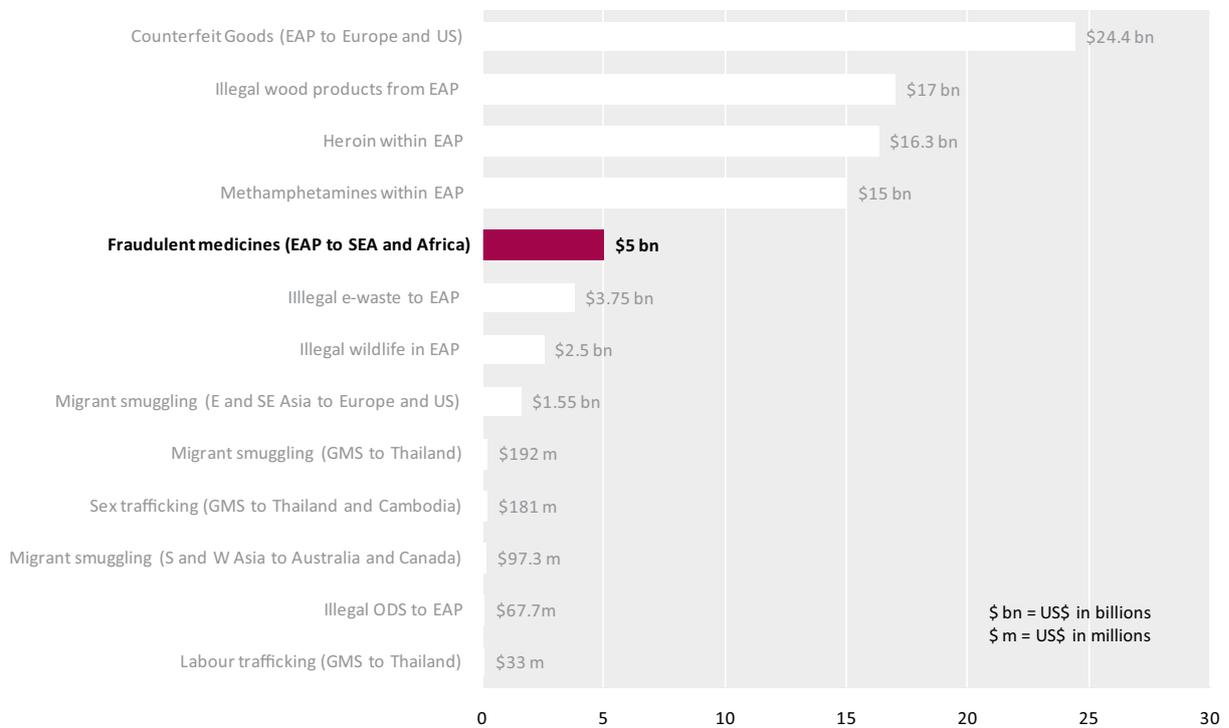


Chapter 12

Fraudulent essential medicines from East Asia to Southeast Asia and Africa



NATURE OF THE THREAT

1. Severe health risks including death: presence of toxins; lack of active ingredient.	2. Drug resistant strains: microbial resistance: under-medicated patients become vectors for drug-resistant strains; “superbugs”.
3. Revenue loss: financial losses to private industry and government revenues.	

1. What is the nature of this market?

This chapter refers to fraudulent medicines, not counterfeit medicines, and this choice of terminology is important. “Counterfeit” is often used to refer to falsely-branded or unlicensed products, where the crime involved is intellectual property theft. In contrast, the act of deceiving buyers as to the content of what they are buying is fraud. This includes misbranding, but is broader, and – crucially – encompasses products that do not contain what they purport to contain.

In the context of pharmaceuticals, fraud is a very serious matter indeed. When sick people are not properly medicated, two things can happen. One, they don't get better, and the inappropriate medicine may even make them worse. The best doctors in the world cannot provide healing when they don't know what is in the drugs they are administering. Two, when antimicrobial drugs are given in insufficient doses to kill the pathogen, drug resistant strains can develop, posing a global health threat.

