



**PROJECT TITLE:**

**THE INFLUX AND SALE OF FAKE MALARIA DRUGS IN KENYA,  
ITS ECONOMIC IMPACT AND IMPLICATIONS FOR DRUG-  
RESISTANT MALARIA**

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## Introduction

Malaria still remains the biggest killer in Africa, especially of pregnant women and children and is estimated to kill 3000 people every day. While it is manageable using drugs and insecticide-treated bed nets, drug resistance continues to pose a major problem.

Currently in Africa, many drugs have become virtually useless for treating malaria. Consequently, these drugs have been replaced by artemisinin combination therapy (ACT), considered the last frontier in the fight against drug resistant-malaria.

There is great concern that if resistance to ACT occurs, the fight against malaria in Africa will be set back irredeemably. In Asia, ACT resistance has already been documented. The resistance is driven by drug misuse and an even bigger problem, fake malaria drugs. Scientists now fear that if this occurs in Africa, there will be a major human catastrophe.

It is currently estimated that as much as 70 per cent of all drugs being sold in some African countries are fake. These fakes are reported to be sourced from China, the major manufacturer of artemisinin. This is not surprising when one takes into account the phenomenal increase in trade between African countries and China.

The extent of the fake malaria drugs trade in China was reported by *Reuters* in a story published by the *Daily Nation* of Nairobi, Kenya, on February 14, 2008. It reported that scientists and police had exposed a major Asian trade in life-threatening fake malaria drugs, resulting in the seizure of hundreds of thousands of tablets and the arrest of a dealer in China.

Details of the unique collaboration highlight the growing threat posed by the trade in counterfeit medicines and the difficulty of tracing the suppliers. "The problem is acute in Southeast Asia, where researchers have identified counterfeit versions of the malaria drug artesunate as a problem since 1998," the report says. Artesunate is part of an ACT that is available as arsumam, a combination of artesunate and amodiaquine that is widely used in Africa.

The other is coartem, a combination of artemether and lumefantrine, which is the most widely used ACT in Kenya. The investigation, which was coordinated by Interpol, with input from international researchers, found that as many as half of the malaria tablets sampled in Vietnam, Cambodia, Laos, Myanmar and on the Thai/Myanmar border were counterfeit. They were disguised with authentic-looking packaging, including 16 different types of fake holograms.

Most of the counterfeits examined contained no active drug and some had potentially toxic ingredients, including banned pharmaceuticals and even raw material used to mask ecstasy. Possibly, some tablets also contained small amounts of artesunate, possibly to foil screening tests.

The doses were too low to be effective but high enough to contribute to the development of resistance in malaria parasites, adding to the problems of fighting the mosquito-borne disease, which still claims more than a million lives a year. At least some of the counterfeit supply came from China.

## **The problem of fake malaria drugs in Africa**

The World Health Organisation (WHO) defines a counterfeit drug as one that is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.

Counterfeiting can also include bulk ingredients made to produce drugs. This definition is a major cause of concern in the medicines sector because of the confusion between fake and generics. Unfortunately, there is no consensus about this definition. Countries issuing their own regulations against counterfeiting have their own definitions, making information exchange among them difficult and hindering the development of global anti-fake strategies.

Some countries do not enforce their regulations, and others do not even have any regulations to enforce. Critics of the WHO definition point out that it may end up negatively affecting the legitimate use of generic drugs and thus become an obstacle to access to medicines.

According to Peter Pitts, a Senior Fellow for Health Care Studies at the Centre for Science in the Public Interest in the United States of America, the projected monetary value of global pharmaceutical counterfeiting in 2010 will be US \$75 billion. The human cost is estimated at up to 200,000 deaths globally most of which occur in Sub-Saharan Africa. The problem is more acute in Africa because of poor drug regulatory services.

Those who import and distribute fake anti-malaria drugs have killed with impunity, directly through the criminal importation of a medicine lacking active ingredients and by encouraging drug resistance to spread. If malaria becomes resistant to artemisinin combination therapy that is the mainstay of treating drug-resistant malaria in Africa, the effect on public health in the tropics will be catastrophic.

The problem of counterfeit drugs is especially severe in sub-Saharan Africa. A 2005 study found that half the chloroquine tablets in some selected African countries contained incorrect levels of the active ingredient, rendering them ineffective. Faulty chloroquine contributed to a doubling of malaria deaths in the areas under study.

