

FRAUDULENT ESSENTIAL MEDICINES FROM SOUTH ASIA AND EAST ASIA TO WEST AFRICA

What is the nature of the market?

Many of the flows described in this study can affect grand-scale geopolitical events. Cocaine trafficking has fed instability in Guinea-Bissau; firearms trafficking has fueled a rebellion in northern Mali; maritime piracy threatens to undermine commerce in the Gulf of Guinea. These flows demonstrate that transnational organized crime has truly risen to the level of a security threat in West Africa.

The importation of fraudulent essential medications does not have this kind of dramatic impact. The profits appear to be too diffuse to make corrupt officials into millionaires, and are too small to be of much interest to non-state armed groups. Rather, the effect is subtler, almost impossible to measure. The sick get sicker and resistant strains of disease evolve that won't make headlines until it is too late.

In terms of quality of life for the people of West Africa, however, it would be difficult to imagine an issue of greater importance. There have been very few reliable studies of the quality of medicines in West Africa, but those that have been done suggest a very large share of pharmaceuticals circulating in the region are ineffective or worse. In the richer parts of the world, it is taken for granted that medicines contain what they say they contain. In West Africa, consumers cannot make this assumption. Even doctors and pharmacists cannot know for sure that the drugs they are administering will do what they intend them to do.

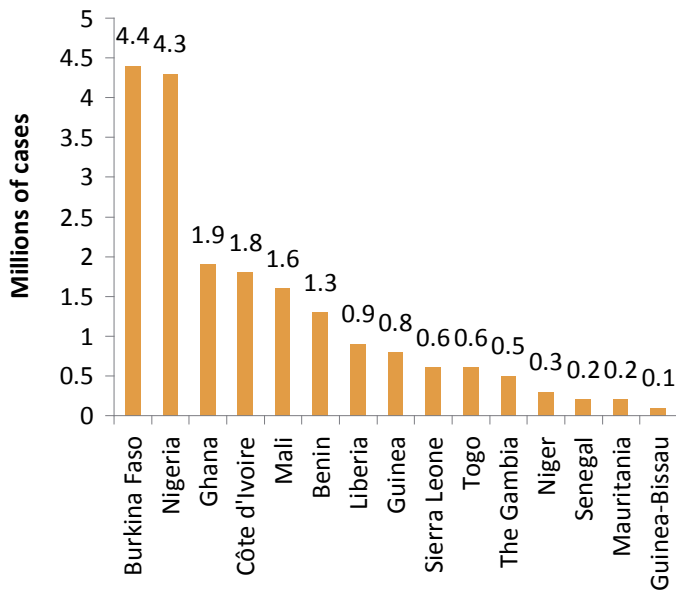
Defining fraudulent essential medicines

In the absence of a universally accepted definition, various terms are used, sometimes interchangeably, to designate the same problem or some of its partly overlapping elements. The difficulty to reach a consensus on the matter was again recently illustrated by the decision of governments, gathered at the May 2012 World Health Assembly, to “use the term substandard/spurious/falsely-labeled/falsified/counterfeit medical products until a definition has been endorsed by the governing bodies of WHO.”⁹¹

This report uses the term “fraudulent medicines,” but different terms appear as well in relation to original data drawn from other sources. The crime of fraud is committed when a product is sold deceptively. For example, a vendor selling bags of sand labeled as ‘sugar’ would be guilty of fraud. This is as true with medication as it is with other products, except the consequences are far more grave – rather than simply losing their money, the defrauded parties could lose their lives. Pharmaceuticals are considered fraudulent if they differ substantially from what is indicated on the packaging. Vendors would be guilty of fraud if they were aware of this difference at the time of sale.