The exact percentage remains unclear, but a number of surveys have determined that a large share of the essential medicines sold in Southeast Asia and Africa are bogus. Forensic testing of samples from these regions has produced alarming results – in most, one-third to two-thirds of the samples tested were found

to be deficient or falsified (see Figures 1 and 2). In some cases, there is deliberate brand counterfeiting, but in many others, the drugs are generic. For the consumer, the results are the same.

There are many possible reasons why the contents of the medication may not be what the packaging promises. Some of this may be a simple lack of production standards, insufficient mixing, or contamination and degradation. The fact that some tested samples actually included more than the specified dose is evidence that sloppiness occurs. But the market incentives for under-dosing are surely a factor as well. In order to under-price their competitors, producers of fraudulent medicines may include less of the expensive active ingredients and more filler.

In general, organized crime flourishes in times of rapid transition, when the old norms no longer apply and the new have yet to take hold. Thus, we should expect abuses to emerge in countries with rapidly growing pharmaceutical industries. The countries with the most rapidly-expanding pharmaceutical industries in the world today are India and China (see Figure 3).

If those involved in this industry were aiming at getting the highest price for their wares, almost all fraudulent medicines would be shipped to the G8 countries. Looking exclusively at the seizure figures, one might conclude that this is, in fact, the case. But the high rate of seizures in the richer nations is a direct result of their ability to detect the fraud. Forensic testing has shown that the prevalence of fraudulent medicines is much higher in poor countries than in rich ones, with some of the highest rates being detected in Africa and Southeast Asia. The low value of these markets suggests this is a crime of opportunism. Fraud is mainly perpetrated where there is lowest risk of detection, not highest rate of return.

The nature of the medicines involved also varies depending on the destination. Seizures made in the wealthier countries are mostly of mail-order lifestyle medicines, such as the erectile

Figure 1: Share of anti-malarial medications found to be falsified in Southeast Asia

Location	Date of Sample Collection	Falsified
Cambodia, Laos, Myanmar, Thailand, Viet Nam	1999–2000	39 out of 104 (38%)
Cambodia, Laos, Myanmar, Thailand-Myanmar border, Viet Nam	1999-2005	195 out of 391 (50%)
Cambodia, Laos, Myanmar, Thailand, Viet Nam	2002–2003	99 out of 303 (33%)
Cambodia	2003	88 out of 111 (79%)
Laos	2003	27 out of 30 (90%)

Source: Keledsis and others 2007

Figure 2: Share of anti-malarial medication that failed chemical assay analysis in Africa

Location	Date of sample collection or study publication	Failed chemical analysis
Uganda	2001	57 out of 92 (62%)
Cameroon	2001	112 out of 284 (39%)
Kenya	2002	47 out of 116 (41%)
Kenya	2001–2005	11 out of 41 (27%)
Laos	2003	27 out of 30 (90%)
Kenya and Democratic Republic of Congo	2004	9 out of 24 (38%)
Burkina Faso	2006	32 out of 77 (42%)
Madagascar, Senegal, Uganda	2008	64 out of 197 (32%)
Ghana, Kenya, Nigeria, Tanzania, Ethiopia, Cameroon	2008	72 out of 267 (27%)
Kenya	2000	23 out of 33 (69%)
Tanzania	2000	5 out of 9 (55%)
Nigeria	2001	119 out of 284 (42%)
Senegal	2002	15 out of 27 (56%)
Tanzania	2003	10 out of 33 (30%)
Congo, Burundi, Angola	2007	16 out of 28 (57%)
Nigeria	2007	19 out of 32 (59%)
Tanzania	2008	38 out of 301 (12%)
Ghana, Kenya, Nigeria, Rwanda, Tanzania, Uganda	2008	73 out of 210 (35%)
Ghana	2009	14 out of 17 (82%)
Nigeria	2009	60 out of 225 (27%)
Burkina Faso, Chad, Cameroon, DR Congo, Ghana, Kenya, Nigeria, Rwanda, Senegal	2002-2010	35 out of 59 (59%)