Nigeria presented the worst case of drug counterfeiting in Africa until very recently when, under the leadership of its tough chief pharmaceutical regulator, Dora Akunyili, the country began taking significant action against counterfeiters.

Consequently, the data from Nigeria are the most complete available, but even there, the beneficial impact of more rigorous oversight has not been consistently recorded. Data vacuums persist. Still, customs investigations and simple studies of samples bought in markets, kiosks, and pharmacies in various countries are building a body of evidence about counterfeit drugs in Africa.

With several reports of sub-standard and counterfeit anti-malarial drugs circulating in the markets of developing countries; Dr A. A. Amin and Prof G.O Kokwaro of Kemri-Wellcome Trust decided to review the literature for the African continent.

A search was conducted in PubMed in English using the medical subject headings (MeSH) terms: “Antimalarials/analysis”[MeSH] or “Antimalarials/standards”[MeSH] and “Africa”[MeSH]” to include articles published up to and including 26/02/07. Data were augmented with reports on the quality of antimalarial drugs in Africa obtained from colleagues in the World Health Organization.

They summarised the data under the following themes: content and dissolution; relative bioavailability of antimalarial products; antimalarial stability and shelf life; general tests on pharmaceutical dosage forms; and the presence of degradation or unidentifiable impurities in formulations.

The search yielded 21 relevant peer-reviewed articles and three reports on the quality of antimalarial drugs in Africa. The literature was varied in the quality and breadth of data presented, with most bioavailability studies poorly designed and executed.

The review highlights the common finding in drug quality studies that 1) most antimalarial products pass the basic tests for pharmaceutical dosage forms, such as the uniformity of weight for tablets 2) most antimalarial drugs pass the content test 3) *in vitro* product dissolution is the main problem area where most drugs fail to meet required pharmacopoeial specifications, especially with regard to sulfadoxine-pyrimethamine products.

In addition, there are worryingly high quality failure rates for artemisinin monotherapies such as dihydroartemisin (DHA); for instance all five DHA sampled products in one study in Nairobi, Kenya were reported to have failed the requisite tests.

They concluded that there was an urgent need to strengthen pharmaceutical management systems such as post-marketing surveillance and the broader health systems in Africa to ensure populations in the continent have access to antimalarial drugs that are safe, of the highest quality standards, retain their integrity throughout the distribution chain through adequate enforcement of existing legislation and enactment of new ones if necessary and provision of the necessary resources for drug quality assurance.

While improvements have occurred in some places, such as Nigeria in the past few years, there is still a long way to go before the pharmaceutical markets in many African countries can be considered safe. One problem common to many developing countries is the persistent willingness, often driven by wretched poverty, of many patients to buy drugs from street vendors or those selling drugs on doorsteps.

In Burkina Faso, for example, where national regulations stipulate that consumers must buy medicines with a prescription, many consumers regularly buy drugs without them in street markets where counterfeits are common.

According to the Ministry of Health, one in five pharmaceutical drugs bought in the capital city of Ouagadougou is counterfeit and sold without a prescription or expiry date. Breaking the rules may be a rational decision for somebody who does not appreciate the risk, or cannot afford to travel to a proper pharmacy because the informal trader's goods will probably be cheaper and more readily available, often because they are not the real thing.

Even branded products may be compromised by poor storage conditions - such as being held up on a quay by customs officials. This may contribute to an inherent mistrust of Western medicines and resentment of Western imports in some countries, and make a locally produced version more acceptable. This means that the poorest, least mobile, least educated people are the most vulnerable to fakes.

In Africa, where HIV/AIDS and malaria kill millions of people each year, the demand for medicine for these deadly diseases is enormous. Unfortunately, as a result of poverty, low literacy and general ignorance counterfeiters have been able to take advantage of desperation. In fact, many Africans will buy single pills at kiosks with no more packaging than handmade envelopes.

Even in pharmacies, where blister packs are more likely to be available, there is close to no chance that a non specialist will have any knowledge about the correct appearance of the products. The customer must rely on the knowledge and integrity of the pharmacist.

