. These are available countrywide, but are most prevalent in the malarious south. In 2000, the proportion of fake artesunate in Laos was reported to be 38 percent.¹⁰⁰⁰ In 2002, authorities confiscated four artesunate products on sale in 17 provincial Health and Drug districts.¹⁰⁰¹ In 2003, a survey of 180 drug outlets in 12 of the 18 provinces found that the majority of those artesunate sellers sold one of seven fake versions.¹⁰⁰² A follow-up study in 2005 found that 96 percent of the artesunate tablets collected had no active ingredient.^{1003,1004} Another 2006 study discovered that 68 percent of artesunate

⁹⁹⁵ Day, Nicholas P.J., et al. "Counterfeit Anti-Infective Drugs." *The Lancet Infectious Diseases* 6:9, 602-613 (Sep 2006), available at [http://www.thelancet.com/journals/laninf/article/PIIS1473-3099 percent2806 percent2970581-3/fulltext](http://www.thelancet.com/journals/laninf/article/PIIS1473-3099%20percent2806%20percent2970581-3/fulltext) (accessed Feb 12 2010).

⁹⁹⁶ Freudenthal, Solveig, et al. "Knowledge And Perceptions Of Drug Quality Among Drug Sellers And Consumers In Lao PDR." *Health Policy and Planning* 19:6 391-401 (2004), available at <http://heapol.oxfordjournals.org/cgi/content/abstract/19/6/391> (accessed Feb 12 2010).

⁹⁹⁷ Cat, Huong. "Vietnam Second In Southeast Asia In Counterfeit Drugs." *VietNamNet* (Sep 22 2008), available at <http://english.vietnamnet.vn/social/2008/09/804985/> (accessed Mar 16 2010).

⁹⁹⁸ Morris, Julian, and Stevens, Philip. "Counterfeit Medicines In Less Developed Countries: Problems and Solutions." *International Policy Network* (2006), available at http://www.fightingdiseases.org/pdf/IPN_Counterfeits.pdf (accessed Feb 8 2010).

⁹⁹⁹ Freudenthal, Solveig, et al. "Knowledge And Perceptions Of Drug Quality Among Drug Sellers And Consumers In Lao PDR." *Health Policy and Planning* 19:6 391-401 (2004), available at <http://heapol.oxfordjournals.org/cgi/content/abstract/19/6/391> (accessed Feb 12 2010).

¹⁰⁰⁰ Chotivanich, K., et al. "Fake Artesunate In Southeast Asia." *Lancet* 357, 1948-1949 (2001), available at <http://www.ncbi.nlm.nih.gov/pubmed/11425421> (accessed Feb 19 2010).

¹⁰⁰¹ Phanouvong, S. "Antimalarial Drug Quality Monitoring Project In The Mekong Sub-region." *United States Pharmacopeia Drug Quality and Information Program* (2004), available at http://www.who.int/prequal/trainingresources/pq_pres/workshop_Thailand/uspdqjQAandGMP.ppt (accessed Jan 28 2010).

¹⁰⁰² 'Mystery' shoppers were asked to buy artesunate tablets from 180 outlets in 12 of the 18 Lao provinces; outlets were selected using stratified random sampling by investigators not involved in sampling. Samples were analyzed for packaging characteristics, by the Fast Red Dye test, high-performance liquid chromatography (HPLC), mass spectrometry (MS), X-ray diffractometry and pollen analysis. Of 180 outlets sampled, 25 (13.9 percent) sold oral artesunate. Outlets selling artesunate were more commonly found in the more malarious southern Laos. Of the 25 outlets, 22 (88 percent; 95 percent CI 68-97 percent) sold counterfeit artesunate, as defined by packaging and chemistry. No artesunate was detected in the counterfeits by any of the chemical analysis techniques and analysis of the packaging demonstrated seven different counterfeit types. There was complete agreement between the Fast Red dye test, HPLC and MS analysis. A wide variety of wrong active ingredients were found by MS. Of great concern, 4/27 (14.8 percent) fakes contained detectable amounts of artemisinin (0.26-115.7 mg/tablet).

See: "A Stratified Random Survey Of The Proportion Of Poor Quality Oral Artesunate Sold At Medicine Outlets In The Lao PDR - Implications For Therapeutic Failure And Drug Resistance." *Malaria Journal* 8:172 (Jul 28 2009), available at <http://ukpmc.ac.uk/articlerender.cgi?accid=PMC2734859> (accessed Mar 12 2010).

¹⁰⁰³ Funded by the government, Wellcome Trust, CDC, and the British Embassy in Bangkok.

¹⁰⁰⁴ Newton, P. "Fake Antimalarials In SE Asia." *Proceedings of the 2nd Global Forum on Pharmaceutical Anticounterfeiting* (Mar 15 2005), cited by McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

drugs collected in Laos, Burma, Vietnam, and Cambodia did not contain the correct amount of active ingredient.¹⁰⁰⁵

In December 2008, substandard ampicillin was found.¹⁰⁰⁶ From 1990 to 1993, the Drug Quality Control Center (DQCC) performed two studies and respectively found that 17 percent and 33 percent failed to meet quality standards. A third study analyzed 25 samples, and the amounts of active ingredients found in the drugs ranged from 0 percent to 95 percent.¹⁰⁰⁷ In 1995, a similar study which sampled pharmaceutical products obtained from markets across the country revealed that samples included some substandard drugs and some products which contained no active ingredient at all.¹⁰⁰⁸

A regional study from 1997 assessed the quality of four essential drugs from 366 samples obtained from 106 private pharmacies in the Savannakhet province and found that 46 percent were substandard.¹⁰⁰⁹

In 1999, a follow up study conducted to assess the impact of regulatory intervention in private pharmacies tested a total of 300 samples (from 92 pharmacies) of the same drugs used in the 1997 baseline study, and found a significant decrease in the percentage of substandard drugs to 22 percent (66/300).¹⁰¹⁰ The authors of this study attributed the improvement in drug quality to the development and enforcement of the Quality Assurance system within the National Drug Policy Program. Despite this improvement, the prevalence of substandard drugs (22 percent) at the turn of the century was still very high.¹⁰¹¹

Between 2005 and 2009, the USP Medicines Quality Monitoring Program collected a total of 1,567 samples, of which 18 failed confirmatory testing. However, the percentage of samples that

¹⁰⁰⁴ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

¹⁰⁰⁵ De Veij, M., et al. "Characterization Of Counterfeit Artesunate Antimalarial Tablets From Southeast Asia." *American Journal of Tropical Medicine and Hygiene* 75:5, 804–811 (2006), available at <http://www.ajtmh.org/cgi/content/full/75/5/804> (accessed Feb 22 2010).

¹⁰⁰⁶ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

¹⁰⁰⁷ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 19 2010).

¹⁰⁰⁸ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 19 2010).

¹⁰⁰⁹ Lindgren, Björn H., et al. "The Quality Of Drugs In Private Pharmacies In The Lao People's Democratic Republic." *International Journal of Risk and Safety in Medicine* 11:4, 243-249 (1998), available at <http://iospress.metapress.com/content/m7j99qbp2915hw6r/> (accessed Feb 12 2010).

¹⁰¹⁰ Lindgren, Björn H., et al. "The Quality Of Drugs In Private Pharmacies In The Lao People's Democratic Republic." *International Journal of Risk and Safety in Medicine* 11:4, 243-249 (1998), available at <http://iospress.metapress.com/content/m7j99qbp2915hw6r/> (accessed Feb 12 2010).