Source: Gaurvika and others 2012

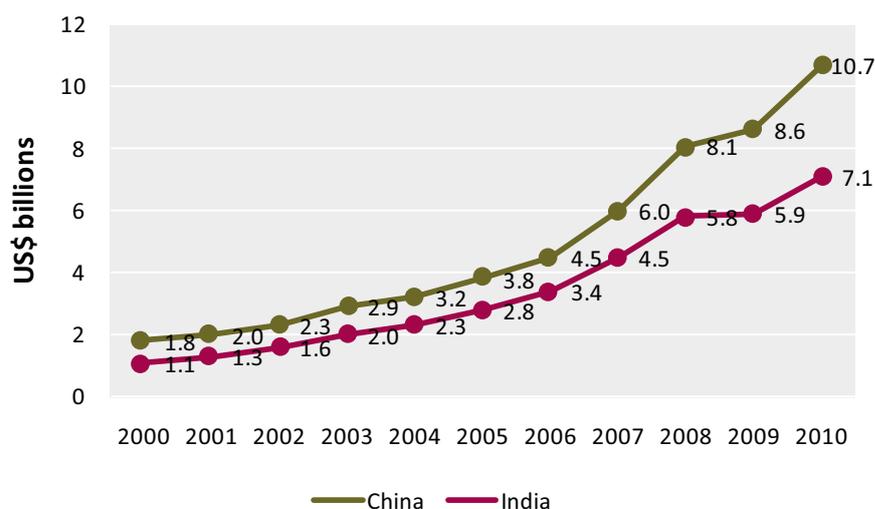
dysfunction drug, Viagra. Internet pharmaceutical fraud can have serious health consequences for individual users, but users in the wealthier countries can largely avoid this hazard by buying from reliable domestic sources. Those in developing countries do not have this choice, and the damage is far more widespread.

Both seizure data and forensic testing have – again – confirmed that the largest sources of both fraudulent lifestyle medicines and fraudulent essential medicines are India and China. The Pharmaceutical Security Institute, a trade association that monitors counterfeit seizures globally, found that China and India were the top origins of detected counterfeits in 2010 (see Figure 4). They also found that China detected more counterfeit manufacturing operations than any other country that year.¹

Statistics from the World Customs Organization (WCO) indicate that China was the departure point of nearly 60% of the counterfeit medical products (medicines and condoms) seized worldwide between 2008 and 2010.² These statistics reflect the departure points (provenance) of seized shipments, not their origin. The provenance of these shipments is often from countries that have no known pharmaceutical production, licit or otherwise, and so the share of shipments originating in India and China could actually be higher.

Unlike in Europe or the U.S., there is no consolidated database of African or Southeast Asian pharmaceutical seizures. Lifestyle drugs are also seized in Southeast Asia, but most of the fraudulent medicines encountered in East Asia and the Pacific are antibiotics, anti-microbials, anti-hypertensives, cardiovascular

¹ PSI 2010² WCO 2008; WCO 2009; WCO 2010

Figure 3: Pharmaceutical exports

Source: World Trade Organization 2012

medicines and anti-diabetics.³ Large quantities of fraudulent essential medicines have been seized in Interpol-led law enforcement sweeps aimed at detecting fraudulent products and their purveyors:

- The 2008 Operation Storm detected counterfeit anti-malarials in Myanmar (produced in Thailand) and Kenya (produced in China).
- The 2010 Operation Storm II in Southeast Asia led to the seizure of millions of dollars worth of fraudulent antibiotics, anti-malarials, birth control medicines, anti-tetanus serums, and pain-relief medications.⁴
- The 2008 Operation Mamba in East Africa led to the seizure of more than 100 different products (including anti-malarials, cardiac medicines, and others).
- The 2009 and 2010 Operations Mamba II and III in East Africa led to the seizure of essential medicines such as vaccines, anti-malarials and antibiotics.
- The 2009 Operation Zambezi in Southern Africa led to seizure of counterfeit and illicit anti-malarials, antibiotics, and steroids.
- The 2011 Operations Cobra and Harmattan in West Africa led to the seizure of counterfeit anti-malarials and antibiotics.
- The 2006 Operation Jupiter in Southeast Asia found that of the 321 samples manufactured by

³ UNODC Communication with Dr. Budiono Santoso, Regional Advisor, Western Pacific Regional Office of the World Health Organization, Manila, Philippines), 21 December 2011.