Analysis of antimalarials in Angola, Burundi, and the Democratic Republic of Congo in 2006 discovered that 46 percent of drugs had been incorrectly formulated and in more than 50 percent of cases, drugs were sold loose (without the original primary packaging, with the name of the active ingredient, strength, the expiry date and only in some cases, the producer's name and country written in pen), providing a ready opportunity for counterfeiting.

In Cameroon, a U.S. Pharmacopoeia study found that 39 percent of samples had no active ingredients, insufficient active ingredients or the wrong ingredients. The link between sub-therapeutic levels of antimalarial drugs and antimalarial drug resistance is usually explained in terms of "selection pressure" in the literature, i.e. low levels of a drug selectively kill susceptible parasites, leaving resistant parasites to flourish in their stead (sustained and haphazard use of drugs has the same effect).

This is especially true for drugs with long half-lives such as Sulfadoxine Pyrimethamine (SP) and which therefore are more likely to spend part of their time in the body below the minimum inhibitory concentration required for parasite kill. This residual and sub-therapeutic drug in the host is likely to encounter re-infecting parasites, a common feature in areas of high transmission (most of sub-Saharan Africa), resulting in selective kill of susceptible parasites. This is now known to be a major driver of resistance to antimalarial drugs.

### **Fake drugs problem in Kenya**

On December 7<sup>th</sup> 2009, the Pharmacy and Poisons Board disowned a report it had presented to parliament on fake drugs. This unprecedented move came after the Parliamentary Committee on Health had poked holes in the report, saying it was incomplete and flawed. The committee members had indicated that at least 11 firms were supplying fake drugs and that three top hospitals were importing drugs without the Board's authority. Among the drugs mentioned was Metakelfin, an antimalarial drug that is supposed to have been phased out because of resistance to it by malaria parasites.

A survey in 2005 found that almost 30 percent of drugs in Kenya were counterfeit, with some being no more than chalk and water. With counterfeit drug sales estimated at \$130 million every year, the cost of producing such fakes provides huge profit margins to the unscrupulous.

Towards the end of 2008, the Minister for Medical Services, Professor Anyang' Nyong'o, said that a countrywide survey by the Pharmacy and Poisons Board indicated that 16 percent of antimalaria drugs had failed the quality test.

The Minister was reacting to media reports that claimed that 38 percent of the drugs were fake. The Minister said the board would work with the National Security Intelligence Services (NSIS) to trace counterfeit drugs and arrest the importers and those peddling them in the country. This is yet to happen, two years down the line. "We will soon have a joint meeting with the NSIS since they have the means to track and arrest those involved," he said.

However, he would not name the source of the drugs saying the board would soon inform Kenyans about the source of such medicine. Kenyans are still waiting to be told who these people are. Kenya imports 17 million doses of ACT at a cost of KShs 1.5 billion per year.

Yet earlier this year, the media reported that the government had seized KShs 800 million worth of fake malaria and tuberculosis drugs imported into the country from China by a local company. Thus a consignment like the one reported is worth half the total ACT budget yet no action has been taken against the company in question.

This is a clear indication that the government is aware of those behind the importation and distribution of fake drugs yet the deadly trade goes on unabated. This project will expose the individuals and the companies behind the fake drugs trade. In January 2009, an unpublished report obtained by the *Daily Nation* was the source of alarming details on the extent of fake malaria drugs in Kenya.

The report, *Anti-Malarial Medicines in Kenya: Availability, Quality and Registration Status*, was compiled by government officials, University of Nairobi and WHO consultants in November 2008. The report confirmed what has always been known; that well entrenched cartels of drug manufacturers and distributors, working in cahoots with corrupt Health Ministry officials to supply their own drugs, are the biggest obstacle to a successful antimalaria campaign in the country.

The report continues: "Of the 40 medicines on the market, almost half have not been registered with the pharmacy and Poisons Board and of the unregistered products, the majority were from Kenya and India." "Of the 40 different formulations in the country, only 11 are recommended in national malaria treatment guidelines with almost half of them being supplied by 14 local manufacturers," the report continued.

While the study found that 16 percent of antimalarials in the market were sub-standard, some drugs such as amodiaquine and SPs, the most popular, had a failure rate of 45 and 30 percent respectively. Amodiaquine should have been withdrawn from public hospitals in 2006 and SPs gradually discontinued and replaced by the more effective Artemether/Lumefantrine (AL) combination.