¹⁰¹¹ Lindgren, Björn H., et al. "The Quality Of Drugs In Private Pharmacies In The Lao People's Democratic Republic." *International Journal of Risk and Safety in Medicine* 11:4, 243-249 (1998), available at <http://iospress.metapress.com/content/m7j99qbp2915hw6r/> (accessed Feb 12 2010).

failed confirmatory testing dropped from 3.2 percent in 2005 to 0.6 percent in 2009.¹⁰¹² Antimalarials and antibiotics were among the substandard drugs found between 2005 and 2009 were, but no tuberculosis or HIV/AIDS medicines were discovered.¹⁰¹³

Current legislation in Laos punishes the production and sale of “bad quality” drugs with sentences of 3 months to 3 years in prison. These laws are poorly enforced, and the punishment is not harsh enough to deter most counterfeiters.¹⁰¹⁴ The Japan Pharmaceutical Manufacturers Association (JPMA) has spearheaded efforts in recent years to improve quality-control training and identification of counterfeits in Laos, donating high performance liquid chromatography systems to assess the chemical makeup of pharmaceutical drugs and thereby identify potential counterfeits.¹⁰¹⁵

Malaysia

According to Deputy Minister Datuk Dr Abdul Latiff Ahmad, in 2007 the government estimated that 5-8 percent of all medicines on the market in the country were fakes. In 2006, USD 2.2 million worth of fake medicines and beauty products were seized by the Malaysian Health Ministry over the course of 12,362 raids.¹⁰¹⁶ Commonly counterfeited products include erectile dysfunction and psychotropic medicines.¹⁰¹⁷ Malaysian customs officials made its largest drug bust ever in March of 2007 when it seized 142 boxes (1.4 million pills), worth USD 4 million, of fake Viagra. The Minister of Health, Chua Soi Lek, claimed that the medication, deceptively labeled “Miagra,” originated in Singapore.¹⁰¹⁸ In the first half of 2008, law enforcement officials seized USD 17,000 worth of unregistered pharmaceuticals in 14 raids.¹⁰¹⁹

In 2005, Malaysia introduced its Meditag program, which required all products registered with the Malaysian Drug Control Authority to bear a holographic security device. In 2006, the program expanded by supplying pharmacies with decoder units designed to be placed on store counters or shelves with instructions on their use. Pharmacists and consumers are encouraged to check the authenticity of a given medicine’s Meditag by sliding the medicine pack under the decoder unit. Consumers were also encouraged to verify the registration numbers of the

¹⁰¹² Leukai, Xayxana. “Regional Progress On Fake Drugs Reviewed.” *Lao Voices* (Mar 30 2010), available at <http://laovoices.com/2010/03/30/regional-progress-on-fake-drugs-reviewed> (accessed Apr 7 2010).

¹⁰¹³ Leukai, Xayxana. “Regional Progress On Fake Drugs Reviewed.” *Lao Voices* (Mar 30 2010), available at <http://laovoices.com/2010/03/30/regional-progress-on-fake-drugs-reviewed> (accessed Apr 7 2010).

¹⁰¹⁴ “Counterfeit And Substandard Medicine In Laos.” *World Health Organization Country Report* (2007), available at www.who.int/entity/impact/activities/LaoPDR_JAKARTA_Conf.ppt (accessed Feb 12 2010).

¹⁰¹⁵ Bate, Roger. “Making a Killing: The Deadly Implications of the Counterfeit Drug Trade.” *The American Enterprise Institute Press* 57-58 (2008), available at http://www.aei.org/docLib/20080520_MakingaKillingnew.pdf (accessed 14 Feb 2011).

¹⁰¹⁶ “Fake Medicines Worth RM7.8 Million Seized Last Year,” *Materia Medica Malaysiana* (Apr 5 2007), available at <http://malaysianmedicine.wordpress.com/2007/04/05/fake-medicines-worth-rm78-million-seized-last-year/> (accessed Jan 28 2010).

¹⁰¹⁷ “Malaysia Pharmaceuticals & Healthcare Report Q3 2007.” *Business Monitor International* (Oct 2007), available through ProQuest Research Library (accessed Mar 26 2010).

¹⁰¹⁸ “Malaysia Seizes Fake Sex Drug ‘Miagra’.” *Channel News Asia* (Mar 22 2007), available at http://www.channelnewsasia.com/stories/afp_asiapacific/view/265625/1/.html (accessed Mar 9 2010).

¹⁰¹⁹ Lim, Brenda. “Sex Stimulants Top Counterfeit Drugs Seized.” *New Straits Times Online* (May 14 2008), available at http://findarticles.com/p/news-articles/new-straits-times/mi_8016/is_20080514/stimulants-counterfeit-drugs-seized/ai_n44401233/ (accessed Jan 28 2010).

medicines by checking with the pharmacy enforcement branch of the ministry or by visiting its website.¹⁰²⁰ In addition to enabling consumers to police their own purchases, Meditag has buttressed local law enforcement. Some of Malaysia's three hundred roving enforcement officers are equipped with portable readers.

In September 2008, the Malaysian Government also proposed a new bill to combat pharmaceutical counterfeiters, urging the inclusion of heavier fines and mandatory jail sentences to current penalties.¹⁰²¹ The bill came out of roundtable discussions held under the auspices of the Special Taskforce to Combat Counterfeit Products, a unit established this year and overseen by the Ministry of Domestic Trade and Consumer Affairs, and the Pharmaceutical Association of Malaysia.¹⁰²²

Though these efforts have had some positive impact on the trade, the problem persists. In 2009, seizures of fake medicine totaled USD 1.4 million, nearly double the amount in 2008.¹⁰²³

Myanmar (Burma)

The drugs most counterfeited are generally common antibiotics and antimalarial drugs. In 1999, an investigation of eight anti-infectives, researchers found 3.23 percent of the samples were counterfeit but far more were substandard; 35 percent of chloramphenicol samples, 19 percent of co-trimoxazole samples, and 15 percent of ampicillin/amoxicillin samples failed pharmacopeial tests.¹⁰²⁴

In February 2005, a 23-year old Burmese man died after being treated with oral artesunate. The pills he took contained only 10 mg of artesunate, the active ingredient, per tablet, instead of the 50mg present in the genuine product.¹⁰²⁵ A charity working in Myanmar tested 100,000 tablets of artemisinin it had purchased in 2007 and discovered that all of the pills were fakes.¹⁰²⁶ In 2008, other artesunate samples collected along the Burma-Thailand border were found to contain only

¹⁰²⁰ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

¹⁰²¹ "New Bill To Help Curb Counterfeit Medicines." *The Malaysian Bar* (Sep 22 2008), available at http://www.malaysianbar.org.my/legal/general_news/new_bill_to_help_curb_counterfeit_medicines.html?date=2010-08-01 (accessed Feb 15 2011).

¹⁰²² "New Bill To Help Curb Counterfeit Medicines." *The Malaysian Bar* (Sep 22 2008), available at http://www.malaysianbar.org.my/legal/general_news/new_bill_to_help_curb_counterfeit_medicines.html?date=2010-08-01 (accessed Feb 15 2011).

¹⁰²³ "Spotlight/Fake Medicines: Listen Up, There's No Easy Cure." *New Straits Times* (Feb 1 2010), available at <http://fakemed.ph/news.php?newsId=252> (accessed Mar 9 2010).

¹⁰²⁴ Wondemagegnehu E. "Counterfeit And Substandard Drugs In Myanmar And Viet Nam." *World Health Organization Essential Drugs and Other Medicines Research Series* 29 (1999), available at <http://apps.who.int/medicinedocs/en/d/Js2276e/> (accessed Mar 26 2010).

¹⁰²⁵ Bojang, Kalifa, et al. "Manslaughter By Fake Artesunate In Asia—Will Africa Be Next?" *PLoS Medicine* 3:6 (Jun 13 2006), available at <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030197> (accessed Mar 9 2010).

¹⁰²⁶ McNeil Jr., Donald. "A Growing Epidemic Of Fake Medications In Asia." *The New York Times* (Feb 20 2007), available at <http://www.nytimes.com/2007/02/20/health/20iht-drugs.4656560.html> (accessed Jan 28 2010).