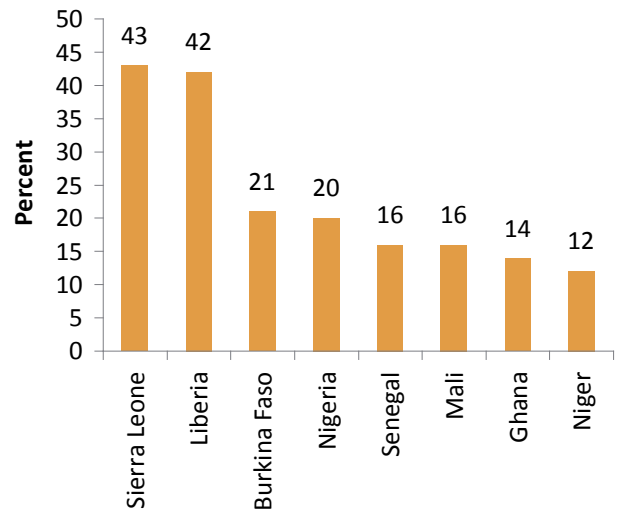
One of the best-studied examples is anti-malarial medication. West Africa suffered from some 21 million cases of malaria in 2010.⁹² All of these people could have benefited from appropriate medication, but it appears that even those who managed to access the recommended pharmaceuticals might have seen no benefit.

Figure 29: Millions of cases of malaria in 2009 in West Africa



Source: World Health Organization⁹³

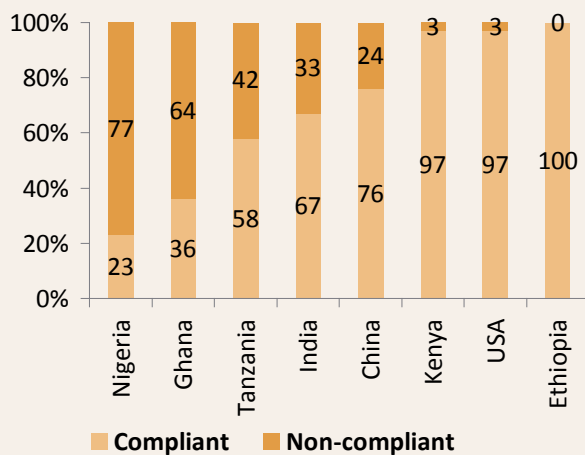
Figure 31: Share answering "yes" to the question "Have you yourself or a member of your household been a victim of fake medicine?" in 2010



Source: Gallup⁹⁸

In 2011, a World Health Organization cross-national study of anti-malarial medication quality in Africa and elsewhere found the highest rates of failure in the West African region.⁹⁴ Individual studies conducted in the region since 2000 found varying shares of anti-malarial medication failed chemical assay analysis, ranging from 27% (in Nigeria in 2009) to 82% (in Ghana in 2009).⁹⁵ Thus, even in the study where performance was best, almost a quarter of the anti-malarial medication in circulation was found to be ineffective.

Figure 30: Share of anti-malarial medication found to be compliant with quality standards in selected countries



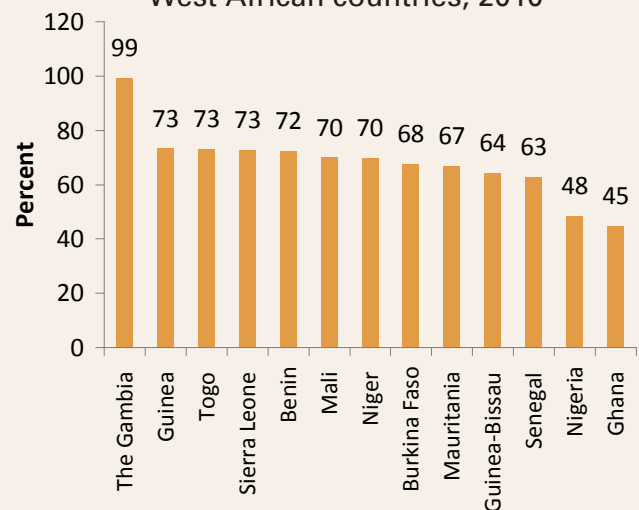
Source: World Health Organization⁹⁶

West Africans are acutely aware of the problem. In one recent poll,⁹⁷ an average of 74% of respondents in eight West African countries said they knew of fake medicine in their countries, and significant shares reported having been victimized themselves.