Another study conducted by the government and researchers from the universities of Boston and Oxford says that it is puzzling that health facilities are well stocked with non-recommended antimalarials such as amodiaquine. Of five samples that failed tests at the National Quality Control Laboratory on content of active ingredient, four were made locally while one was from India. The study shows that monotherapies and other formulations that should not be on the shelves are outperforming the recommended ACT.

### **Fake malaria drugs and election campaigns in Kenya**

Few people would find a direct link between the importation of fake drugs and election campaigns in Kenya. However, investigations now points to a clearly discernible link between these two. Going back to the 1997 election, Joshua Kulei and Phillip Moi, aide and son to the former President Moi respectively, were accused of importing fake drugs worth KShs 95 million. The company at the centre of the multi-million shilling drug supply tender at the Ministry of Health was Bulk Medical Limited which was said to belong to Kulei.

The company was said to be linked to another plot two years earlier where it attempted to swindle the government of some KShs 7.2 billion in a shady deal to supply malaria control chemicals. The Permanent Secretary in the Ministry of Health at the time was Mr. Donald Kimutai who was later relieved of his duties. Many saw this as a case of being the sacrificial lamb in a massive scandal involving the government.

Following the publication of the story in *The People* on December 10 1998, there were verbal threats by the president's son but Kulei went a step further by taking the newspaper to court. What followed was the shocking award of KShs 10 million in damages to Kulei, one of the largest amounts ever awarded for damages at the time.

The case sent shockwaves throughout the media fraternity and many saw it as a blatant attempt to silence the media in its war against high-level corruption. Sources at the National Security Intelligence Service (NSIS) say that the money was meant to fund the 1997 campaign where Moi was one of the candidates and he went on to win the presidency against Kibaki and Raila. "It is common practice to use such drug importation to establish a slush fund for election campaigns and this is exactly what happened in that year," says a source.

This was to be seen later when another massive cargo of fake malaria drugs was imported into the country. This was in 2005 and was linked to a former minister in the Kibaki government and a son of a top politician. My source says that a former State House aide and advisor to the president was an expert in raising campaign slush funds and was behind this scheme. Another person mentioned in such schemes is a son of a former minister, a Nairobi operative.

Sources says the importation was meant to raise slush funds for the referendum and the 2007 presidential campaign. This brings to mind the John Githongo tapes when a Minister is on record as telling Githongo to go slow on the Anglo-Leasing scandal since the Bomas constitution review group was becoming difficult and they needed money to fight it.

But for these schemes to succeed, there must be collusion with professional bodies that are charged with inspecting and approving drugs that are imported into the country. One such body

is the Pharmacy and Poisons Board. The board has to sanction the importation and for them to do this means that they are also players in this game, willing or unwilling.

The feeling here is that the board is constituted by the government with the knowledge that the members can be used in such corrupt scandals and therefore they must be people that the government can manipulate when the need arises. I am in the process of investigating how these boards are constituted.

There must also be a high level of corruption along the border points and more so the ports of entry of these drugs. The final level of corruption involves international criminal cartels that manufacture and sell fake drugs. These are mostly found in S.E. Asia and investigating them may be outside the scope of this investigation.

According to Dr. Moses Mwangi, the chairman of the Kenya Association of Pharmaceutical Industries (KAPI) there is a difference between counterfeits and fakes. He says the study that found that 38 per cent of malaria drugs were fake means that they did not meet the quality standards.

This means that they were substandard and therefore did not pass the test of the active ingredient. Mwangi says that a fake drug is one that is said to be what it is not. He says it is difficult to have hard facts in the absence of proper and adequate data. "Counterfeits are as a result of efforts by manufacturers or pharmaceutical dealers to offer for sale a medicine they know for sure it is not what it is claimed to be," he says.

To register a drug, one needs to apply for registration with the Pharmacy and Poisons Board. The drug to be registered is then taken to the National Quality Control Laboratory (NQCL) to make sure it conforms to international standards. Kenya uses the British and American pharmacopoeia as standards, once registered the drug can then be imported.

However, after importation, there must be post-licence surveillance to make sure that the drugs imported are not compromised after licensing. Dr Mwangi says that post-licensing surveillance in Kenya is very weak and this is where most importers of counterfeit drugs have taken advantage of the system to import fake drugs. "The regulatory authority should be held accountable for the weak post-licensing surveillance," says Dr. Mwangi.

