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**COUNTERFEIT
PRODUCTS**

COUNTERFEIT PRODUCTS

Product counterfeiting is a form of consumer fraud: a product is sold, purporting to be something that it is not. This is different from the crime of copyright violation, which involves the unauthorized transfer of licensed material, such as the sharing of music or video files electronically.¹ Product counterfeiting is typically an organized group activity, because the manufacturing of goods takes people and time, and the goal is invariably profit. Many jurisdictions take the offence quite seriously, for reasons described below. As a result, most product counterfeiting would be considered organized crime under the Convention.

Lesser goods have been passed off as high-quality merchandise since the dawn of organized commerce, but the practice has taken on new meaning and proportions in the latest wave of globalization. With the advent of “outsourcing”, companies in developed countries are responsible for the research, design and marketing of products, while the actual manufacturing of the goods takes place in countries with a productive, yet cheaper, workforce. These manufacturing countries are also generally poorer, and so have lower capacity for oversight. This is usually not a problem, because the licensing company provides quality control – shoddy workmanship or substandard materials mean loss of contracts and possibly legal action.

But this same lack of regulatory capacity makes unauthorized production possible. Products in high demand can be manufactured based on the same or similar designs, often packaged and branded in ways to make them indistinguishable from the original. The counterfeit goods can then be sold through parallel markets, or even introduced into the licit supply chain. Without the overheads of the licit products, these counterfeits can be priced extremely competitively while remaining vastly more profitable. Due to this competitive edge, in some markets in some parts of the world, counterfeit products are far more common than the originals.

Product counterfeiting is widespread: products destined for 140 countries were detected in 2008, according to the World Customs Organization.² The scale of the global problem has not been well documented, however. The International Chamber of Commerce continues to cite a frequently used estimate: “Counterfeiting accounts for between 5-7% of world trade, worth an estimated US\$600 billion a year.”³ This figure does not appear to have an empirical basis, however, and has been criticized

as excessively high. In 2007, the Organization for Economic Co-operation and Development tentatively estimated the value of counterfeit and pirated goods that are traded internationally at 2% of the world trade in goods, or US\$176 billion, in 2007.⁴ This estimate appears to have a stronger evidential base, but was released with substantial caveats due to the lack of comprehensive data.

The production and trafficking of counterfeit goods is often portrayed as a matter of intellectual property theft, and through this prism it garners little sympathy. Many otherwise law-abiding citizens think nothing of buying a knock-off version of a designer article. Though many are aware that the loss of income reduces the incentives for creativity, the impact seems too remote and the victims too affluent for many people to give the matter a second thought.

In aggregate, however, product counterfeiting poses a serious global challenge. The branding of a product provides implicit quality assurance and a legal line of accountability that consumers have come to take for granted. Without a brand to protect, counterfeiters have no incentive to produce anything but superficial quality. Where it becomes impossible to distinguish the real from the counterfeit, poor quality products destroy the reputation of the copied brand, and the cheaper goods will inevitably dominate. The ultimate threat of counterfeiting has been realized in some parts of the developing world: the original, high-quality products have been essentially priced out of the market.

Unaccountable products are often dangerous products. Knockoff toy producers need not worry about choking hazards or paint toxicity. Counterfeit auto parts are not subjected to the rigorous safety testing borne by their licit counterparts. Due to cheaper materials and workmanship, counterfeit batteries and cigarette lighters are prone to explode. Counterfeit medicines need not contain any active ingredient at all. Worse, they could contain a substandard dose, allowing the target microbes to develop resistance. In this way, the proliferation of counterfeits anywhere in the world can have ramifications for global health. And counterfeit products have indeed proliferated, as detailed in the flow studies below.

Electronic goods are one of the most commonly encountered counterfeit products, and detection of pharmaceuticals has also been rising. The single most commonly counterfeited class of goods, however, is apparel: clothing, accessories and shoes. The safety hazards of knock-off designer handbags are

less obvious than dilute penicillin, but all counterfeits undermine national and global attempts to regulate commerce in the common interest.

For example, counterfeit products are often smuggled, both to circumvent problematic inspections and to evade import taxes. Since they are generally retailed irregularly, sales taxes are avoided. Tax evasion also allows counterfeit goods to be priced extremely competitively, while at the same time affording attractive profits for the dealers. By displacing the sales of legitimate products, they undermine the tax base, and thus affect public services available for all.

The damage is not just felt in the receiving countries: the producing countries also suffer. Even as the major brands work to improve labour standards and workplace safety at their outsourced manufacturing sites, counterfeit goods producers take advantage of global sweatshops. As licensed manufacturers try to improve their environmental impact standards, counterfeiters enjoy the cost savings of dirty production. In short, anywhere that the international community attempts to establish good practice standards for industry, counterfeiters undercut them.

Thus, much of the impact of product counterfeiting is long-term, subtle and diffuse. Deaths, many of which occur in developing countries, are often not tied back to the counterfeit product, or if they are, there is little organized response. As a result, the impact of counterfeiting can be frustratingly difficult to quantify. The most accessible metric is loss of revenues, and so counterfeiting is often reduced to a revenue issue, despite being much more than that.

Much of global outsourcing is contracted to firms in Asia, both for manufacturing and, increasingly, for services. In pharmaceutical contract manufacturing, for example, India and China are among the market leaders. It is therefore not surprising that a large share of global counterfeit seizures originate in Asia, and that this region is the focus of the following section. This is not to suggest the problem is limited to Asia, and in many cases the goods are only misbranded far from the production sites. As reiterated throughout this report, these are global problems, and solving them will require interventions at the level of the problem.



8.1. Counterfeit consumer goods from East Asia to Europe

Route

Source:	<i>China</i>
Vector:	<i>Sea</i>
Destination:	<i>All EU countries</i>

Value

Annual market volume:	<i>Some 2 billion articles per year</i>
Annual value at destination:	<i>US\$8.2 billion</i>

Traffickers

Groups involved:	<i>Chinese, South Asian and European groups</i>
Residence of traffickers:	<i>China, transit hubs such as Dubai, Europe</i>

Threat

Estimated trend:	<i>Increasing</i>
Potential effects:	<i>Loss of product safety and accountability, loss of revenue</i>
Likelihood of effects being realized:	<i>High</i>

What is the nature of this market?

The massive growth of Chinese manufacturing has been one of the key drivers of the twenty-first century global economy. Much of this growth is the result of outsourcing by overseas companies, looking to take advantage of China's high productivity and low costs. Most of the retail value of these products accrues to the companies doing the outsourcing, while the Chinese manufacturing firms retain a relatively small share. This mutually beneficial arrangement is only possible because most Chinese firms respect the intellectual property rights of the outsourcing companies.