3-10 mg of artesunate per tablet.¹⁰²⁷ That same year, two separate samples of artesunate were collected for testing, and contained no measurable amount of artesunate.¹⁰²⁸

Philippines

In 1995, the Philippines Counterfeit Action Program (Philcap) analyzed 1,359 drug samples collected from 473 drugstores and found that 8 percent of the samples were counterfeit. Eleven percent of the drugstores visited by surveyors sold counterfeit drugs.¹⁰²⁹ Fake drugs included cardiovascular, rheumatoid arthritis, osteoarthritis, asthma, anti-infective, and anti-inflammatory medications.¹⁰³⁰¹⁰³¹ Seventeen percent of all the medicines obtained for the study had been smuggled into the country.¹⁰³²

In 2001 the Bureau of Food and Drugs (BFAD) found 30 percent of drug outlets visited selling counterfeit drug products.¹⁰³³

From 2002-2005, the DoH estimates that 10 percent of the medicines available in the Philippines were fake.¹⁰³⁴ In 2004, USD 554.8 million of fake medicines was being sold in the country; these drugs included maintenance drugs for cancer, diabetes, and cardiovascular diseases in addition to analgesics, antibiotics, and cough syrups. The director of BFAD admitted that her office failed to conduct random sampling of drugs in the past due to limited resources.¹⁰³⁵

¹⁰²⁷ Huanok, Withaya. "Counterfeit Antimalarial Drugs Sold In Shan State." *The Irrawaddy News Magazine* (Feb 8 2008), available at http://www.irrawaddy.org/article.php?art_id=10221 (accessed Jan 28 2010).

¹⁰²⁸ Huanok, Withaya. "Counterfeit Antimalarial Drugs Sold In Shan State." *The Irrawaddy News Magazine* (Feb 8 2008), available at http://www.irrawaddy.org/article.php?art_id=10221 (accessed Jan 28 2010).

¹⁰²⁹ Unpublished Report Of Project Philcap (Apr 1995), cited by Wondemagegnehu E. "Counterfeit And Substandard Drugs In Myanmar And Viet Nam." *World Health Organization Essential Drugs and Other Medicines Research Series* 29 (1999), available at <http://apps.who.int/medicinedocs/en/d/Js2276e/> (accessed Mar 26 2010).

¹⁰³⁰ "Department Of Health-Bureau Of Food And Drugs Health Advisory No. 01-06." *Department of Health, Republic Of The Philippines* (Nov 7 2001), available at http://www.bfad.gov.ph/oldsite/Advisory/BA_percent2001-06.pdf (accessed Feb 19 2010).

¹⁰³¹ Unpublished Report Of Project Philcap (Apr 1995), cited by Wondemagegnehu E. "Counterfeit And Substandard Drugs In Myanmar And Viet Nam." *World Health Organization Essential Drugs and Other Medicines Research Series* 29 (1999), available at <http://apps.who.int/medicinedocs/en/d/Js2276e/> (accessed Mar 26 2010).

¹⁰³² Unpublished Report Of Project Philcap (Apr 1995), cited by Wondemagegnehu E. "Counterfeit And Substandard Drugs In Myanmar And Viet Nam." *World Health Organization Essential Drugs and Other Medicines Research Series* 29 (1999), available at <http://apps.who.int/medicinedocs/en/d/Js2276e/> (accessed Mar 26 2010).

¹⁰³³ "Counterfeit Medicine Factsheet." *World Health Organization* (Nov 14 2006), available at http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html (accessed Feb 19 2010).

¹⁰³⁴ Fabunan, S. "Counterfeit Of Drugs Still A Nuisance." *Business Mirror* (Nov 12 2008), cited by McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

¹⁰³⁵ Martin, S. "P7-B Fake Drugs For Sale From Maintenance To Paracetamol." *The Manila Times* (Oct 7 2004), cited by McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

In 2006 the top five counterfeited drugs in the Philippines include antihypertensive drugs, antiasthmatics, analgesic medicines, anti-diarrhea medications and vitamins.¹⁰³⁶ Other commonly counterfeited medications include drugs to treat cardiovascular disease, local anesthetics, pain relievers, and Viagra.

Most of the counterfeits come from India, China, Taiwan, and Pakistan, but counterfeits infiltrated the Philippines from countries as diverse as Saudi Arabia, Thailand, Malaysia, Singapore, Colombia, Indonesia, Nepal and Myanmar.¹⁰³⁷ Local production of fakes has also been reported; from 2002–2005, there were 20 cases reported of companies manufacturing fake medicines.¹⁰³⁸

Due to insufficient health funding, government health facilities typically only stock about 30 percent of the essential drugs they need, forcing the public to buy their drugs from unlicensed vendors and market stalls, where counterfeit and substandard products abound.¹⁰³⁹

According to a 2008 report by a private investigating firm, the Cebu province is a particular hotspot for the sale and distribution of counterfeit drugs in the Philippines.¹⁰⁴⁰ The Department of Health (DoH) has warned that fake drugs are commonly sold in Davao City, the largest city located on the island of Mindanao;¹⁰⁴¹ Cagayan Valley, a large region in the Philippines comprised of five provinces;¹⁰⁴² Manila, the capital city; and in the Laguna province.

Reports of official drug seizures since 2005 have increased steadily. According to Normita Leyesa, president of the Philippine Pharmaceutical Association, approximately USD 99,000 in fake drugs were seized in the Pampanga province alone.¹⁰⁴³ In December 2006, enforcement

¹⁰³⁶ Morris, Julian, and Stevens, Philip. "Counterfeit Medicines In Less Developed Countries: Problems and Solutions." *International Policy Network* (2006), available at http://www.fightingdiseases.org/pdf/IPN_Counterfeits.pdf (accessed Feb 8 2010).

¹⁰³⁷ Parco, Bernadette. "Cebu: Hotspot For Fake Drugs." *Cebu Daily News* (Nov 26 2008), available at <http://globalnation.inquirer.net/cebudailynews/news/view/20081126-174460/Cebu-Hotspot-for-fake-drugs> (accessed Feb 8 2010).

¹⁰³⁸ Fabunan, S. "Counterfeit Of Drugs Still A Nuisance." *Business Mirror* (Nov 12 2008), cited by McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

¹⁰³⁹ "Counterfeit Medicines: Some Frequently Asked Questions – May 2005." *World Health Organization Fact Sheet* (May 6 2005), available at http://www.wpro.who.int/media_centre/fact_sheets/fs_20050506.htm (accessed Feb 19 2010).

¹⁰⁴⁰ Parco, Bernadette. "Cebu: Hotspot For Fake Drugs." *Cebu Daily News* (Nov 26 2008), available at <http://globalnation.inquirer.net/cebudailynews/news/view/20081126-174460/Cebu-Hotspot-for-fake-drugs> (accessed Feb 8 2010).

¹⁰⁴¹ Gevera, Mai B. "Fake Drugs Alarm DOH." *Philippine Information Agency Press Release* (Oct 13 2005), available at <http://www.pia.gov.ph/?m=12&sec=reader&rp=1&fi=p051013.htm&no=6&date=10/13/2005> (accessed Mar 16 2010).

¹⁰⁴² "DOH Warns Public On Fake Drugs." *Philippine Information Agency Press Release* (Jun 4 2009), available at <http://www.pia.gov.ph/?m=12&sec=reader&rp=1&fi=p090604.htm&no=10&date=06/04/2009> (accessed Mar 16 2010).

¹⁰⁴³ "Fake Medicines Are Everywhere On A Daily Basis, Many Unknowingly Risk Death." *The News Today* (Aug 11 2006), available at <http://www.thenewstoday.info/2006/08/11/fake-medicines-are-everywhere.html> (accessed Feb 19 2010).

actions against a total of 23 drugstores selling fake drugs were undertaken: 8 in the Manila metropolitan area, 10 in various parts of Southern Luzon, and 5 in Northern Luzon.¹⁰⁴⁴

Officials believe many of the fakes infiltrating the Philippines originate in China. In January 2007, raids on several drug stores in Binondo, Manila, resulted in the arrests of five individuals, including four Chinese nationals. Officers confiscated roughly USD 16,600 worth of fake erectile dysfunction drugs, vitamin and mineral supplements, and sleep enhancers during these raids.¹⁰⁴⁵ In June 2007, police seized an estimated USD 39.6 million worth of counterfeit drugs in Manila and arrested six Chinese nationals for manufacturing, repacking and distributing Chinese medicine; some of the drugs and herbal medicines were shipped from China and repacked into cartons and sachets in the Philippines for distribution nationwide.¹⁰⁴⁶¹⁰⁴⁷