The Pharmacy and Poisons Board (PPB) is the drug regulatory authority of the Ministry of Health in Kenya, established in 1957 under the Pharmacy and Poisons Act, Chapter 24 of the laws of Kenya. The PPB has the mandate to regulate pharmaceutical services, ensure the quality, safety and efficacy of human and veterinary medicines and medical devices, and advice the Minister of Health on all aspects of medicines regulation, in order to safeguard the health of Kenyans.

Within the PPB, the department of Pharmacovigilance, set up in 2004, is responsible for ensuring that the quality of medicines in Kenya meets the required standards, through developing appropriate systems for detecting, reporting and monitoring adverse drug reactions, as well as relevant tools and systems for post-market surveillance. He says there is also weakness in the structure of the board which makes it vulnerable to abuses. "The CEO (registrar) of the board is also the chief government pharmacist.



This means that operationally he is a civil servant and in government it is easy to have a loophole. Who is he accountable to? The people working at the board are not accountable to anybody except to the civil service,” says Dr. Mwangi. Dr. Mwangi says this situation arose following what he calls a mischievous amendment to the Pharmacy and Poisons Board Act in 1993 that saw the Chief Government Pharmacist also become the Registrar of the PPB.

“The fact that the registrar of the PPB is also a civil servant makes him answerable to the government which means he can be manipulated,” says Mwangi. But the Chief Pharmacist and Registrar of the PPB, Dr. Kipkerich Koskei disagrees with this.

He maintains that the Pharmacy and Poisons Board can not be completely de-linked from the government. “The ministry must give guidance to the board and there is no country in the world where the regulatory authority is completely de-linked from the government,” he says. He cites the Food and Drug Administration of the US saying even this is not completely autonomous from the federal American government.

He says that the board is not a profit making organization and it would be very difficult for the government to fund an autonomous board since it would have to hire its own staff who would demand to be paid salaries on market rates and the government may not afford this.

However, he says plans to de-link the board from the government partially are underway. But Dr. Koskei wonders why people are so concerned about having the chief pharmacist double up as the registrar yet the Director of Medical Services serves as the Secretary of the Medical Practitioners Board yet no one is complaining.

Mwangi counters by saying that this leaves the board very weak. “It should be autonomous with its own CEO who controls staff and implements policy. The people who work for the board are capable but are not motivated.”

Dr. Mwangi says the situation is further compounded by a lot of people who are called parallel importers. They are not licence holders but they import standard drugs.

This, he says, is a loophole for people to make money where individuals are offered importation permits without the regard for procedure. He adds that there are individuals in this group who want the status quo to remain so that they can continue making huge profits.

He says that only two organizations in Kenya have been pre-qualified by the World Health Organization to analyze drugs, and these are the National Quality Control Laboratory (NQCL) and the Mission for Essential Drugs (MEDS) and that drug analysis is a very expensive undertaking that is beyond the scope of this investigation. Dr. Mwangi adds that the Kenya Medical Supplies Agency (KEMSA) has a minimal role to play since their main role is to procure warehousing and distribute drugs to public hospitals.

Nevertheless, KEMSA has had its fair share of problems. A source at the Agency says there are estimated to be around 700 wholesalers operating in Kenya, along with around 1,300 registered retail pharmacies, staffed by pharmacists. These figures do not include the multitude of roadside kiosks from which both OTC and prescription drugs are relatively freely available.

In October 2008, pharmaceutical suppliers wrote a letter to Kenya's Ministry of Medical Services, demanding that it settle outstanding payments for drugs procured by KEMSA, which reportedly owed KShs1.6bn (US\$20.2m) for pharmaceuticals procured between January and June 2008.

According to *The Standard*, around 20 pharmaceutical companies were owed money. Under the terms of the Public Procurement and Disposal Act 2005, drug makers are entitled to charge interest on the outstanding amounts at the market rate. In a move that would have serious consequences for access to medicine, suppliers threatened to stop working with KEMSA until they received payment.

The Ministry of Medical Services refused to step in to settle the debt until an independent review of KEMSA reported its findings. In July 2008, Medical Services Minister Peter Anyang' Nyong'o dismissed the entire KEMSA board, citing inefficiency and the supply of sub-standard products as reasons for the dismissal. A taskforce led by KEMSA's former director of medical services, Richard Muga, was set up to review the agency's operation.