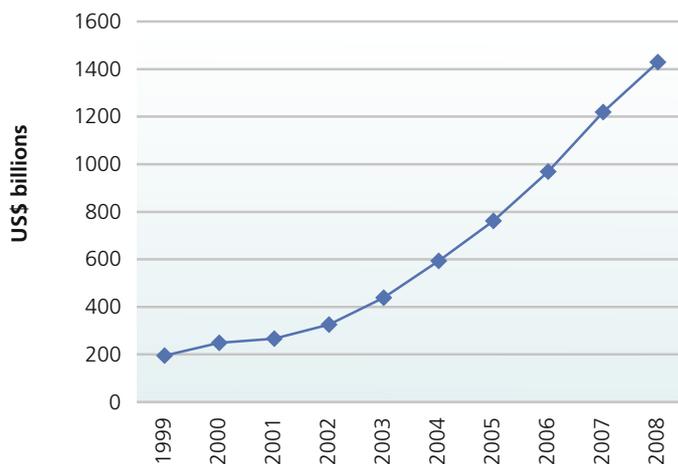
Unfortunately, this situation – in which the designers and manufacturers of a product often live on different continents – has fostered the growth of

counterfeiting. Counterfeiting is an attractive alternative to licit commerce because costs are reduced to manufacturing, transport and distribution. The costs involved in research, design and marketing are all avoided. Because counterfeiters are essentially unaccountable and have no interest in building a brand reputation, costs can be additionally reduced by cutting corners in the production phase, such as employing sweatshop labour, engaging in environmentally unsound manufacturing processes and using inferior-grade materials. Profits can be further maximised by avoiding taxes: import duties are evaded through customs fraud or outright smuggling, and sales taxes are avoided through informal retailing, which itself often makes use of illegal migrants working for little compensation. The end result is a product that can look very much like the original, but which can be sold for much less while generating a larger profit.

Both the scale and the nature of Chinese manufacturing – which often involves a large number of small firms collaborating to produce a single product – leave the country vulnerable to this abuse. The situation is similar to that found around Naples, where a large number of cottage industries have traditionally produced the world's *haute couture* alongside the world's best counterfeits. In addition, many of China's largest exports are products where branding is either a key signal of product quality (as is the case with electronic devices), provides value as a status symbol (as is the case with many apparel items) or is an end in itself (as is the case with certain toys).

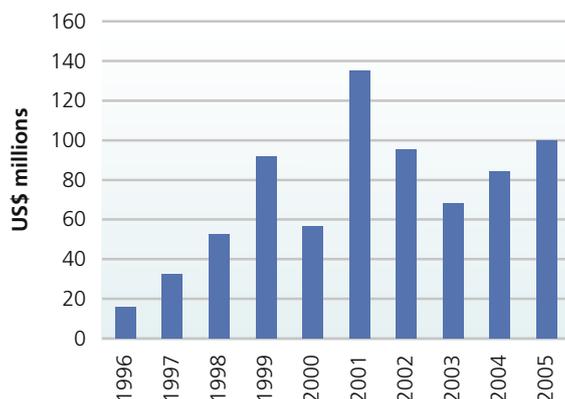
Mass-scale counterfeiting for export in China seems to be mainly a product of the last decade – in 2000, China ranked fourth among national sources of counterfeits to the EU, responsible for only 8% of the cases.⁶ The problem of counterfeiting is, of course, not limited to China, and the Chinese Government has taken extensive measures to address it. In 2009, the General Administration of Quality Supervision, Inspection and Quarantine dealt with some 200,000 cases of counterfeit or substandard products, dispatching nearly two million quality inspectors and seizing an estimated US\$490 million worth of goods.⁷ The State Administration for Industry and Commerce announced seizing US\$221 million in counterfeits in 2008.⁸ In addition, Chinese Customs annually seize tens of millions of dollars worth of counterfeits bound for export. Those convicted stand to face stiff sentences: the ringleader of a software piracy operation was sentenced to seven years imprisonment in 2009.⁹ The problem is also regarded as serious by the Chinese

FIG. 142: VALUE OF EXPORTS FROM CHINA, 1999-2008



Source: Chinese Customs

FIG. 143: VALUE OF SEIZURES MADE BY CHINESE CUSTOMS FOR INTELLECTUAL PROPERTY VIOLATIONS, 1996-2005



Source: Chinese Customs⁵

public. A recent poll indicated that Chinese citizens regard counterfeiting and substandard goods as the greatest taint on the national image, second only to corruption.¹⁰

According to independent statistics from the World Customs Organization, the United States Government and the European Commission, most of the world's counterfeit products can be traced back to China. In 2008, the World Customs Organization, reporting on data collected from 121 countries, found that 65% of the total of counterfeit shipments detected departed from mainland China, accounting for some 241 million pieces seized globally. Hong Kong, China was the departure point for another 8 million, bringing the figure above two thirds of the global total.¹¹

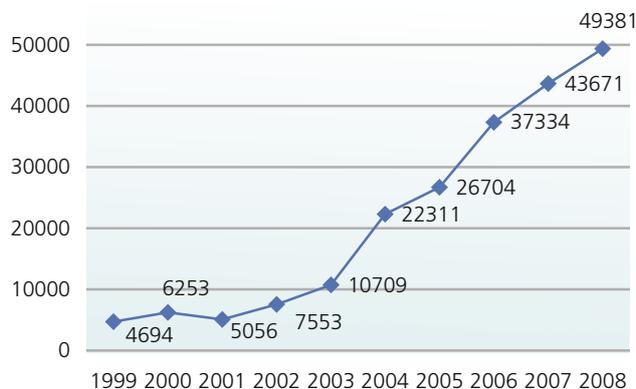
In the financial year 2009, mainland China was the source of US\$205 million worth of goods seized in the United States, which was 79% of the value of all counterfeit products seized that year. Hong Kong, China was the source of another US\$26 million, or 10%, and Taiwan Province of China contributed another 1%. Collectively, then, some 90% of the value of the counterfeits seized in the US in 2009 came from China.¹²

The European Customs Union does not provide a similar valuation figure, but there is good reason to believe the problem is even more acute in Europe. The number of seizures in the US (some 15,000 in 2008) was less than one third of the number of cases registered at the European border (just under 50,000 in 2008), and the flow of counterfeits into the EU appears to be growing at a much faster rate.

Either due to increasing incidence or increasing detection rates, the number of counterfeit seizures at the European border has increased tenfold in the last 10 years. In 2008, almost 200 million counterfeit items were detected. Most of the cases (57%) involved articles of clothing or accessories, followed by jewellery and watches (10%) and electrical equipment (7%). While encountered in a smaller number of cases, the most numerous items were CDs, DVDs and cassettes. France detected the greatest number of cases, while the Netherlands confiscated the greatest number of articles.¹³

Mainland China was the origin of 55% of the counterfeits seized at the European borders, with Taiwan, Province of China accounting for another 10% and Hong Kong, China for another 1%. In other words, two thirds of the counterfeit products seized at the European border in 2008 were produced in China as a whole.¹⁴ China was by far the leading source of