⁴ Interpol 2010a

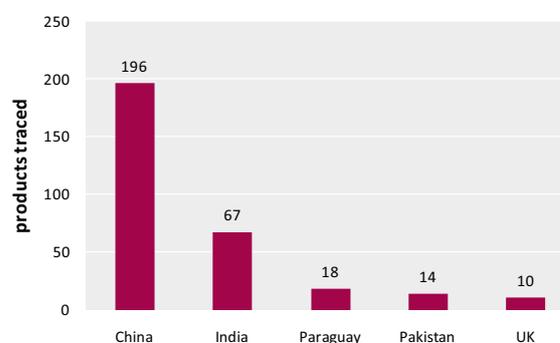
one major Asian producer (Guilin Pharmaceutical from China's Guangxi region), 61% were found to be counterfeit.

Forensic testing has also demonstrated the extent of the problem. A recent review of the literature found that between one-third and nine-tenths of the anti-malarial medicines tested in Southeast Asia in recent years were found to be false. Similarly, between 12% and 82% of anti-malarial drugs tested in Africa have failed chemical

assay analysis. Chemical analysis of samples of other essential drugs has produced similar results.⁵

It is possible to determine the origin of fraudulent medicines forensically, although this has rarely been done. Testing in connection with Operation Jupiter traced the origin of certain counterfeits to a particular region of China, and arrests were then made on this basis.⁶ A recent forensic study of fraudulent medicines detected in Africa confirmed an Asian origin for these drugs.⁷

The Chinese government is aware of risks involved in a rapidly growing pharmaceutical industry, and has launched a number of campaigns to address abuses.

Figure 4: Top five origins of counterfeit medicines detected

Source: Pharmaceutical Security Institute 2010

⁵ Kelesidis and others 2007

⁶ Newton and others 2008

⁷ Newton and others 2011

The former head of the Chinese Food and Drug regulatory agency was executed in 2007 for receiving close to one million dollars in bribes for approving hundreds of medicines. In 2008, the melamine scandal – in which babies died from drinking tainted formula – showed that the problem ran deeper than one official. More recently, sweeps in 2011 found widespread counterfeiting in Henan province, with hundreds of operations detected.⁸ That same year, a network in Guangxi Zhuang Autonomous Region was found producing 710 different products, from lifestyle drugs to antibiotics.⁹

2. How is the trafficking conducted?

Fraudulent pharmaceutical production is not a homogeneous industry. There are firms of all sizes in the region, some specialized in a particular type of product and others offering a wide range. Some operations are exclusively focused on producing counterfeits, while others produce licit products (pharmaceuticals, traditional medicines, industrial chemicals) as well. A single firm can produce licit pharmaceuticals for one market and fraudulent ones for another. The share of fraudulent medicine produced by a firm may also vary over time.

The World Health Organization reports that the manufacture of fraudulent medicines is often a small-scale cottage industry, conducted in informal settings such as garages or small warehouses.¹⁰ Many detected operations fit this description, with chemicals stored in piles on the floor and distributed with shovels. But mainstream pharmaceutical firms can also produce fraudulent medicines. For example, in March 2012 Furentang Pharmaceutical, a company based in Jiangxi, China, had its license revoked for producing counterfeits. The company had been using forged documents to justify manufacturing products they had no license to produce.¹¹

Mainstream companies under financial pressure can stray into fraud. Wary of protecting their reputations, they may substitute cheaper chemicals that mimic the effects of the medicines they are purporting

to sell. For example, fraudulent heparin, a well-established drug with many clinical applications, was exported to the US from China in 2008. The heparin was diluted with a cheaper chemical that mimicked the effect of the original drug.¹² Similarly, products sold as the anti-malarial artesunate in Southeast Asia have been found to contain cheaper substances, including out-of-use anti-malarials and drugs with possible dangerous side effects.¹³ Companies under pressure can also cut corners by skipping steps in manufacturing process, including quality control checks.¹⁴ They can alter the expiration date of standing stocks, fail to maintain appropriate storage conditions, or add cheap ingredients not intended for human consumption.