How is the trafficking conducted?

Not all of the pharmaceuticals consumed in West Africa are imported. Most West African countries manufacture at least some pharmaceutical products. The share of imports in total pharmaceutical expenditure varies by country, but mostly ranges between two-thirds and three-quarters. At least one study found that locally manufactured drugs were even more likely to be fraudulent than imported ones.⁹⁹

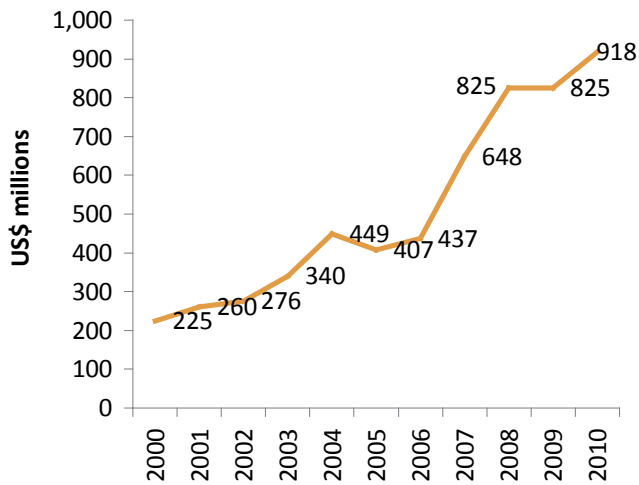
Figure 32: Pharmaceutical imports as a share of total pharmaceutical sales in 13 West African countries, 2010



Source: International Federation of Pharmaceutical Manufacturers and Associations¹⁰⁰

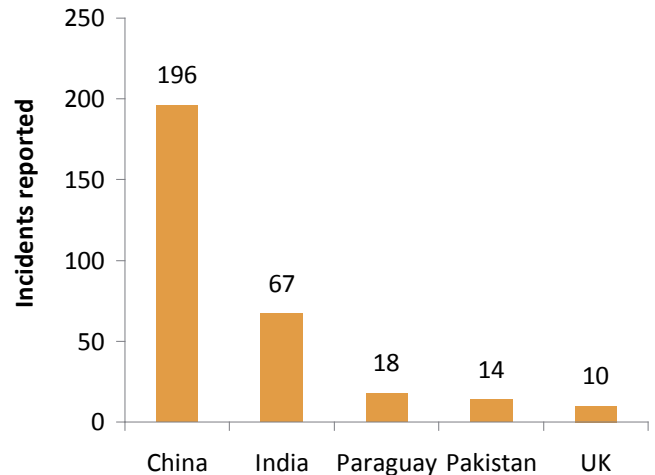
The amount of pharmaceuticals imported into West Africa has grown remarkably in recent years, with the value of imports more than tripling between 2004 and 2010. It appears most of these drugs are generics imported from China and India, which host two of the fastest growing

Figure 33: Pharmaceutical imports for eight West African countries,¹⁰¹ in millions of US\$, 2000-2010



Source: World Trade Organization database

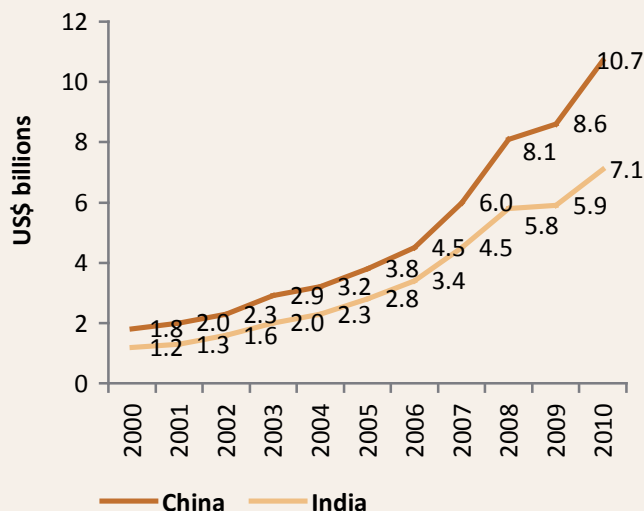
Figure 35: Top five origins of counterfeit medicines detected worldwide, by number of incidents reported to the Pharmaceutical Security Institute, 2010