FIG. 144: ATTEMPTS TO IMPORT COUNTERFEIT GOODS DETECTED AT EUROPEAN CUSTOMS UNION BORDERS, 1999-2008

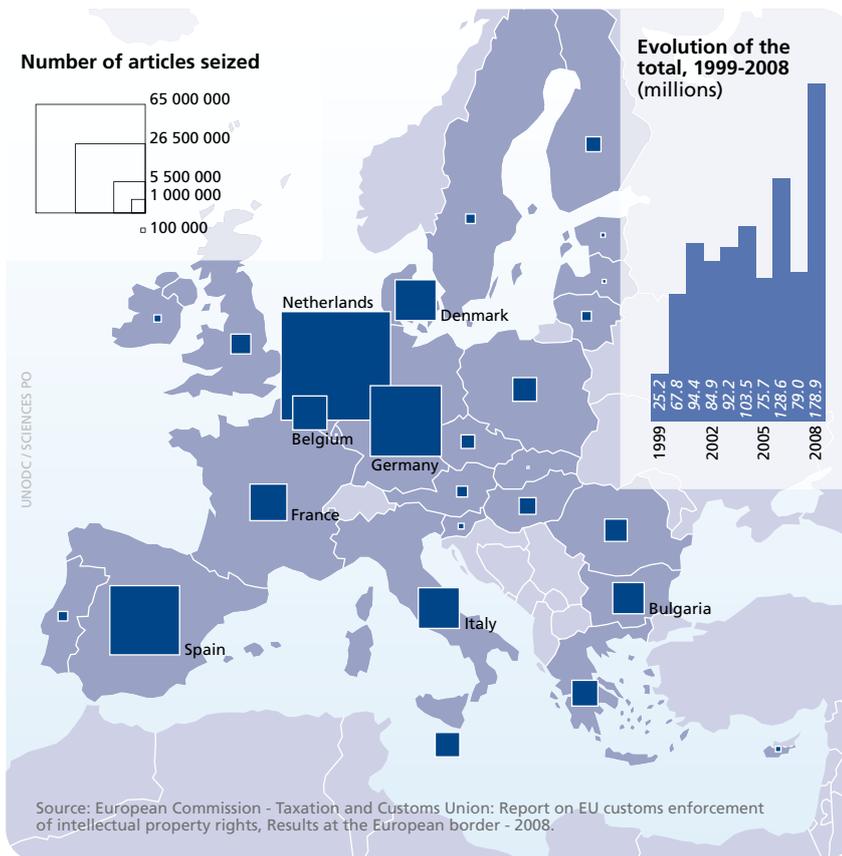


Source: European Commission¹⁵

clothing items, CD/DVDs, electrical equipment and toys. But China is also a leading licit supplier of many of these same commodities.

Indeed, looking at any particular sector, the number of counterfeits seized is generally dwarfed by licit imports. For example, in 2008, just under 6 million pairs of counterfeit shoes made in China were seized entering the EU, which sounds like a lot.¹⁶ But that

FIG. 145: COUNTERFEIT GOODS SEIZED IN THE EUROPEAN UNION (NUMBER OF ARTICLES), 2008



Though sold everywhere, the main volume outlets for counterfeit CDs and DVDs in South-East Asia are Mong La and Tachilek in Myanmar and Phnom Penh in Cambodia. Law enforcement in Thailand has made it less of a direct destination for such goods; Chiang Mai residents (Thai as well as foreign) usually travel to Mae Sai/Tachilek to buy fake CDs and DVDs. Such goods are also available in Mae Sot (Thailand) opposite Myawady (Myanmar) and other border crossing points.

It appears that most of the counterfeits trafficked to the EU are shipped by sea. Containerized transport, often with a confusing series of way stations, is common for long distance traffic. Goods may also be ferried by speedboat to Hong Kong, China before being trafficked on from there. In addition, they may transit Xiamen, Quemoy or Matsu on their way to Taiwan, Province of China. Those destined for South-East Asia often make use of the land border crossing from Guangxi and Yunnan. Web-based sales and courier delivery have become increasingly popular.

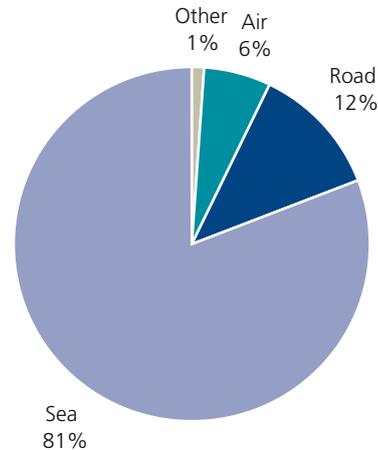
As for many other forms of seemingly licit contraband, counterfeit goods from East Asia often transit free trade zones on their way to Europe, particularly Jebel Ali (Dubai) and other free trade areas in the United Arab Emirates. This allows the origin of the goods to be disguised, and it also allows unbranded products to be decorated with the appropriate logos close to the destination market. The United Arab Emirates is the second biggest source of counterfeit goods seized at the borders of the EU, the provenance of more than 15% of all cases recorded in 2008. Many of these goods may have been based on “raw” (unbranded) merchandise from East Asia.

While sea and road transport are responsible for the greatest volumes of good imported, there are a larger number of smaller consignments sent by air and by post. Both postal and road traffic appear to be growing in popularity.

In Europe, counterfeits enter at all the major sea-ports. Not surprisingly, the Netherlands, with the biggest port in Europe (Rotterdam), detects the largest volume of counterfeits entering the EU, followed by Germany, with the second (Hamburg) and fourth (Bremen) largest ports. In Spain, Valencia is a primary entry point for textile goods, and, with Algeciras and Barcelona, is the gateway for the vast majority of all counterfeit products entering the country. While France detected a fraction of the volume of these major ports, it did detect the largest number of cases, suggesting the country is a favourite of those preferring to ship small amounts by air.

FIG. 148:

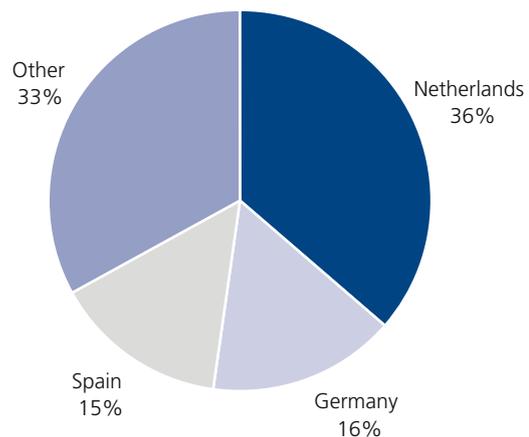
COUNTERFEIT ITEMS SEIZED ENTERING THE EU, BY MEANS OF CONVEYANCE, 2008



Source: European Commission

FIG. 149:

SHARE OF ALL COUNTERFEITS DETECTED AT EUROPEAN BORDERS, BY COUNTRY, 2008



Source: European Commission

Once through customs control, the merchandise is generally transported to a warehouse district for storing, repackaging and distribution. One example is the Cobo Calleja district near Madrid, which is host to a 2 million square meter zone known locally as “mercachina.” This zone houses more than 300 Chinese commercial distribution companies. The area was the subject of a recent police crackdown, which netted more than 1.5 million items.²⁰

Merchandise that has still not been branded may be further processed in the destination countries or elsewhere in the EU. Major counterfeit operators may set up legitimate businesses, such as clothing manufacturing or sales businesses, as fronts for counterfeit operations and sales. Some may be involved in licit import and export operations as well.

The Internet may be used to market the products, particularly for products like “lifestyle” drugs, watches and perfumes. But the most common conduit for counterfeit goods are illegal immigrants, working in informal markets. These hucksters often bear the brunt of enforcement efforts, but are symptoms, rather than causes, of the problem.