In July 2007, National Bureau of Investigation (NBI) agents raided more establishments in Manila and in Caloocan City, seizing hundreds of counterfeit medicines including 806 tablets of pain relievers and a anti-hypertension drug.¹⁰⁴⁸¹⁰⁴⁹ In early 2008, the National Bureau of Investigation (NBI) filed charges against eight people who were allegedly involved with the sale and distribution of fake Viagra in Manila; investigators seized USD 2,800 worth of counterfeit Viagra from the drugstore where one of the suspects was arrested.¹⁰⁵⁰

Another government raid of a warehouse in Paranaque City in July 2008 found boxes fake Viagra among boxes of counterfeit medicines.¹⁰⁵¹ In October 2008, NBI agents raided a drug store in Punta Princesa in Cebu City for selling counterfeit Virlix, anti-allergy tablets.¹⁰⁵² In July 2009, NBI agents seized USD 81,800 worth of fake flu vaccines in San Pedro, Laguna and

¹⁰⁴⁴ “Fake Viagras Abound, NBI Warns.” *Manila Standard Today* (Dec 7 2006), cited by McGinnis, Milissa. “Matrix of Drug Quality Reports Affecting USAID-Assisted Countries.” *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

¹⁰⁴⁵ Mananghaya, J. “4 Chinese Nabbed In Binondo.” *The Philippine Star* (Jan 10 2007), cited by McGinnis, Milissa. “Matrix of Drug Quality Reports Affecting USAID-Assisted Countries.” *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

¹⁰⁴⁶ “P500-M Fake Drugs Seized In Tondo Warehouse.” *GMA News* (Jun 22 2007), available at <http://www.gmanews.tv/story/47795/P500-M-fake-drugs-seized-in-Tondo-warehouse> (accessed Feb 8 2010).

¹⁰⁴⁷ Evangelista, Romie A. “P500M In Fake Drugs Seized.” *Manila Standard Today* (Jun 23 2007), available at <http://www.manilastandardtoday.com/2007/june/23/police1.htm> (accessed Feb 19 2010).

¹⁰⁴⁸ Santos, Tina G. “Fake Anti-Hypertension, Pain-Reliever Drugs Seized.” *Philippine Daily Inquirer* (Jul 12 2008), available at <http://newsinfo.inquirer.net/breakingnews/metro/view/20080712-148076/Fake-anti-hypertension-pain-reliever-drugs-seized> (accessed Feb 19 2010).

¹⁰⁴⁹ Agcaoili, Theo, and Macairan, Evelyn. “NBI Raids Yield P100,000 In Fake Hypertension Drugs.” *The Philippine Star* (May 1 2007), available at <http://www.philstar.com/Article.aspx?articleId=396853> (accessed Feb 19 2010).

¹⁰⁵⁰ Santos, Tina G. “8 Charged For Selling Fake Viagra In Manila,” *Philippine Daily Inquirer* (Feb 14 2008), available at <http://newsinfo.inquirer.net/breakingnews/metro/view/20080214-118909/8-charged-for-selling-fake-Viagra-in-Manila> (accessed Feb 19 2010).

¹⁰⁵¹ Merueñas, Mark. “Authorities Seize P200M Worth Of Counterfeit Goods In Parañaque.” *GMA News* (Jul 30 2008), available at <http://www.gmanews.tv/story/110287/authorities-seize-p200m-worth-of-counterfeit-goods-in-paraaque> (accessed Feb 19 2010).

¹⁰⁵² Cavanlit, Carmi. “NBI Agents Seize Alleged Counterfeit Medicines In Cebu Drug Store.” *ABS-CBN News* (Oct 16 2008), available at <http://www.abs-cbnnews.com/nation/regions/10/16/08/nbi-agents-seize-alleged-counterfeit-medicines-cebu-drug-store> (accessed Feb 19 2010).

arrested a former representative of the pharmaceutical firm, Cristobal, for distributing the fake vaccines which actually contained "mineral water."^{1053, 1054}

Since 2008, the Philippine Department of Health, the Bureau of Food and Drugs, and the local industry association have been working together to raise awareness of the risks of counterfeit drugs.¹⁰⁵⁵ In 2008, the DOH reported that the prevalence of counterfeit drugs in the country had dropped from 30 percent to 10 percent.¹⁰⁵⁶ Of the confiscated drugs, 80 percent were not officially registered while the rest did not meet state quality standards, and most were imported illegally from other Asian markets, particularly India, China, Taiwan, and Pakistan.^{1057,1058}

Singapore

Despite regular investigation over the past decade by the Singaporean Health Services Authority, fake drugs pose a danger to many Singaporeans.¹⁰⁵⁹ The most common counterfeits in Singapore are anti-impotence drugs, general antibiotics, and antimalarials.¹⁰⁶⁰ In 2008, police arrested a man after discovering approximately 2,000 counterfeit anti-impotence drugs in several raids, valued at USD 144,000.¹⁰⁶¹ These drugs led to an adverse reaction in at least ten men; one consumer even suffered a stroke.¹⁰⁶² Between 2008 and 2009, Singapore's Health Sciences

¹⁰⁵³ "NBI Nabs Medrep Selling Fake Sanofi Flu Vaccines." *ABS-CBN News* (Jul 28 2009), available at <http://www.abs-cbnnews.com/nation/metro-manila/07/28/09/nbi-nabs-medrep-selling-fake-sanofi-flu-vaccines> (accessed Feb 8 2010).

¹⁰⁵⁴ Crisostomo, Sheila. "DOH Warns vs Fake Flu Vaccines." *The Philippine Star* (Jul 30 2009), available at <http://www.philstar.com/Article.aspx?articleid=491466> (accessed Feb 19 2010).

¹⁰⁵⁵ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 19 2010).

¹⁰⁵⁶ Parco, Bernadette. "Cebu: Hotspot For Fake Drugs." *Cebu Daily News* (Nov 26 2008), available at <http://globalnation.inquirer.net/cebudailynews/news/view/20081126-174460/Cebu-Hotspot-for-fake-drugs> (accessed Feb 8 2010).

¹⁰⁵⁷ Primo-Carpenter, Joyce. "A Review of Drug Quality in Asia with Focus on Anti-Infectives." *United States Pharmacopeia Drug Quality and Information Program* (Feb 2004), available at <http://www.usp.org/pdf/EN/dqi/aneReview.pdf> (accessed Feb 19 2010).

¹⁰⁵⁸ Martin, S. "P7-B Fake Drugs For Sale From Maintenance To Paracetamol." *The Manila Times* (Oct 7 2004), cited by McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

¹⁰⁵⁹ "HSA Investigates Counterfeit Viagra." *Health Sciences Authority Press Release* (Oct 4 2001), available at http://www.hsa.gov.sg/publish/etc/medialib/hsa_library/corporate/press_release_20010.Par.27740.File.tmp/phase2-NEWS-PR-CounterfeitViagra-4oct01.pdf (accessed Feb 8 2010).

¹⁰⁶⁰ "HSA Investigates Counterfeit Viagra." *Health Sciences Authority Press Release* (Oct 4 2001), available at http://www.hsa.gov.sg/publish/etc/medialib/hsa_library/corporate/press_release_20010.Par.27740.File.tmp/phase2-NEWS-PR-CounterfeitViagra-4oct01.pdf (accessed Feb 8 2010).

¹⁰⁶¹ Ching, Ng Wan. "That's How Raid Team Knew Where "Sex Drugs" Were." *The New Paper* (Feb 25 2008), available at <http://www.asiaone.com/Health/News/Story/A1Story20080225-51285.html> (accessed Mar 16 2010).

¹⁰⁶² Ching, Ng Wan. "That's How Raid Team Knew Where "Sex Drugs" Were." *The New Paper* (Feb 25 2008), available at <http://www.asiaone.com/Health/News/Story/A1Story20080225-51285.html> (accessed Mar 16 2010).