Source: Pharmaceutical Security Institute 2010 Situation Report

pharmaceutical industries in the world.¹⁰² China and India are also the two most frequently identified sources of fraudulent medicines globally, as reflected, for instance, in the incidents reported to the Pharmaceutical Security Institute.¹⁰³ A recent forensic study of fraudulent medicines detected in Africa confirmed an Asian origin for these drugs.¹⁰⁴

Figure 34: Pharmaceutical exports from India and China, in billions of US\$, 2000-2010



Source: World Trade Organization database

The nature of the firms producing the fraudulent medicines ranges from crude warehouse operations to legitimate drug producers fallen on hard times. Any entrepreneur with a laser printer can produce fraudulent packaging and affix it to medications that are expired or are of lower value than the forged product. On the other end of the scale, formal

drug manufacturers may feel compelled by economic conditions to reduce the amounts of active ingredient or to substitute cheaper substances that have little or no therapeutic value. Factories that produce legitimate medicines by day may bolster their profits by producing bogus drugs at night. Companies that may be licensed to produce chemicals or precursors for the domestic market may sell their products as pharmaceuticals for export. If necessary, these may be repackaged for retail sales in transit or at destination.

These drugs proceed to their destination through the mainstream channels of international commerce. Containerized shipment is used for larger volumes, while air or postal shipment suffices for smaller amounts. Fraudulent medicines have even been exported using commercial air couriers – a number of these have been apprehended in China en route to African countries.¹⁰⁵ But for most products, large volumes are required for a reasonable profit to be realized, so containers are typically the preferred method of shipment.

Containerized shipments of fraudulent medicines have been detected transiting northern Europe, but more frequently proceed via free trade zones. These areas accept freight for storage and re-routing without requiring the payment of import duties, and provide an opportunity for fraudsters to repackage and mislabel products that were legitimately exported. The Jebel Ali Free Zone in Dubai appears to be a particularly popular hub in this respect.¹⁰⁶

Containerized shipments may be marked as destined for inland markets, thus avoiding controls at the ports of ingress. Niger is a popular putative destination for a wide range of products seeking to avoid inspection on making

landfall.¹⁰⁷ Once within ECOWAS territory, the cargo may be directed anywhere in the region.

Within the destination country, pharmaceuticals are delivered to the West African public through four main channels:

- The national public health systems
- Faith-based and other non-governmental public health programs
- Private health care practitioners and formal pharmacies
- The informal market

All are vulnerable, to varying degrees, to the introduction of fraudulent medicines. One 2008 study of anti-malarial drugs in Senegal found that one-quarter were found deficient in the public sector, 35% in the private sector, and 68% in the informal sector.¹⁰⁸

Historically, the procurement and distribution of public medicines has been a function of national “central medical stores,” which are usually maintained as a division of the Ministry of Health. But these institutions have been typified by malfeasance and inefficiency, so governments have come under growing pressure to expose central stores to market competition.¹⁰⁹ Private sector providers have grown to address the shortcomings of national health programs. Even in a country as poor as Mali, polls reveal that a large share of the population obtains its medications from both formal and informal private providers.¹¹⁰

The nature of the pharmaceutical supply chain varies dramatically between countries. In Mali, 85% of imported medications come from two large wholesalers, while in Ghana there are 60 importers, 12 manufacturer/wholesalers, 166 wholesalers, 328 wholesaler/retailers, 700 retail pharmacies, and 11,159 registered ‘chemical sellers.’ In both countries, vendors with no medical qualifications (known as ‘chemical sellers’ in Ghana, or *dépôts de vente* in Mali) are allowed to sell a wide range of medications, including anti-malarial drugs.¹¹¹ The idea behind registering these dispensaries is to increase access to medicines, which they certainly do, but they also pose a point of vulnerability to the introduction of fraudulent medicines.