Who are the traffickers?

Counterfeiting operations in East Asia vary greatly in their size and sophistication. Operations that gain their supply from over-runs or use of factory seconds make use of the same infrastructure as the licensed producers. In general, counterfeit production is as decentralized as other aspects of manufacturing. For example, in 2007 two brothers were charged with producing 160,000 fake branded razor blades from their home, using family members for labour and selling the counterfeits to a connection in Shanghai.²¹

Many of the larger operations producing counterfeits in China today were founded, or at least funded, by people from Hong Kong, China and Taiwan, Province of China, who had already been active in the trade. The lower-end production in Anhui and Henan, aimed at the local and border markets, has traditionally been financed by businesspeople from Guangdong and Zhejiang. New operations likely spring up whenever demand for a new product necessitates new supply chains. Many of those participating in creating components of the final counterfeit product may have no notion that they are involved in anything illegal. They are simply responding to new orders for products or services in an extremely complicated open market.

Since mainstream transportation channels are utilized, those who move the cargo internationally may also be unaware of the illicit nature of the consignment. If the products are only falsely branded at a re-routing hub or at destination, they may actually be entirely legal during transit. Those knowingly committing a crime may be confined to the destination countries. Expatriate Chinese who are resident in Europe appear to play an important role in receiving and processing the goods in many instances, as do vendors from South Asia.

Some of these goods are directed into licit commercial outlets. In some cases, the retailers may not be aware of the nature of what they are selling, but most of the time, it appears that there is at least willing blindness to the origin of this drastically discounted merchandise. A survey from the British Home Office found that 44% of the businesses in three high-crime areas had been offered counterfeit goods in the year prior to the survey.²²

Whatever the role of licit retailers, the bulk of the trade appears to be conducted through informal markets and street sales. From places like Warsaw’s once notorious Stadium Market to dozens of municipal flea markets across the United Kingdom, thousands of small entrepreneurs flog counterfeit merchandise. Street sales people are most often illegal immigrants, often from Africa or Asia. There have been many documented cases of illegal immigrants being forced into counterfeit distribution by the migrant smugglers. The pattern is similar to what is seen in human trafficking for the purposes of sexual exploitation from West Africa to Europe. The debt incurred by the migrant is so great that they cannot resist demands from their sponsor to engage in illicit work, and the activity becomes tantamount to human trafficking.

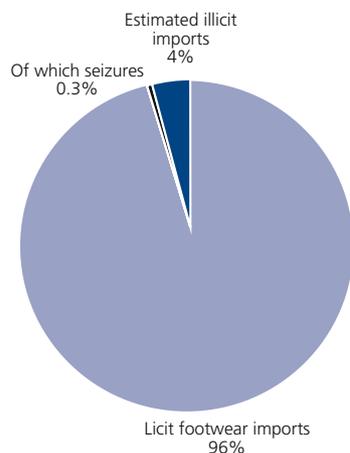
There is also involvement by traditional organized crime groups such as the Neapolitan Camorra, which has long sold designer knock-offs manufactured by the same craftspeople who produce the originals. Today, the Camorra increasingly sells products manufactured in Asia, using the same marketing channels.

How big is the flow?

The European Union does not attach a financial value to the seizures of counterfeit goods it makes. The United States does, and puts the figure at around US\$261 million from 14,841 seizures in financial year 2009.²³ The types of products seized in both the US and the EU are similar. For example, 57% of the goods seized at the European border in

FIG. 150:

EUROPEAN MARKET FOR CHINESE FOOTWEAR – SHARE OF LICIT, ESTIMATED ILLICIT AND SEIZURES, 2008



Source: Elaborated from data from the European Commission

2008 fell under the heading of clothing, shoes and accessories; in the US, it was 58%. If average value of each item seized in the EU was about the same as in the US, the European seizures from all sources would be worth roughly US\$867 million in 2008.

The question is: what share of the total flow does this seizure total represent? If about half the flow were intercepted, this would suggest a market worth at least half a billion dollars; this could be considered a minimum figure. If the share seized were 10%, the figure would be US\$8.7 billion. If only 1%, it could be as high as US\$87 billion; higher than this would suggest extraordinarily weak enforcement. Of this, some two thirds would come from China. Which order of magnitude is correct?

There are several possible ways of getting a sense of which interception rate is most likely, all of which rely on clarifying the extent of demand. One is to compare an illicit flow to what is known about licit demand for the same goods. This is the approach implied by the International Chamber of Commerce in estimating the size of the world counterfeit market at between 4% and 7% of global trade.

China exports a huge variety of manufactured goods, so it makes sense to focus on just one sector. Returning to the footwear example again, in 2008, just under six million pairs of counterfeit shoes made in China were seized entering the EU.²⁴ If every item exported was seized (a 100% interception rate), then six million counterfeit shoes were exported. The same year, 1.8 billion pairs were legally imported.²⁵ If the number of counterfeit Chinese shoes imported were as large as the number of legal ones imported, the interception rate would be only three tenths of one per cent.

Both a 100% interception rate and a 0.3% interception rate seem unlikely; the true value is likely somewhere in between. If, as the ICC suggests, the counterfeit market were around 5% the size of licit market, then the interception rate of counterfeit footwear from China would be around 7%. This seems plausible, but needs further verification.

Another way of getting at the extent of demand is to look to consumer surveys. One poll of consumers in Spain in 2006 estimated that Spaniards spent 285 million euros on counterfeit goods in the previous year.²⁶ This boils down to about six euros per citizen per year. A similar study in the United Kingdom in 2007 found expenditures of 261 million pounds on watches, 351 pounds on fragrances, and some 3 billion pounds on clothing and footwear.²⁷ This is equal to about 59 pounds (about 66 euros) per citizen for the year.

If all 500 million EU citizens spent between six and 60 euros each year on counterfeits, and the source of these counterfeits was the same as the counterfeits seized at the borders, then EU citizens would spend between about 2 billion and 20 billion Euros per year on counterfeit goods imported from China. This suggests an interception rate of between 3% and 30%. The true interception rate is unlikely to be as high as 30%, given that counterfeit clothing and footwear consumption in the UK alone is estimated to be worth more than 2 billion euros. Using the 7% interception rate posited for footwear above, an estimate of US\$8.2 billion in 2008 can be derived. If the volume varies at the same rate as the value, this would involve some 2.5 billion counterfeit items. These figures suggest the likely order of magnitude, but are only as reliable as the assumptions on which they rest.



8.2. Counterfeit medicines from South- and East Asia to South-East Asia and Africa

Route

Source:	<i>China and India</i>
Vector:	<i>Sea and air</i>
Destination:	<i>South-East Asia and Africa</i>

Value

Annual market volume:	<i>Billions of dose units</i>
Annual value at destination:	<i>US\$1.6 billion</i>

Traffickers

Groups involved:	<i>Chinese and Indian distributors and their African contacts</i>
Residence of traffickers:	<i>China, India, South-East Asia, Africa</i>

Threat

Estimated trend:	<i>Unclear</i>
Potential effects:	<i>Death, drug-resistant pathogens</i>
Likelihood of effects being realized:	<i>High</i>

What is the nature of this market?