Authority recorded a total of 302 adverse reactions to counterfeit medications, including 11 deaths and 24 coma cases.¹⁰⁶³

A study in 2010 reported that 150 patients had been admitted to hospitals in Singapore after taking counterfeit impotence drugs, four subsequently died.¹⁰⁶⁴ Illegal traders stashed these products in drain gutters, water pipes, and elsewhere to elude Health Sciences Authority (HSA) raid.¹⁰⁶⁵

The Singapore Association of Pharmaceutical Industries and the Singapore Medical Association are continuing an education program to warn the public about the dangers of counterfeit medications.¹⁰⁶⁶ The 1975 Singapore Medicines Act lists requirements of drugs to protect national health. Singapore participates in INTERPOL exercises, including Operation Pangea II and Operation Storm II.^{1067,1068}

Thailand

Due to major counterfeiting and drug trafficking problems in Thailand, the US has placed Thailand on its “Priority Watch List,” and continues to exert pressure on Thai officials to crack down on smuggling rings.¹⁰⁶⁹ In 1997, samples collected from several non-pharmacy outlets showed 40 percent of samples had active ingredients outside acceptable limits, and three of the five chloroquine samples had no active ingredient at all.¹⁰⁷⁰

¹⁰⁶³Tan, Sylvia. “Counterfeit Sex Drugs: 11 Deaths And 24 Coma Cases.” *Fridae* (Sep 18 2009), available at <http://www.fridae.com/newsfeatures/2009/09/18/8965.counterfeit-sex-drugs-11-deaths-and-24-coma-cases> (accessed Feb 8 2010).

¹⁰⁶⁴ “Counterfeit Internet Drugs Pose Significant Risks And Discourage Vital Health Checks.” *International Journal of Clinical Practice Press Release* (Jan 20 2010), available at <http://www.wiley.com/WileyCDA/PressRelease/pressReleaseId-66937.html> (accessed Feb 8 2010).

¹⁰⁶⁵ Chow, Jermyn. “Peddlers Use Novel Tricks To Hide Sex Drugs.” *AsiaOne News* (Apr 13 2009), available at <http://news.asiaone.com/News/the%2BStraits%2BTimes/Story/A1Story20090413-134890.html> (accessed Mar 16 2010).

¹⁰⁶⁶ “Singapore.” *No To Fakes* (2009), available at <http://www.notofakes.com/Resources/TravelAdvisory/AsiaPacific/Singapore/tabid/429/Default.aspx> (accessed Feb 8 2010).

¹⁰⁶⁷ “Singapore Joins International Fight Against Counterfeit and Illegal Medicine.” *The Gov Monitor* (Nov 22 2009), available at http://thegovmonitor.com/world_news/asia/singapore-joins-international-fight-against-counterfeit-and-illegal-medicine-16123.html (accessed Feb 8 2010).

¹⁰⁶⁸ “\$12 Million In Counterfeit Drugs Seized In Southeast Asia.” *The Partnership for Safe Medicines* (Jan 28 2010), available at <http://www.safemedicines.org/2010/02/12m-in-counterfeit-drugs-seized-in-southeast-asia.html> (accessed Feb 4 2011).

¹⁰⁶⁹ “Serious Crackdown On Counterfeit Drugs Planned.” *The Nation* (Sep 29 2010), available at <http://www.nationmultimedia.com/home/2010/09/29/business/Serious-crackdown-on-counterfeit-drugs-planned-30138956.html> (accessed Feb 4 2011).

¹⁰⁷⁰ Behrens, R.H., Shakoor, O., and Taylor, R.B. “Assessment Of The Incidence Of Substandard Drugs In Developing Countries.” *Tropical Medicine International Health* 2:9, 839-845 (1997), available at <http://www.ncbi.nlm.nih.gov/pubmed/9315042> (accessed Feb 19 2010).

A five-country study conducted between 1999 and 2000 reviewed the quality of artesunate tablets collected from shops, pharmacies, NGOs, and hospitals in five Asian countries. Results showed that 11 percent of artesunate sold in Thailand at the time was fake.¹⁰⁷¹

The WHO estimated in 2003 that 8.5 percent of all medicines on the market in Thailand were substandard.¹⁰⁷² That same year, a senior pharmaceutical inspector from the FDA, working with the pre-International Conference of Drug Regulatory Authorities, found counterfeit Furosemide (Lasix), levonorgestrel (Postinor), norethisterone (Primolut), finasteride (Proscar), and sildenafil (Viagra) in Thai drugstores.¹⁰⁷³

In 2007, Public Health Minister, Morakot Kornkasem estimated that roughly USD 26.6 million worth of fake medicines were sold in Thailand every year, but claimed that such drugs accounted for less than 1 percent of the country's total drug market.¹⁰⁷⁴ In 2009, a single raid at a pharmacy in Bang Rak district led to the seizure of more than USD 756,000 worth of fake medicines.¹⁰⁷⁵ Thai officials estimate total seizures of counterfeit medications in 2009 were worth USD 1.6 million.¹⁰⁷⁶

In late 2007 more than USD 454,000 of illegal erectile dysfunction medicines was seized from pharmacies and drug stores in the Yaowarat area of Bangkok.¹⁰⁷⁷ A 2008 news article reported that 93 percent of purchased Viagra was fake, containing between 17 and 48 percent of the genuine active ingredient. The packaging on most drugs was "near perfect" and even included a hologram.¹⁰⁷⁸

In 2004 Food and Drug Administration of Thailand undertook an investigation to discover the root origins of substandard quinine, artesunate, and chloroquine.¹⁰⁷⁹ It appears as though medications are filtering in via Thailand's porous borders; substandard malaria drugs were found in ten provinces in Thailand along the Burmese border and in 4 provinces along the Cambodian

¹⁰⁷¹ Chotivanich, K., et al. "Fake Artesunate In Southeast Asia." *Lancet* 357, 1948-1949 (2001), available at <http://www.ncbi.nlm.nih.gov/pubmed/11425421> (accessed Feb 19 2010).

¹⁰⁷² Pincock, Stephen. "WHO Tries To Tackle Problem Of Counterfeit Medicines In Asia." *British Medical Journal* 327:7424 (2003), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1126859/> (accessed Feb 19 2010).

¹⁰⁷³ McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

¹⁰⁷⁴ "FDA Proposes Heavier Fines for Fake Drug Business." *The Nation* (Dec 6 2007), available at http://nationmultimedia.com/2007/12/06/national/national_30058402.php (accessed Feb 15 2011).

¹⁰⁷⁵ "FDA Proposes Heavier Fines for Fake Drug Business." *The Nation* (Dec 6 2007), available at http://nationmultimedia.com/2007/12/06/national/national_30058402.php (accessed Feb 15 2011).

¹⁰⁷⁶ "Serious Crackdown On Counterfeit Drugs Planned." *The Nation* (Sep 29 2010), available at <http://www.nationmultimedia.com/home/2010/09/29/business/Serious-crackdown-on-counterfeit-drugs-planned-30138956.html> (accessed Feb 4 2011).

¹⁰⁷⁷ "FDA Proposes Heavier Fines for Fake Drug Business." *The Nation* (Dec 6 2007), available at http://nationmultimedia.com/2007/12/06/national/national_30058402.php (accessed Feb 15 2011).

¹⁰⁷⁸ "Editorial: The Scourge Of Fake Medicine," *Bangkok Post* (Feb 9 2008), available at <http://www.aegis.org/news/bp/2008/BP080204.html> (accessed Mar 9 2010).

¹⁰⁷⁹ Blum, Nancy, and Phanouvong, Souly. "Mekong Malaria Initiative Antimalarial Drug Quality Monitoring and Evaluation." *United States Pharmacopeia Drug Quality and Information Program* (Mar 2004), available at <http://www.usp.org/pdf/EN/dqi/drugQualityMonitoringIndicators.pdf> (accessed Feb 19 2010).

border.¹⁰⁸⁰ Samples of tablets taken from the border between Myanmar (Burma) and Thailand contained only 3-10 mg of artesunate per tablet; genuine tablets should contain approximately 50 mg.¹⁰⁸¹ Local pharmacies in these areas were the main source of counterfeit and expired drugs.¹⁰⁸²

Prior to 2007, the maximum fine for manufacturers was USD 1,600, sellers and importers faced meager fines of USD 332.¹⁰⁸³ In 2007, the FDA proposed raising the cap on fines for manufacturers up to USD 166,000, and for sellers and importers up to USD 66,500.¹⁰⁸⁴

Vietnam

Vietnam's counterfeit drug market ranks second in size only to that of Laos, according to an INTERPOL report.¹⁰⁸⁵ Common counterfeits, most of which are imported from China, include antibiotics, erectile dysfunction treatments, and traditional Oriental medications.¹⁰⁸⁶¹⁰⁸⁷ Hanoi police cracked twenty counterfeiting cases between 2004 and 2006, and discovered widespread use of counterfeit antibiotics.¹⁰⁸⁸

In June 2006, Hanoi Police and Lang Son Police seized a large batch of fake medicines worth USD 187,000.¹⁰⁸⁹ In May 2008, the Hanoi Police Department prosecuted a trans-national counterfeit ring that produced fake Bakona, used to treat liver function disorder, and Cotaxoang, a medicine for sinusitis.¹⁰⁹⁰ In July of the same year, Hanoi police exposed two gangs which had

¹⁰⁸⁰ Silp, Sai. "Thai Officials Worried About Counterfeit Malarial Drugs." *The Irrawaddy* (Sep 7 2006), available at http://www.irrawaddy.org/article.php?art_id=6141 (accessed Feb 19 2010).