Informal dispensaries are popular because they are cheaper than using the formal system. Because no prescription is required, there is no need to pay for a consultation with a doctor. A 2003 survey in Benin found that over one third (36%) of household heads reported purchasing medicine from the illicit market at least once, although 82% said they were aware of the risks of doing so. Over 86% said they thought these medicines were cheaper than in pharmacies, and 82% said they were cheaper than in public health centers. Two main sources for these drugs were cited: just under 65% said that they were visited by itinerant salesmen several times per month, and the same share said that these drugs were available at a nearby market.¹¹²

Who is doing the trafficking?

Investigations have revealed a wide range of participants in fraudulent medicines manufacturing and distribution. From former high-level executives in the pharmaceutical industry right down to mom-and-pop shops, the trade has proven attractive to all manner of opportunists.

It appears that both West Africans based in Asia and Asians based in West Africa play a special role in facilitating the illicit commerce. For example, in one case prosecuted by the Chinese government, a Nigerian businessman resident in China placed an order with a Chinese medicine exporter for fraudulent anti-malarial medication. The job was then sub-contracted to a pharmaceutical company employee, packaging specialists, and a shipper who combined the order with an unrelated lot of fraudulent drugs. The case resulted in the seizure of 43 tons of fraudulent medication.¹¹³

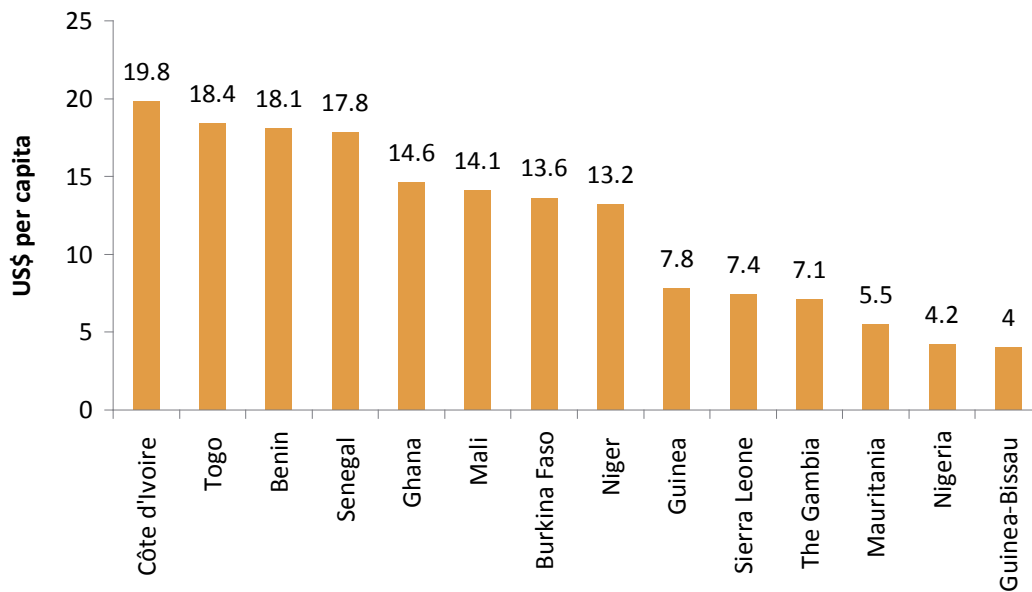
In 2009, staff from UNODC’s Laboratory and Scientific Section were asked to inspect a fraudulent pharmaceutical manufacturing operation in Guinea. Allegedly linked to the Conté family, this facility had equipment for producing bubble packs and cardboard packaging mimicking that of a well-known French pharmaceutical firm. What was presented as amoxicillin was, in fact, flour packed in gelatin capsules. The government reported that several Chinese citizens had been arrested in connection with this operation, and the flour was packed in bags with Chinese markings.