There has been much debate around what comprises a “counterfeit” medication, and the issue has become highly politicized. On the one hand, large international pharmaceutical companies invest more of their income in research and development than in just about any other industry, and need to protect this investment in order to continue to do so. On the other, smaller manufacturers in developing countries seek to meet the needs of the poorer countries, but some may have difficulties in meeting international quality standards. In some cases, cheaper, but lesser quality, medication is better than nothing; in other cases, it clearly is not.

Counterfeit versus substandard

The terms “counterfeit drugs” and “substandard drugs” are often conflated or confused. For public health purposes, the World Health Organization defines a counterfeit drug as one that is “deliberately and fraudulently mislabelled with respect to identity and/or source,” and substandard drugs as “genuine drug products which do not meet quality specifications set for them.” Since counterfeiters seek to maximize profits, most counterfeits would be considered substandard if they were genuine products. Not all substandard drugs represent intentional frauds, however, because manufacturers may believe that their products contain the active ingredients specified on the labels.

Normally, for inaccurate labelling to amount to the crime of consumer fraud, some degree of intent must be demonstrated, but constructive fraud can be imputed where the perpetrator has a duty of care to the victim. Given that the manufacturing of pharmaceuticals is an activity with life-and-death consequences, a very high standard of care should be expected from drug producers. Particularly with regard to the amount of active ingredient, a matter where profit incentives favour mislabelling, anything other than the strictest adherence to standard could be regarded as reckless and any deaths that result could be deemed manslaughter.

Products that are packaged in a way to misrepresent the manufacturer are clearly counterfeit, whatever their chemical content, but so are authentic products where the expiration date has been altered. Drugs that do not contain the amount of active ingredient specified on the label fall into a grey area. Those that are completely inert are unlikely to be the product of genuine mistakes. Similarly, those that contain pharmaceutically inappropriate chemicals or binders, especially those intended to mimic the effects of the specified drug, show the required level of intentionality to be considered counterfeits. Drugs containing certain contaminants, moulds or excessively high levels of active ingredient are unlikely to be deliberate frauds, but may rise to the level of recklessness to be considered a criminal act, especially when repeatedly traced back to the same source.

Products labeled as “counterfeit” run the range from overt forgeries to pharmaceutically-sound close imitations; from substandard generic medications to repackaged expired drugs. The contents may be inert or dilute or inappropriate or poisonous. For the purposes of this discussion, “counterfeit” means any product that does not contain what the packaging indicates. This applies equally to branding as to

chemical content, freshness and potency. Defined in this way, pharmaceutical counterfeiting is a form of health fraud that often amounts to mass manslaughter.

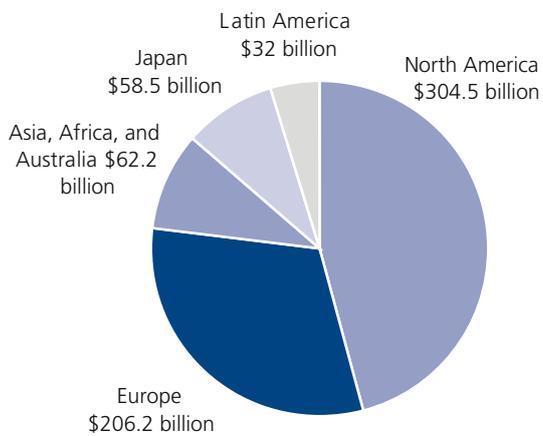
A frequently cited estimate, attributed to the World Health Organization, is that 10% of the global medicine supply is counterfeit, rising to 30% in the developing world. Though the basis of this estimate is unclear, the figure is alarming, especially given the narrow definition of “counterfeit” used by the WHO. The bulk of world pharmaceutical sales occur in North America and Europe. These areas are not immune to counterfeit medicines: in 2008, the European Customs Union detected over 3,200 attempts to import bogus drugs, involving almost 9 million items, over half of which originated in India. Much of this trade involves so-called “lifestyle drugs” (particularly Pfizer’s “Viagra”), however, often ordered from on-line pharmacies, although there have been a number of well publicized detections of counterfeit essential medicines destined for the legitimate supply chain in North America and Europe.²⁸

The rest of the world consumes far fewer pharmaceuticals. If Japan is excluded, then Asia, Africa, and Australia combined represent less than 10% of the global market. Despite the relatively low value of drug sales in developing countries, pharmaceutical counterfeits are particularly prevalent in South-East Asia and Africa. According to the World Health Organization, counterfeits comprise less than 1% of the market value in most developed countries, although this figure may be increasing. In some developing countries in Africa, Asia and Latin America, the share is much higher, between 10% and 30%.²⁹ As much as 50% to 60% of anti-infective medications tested in parts of Asia and Africa have been found to have active ingredients outside of acceptable limits.³⁰

In other words, this is an opportunistic crime, emerging where regulatory capacity is low, not where profits would be highest. It is also an extremely callous one, depriving the poorest of lifesaving medicine, leading to countless deaths, for a relatively meager return. Beyond the direct impact on the victims, substandard medicines can fuel microbial resistance. Each under-medicated patient becomes an evolutionary vector through which “superbugs” can develop, posing a global threat to public health.

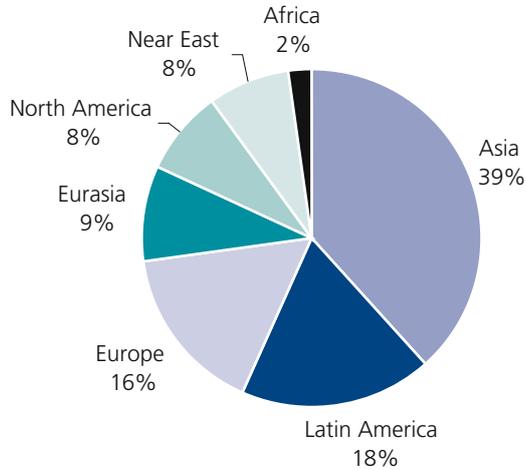
According to the incident database of the Pharmaceutical Security Institute, countries in Asia report the largest share of counterfeits detected globally,

FIG. 151: GEOGRAPHIC DISTRIBUTION OF GLOBAL PHARMACEUTICAL SALES, 2007



Source: IMS Health 2008³¹

FIG. 152: DISTRIBUTION OF COUNTERFEIT INCIDENTS DETECTED BY THE PHARMACEUTICAL SECURITY INSTITUTE, 2008



Source: Pharmaceutical Security Institute³⁴

with Africa responsible for only 2%. But this is undoubtedly a product of enforcement capacity, because field tests of pharmaceuticals in both regions have produced similarly high shares of counterfeits.

For example, one of the most commonly counterfeited drugs is artesunate, an antimalarial artemisinin derivative developed in China and widely used in South-East Asia and Africa. There are at least 16 manufacturers of artemisinin in Asia and millions of tablets are produced each year for local consumption and export.³² According to street vendors in West Africa, anti-malarials are among their most popular products.