In the meantime, drug shortages looked inevitable. According to the Kenya Pharmaceutical Distributors Association (KPDA), procurement problems had already begun to emerge, with shortages of essential medicines such as antimalarials being reported earlier in 2008. While the earlier problems could be attributed to violent unrest in the wake of the disputed presidential election in late 2007, it appears that the government's precarious financial situation resulted in a significant further squeeze on public drug procurement.

The non-payment and uncertainty could have seriously damaged Kenya's pharmaceutical industry. According to industry sources, pharmaceutical companies have already been forced to sack employees and have been unable to participate in tenders in the region due to their debt burden caused by the failure of KEMSA to settle its contracts.

This has led to foreign companies being awarded tenders to supply drugs but they are not any better and are also to blame for drug shortage and importation of counterfeits. It emerged in January 2009 that Indian drug maker Ajanta Pharma had only delivered 400,000 out of 8million doses of the malaria medicine *Artefan* (artemether/lumefantrine) to the Kenyan government, leaving only a month's supply of the essential medicine. According to the *Daily Nation*, Ajanta promised to airlift what it could to Nairobi and have the rest shipped 'as soon as possible'.

Ajanta won this tender to supply Kenya's public sector with antimalarials in 2008. Kenyan drug importers said the government chose the Mumbai-based drug maker because it was the least expensive option. However, industry stakeholders implied that this decision was a false economy. They intimated that the government would have to pay for the air freight and that product expiries were likely, mainly because *Artefan* has a short shelf life and Kenya's supply chain is notoriously unreliable.

Sources add that Kenya's drug supply management systems, characterized by the tedious and time consuming manual maintenance of records, have not proved efficient. A shortage of drugs, including medicines used to treat malaria and tuberculosis, has affected public hospitals in the Western Province, forcing patients to purchase drugs from costly private chemists.

There are several indigenous companies that manufacture anti-malarial drugs. The biggest of which, is Dawa Limited based in Ruaraka.

A SWOT analysis of the company indicates that cheap Indian and Chinese generic drugs and parallel imports could threaten viability of local manufacturing and that a large counterfeit drug market limits legitimate drug market size. This is compounded by an underdeveloped public healthcare and pharmaceutical procurement system.

Dawa Limited began operations in 1977 as Dawa Pharmaceuticals. Following its acquisition by fellow Kenyan pharmaceutical company Medisel in 2004, it was renamed Dawa Limited. It employs around 200 people and is one of the leading domestic players.

Dawa manufactures over 200 products, including tablets, creams and injectables for human and veterinary use. Its products are exported to most countries in the COMESA region. Medisel itself was established in 1990 and is involved in the import, marketing and distribution of medical devices and generic pharmaceuticals. It sources its products from China, India and Greece.

In April 2009 Dawa Limited was accused of selling unregistered drugs to the country's citizens. The Pharmacy and Poisons Board (PPB), responsible for the registration of pharmaceuticals and medical devices in Kenya, has said that only 35 of Dawa's products are currently registered. The company manufactures and sells over 100 generic medicines in Kenya, including antimalarials, analgesics and antibiotics.

Dr. Titus Kieni, Dawa's quality assurance manager said, 'We do not sell that which has not been registered. Once our drug has been registered for five years, we normally apply for registration three months before the expiry of the registration.' He added that although authorisations had been granted for certain drugs in 2007, registration certificates had not been released by the PPB and as a result the company was using approval letters issued by the board.

This was not the first time Dawa had negative press. In early 2008, the company had supplied 114million tablets of the antibiotic erythromycin to the Kenya Medical Supplies Association to be distributed to health facilities across Kenya. The whole batch of drugs was returned to the drug maker due to quality problems associated with the coating on the tablets.

Furthermore, in June 2009, the Kenyan government banned the drug maker from carrying out any business with KEMSA. It was claimed that the company had imported drugs from China but was going to sell them in the Kenyan market claiming that they were manufactured locally. Dawa's products include antibiotics, antimalarials, antihistamines, antihypertensives and cough and cold drugs.