Of course, these linkages are just part of the increasing integration of the Chinese and African economies. As Chinese investment in Africa has grown, so have Chinese expatriate populations in Africa. Both Chinese and Indian pharmaceutical manufacturing firms have also opened factories in the region. And as the Chinese economy has opened, the West African diaspora in China has also expanded. These links provide a platform for both cooperative development and transnational organized crime.

How big is the flow?

There can be little doubt that a large share of the essential medicines circulating in West Africa are not what they appear to be. The main question is: how much of this is a product of intentional fraud, and how much is simply negligence? Certain indicators, such as counterfeit packaging or drugs containing substitute chemicals (included to mimic the effects of the active ingredient) strongly indicate fraud, while others (such as having too much of the active ingredient) imply negligence.

Many samples fall into a grey area, however. Those deficient in the active ingredient could indicate a number of things. Fraudsters often put enough of the active ingredient in their product to pass simple reagent (qualitative) tests. Legitimate pharmaceutical producers who under-dose to cut

Figure 36: Annual pharmaceutical expenditure per capita in 2010

Source: International Federation of Pharmaceutical Manufacturers and Associations¹¹⁴

costs could also be deemed guilty of health fraud. But under-dosing could also result from poor batch mixing or other simple mistakes. Due to this uncertainty, low-dose medication cannot be assumed to be fraudulent without other supporting evidence.

There is clearly an opportunistic character to medicinal fraud. The prevalence is highest not in the markets where profits would be greatest, but in those where the chances of detection are lowest. Global pharmaceutical sales were almost one trillion US dollars in 2011.¹¹⁵ West African sales were just under US\$3 billion in 2010,¹¹⁶ or less than 3% of the global total. Pharmaceutical imports to West Africa were just US\$1.5 billion.

What share of this US\$1.5 billion in imports was fraudulent? The most recent cross-national study by the World Health Organization indicated that most of the anti-malarial medication tested in Nigeria (77%) and Ghana (64%) did not pass quality tests.¹¹⁷ Other studies have found lower shares.¹¹⁸ The fact that some of these medicines were likely domestically produced complicates the picture. Using the most conservative figures, at least one quarter of the anti-malarial medication in circulation is not what it is purported to be. Testing of other essential medicines has found comparable results.¹¹⁹ But many of these failures may have been cases of under-dosing, and so cannot be classed as fraudulent.

Scholars have recently tried using a set of indicators to determine whether a given sample is “falsified” or not. Newton *et al.* reviewed a series of studies, noting cases where analysis satisfied one of three criteria of falsification:¹²⁰

- Falsified packaging

- No active ingredient
- Active ingredients other than the ones specified in the packaging.

On the basis of this work, it appears that between 40% and 100% of samples failing chemical analysis were found to be falsified. Again, taking the lower figure, this would suggest that at least 10% (40% of 25%) of the imports are fraudulent. This would amount to at least some US\$150 million of fraudulent medicines in annual imports to West Africa in recent years.

Implications for policy

West African pharmaceutical markets are greatly in need of regulation, but it is unlikely that many West African states will have the capacity to regulate them in the near term. Past experience with bureaucratic and inefficient central medical stores has demonstrated that poorly managed regulation can greatly increase costs and reduce access. On the other hand, the current situation affords consumers very little protection. Other market-based solutions should be pursued.

At present, the region has both very open borders and completely disparate pharmaceutical distribution systems. Since medicine entering the region at any point can easily find its way to any other point, a regional approach should be taken to pharmaceutical procurement. One way of limiting abuses would be to create a region-wide list of approved producers. Manufacturers who repeatedly introduce substandard medications would be blacklisted. Medicines from non-approved sources would be subject to confiscation. This list should be centrally managed to reduce abuses and to promote competition.