In 2003, researchers conducted a randomized study of artesunate tablets sold in the Lao People's Democratic Republic. Of the 25 outlets selected where artesunate was sold, 22 sold counterfeit artesunate, as defined by packaging and chemistry. Four of the fakes contained detectable amounts of artemisinin, which may encourage malaria resistance to artemisinin derivatives.³³

In 2008, many of these same researchers collected a total of 391 samples of genuine and counterfeit artesunate in Viet Nam, Cambodia, Lao People's Democratic Republic, Myanmar and along the Thai/Myanmar border. Sixteen different fake holograms, a safety feature introduced into the packaging to reduce counterfeiting, were identified. Half of the samples were believed to be counterfeit based on the packaging, and this was confirmed chemically. The tablets contained no or small quantities of artesunate, as well as other active adulterants. Analysis was able to trace some of the samples to

southern China, close to the border with Viet Nam, the Lao People's Democratic Republic and Myanmar.³⁵

Based in part on this evidence, INTERPOL coordinated Operation Jupiter III, one in a series of anti-counterfeiting operations. Chinese authorities arrested a suspect in Yunnan Province in 2006, alleged to have traded 240,000 blister-packs of counterfeit artesunate. Police seized only a tenth of this amount, the rest of which had already been sold on the Myanmar border.³⁶

FIG. 153: COUNTERFEIT MEDICINES FLOWS

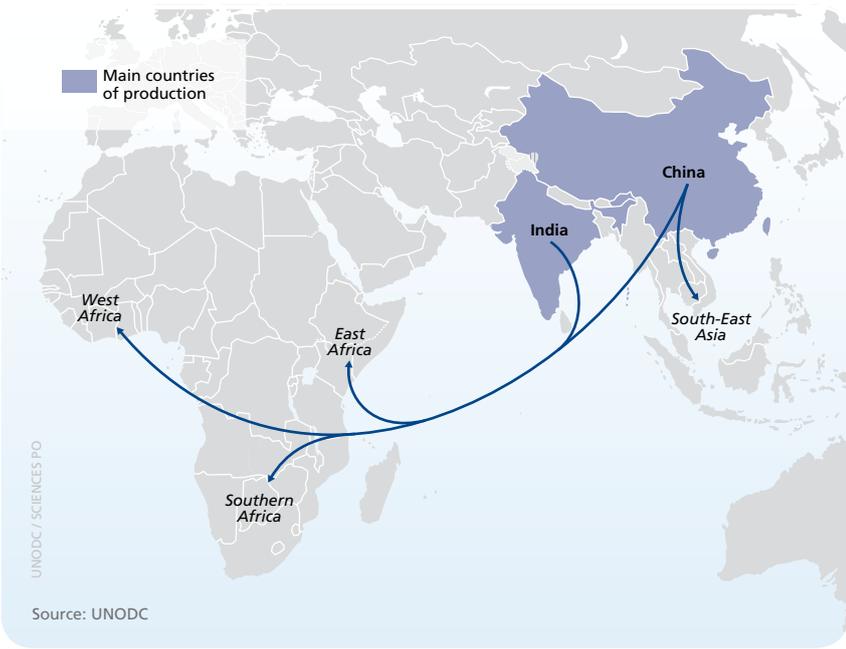
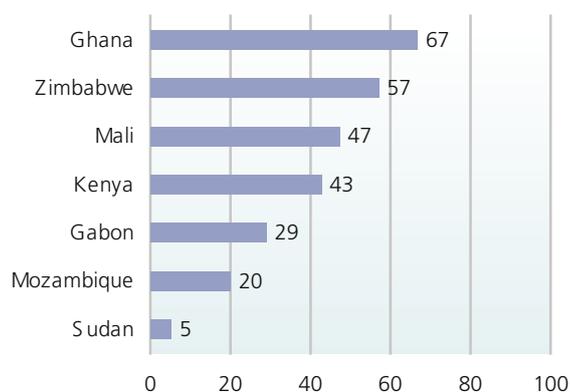


FIG. 154:

PERCENTAGE OF CHLOROQUINE TABLETS FAILING POTENCY TESTS IN SELECTED COUNTRIES, 2003


Source: World Health Organization³⁷

In 2008, INTERPOL coordinated “Operation Storm”, in which nearly 200 raids were carried out, in Cambodia, China, the Lao People’s Democratic Republic, Myanmar, Singapore, Thailand and Viet Nam, resulting in 27 arrests and the seizure of more than 16 million pills with an estimated value of US\$6.6 million.³⁸ In late 2009, Operation Storm II resulted in the seizure of 20 million counterfeit and illegal medicines, at least 33 arrests, and the closure of some 100 pharmacies and illicit drug outlets in Cambodia, China, Indonesia, the Lao People’s Democratic Republic, Myanmar, Singapore, Thailand and Viet Nam.³⁹

Systematic pharmaceutical quality testing is rare in Africa, but there is rich anecdotal evidence indicating a problem every bit as severe. One of the only studies involving random sampling in West Africa tested medicines from 581 Nigerian pharmacies and found that 48% of anti-infectives contained active ingredients outside acceptable limits.⁴⁰ One small scale study of artesunate sold in Ghana found that of 17 brands sold, only six passed the International Pharmacopoeia content uniformity test and only three met the European Pharmacopoeia content requirements.⁴¹ A 2003 study of counterfeit chloroquine, the traditional anti-malarial, in seven African countries showed not only the high percentage of the sample that failed to meet drug standards, but also how widely spread the counterfeits were, showing up everywhere, from district hospitals to local vendors and households.⁴²

There have also been many recent detections by law enforcement of counterfeit drugs in Africa. In Tanzania in 2009, INTERPOL coordinated Operation Mamba, in which 191 locations, including pharmacies, warehouses and illicit markets, were inspected.

Medicines of all types, including anti-malarials, were confiscated, and 22 drug retailers were shut down. A similar effort was made in Uganda.⁴³ In Egypt, INTERPOL also led six combined operations in April and May 2009 in which 10 containers were seized, each holding hundreds of thousands of counterfeit medicines bound for the Middle East,⁴⁴ likely for trans-shipment.

While some of these drugs are produced locally, the bulk are said to be produced in Asia, in particular in India and China. According to the Commonwealth Business Council Working Group on Healthcare, “The vast majority of counterfeit medicines are currently thought to be produced in China, India and the Russian Federation, although significant numbers of illegal factories have also been reported in Nigeria, and the Philippines.”⁴⁵ According to Dora Akunyili, former Director General of the National Agency for Food and Drug Administration and Control (NAFDAC) of Nigeria, “Most of the fake drugs in Nigeria come from India and China.”⁴⁶

These allegations need further corroboration. There has been evidence from law enforcement; for example, large consignments of counterfeit drugs made in India and bound for Africa have been seized in Europe.⁴⁷ Forensic study of the origin of these drugs, similar to what has been conducted in South-East Asia, is forthcoming.⁴⁸ Until this evidence is produced, the origin of these drugs will remain in dispute.

China’s licit pharmaceutical export trade has boomed alongside the rest of the economy, growing eight times larger in less than a decade; from US\$3.4 billion in 1998 to US\$24.6 billion in 2007.⁴⁹ But this has been paralleled by a growth in imports, which have grown by nearly a factor of 10, from US\$1.5 billion in 1998 to US\$14 billion in 2007.⁵⁰ India’s export of pharmaceuticals has also expanded rapidly since the start of the twenty-first century, growing four times larger since that time.