Dawa Limited was yet again in trouble with the government after being caught allegedly trying to sneak in 30 tonnes of suspected counterfeit drugs labelled GoK (Government of Kenya) through the port of Mombasa. This story was published by *The Standard* on June 24, 2009.

The World Health Organisation defines a counterfeit drug as that which is deliberately or fraudulently mislabelled with respect to identity or source. The KShs10 million consignments ordered by Dawa Limited from China were at the centre of investigation over the suspected irregular importation.

These were the medical drugs the government was supposed to pay KShs16.7 million for but things went awry for the importers. The import licence used by Dawa Limited, investigations further revealed, was forged. The Pharmacy and Poisons Board claimed the import licence had been issued a year before and had expired.

"The permits they were using are expired and they altered the dates to make it look as if it is new. This is what made our officers suspicious and the goods were impounded," Pharmacy and Poisons Board's chief pharmacist, Kipkerich Koskei said.

The whistle was first blown by Pharmaceutical Society of Kenya's National Chairman, Dr Dominic Karanja on June 12.

"It has come to our attention that a consignment of medicines manufactured in China and consigned to KEMSA (Kenya Medical Supplies Agency) is lying at the port of Mombasa awaiting clearance," Karanja wrote to the Ministry of Medical Services Permanent Secretary, Prof. James ole Kiyiapi.

Earlier on June 10, a member of Pharmaceutical Society of Kenya, Kariuki Muema, had circulated details of the consignment and pointed out dangers of the drugs being released into the country.

Karanja wrote his letter on June 11, only a day, after the ship carrying the two 40-foot containers docked at Mombasa. The cargo was put under 24-hour surveillance by the police, Pharmacy and Poisons Board, Kenya Revenue Authority and Customs officials.

Karanja's letter, which was accompanied by a detailed schedule of the contents of the two containers, set off a series of actions as the government moved swiftly to safeguard the lives of its citizens.

Upon receiving the letter, the Permanent Secretary in the Ministry of Industrialisation, Prof. John Lonyangapuo responded on June 17. "We have information from the Pharmaceutical Society of Kenya concerning a drug consignment alleged to be originating from China and destined for KEMSA," he wrote.

"This consignment is said to be at the port of Mombasa awaiting clearance. It therefore, requires us to move with speed to ascertain the nature of the consignment to avoid a scenario where counterfeit and most likely sub-standard medicine get released to the public," Lonyangapuo added.

He warned that cases of counterfeit merchandise, particularly medicine are on the rise exposing Kenyans to grave danger and affirming the country's efforts to combat diseases.

Kiyiapi further declared that the problem needed to be arrested with such determination to ward off unscrupulous business people and other criminal cartels from finding a safe haven in Kenya. And for a time the cogs in the wheels of justice seemed to be moving as the various government agents flocked to Mombasa to ascertain PSK's fears.

But something went wrong.

On June 15, the day the container with the drugs was to be opened, Dawa Limited managers were unavailable and the grand opening was pushed to the following day. But this was not to be

as the press and the very experts who had raised concern about the consignment were locked out from witnessing the testing, raising eyebrows about the sincerity of the government.

Some health officials too were kept in the dark as the process of verifying what was contained in the controversial cargo started. Even after the containers were opened, Koskei declined to reveal the contents. "The contents of the containers are similar to what the government had awarded Dawa Limited to supply," Koskei told journalists.

Documents showed the consignment comprised mostly of antibiotics. The drugs were labelled "Government of Kenya. Not for Sale" perhaps to hide the origin of the drugs. Players in the industry felt that if the products were made by Dawa Ltd in their Baba Dogo industries in Nairobi, they should not have been in a shipment originating from China.

"We do not need to test fake drugs. We do not even need to look for the middleman. The government knows the company which ordered the consignment," Karanja said then.

Medical Services PS said: "The matter is very serious as the firm had won a tender to supply drugs worth Sh17 million. This could be a cartel attempting to defraud the government."

But the Pharmacy and Poisons Board said they were even more worried.

"Our worry is bigger than the consignment. We are now trying to conduct investigation to find out whether other consignments have arrived or they are going to be brought into the country," Koskei said. There were fears that some major companies had been raking in millions of shillings, supplying sub-standard drugs to government hospitals. These fears still abound today.