¹⁰⁸¹ Newton, P. "Counterfeit Medicines And The Artesunate Problem." *Proceedings of the 3rd Global Forum on Pharmaceutical Anticounterfeiting* (Mar 13 2007, cited by McGinnis, Milissa. "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries." *Report by the U.S. Pharmacopeia Drug Quality and Information Program* (Aug 3 2010), available at <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf> (accessed Feb 19 2010).

¹⁰⁸² Silp, Sai. "Thai Officials Worried About Counterfeit Malarial Drugs." *The Irrawaddy* (Sep 7 2006), available at http://www.irrawaddy.org/article.php?art_id=6141 (accessed Feb 19 2010).

¹⁰⁸³ "FDA Proposes Heavier Fines for Fake Drug Business." *The Nation* (Dec 6 2007), available at http://nationmultimedia.com/2007/12/06/national/national_30058402.php (accessed Feb 15 2011).

¹⁰⁸⁴ "FDA Proposes Heavier Fines for Fake Drug Business." *The Nation* (Dec 6 2007), available at http://nationmultimedia.com/2007/12/06/national/national_30058402.php (accessed Feb 15 2011).

¹⁰⁸⁵ Cat, Huong. "Vietnam Second In Southeast Asia In Counterfeit Drugs." *VietNamNet* (Sep 22 2008), available at <http://english.vietnamnet.vn/social/2008/09/804985/> (accessed Mar 16 2010).

¹⁰⁸⁶ Cat, Huong. "Vietnam Second In Southeast Asia In Counterfeit Drugs." *VietNamNet* (Sep 22 2008), available at <http://english.vietnamnet.vn/social/2008/09/804985/> (accessed Mar 16 2010).

¹⁰⁸⁷ Quang, Minh. "Fake Drugs Made Easy." *ThanhNien News* (Sep 21 2008), available at <http://www.lookatvietnam.com/2008/09/fake-drugs-made-easy.html> (accessed Feb 8 2010).

¹⁰⁸⁸ Alter Hall, Krystn, et al. "Characterization Of Counterfeit Artesunate Antimalarial Tablets From Southeast Asia." *American Journal of Tropical Medicine and Hygiene* 75:5, 804-11 (2006), available at <http://www.ajtmh.org/cgi/content/full/75/5/804> (accessed 15 Feb 2011).

¹⁰⁸⁹ Alter Hall, Krystn, et al. "Characterization Of Counterfeit Artesunate Antimalarial Tablets From Southeast Asia." *American Journal of Tropical Medicine and Hygiene* 75:5, 804-11 (2006), available at <http://www.ajtmh.org/cgi/content/full/75/5/804> (accessed 15 Feb 2011).

¹⁰⁹⁰ Alter Hall, Krystn, et al. "Characterization Of Counterfeit Artesunate Antimalarial Tablets From Southeast Asia." *American Journal of Tropical Medicine and Hygiene* 75:5, 804-11 (2006), available at <http://www.ajtmh.org/cgi/content/full/75/5/804> (accessed 15 Feb 2011).

been relabeling generic drugs, including contraceptives, with brand-name labels, then selling the drugs to large hospitals in Hanoi and Hai Phong at artificially high costs.¹⁰⁹¹

Many drugs are sold through unregulated pharmacies and private dealers, which handle around 11,000 drugs with a market value of USD 450 million each year.¹⁰⁹² Porous and under-regulated borders with countries like China, Laos, and Cambodia, which are infamous for exporting counterfeits, allow smugglers easy access to Thai pharmaceutical markets.¹⁰⁹³

Thai officials have initiated programs to counter the problem. Since 2005, police and customs officials have been trained to use GPHF's Minilab, a mobile, compact laboratory, to quickly detect counterfeit and substandard drugs.¹⁰⁹⁴ However, counterfeiters have also adopted new technologies. Interpol reported decreasing smuggling rates in 2008, but advanced technologies used by counterfeiters may simply be allowing more smuggled medications to enter the country undetected.^{1095,1096}

Vietnam also faces increasing problems with common anti-infectives and antimalarial medications. An investigation in 1999 into the quality of eight anti-infectives in Vietnam revealed that 8 percent were substandard.¹⁰⁹⁷ By 2006, a similar study found that 68 percent of artesunate (another anti-infective) tablets did not contain the correct amount of active ingredient.¹⁰⁹⁸

In 2006, only 40 percent of medicines sampled were registered.¹⁰⁹⁹ To rectify the situation, the HCM City Department of Health licensed more than 5,800 medicine-related businesses, including 388 drug trading companies, 84 drug wholesale units, 3,356 drugstores, 460 pharmaceutical companies' drug agents, over 300 Oriental medicine stores, and 105

¹⁰⁹¹ "Police Battle Counterfeit Drugs." *VietNamNet* (Jul 31 2008), available at <http://english.vietnamnet.vn/social/2008/07/796548/> (accessed Feb 8 2010).

¹⁰⁹² "Vietnam Takes Action Against Drug Fakers." *in-Pharma Technologist* (Jan 20 2005), available at <http://www.in-pharmatechnologist.com/Processing-QC/Vietnam-takes-action-against-drug-fakers> (accessed Feb 8 2010).

¹⁰⁹³ "Vietnam Takes Action Against Drug Fakers." *in-Pharma Technologist* (Jan 20 2005), available at <http://www.in-pharmatechnologist.com/Processing-QC/Vietnam-takes-action-against-drug-fakers> (accessed Feb 8 2010).

¹⁰⁹⁴ "Vietnam Takes Action Against Drug Fakers." *in-Pharma Technologist* (Jan 20 2005), available at <http://www.in-pharmatechnologist.com/Processing-QC/Vietnam-takes-action-against-drug-fakers> (accessed Feb 8 2010).

¹⁰⁹⁵ "Vietnam Takes Action Against Drug Fakers." *in-Pharma Technologist* (Jan 20 2005), available at <http://www.in-pharmatechnologist.com/Processing-QC/Vietnam-takes-action-against-drug-fakers> (accessed Feb 8 2010).

¹⁰⁹⁶ Cat, Huong. "Vietnam Second In Southeast Asia In Counterfeit Drugs." *VietNamNet* (Sep 22 2008), available at <http://english.vietnamnet.vn/social/2008/09/804985/> (accessed Mar 16 2010).

¹⁰⁹⁷ Wondemagegnehu E. "Counterfeit And Substandard Drugs In Myanmar And Viet Nam." *World Health Organization Essential Drugs and Other Medicines Research Series* 29 (1999), available at <http://apps.who.int/medicinedocs/en/d/Js2276e/> (accessed Mar 26 2010).

¹⁰⁹⁸ Alter Hall, Krystn, et al. "Characterization Of Counterfeit Artesunate Antimalarial Tablets From Southeast Asia." *American Journal of Tropical Medicine and Hygiene* 75:5, 804-11 (2006), available at <http://www.ajtmh.org/cgi/content/full/75/5/804> (accessed 15 Feb 2011).