Some counterfeit medications made in China are not exported, though the share of the domestic market that is fraudulent or substandard is not documented.⁵¹ In India, forensic testing has found that a very small share of the drugs were deemed “spurious” (falsely branded), less than 2% of the anti-infectives, for example.⁵² Most of these instances were in the under-developed provinces of Bihar, West Bengal and Uttar Pradesh, as well as in Gujarat. While small in Indian terms, the spurious drugs market in India has been estimated at some US\$250 million sales per annum.⁵³

The same study found, however, that as much as 10% of the drugs tested were substandard.⁵⁴ Under the definition used for this chapter (a “product that does not contain what the packaging indicates”), all substandard medication would be considered counterfeit. The active ingredient accounts for 90% of the cost of most drugs, so even a 10% dilution can translate into a significant competitive edge. Diluted drugs can be difficult to detect, requiring quantitative chemical analysis. Even when they are detected, it is difficult to prove the dilution was intentional, and most such offences would be regarded as a trade infraction, rather than a criminal matter. Producers who lose their licenses in such matters may reincorporate under another name.

How is the trafficking conducted?

Production

The production of counterfeit pharmaceuticals can be as simple as producing alternative packaging materials using a laser printer or as complicated as the production of the original product. In general, counterfeit production in China appears to be more sophisticated than in India. In China, counterfeit drug producers are often chemical companies that are not licensed to produce pharmaceuticals,⁵⁵ or even licensed companies that produce both legitimate and bogus drugs. In 2008, the Chinese Government shut down 363 fake medicine production facilities.⁵⁶

In India, the manufacturers can be loosely grouped into three categories: unlicensed manufacturers who operate out of small cottage factories, licensed manufacturers who secretly make fake drugs alongside their legitimate products, and importers who bring in drugs from China and then fraudulently repackage them.

The small manufacturers operate from the outskirts of major cities. In the past, their products were crude, but the dispersion of printing and packaging technology has brought credibility within the reach of even the small entrepreneur. Medications may contain the right active ingredient in dilute amounts, and are distributed through informal channels to local retailers. Agra is reportedly a major outlet for these drugs.⁵⁷

Counterfeiters may produce licensed pharmaceuticals by day and knock-offs by night. One case in point involved a pharmaceutical company in Gurgaon, Haryana. When the Food and Drug Administration confronted the owner with evidence of the counterfeit goods, he disavowed all knowledge of

the products except for one: a tablet containing a new generation antibiotic ciprofloxacin. Upon testing at the state and central drug laboratories, it was found that the pill contained no ciprofloxacin at all, and the company’s manufacturing license was revoked. But the factory continued to operate at night, until an evening raid by police uncovered an underground cellar in the factory, where exact look-alikes of several popular, fast-moving, high-cost medicines were being manufactured, most of which contained no active ingredient.⁵⁸

The latest trend may be the importation and repackaging of difficult to counterfeit drugs, such as biological formulations. The November 2009 seizure of illegally imported human immunoglobulin vials from a company in Mumbai is a case in point. As the product did contain some immunoglobulin, it appears that the vials were imported from a lesser producer in China and repackaged under a leading brand name. The counterfeits were being offered at 25% less than the market price.⁵⁹ Another case involved the seizure in Kochi, Kerala, of counterfeit name brand immunosuppressants, drugs designed to support organ transplantation, worth some US\$11 million. Further evidence that counterfeit pharmaceutical products are being imported illegally from China emerged with three seizures at the port of Chennai in May 2009 alone.⁶⁰

Trafficking

There are a number of ways counterfeit distributors in Africa can link up with producers in China or India. One case, adjudicated in China, started when a Nigerian businessman resident in China placed an order with a Chinese medicine exporter for counterfeit anti-malarial medication. The exporter contracted the job to a pharmaceutical company employee, providing samples of the drug to be copied. This employee subcontracted the printing of the boxes and package inserts to a printing company employee. False shipping documents were obtained to indicate the source of the drug was Thailand. The drugs were seized en route in Belgium, shipped alongside counterfeit antibiotics, exported by a different Chinese counterfeiting group. On arrest of this second group, some 43 tons of counterfeit drugs were seized.⁶¹

As with other ostensibly legitimate cargo, pharmaceuticals are often shipped out through regular freight companies. The contents may be falsely declared to avoid targeted inspections. Many of the counterfeit pharmaceutical consignments exported from China are containerized, some passing through

customs by means of stealth or bribery. Some of the products destined for South-East Asia are shipped to Hong Kong by speedboat, consolidated, and shipped on by container.

Smaller amounts, such as those associated with Internet sales, are dispatched by international courier services. According to the International Narcotics Control Board, “India has become one of the main sources of drugs sold through illegally operating Internet pharmacies. Orders placed with such pharmacies are often dispatched to buyers in other countries using courier or postal services. Since 2002, Indian law enforcement agencies have detected and disbanded several groups that were operating illegal Internet pharmacies.”⁶²

Law enforcement officials in South-East Asia say that the majority of the counterfeit pharmaceuticals in their countries come from Fujian, Guangdong and Yunnan provinces of China. Some of this traffic moves first through Shenzhen and Hong Kong, China before arriving in South-East Asia. Some is smuggled directly into Viet Nam at border crossings in Pinxiang and Nanning (on the Chinese side) to Huu Nghi at Dong Dang in Viet Nam’s Lang Son province. The Lao Cai border crossing point is more popular when the medicine is coming from Kunming (Yunnan province). When coming from Quangzhou, the border-crossing point at Mong Cai is used. The goods do not necessarily pass through official checkpoints at these border crossings. Rather, the main roads are used until the goods are close to the border. If necessary to avoid inspection, the goods can be moved across the border at unofficial crossing points.

Medicine coming from Kunming (but not necessarily originating there) is also smuggled into Myanmar, from Daluo (Yunnan province) to Mong La. As with other trafficked goods, the Je-Gao Chinese enclave in Myanmar connected to Ruili (Yunnan) and close to Muse (Myanmar) is a popular crossing spot. The Cangyuan Va Autonomous County is also close to Saohin-Saohpa (Panghwei) in the northern Wa Hills of Myanmar, a rebel controlled area. Another route is from China along the Namting river into the Kokang area of northeastern Myanmar near the towns of Nam Teuk and Chin-sweho. From there, the road leads west to Hsenwi (Theinwi) and Lashio in north-eastern Myanmar, and on to Mandalay and other urban centres in central Myanmar. Goods can proceed through Monywa near Mandalay to Tamu/Moreh on the Indian border. Counterfeit medicines are also smuggled to the Lao People’s Democratic Republic, and

through Laos to Cambodia. In Thailand, however, the availability of fake medicines is relatively limited.

Trafficking from India would proceed from the source provinces to exporters in Maharashtra, Gujarat, and Tamil Nadu.⁶³ The exact distribution channels in Africa are not well known. Nigeria appears to act as a clearing house for goods imported for regional distribution.

Who are the traffickers?