In East Asia, traditional and herbal medicines are a multibillion-dollar business. Equipment to manufacture and package these products can be very similar to that used for pharmaceuticals, so transitioning to counterfeiting is easy. Pharmaceutical drugs may be secretly added to herbal products to increase the appearance of efficacy. A 2010 study of 20 herbal products and “natural” dietary supplements (over half of which came from China) found that only four had a composition corresponding to declared ingredients on the packaging or associated leaflet; the remainder were adulterated with unadvertised active pharmaceutical ingredients, some of which are believed to be dangerous to human health and are banned in various countries.¹⁵

Another example was an incident in 2009, when 150 Singaporeans were admitted to hospital after taking fraudulent herbal supplements marketed as erectile dysfunction remedies. The herbal supplements contained glyburide, a powerful pharmaceutical used for the treatment of diabetes that can be dangerous for non-diabetics. Seven patients were comatose as a result of severe brain damage and four patients subsequently died.¹⁶ In May 2010, Taiwanese authorities seized 650,000 diet capsules from a

⁸ Xinhua News Agency 2011a, “Chinese police busts multi-million-dollar fake drug cases”, *Xinhua News Agency*, 29 November 2011.

⁹ Xinhua News Agency 2011b, “Police detain 39 for fake drugs in SW China”, *Xinhua News Agency*, 31 December 2011.

¹⁰ WHO 2012. Also UNODC communication with East Asia-based fraudulent medicine expert, 12 January 2012.

¹¹ Xinhua News Agency 2012, “Drug maker punished for counterfeiting: SFDA”, *Xinhua News Agency*, 1 April 2012.

¹² Traynor 2010; Bogdanich 2008

¹³ Hall and others 2000. Such active ingredients no longer used in anti-malarials include chloramphenicol (an inexpensive antibiotic), pyrimethamine-sulfadoxine (an out-of-use antimalarial) and metamizole (an analgesic that has fallen into disuse due to possible dangerous side-effects).

¹⁴ UNODC Communication with Mr. Thomas Kubic, Pharmaceutical Security Institute, USA, 20 December 2011.

¹⁵ Vaysse and others 2010; BBC News 2011, “Fake medicine trade: UK crackdown on drug importers”, *BBC News*, 29 September 2011

¹⁶ WHPA 2011: p.8. See also Poon and others 2008.

licensed manufacturer that were found to contain phenolphthalein, a possible carcinogenic organic acid that has been banned in several countries.¹⁷

Of course, the crime of pharmaceutical fraud does not require a coherent organization at all, and can be the product of a chain of actors with no institutional identity. The fraud can be introduced at any point in the supply chain, with or without the knowledge of the other participants. For example, producers of chemical ingredients may export these to buyers in other countries, who combine them to produce bulk powders or solutions that are then again exported to be broken into dose units and packaged. Because the point at which an adulterant has been introduced may not be clear, the level of intent of any of these actors may be difficult to discern, but the end product can be as deadly as any produced in its entirety on one site.

Fraudulent Herbal Medicines in New Zealand

The New Zealand Medicines & Medical Devices Safety Authority (Medsafe), which inspects all medical consignments sent through the country's International Mail Centre, reports that falsely labelled herbal medicines have been problematic since the agency began functioning in mid-2007. These fraudulent medicines typically purport to be purely herbal treatments for erectile dysfunction or weight loss, but in fact are often found to contain hidden or undeclared prescription medicines, including those typically found in commonly used treatments for erectile dysfunction. From July 2007 through 2010, Medsafe found 1,721 consignments of such fraudulent herbal medicines, although annual incidents declined by 23% between 2008 and 2010. More than 60% of the consignments of fraudulent herbal medicines shipped by international mail to New Zealand from mid-2007 to 2010 came from China.

For example, in 2007, a small factory in China produced a syrup containing diethylene glycol – commonly used as antifreeze – and sold it as pharmaceutical grade glycerin. The fraudulent glycerin was sold to a Beijing brokerage company, which shipped it from Shanghai to another broker in

Barcelona, who forged some paperwork and sold it on to yet another broker in Panama. The syrup was used to manufacture medicines in Panama, resulting in at least 100 deaths.