¹⁰⁹⁹ Alter Hall, Krystn, et al. "Characterization Of Counterfeit Artesunate Antimalarial Tablets From Southeast Asia." *American Journal of Tropical Medicine and Hygiene* 75:5, 804-11 (2006), available at <http://www.ajtmh.org/cgi/content/full/75/5/804> (accessed 15 Feb 2011).

pharmaceutical material trading firms in the first half of 2008. However, it is unlikely that these licensing programs accurately identified legal traders, as the Department's Inspectorate had only four university-level pharmacists at the time, and half of the local inspectors had no college pharmaceutical degree.¹¹⁰⁰

Enforcement appears to be getting better as the country improves its capacity to effectively monitor drug quality. In March 2010, the Ministry of Health reviewed the performance of agencies in inspecting and monitoring the quality of drugs sold in the market. Dr Trinh Van Lau, director of the ministry's Central Institute of Medicine Analyzing, said that the proportion of fake medicines in the market is "lower than in other countries in the region."¹¹⁰¹ He also noted that most low-quality medicines discovered were traditional and herbal medicines, with 33 samples found in various regions of the country.¹¹⁰² According to Lau, the Institute was able to prevent a third of low quality medicine from entering the country at various borders with the help with the World Health Organization.¹¹⁰³

¹¹⁰⁰ Cat, Huong. "Vietnam Second In Southeast Asia In Counterfeit Drugs." *VietNamNet* (Sep 22 2008), available at <http://english.vietnamnet.vn/social/2008/09/804985/> (accessed Mar 16 2010).

¹¹⁰¹ "Health Ministry Reviews Inspection Of Drug Quality." *Viet Nam News* (Mar 27 2010), available at <http://vietnamnews.vnagency.com.vn/Social-Issues/198086/Health-ministry-reviews-inspection-of-drug-quality.html> (accessed Mar 29 2010).

¹¹⁰² "Health Ministry Reviews Inspection Of Drug Quality." *Viet Nam News* (Mar 27 2010), available at <http://vietnamnews.vnagency.com.vn/Social-Issues/198086/Health-ministry-reviews-inspection-of-drug-quality.html> (accessed Mar 29 2010).

¹¹⁰³ "Health Ministry Reviews Inspection Of Drug Quality." *Viet Nam News* (Mar 27 2010), available at <http://vietnamnews.vnagency.com.vn/Social-Issues/198086/Health-ministry-reviews-inspection-of-drug-quality.html> (accessed Mar 29 2010).

Oceania

In May 2009 a meeting of the Oceania Customs Organization in Vanuatu called for member nations to develop national strategies to curb regional trade of counterfeit medicines, noting that it poses a threat to health and consumer safety.¹¹⁰⁴

The presence of counterfeits in the region depends largely on national regulation and enforcement systems. In developed places like Australia and New Zealand, the percentage of counterfeits is low. In places like Papua New Guinea, where virtually no regulatory body exists, fake medicines are widely available. Documented cases of fakes in the Oceania region include antibiotics and anti-malarials.

There is evidence that counterfeiters have used destinations in Oceania, such as Vanuatu, as intermediaries for fake medicines sent from China and the Middle East.¹¹⁰⁵ From there, products are distributed throughout Europe and other regions, and some are sold via online traders masquerading as legitimate pharmacies based in Europe, Canada, and the United States.¹¹⁰⁶

Information on counterfeits in the region is largely drawn from customs seizures, various studies on drug quality, and health ministry reports, in addition to news articles. While information was not available for every country in the region, below is a comprehensive overview of the information available on counterfeit and substandard medicines in Oceania.

Australia

Like most industrialized countries with effective regulatory systems and market control, Australia's counterfeit drug market is small, measuring less than 1 percent of medications in circulation, according to the WHO.¹¹⁰⁷ During the last quarter of 2003, seizures of counterfeits in Australia equaled the amount seized in the four prior quarters combined.¹¹⁰⁸

According to the Pharmacy Guild of Australia and the Australian Government, the scarcity of counterfeits can be partially attributed to the nation's island geography, which maintains high transportation costs, thus providing some protection against the threat of counterfeits. Furthermore, it is difficult to inject fakes into supply lines, due to streamlined shipment chains

¹¹⁰⁴ "Communiqué." *Oceania Customs Organization* (May 4-8 2009), available at <http://www.ocosec.org/resources/uploads/attachments/documents/Communique%20-%20Vanuatu%20-%20Final%208%20May.pdf> (accessed Apr 7 2010).

¹¹⁰⁵ "The Counterfeiting Superhighway." *European Alliance for Access to Safe Medicines* (2008), available at <http://counterfeiting.unicri.it/docs/Counterfeiting%20Superhighway.%20EAASM%202008.pdf> (accessed Apr 7 2010).

¹¹⁰⁶ "The Counterfeiting Superhighway." *European Alliance for Access to Safe Medicines* (2008), available at <http://counterfeiting.unicri.it/docs/Counterfeiting%20Superhighway.%20EAASM%202008.pdf> (accessed Apr 7 2010).

¹¹⁰⁷ "Counterfeit Medicines." *World Health Organization Fact Sheet* (Nov 14 2006), available at http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/ (accessed Apr 5 2010).

¹¹⁰⁸ "Fact sheet – The Impact And Scale Of Counterfeiting." *First Global Congress on Combating Counterfeiting* (May 24-26 2004), available at <http://counterfeiting.unicri.it/docs/First%20GCCCP%20fsheet.doc> (accessed Apr 5 2010).

that go straight from manufacturers to wholesalers then to pharmacists.^{1109,1110,1111} reference in triplicate! In addition, Australia's relatively cheap drug prices make the market less lucrative for counterfeiters.¹¹¹²

Nevertheless, the growth of internet pharmacies is a cause of alarm across the continent, as it renders the population more vulnerable to fakes.^{1113,1114} repeated dead link When a 2009 swine flu outbreak increased the demand for Tamiflu, there were several reports of counterfeit versions of the drug bought over the internet.^{1115,1116} duplicated ref

Fiji

According to its Ministry of Health, Fiji does not have significant issues with counterfeit medicine, though the country is not totally free of the problem. While the Ministry of Health claims that counterfeits are kept out by an import screening process, which only accepts and drugs that are manufactured and produced under the British and United States Pharmacopoeia standards, other government officials, including the chief pharmacist, have challenged this view, asserting in print that there is, in fact, no existing regulatory body that looks at all the drugs coming into the country before they are distributed to pharmacies.^{1117,1118}

¹¹⁰⁹ "Fake Medicines a Minor Threat in Australia." *The Pharmacy Guild of Australia Media Release* (Nov 23 2006), available at http://www.guild.org.au/uploadedfiles/National/Public/News_and_Events/Media_Release_Archive/20061123_fake_medicines.pdf (accessed Apr 5 2010).

¹¹¹⁰ "Counterfeit Tamiflu Purchased over the Internet." *Australian Government Department of Health and Ageing Media Release* (Aug 12 2009), available at <http://www.health.gov.au/internet/healthemergency/publishing.nsf/Content/news-120809> (accessed Apr 5 2010).

¹¹¹¹ Gertsakis, Mark. "Fake Drugs Not a Worry in Australia." *Pharmacy News* (Aug 25 2009), available at <http://www.pharmacynews.com.au/article/fake-drugs-not-a-worry-in-australia/495644.aspx> (accessed Apr 5 2010).

¹¹¹² "Fake Medicines a Minor Threat in Australia." *The Pharmacy Guild of Australia Media Release* (Nov 23 2006), available at http://www.guild.org.au/uploadedfiles/National/Public/News_and_Events/Media_Release_Archive/20061123_fake_medicines.pdf (accessed Apr 5 2010).

¹¹¹³ "Counterfeit Tamiflu Purchased over the Internet." *Australian Government Department of Health and Ageing Media Release* (Aug 12 2009), available at <http://www.health.gov.au/internet/healthemergency/publishing.nsf/Content/news-120809> (accessed Apr 5 2010).

¹¹¹⁴ "Counterfeit Tamiflu Purchased over the Internet." *Australian Government Department of Health and Ageing Media Release* (Aug 12 2009), available at <http://www.health.gov.au/internet/healthemergency/publishing.nsf/Content/news-120809> (accessed Apr 5 2010).

¹¹¹⁵ Gertsakis, Mark. "Fake Drug Sales on the Rise." *Pharmacy News* (Feb 19 2010), available at <http://www.pharmacynews.com.au/article/Fake-drug-sales-on-the-rise/511640.aspx> (accessed Apr 5 2010).