On fake malaria drugs, Koskei says that the only scientifically sound study conducted in Kenya was in 2006 when a baseline study was undertaken prior to the nationwide distribution of the Artemisinin Combination Therapy (ACT) known as Artemether/Lumefantrine.

It was jointly undertaken by the Pharmacy and Poisons Board and the Division of Malaria Control. Its findings were meant to guide the board to root out sub-standard antimalarial medicines, and those that do not conform to regulatory and treatment guidelines.

According to the study, of all antimalarial products found in the market, 42.6 percent were registered by the PPB while 42.2 percent were unregistered. The registration status of 15.2 percent of the products could not be established at the time of the survey. In conclusion, the study found that out of 43 batches on antimalarials tested, 7 failed the analysis, giving a failure rate of 16 percent.

This is the figure that Dr. Koskei says is the correct figure as the study was conducted with technical support from the WHO and Health Action International (HAI). The study concludes by stating that a wide range of antimalarial medicines are available in the market, the majority of which are not in the current malaria treatment guidelines.

A high proportion of the antimalarial medicines were unregistered, with the majority of unregistered products originating from Kenya and India. It says that one of the major lessons learnt is that there is a lack of strategic engagement on medicines regulation at the wider health sector, and a lack of awareness of the role and work of the PPB.

The study recommends that there is need for a concerted effort by the PPB, MOH and stakeholders in the pharmaceutical sub-sector to strengthen post-market surveillance to protect the market and patients from the dangers posed by medicines whose safety, quality and efficacy can not be guaranteed.

According to the WHO definition, the term 'substandard' is used to describe the quality status of genuine drugs produced by legitimate manufacturers. A drug is considered substandard, if, upon laboratory testing in accordance with the specifications it claims to comply with, it fails to meet the specifications.

Counterfeit medicine is defined by the WHO as "medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source. Thus counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging".

The Director of Medical Services, Dr. Francis Kimani, admits that counterfeit malaria drugs have been a problem in Kenya but the government is doing its best to fight them. He gives an example of the Dawa Limited consignment of antibiotics that were imported from China but labelled as being manufactured in Kenya. "The Ministry seized the whole consignment and it was destroyed by burning in Athi River," says the DMS.

Dr Kimani had a tough time trying to explain fake and substandard drugs in the market saying he had not been informed. "I take action on cases brought to my attention," he told the committee. That Dr. Kimani, who is also the board chairperson, did not have access to complaints filed by consumers annoyed the committee which fell short of labelling the board incompetent. Committee chairman Dr. Robert Monda, Nyando MP Fred Outa and nominated MP Sheikh Mohammed Dor insisted that the board respond to claims that at least 11 firms were supplying fake drugs. "Kenyans are dying because of negligence on your part.....you don't even have details," Monda told the board.

The committee also said three top hospitals were importing drugs without the regulator's authority. "There are glaring failures in the way you are managing the supply of medicine. You are exposing Kenyans to very high health risks," he added. Dr. Kimani had presented a report on complaints regarding several fake drugs, among them metakelfin, an antimalarial drug. The report showed that all the complaints had been acted upon but the culprits were left off the hook with meagre fines.

Later, Dr. Kimani and his team withdrew their presentation and admitted that it was incomplete. But In an interview with the DMS in his office, Dr. Kimani defended the report saying that there were only a few discrepancies in it. On how the fake drugs enter the country, Dr Kimani said that there were a lot of people who were importing drugs in their briefcases in airplanes as they travel back to the country from abroad.

He said this makes it very difficult to detect such imports because they come in as personal effects and therefore easily escape detection despite the presence of drug inspectors in all airports and border entrances.

A source in Mombasa who is a former journalist but now works in the maritime industry says that the fake drugs are imported into Kenya in containers through the port of Mombasa. “The importers place a few cartons of genuine drugs strategically so that the inspectors at the port inspect these and since they can not inspect the whole consignment, they pass the whole consignment off as being genuine while it contains many cartons of fake drugs,” he says.

However, Dr. Koskei says recent unpublished results that he could not release indicate a tremendous reduction in the presence of substandard malaria drugs. He says the results will be published soon. As the countdown to the August referendum begins and the No campaign opposing the new constitution gains momentum, could the country be poised for another wave of the influx of fake malaria drugs to fund the government-fronted Yes campaign?

Only time will tell.