It is not uncommon for counterfeit ingredients to be sent from China to Southeast Asia for production and packaging. These extended transnational networks are inherently flexible: if any supplier or assembler is removed, other partners can be found. As law enforcement and regulatory pressure has increased within China, key aspects of production are moved to other countries, such as the Democratic People's Republic of Korea, Myanmar and Viet Nam.¹⁸

Cases have also been reported where unfinished products have been shipped from China to richer countries for finishing. In 2011, a British national received an eight-year prison sentence for importing more than two million doses of fraudulent cancer, heart disease and schizophrenia medicines from China. To pass off the drugs as a French product, special French-style bar-code labels were produced and imported separately from the fraudulent medicines, and the final product was assembled in the UK prior to distribution.¹⁹

Once the product is finished, it may still be moved internationally many times before being consumed. Fraudulent medicines can change hands more than 30 times before reaching buyers.²⁰ One recent investigation found that fraudulent medicines produced in China were transported by road to Hong Kong (China), sent by air to Dubai, and then through London's Heathrow Airport to the Bahamas. The trafficking organization kept a warehouse center for its fraudulent medicines in the Bahamas from which the drugs were sent back to associates in the UK, who eventually sent the packages to the United States.²¹

As with counterfeit goods, the free-trade zones of the Middle East have emerged as key trans-shipment points for fraudulent medicines.²² In many cases, fraudulent medicines are smuggled by truck over the

¹⁷ Chao-Fu and Kuo 2010; WHPA 2011: p. 8.

¹⁸ UNODC communication with Mr. Thomas Kubic, Pharmaceutical Security Institute, USA, 20 December 2011.

¹⁹ London Evening Standard 2011; Sears and Greenwood 2011.

²⁰ Lewis 2009

²¹ Toscano 2011

²² OECD 2008

border from Guangdong Province into Hong Kong (China). From Hong Kong (China), the fraudulent medicines will transit free-trade zones, such as those in the United Arab Emirates and Syria.²³ Relaxed regulations in free-trade zones give fraudulent medicine traffickers the ability to repackage their goods and conceal their point of origin.²⁴

As with any other business, pharmaceutical fraudsters adapt their production to meet changes in demand. Fraudulent injectable cancer medications have been discovered at an increasing rate over the past three years.²⁵ Incidents involving fraudulent medicines in the “metabolism” category, which includes diabetic medicines, have increased recently.²⁶ The WCO reports that fraudulent forms of the H1N1 vaccine became widely available after the outbreak of this flu strain in 2009.²⁷ And in March 2006, fraudulent forms of rimonabant – an anti-obesity drug – was advertised for sale over the Internet. This was done three months prior to the drug’s approval by European Union authorities.²⁸

3. Who are the traffickers?

Just as there are many forms of pharmaceutical fraud, so too there are many types of traffickers. Those who merely repackage expired medications need little more than printing skills and the connections to acquire and move their product. At the other end of the spectrum are pharmaceutical executives who use their sophisticated understanding of the market to make large criminal profits. Most common are those with some involvement or experience of the industry, who learn that it is possible to make more money selling fraudulent medicines than licit ones.

For example, in 2008, forensic investigations of fraudulent artesunate in mainland Southeast Asia traced ingredients and components to a location in southern China, close to the border with Viet Nam, Lao PDR and Myanmar. An individual arrested

in this case claimed that he had previously sold legitimate pharmaceuticals until he was approached by Myanmar medicine distributors who wanted him to produce fraudulent varieties of medicines in order to increase their profits.²⁹

Producers of drugs which are abused may also be involved in producing counterfeit medications. For example, the veterinary drug ketamine, which is not under international control, is produced in large quantities in China. It is heavily abused in Hong Kong (China) in particular. Investigations in Cambodia have in the past revealed traces of Ecstasy (MDMA) in fraudulent medicines, indicating that the very same pill presses used to manufacture the Ecstasy were used to manufacture fraudulent medicines.³⁰ Similarly, investigations have shown that criminal manufacturers of amphetamine-type substances have been involved in the production and distribution of counterfeit medicines in Southeast Asia.³¹