¹¹¹⁶ "Counterfeit Tamiflu Purchased over the Internet." *Australian Government Department of Health and Ageing Media Release* (Aug 12 2009), available at <http://www.health.gov.au/internet/healthemergency/publishing.nsf/Content/news-120809> (accessed Apr 5 2010).

¹¹¹⁷ "Counterfeit Medicine Life Threatening." *Press Releases - Fiji Government Online* (May 12 2005), available at <http://www.fiji.gov.fj/cgi-bin/cms/exec/view.cgi/62/4586/printer> (accessed Apr 7 2010).

¹¹¹⁸ "Article Warns Fiji Vulnerable to Counterfeit Drugs." *BBC Monitoring International Reports* (Sep 21 2005), available through Lexis Nexis Academic (accessed Apr 7 2010).

New Zealand

According to the WHO, New Zealand's proportion of counterfeits in the market is less than 1 percent.¹¹¹⁹

While there have been no reported cases of counterfeit medicines entering the legitimate market in New Zealand, according to Medsafe, the country's drug regulatory agency, there are anecdotal reports of counterfeits appearing amongst medicines being imported for personal use by consumers.¹¹²⁰ In addition, herbal products and traditional Chinese medicines imported into New Zealand have been found to contain undeclared prescription medicines such as corticosteroids and NSAIDs.¹¹²¹

The number of medicines and therapeutic products intercepted at New Zealand's border has increased in recent years. In 2008, Customs seized 241 packages of fake medicine, mostly Chinese-made erectile dysfunction products; 66 packages of fakes were seized and destroyed in 2009.¹¹²² In 2007 and 2008, only about a quarter of intercepted medicines and products were released to importers, and the rest were destroyed.¹¹²³

In March 2010, the major ingredient in a batch of seized counterfeit Viagra was determined to be bat and bird droppings.^{1124,1125} According to a principal scientist at a state-owned science research organization, other intercepted medicines were found to contain whole insects, dust mites, hair, charcoal and heavy metals, including arsenic and mercury.^{1126,1127} duplicate ref

Papua New Guinea

Counterfeit pharmaceuticals, in addition to medicines stolen from the public health system, are widely available in Papua New Guinea, and are sold in markets throughout the country.¹¹²⁸

¹¹¹⁹ "Counterfeit Medicines." *World Health Organization Fact Sheet* (Nov 14 2006), available at http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/ (accessed Apr 5 2010).

¹¹²⁰ "Counterfeit Medicines – Don't Fake Concern." *Medsafe Pharmacovigilance Team, New Zealand Medicines and Medical Devices Safety Authority* (Jun 2005) available at <http://www.medsafe.govt.nz/profs/PUarticles/counterfeit.htm#7> (accessed Apr 5 2010).

¹¹²¹ "Counterfeit Medicines – Don't Fake Concern." *Medsafe Pharmacovigilance Team, New Zealand Medicines and Medical Devices Safety Authority* (Jun 2005) available at <http://www.medsafe.govt.nz/profs/PUarticles/counterfeit.htm#7> (accessed Apr 5 2010).

¹¹²² Todd, Rebecca. "More Buy Risky Drugs on Internet." *The Press* (Mar 6 2010), available at <http://www.stuff.co.nz/the-press/news/3411488/More-buy-risky-drugs-on-internet> (accessed Feb 16 2011).

¹¹²³ Todd, Rebecca. "More Buy Risky Drugs on Internet." *The Press* (Mar 6 2010), available at <http://www.stuff.co.nz/the-press/news/3411488/More-buy-risky-drugs-on-internet> (accessed Feb 16 2011).

¹¹²⁴ Todd, Rebecca. "More Buy Risky Drugs on Internet." *The Press* (Mar 6 2010), available at <http://www.stuff.co.nz/the-press/news/3411488/More-buy-risky-drugs-on-internet> (accessed Feb 16 2011).

¹¹²⁵ "Fake Viagra Was Made Of Bird Droppings!" *Express Buzz* (Mar 7 2010), available at <http://expressbuzz.com/news/fake-viagra-was-made-of-bird-droppings!/154129.html> (accessed Apr 7 2010).

¹¹²⁶ Todd, Rebecca. "More Buy Risky Drugs on Internet." *The Press* (Mar 6 2010), available at <http://www.stuff.co.nz/the-press/news/3411488/More-buy-risky-drugs-on-internet> (accessed Feb 16 2011).

¹¹²⁷ "Fake Viagra Was Made Of Bird Droppings!" *Express Buzz* (Mar 7 2010), available at <http://expressbuzz.com/news/fake-viagra-was-made-of-bird-droppings!/154129.html> (accessed Apr 7 2010).

¹¹²⁸ "Beware Of Counterfeit Drugs." *Islands Business* (Sep 25 2007), available at http://www.islandsbusiness.com/news/index_dynamic/containerNameToReplace=MiddleMiddle/focusModuleID=1

Known cases of fakes in the country include anti-malarial drugs and antibiotics. For instance, in September 2007, large quantities of drugs, mainly anti-malarial tablets, were stolen and reportedly sold on the streets in Papua New Guinea at cheap prices.¹¹²⁹ In January 2010, tests revealed that half of a sample group of amoxicillin treatments were counterfeits—one purported to be produced by a manufacture that no longer existed, and another claimed to be manufactured by a reputable company in India. Several products contained the wrong amount of amoxicillin, a particularly dangerous flaw in terms of treating infections and avoiding development of drug resistance.¹¹³⁰

The high incidence of counterfeits in Papua New Guinea is not surprising, considering the nation has neither an official authority for regulating medicines nor a laboratory for testing drug products.¹¹³¹

Tonga

Tonga was affected by the 2007 worldwide infiltration of toothpaste tainted with antifreeze, which was manufactured in China.¹¹³²

Vanuatu

Vanuatu is a known site where counterfeit operations send their fake pills to be packaged.¹¹³³ For instance, a 2005 sting operation conducted by the US FDA at three US airports found that 85 percent of drugs labeled to have Canadian origins were actually shipped from other countries, such as India, Costa Rica, and Vanuatu.¹¹³⁴

[30/focusContentID=10176/tableName=mediaRelease/overrideSkinName=newsArticle-full.tpl](#) (accessed Feb 16 2011).

¹¹²⁹ “Beware Of Counterfeit Drugs.” *Islands Business* (Sep 25 2007), available at http://www.islandsbusiness.com/news/index_dynamic/containerNameToReplace=MiddleMiddle/focusModuleID=130/focusContentID=10176/tableName=mediaRelease/overrideSkinName=newsArticle-full.tpl (accessed Feb 16 2011).

¹¹³⁰ Papua New Guinea: Minilab Unmasks Counterfeit Antibiotics.” *Global Pharma Health Fund E.V.* (Jan 29 2010), available at <http://www.gphf.org/web/en/news/meldungen.htm> (accessed Apr 7 2010).

¹¹³¹ Papua New Guinea: Minilab Unmasks Counterfeit Antibiotics.” *Global Pharma Health Fund E.V.* (Jan 29 2010), available at <http://www.gphf.org/web/en/news/meldungen.htm> (accessed Apr 7 2010).

¹¹³² Bogdanich, Walt. “The Everyman Who Exposed Tainted Toothpaste.” *The New York Times* (Oct 1 2007), available at <http://www.nytimes.com/2007/10/01/world/americas/01panama.html> (accessed Apr 7 2010).

¹¹³³ Steve Boggan. “Headache Pills Made of Rat Poison and Viagra Made of Chalk: We Reveal the Chilling Truth about Internet Drugs.” *Mail Online* (Apr 20 2009), available at <http://www.dailymail.co.uk/health/article-1173735/After-deacons-daughter-killed-medicine-bought-online--chilling-truth-internet-black-market-prescription-drugs.html> (accessed Apr 7 2010).

¹¹³⁴ Lutter, Randall W. “Policy Implications of Importing Drugs into the United States.” *Testimony before the Subcommittee on Interstate Commerce, Trade, and Tourism of the Committee on Commerce, Science, and Transportation, United States Senate* (Mar 7 2007), available at <http://www.fda.gov/NewsEvents/Testimony/ucm154233.htm> (accessed Feb 23 2011).