As discussed above, the counterfeit producers may have all the trappings of legitimate businesses and use the licit channels of commerce to distribute their products. People involved in the licit pharmaceutical industry or in other areas of public health may be involved. These people are specialists, and are unlikely to be involved in other forms of criminal commerce.

Pharmaceutical counterfeiters may also make use of the services of traditional organized crime groups, however. For example, in China, if complicit wholesalers and retail outlets decide to default on their debts, it is easier to employ local thugs to collect than to risk exposure in the courts. Competition between rival firms may, in some instances, be settled with hired muscle. But for the most part, corruption achieves what stealth or violence would accomplish in other markets. For example, complicit officials or their relatives may be awarded “stock” in these operations, receiving periodic dividends.

Wholesalers and distributors may also play an important role in introducing counterfeits into the supply chain. They may dilute shipments of legitimate pharmaceuticals by replacing part of the stock with counterfeits, retaining the balance for resale. In India, as well as in destination markets, pharmaceuticals are sold and transported like any other product. Countries where the oversight of these market players is limited are vulnerable to this sort of insider tampering. As a result, legitimate exporters may unwittingly source counterfeit medication for their African and South-East Asian clientele. In a pending case in India, one exporter of antibiotics and painkillers to Nigeria, Benin and the Congo, found that one of its long-term suppliers did not have a manufacturing facility at all and was using a forged export permit.

In China, some of the larger domestic counterfeit drugs operations boast their own truck fleets. Some export operations have agents overseas in both tran-

sit and destination countries. Many of the key agents have important political connections, and some run their operations from Hong Kong, China or overseas.

In India, states in the north and east are affected by counterfeits manufacturing, but exports mostly occur from the southerly states.

How big is the flow?

Quantifying the scale of an activity in rapidly changing societies the size of China or India is a daunting task; estimating the share of this activity that is clandestine is all the more so. Statistics are kept by different agencies at different levels of government, and may never be amalgamated at the national level. The definitions of sector may vary between agencies, and even within agencies over time. Some figures may include traditional medicines and supplements, while others may not. Medical devices, including everything from bandages to prosthetic limbs and pacemakers, may also be included at times. Further, as discussed above, there is no consensus on what defines a counterfeit pharmaceutical, and whether any particular substandard operation is considered egregious to merit the title “counterfeit” is often a matter of judgment.

In China, the official data on seizures are both difficult to access and complex. Independent statistics are kept by each of a range of entities that might act against counterfeiters at local and national levels, including the food and drug administrations; the administrations for industry and commerce; the public security bureaus; and customs officials. The State Food and Drug Administration (FDA) reports having closed over 9,000 unlicensed pharmaceutical manufacturers and “eradicated” 388 counterfeiting operations in 2007. The value of the products confiscated in these proceedings varies substantially from year to year, from 231.8 million yuan in 2006 to 169.1 million yuan in 2007 (about US\$35 million in 2006 and US\$25 million in 2007).⁶⁴ Seizures in China are thought to account for less than 5% of counterfeit medicine output, which would suggest a total market of at least US\$500 million based on the FDA seizures. But this is only part of the picture, since agencies other than FDA seize drugs. For export markets, customs seizures are particularly relevant. Chinese customs seizures of counterfeit pharmaceuticals typically comprise less than 1% of the total value of all counterfeit products seized, however – only 11 such seizures, valued at 850,000 yuan (about US\$125,000), were made in 2005.⁶⁵

Experts estimate that since the mid-1990s, transactions in counterfeit medicines, health-care products and medical equipment in China have been growing at an annual rate of 15%, with the market value currently standing at around 20 billion yuan (about US\$3 billion) per year. The export market and domestic market are believed to account for 40% and 60% of the total respectively. This would suggest an export value of US\$1.2 billion. If correct, the counterfeit export trade would be equal to about 5% of Chinese pharmaceutical exports (estimated at US\$24.6 billion). If a similar figure were applied to India’s exports of US\$7.6 billion, the combined counterfeit export value would be worth about US\$1.6 billion.

These export figures need to be placed in perspective by looking at the import markets in Africa and South-East Asia. The poorer countries in South-East Asia typically consume less than US\$10 per capita per year on pharmaceuticals.⁶⁶ With a population of some 600 million, this would indicate a total market of less than US\$6 billion. Per capita expenditure in Africa is even less, perhaps US\$8 per capita,⁶⁷ representing a total annual expenditure of about eight billion dollars. If half the markets in each of these regions involved counterfeits, this would represent a combined annual market of around seven billion dollars. Given that both the share counterfeit and the per capita expenditures are rather soft figures, the US\$1.6 billion market value cited above seems reasonable, representing about one tenth of all pharmaceutical sales and billions of dose units.

IMPLICATIONS FOR RESPONSE

Counterfeiting can and must be combated at the source, but in a globalized world, this source is increasingly difficult to locate. The technology is widely available; for example, medicinal counterfeiting often involves nothing more than laser-printing new boxes and repackaging. China and India appear prominently because they are large countries promoting exports, and while shutting down production in either of these countries would have global impact, it would also create opportunities for criminals located elsewhere.

Those who might be interested in buying a cheaper version of a popular product are similarly widespread. Little can be done to deter consumers committed to buying fake goods; there is not much support for criminalizing possession, and it would be difficult to prove buyers were not duped. Public awareness campaigns may help reduce demand, but only if members of the public can tell the genuine product from a counterfeit. To prevent fraud, the line between real products and knock-offs must be clearly articulated. Part of the solution is technological, making use of packaging and other markers that are increasingly difficult to imitate. Part is educational, assuring that consumers are aware of these markers and the possible consequences of ignoring them.

There is one market where price is likely to continue to be more important than quality assurance, and that is the market for pharmaceuticals in Africa. For the poorest consumers, the choice may be between questionable medicine and no medicine at all. The ultimate solution to this dilemma is ensure that they are never forced to make this choice, and that life-saving medication is available to all. Until this is possible, vigorous law enforcement is essential to protect the most vulnerable of consumers. African agencies need outside support to protect their populations, while agencies in source countries must continue to crack down on this shameful enterprise. The producers of legal medicines may be reluctant to disclose instances of counterfeiting for fear of hurting their market, but they should be legally compelled to do so. Manufacturers of medicine should be required to adhere to the same standards for exported products as for those made for local consumption.

So long as the bulk of this trade occurs in the open, counterfeit distribution can be targeted geographically. Flea markets, street hawking sites and fringe

retailers are ripe for public education efforts, where the hazards of buying merchandise of questionable origin can be publicized. These sites can also be subjected to preventative policing and police stings. Efforts should be made to break the link between counterfeit sales and migrant smuggling. The main barrier faced in enforcement is getting the authorities to take the matter seriously. So long as the risks are low and profits high, counterfeiting will remain a rational choice for many.

It is imperative that measures be taken to protect the licit supply chain. If reputable wholesalers and retailers assure that their sources are clean, then the buying of counterfeits will remain a marginal activity. These retailers should be motivated to protect their reputations, but those found negligent in screening the products they sell should be held liable. Those outlets that specialize in discounted goods must be scrutinized. On an industrial level, purchasing agents must be carefully monitored. Policy should not encourage buyers to place price over reputability. The public cannot be prevented from buying cheap goods, but consumers should at least be assured that they get what they paid for.