4. How big is the flow?

There are several ways to get a sense of how much fraudulent medicine is being trafficked. One is to look at the legitimate pharmaceutical trade and estimate the comparable size of the illicit trade. One frequently cited estimate, commonly attributed to the World Health Organization, is that the illicit market represents 10% of the global trade.³² The basis for this estimate is unclear. The value of the global trade is heavily concentrated in the richer countries, where incidence of fraudulent medicines appears to be less than 1%. East Asia (except Japan), Africa, and Australia combined account for only 15% of the value of global pharmaceutical sales.³³

As discussed above, those who sell fraudulent essential medicines seem to target the low-value markets of Southeast Asia and Africa, where consumers spend less than US\$100 per year on pharmaceuticals. For example, looking at selected Southeast Asian countries, per capita pharmaceutical

²³ UNODC communication with Sebastian J. Mollo, Intelligence Director, Americas, Pharmaceutical Security Institute, USA, 30 January 2012.

²⁴ UNODC communication with Mr. Thomas Kubic, Pharmaceutical Security Institute, USA, 20 December 2011.

²⁵ UNODC communication with Sebastian J. Mollo, Intelligence Director, Americas, Pharmaceutical Security Institute, USA, 30 January 2012.

²⁶ PSI 2012; Toscano 2011

²⁷ WCO 2009: p. 14. See also Lewis 2009.

²⁸ OECD 2008: p. 348.

²⁹ Bogdanich and Hooker 2008

³⁰ Burki 2010: p. 585.

³¹ UNODC communication with East Asia-based counterfeiting medicine expert, 12 January 2012.

³² The World Health Organization has previously estimated that fraudulent medicines account for less than 1% of pharmaceutical markets in developed countries and between 10-30% of developing countries’ markets. See WHO 2006.

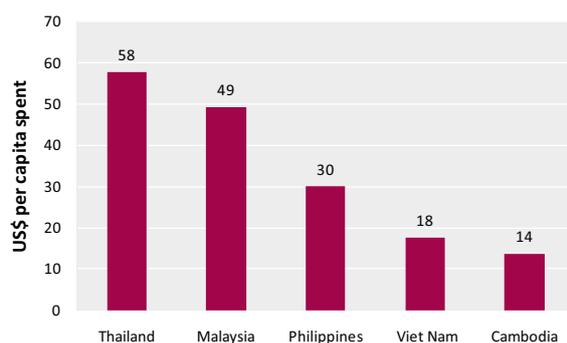
³³ IMS 2011

expenditures vary widely, between US\$14 and US\$58 in 2010 (see Figure 5).³⁴ Per capita expenditures in African countries are generally much less, in the neighbourhood of US\$8 per capita.³⁵

The anti-malarial studies cited above (see Figures 1 and 2)³⁶ indicate that between one-third and 90% of the drugs tested in Southeast Asia were fraudulent, and that between 12% and 82% of drugs tested in Africa failed chemical assay analysis. Studies of other anti-microbial drugs³⁷ indicate similar rates of failure. Given the wide range of values and the many products on offer, it is difficult to come up with a single figure, but an average of the anti-malarial studies cited above gives a figure of 47%.

If consumers in Southeast Asia bought around US\$8 billion in pharmaceutical products³⁸ in 2010 and 47% of them were fraudulent, this represents around US\$4 billion in fraudulent expenditures that year. Similarly, if each of the billion people of Africa spent US\$8 on pharmaceuticals in 2010 and half of these were fake, this represents a market of about US\$4 billion. If, in keeping with WCO seizures in 2010, 60% of these drugs originated in China, then the total flowing from this region to Southeast Asia and Africa would be just under **US\$5 billion**.

Figure 5: Per capita expenditure on pharmaceuticals in 2010, selected Southeast Asian countries



Source: BMI 2011

³⁴ BMI 2011. Viet Nam value is for the year 2009.

³⁵ Bennett and others 1997: p. 9.

³⁶ Gaurvika and others 2012; Kelesidis and others 2007

³⁷ Kelesidis and others 2007

³⁸ An extrapolation based on the per capita expenditures times the national populations.