

## Introduction

*The Pfizer Global Health Fellows Program is an international corporate volunteer program. Through the GHF program, Pfizer colleagues are paired with leading international development organizations in short-term assignments in key emerging markets designed to transfer their professional expertise in ways that promote access, quality and efficiency of health services for people in greatest need.*

*This annual essay collection illustrates how Pfizer's Global Health Fellows are working together with partner organizations in underserved communities to solve global health challenges.*

*To learn more about the Pfizer Global Health Fellows Program please visit [www.pfizer.com/ghf](http://www.pfizer.com/ghf).*

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## Background

As a Supply Chain Fellow with the [International Rescue Committee](#) (IRC) in Kenya, I helped strengthen IRC's quality assurance system related to medicine suppliers prequalification, as well as storage and distribution of medicines for humanitarian relief.

I have realized from my fellowship experience that a strong internal quality assurance system in an organization such as IRC solves only a fraction of the problems associated with counterfeit medicines. An established quality assurance system ensures that the procured medicines meet acceptable quality attributes. At the same time, the organization must accept responsibility for product quality and have a strong commitment for continuous improvement. However, a quality assurance system starts to disintegrate with the infiltration of undermining factors like counterfeit medicines and corrupt practices. Hence, I hope to point out that counterfeit medicines in the supply chain can't be ignored as they gravely impact the social, health, business and legal fabrics of Kenya. Medicines are crucial to the fight against life-threatening diseases such as malaria, tuberculosis and HIV/AIDS in Kenya (and Africa), and the threat of counterfeiting to patients' safety is very real [1].

## What Is a Counterfeit Medicine?

A counterfeit drug is defined differently in different countries. The absence of a universally accepted definition not only makes information exchange between countries very difficult, it also limits the ability to understand the true extent of the problem at a global level. In order to address this problem, the following definition has been developed by the [World Health Organization](#), "A counterfeit medicine is one which is deliberately and fraudulently mislabeled 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."

## Impacts of Counterfeit Medicines on Public Health in Kenya

The extent of counterfeit medicine in East Africa has not been quantified. In August 2010, the International Criminal Police Organization ([INTERPOL](#)) reported seizing 9,072 kilograms of counterfeit medicines and arrested 80 people suspected of illegal trafficking in six East African nations of Uganda, Burundi, Kenya, Rwanda, Tanzania and Zanzibar [2].

At INTERPOL, the Medical Product Counterfeiting and Pharmaceutical Crime ([MPCPC](#)) Unit works to bring together different stakeholders (e.g., police, customs, health regulatory authorities, scientists and the private sector) to tackle crimes related to counterfeit medicines. INTERPOL also has developed targeted enforcement activities against counterfeit medicines through membership in International Medical Products Anti-Counterfeiting Taskforce (IMPACT), which is led by the World Health Organization.

In March 2011, the Kenya Association of Pharmaceutical Industry (KAPI) estimated that counterfeit medicines accounted for approximately Kenya Shilling 9 billion (USD 100 million) in sales annually. This figure corresponds to between 20 percent-25 percent of the total legal commercial pharmaceutical market [3].

Counterfeit medicines pose a public health risk because their content can be dangerous or they can lack active ingredients. Their use can result in treatment failure (and contribute to increased resistance in, for instance, anti-malarials that contain insufficient active ingredients) or even death. Unlike substandard medicines where there are problems with the manufacturing process by a known manufacturer, counterfeit medicines are made by people with the intent to mislead [4].

### **Where Art Thou, Counterfeit Medicines?**

The extreme difficulty in tracing the manufacturing and distribution channels of counterfeit medicines makes their circulation on markets difficult to stop. Even a single case of a counterfeit medicine is unacceptable since it indicates that the pharmaceutical supply system in which it was detected is vulnerable. Worse, it undermines the credibility of national health and enforcement agencies [4].

The public depends on the regulatory and law enforcement agencies to ensure that only good quality and efficacious medicines are available on the shelves. The credibility of the agencies is damaged with each report of a counterfeit medicine or whenever patients do not experience therapeutic value after taking medicines. As a result of the health risk posed by counterfeit medicines, either by lack of efficacy or dangerous side effects, the public and especially rural communities may lose faith in Western medicines and medical practitioners, and may place their faith only in traditional healers and medicines [1]. Given these factors, the establishment of modern health care facilities and systems is hampered in Kenya (and Africa).

According to the Pharmacy and Poisons Board of Kenya, counterfeit medicines are not usually discovered during product registration because, not surprisingly, counterfeiters do not bother to register their products. However, counterfeit medicines become a very big problem once they enter the medicine supply chain! [5] Purveyors of counterfeit medicines avoid going through the established regulatory processes. Counterfeits are only picked from the markets through random surveillance by regulators and enforcement agencies. Often, patients who have bad experiences after taking the products, alert the authorities of the possible existence of counterfeit or substandard products.

### **Key Learnings**

It is important to note that the prevalent issue of counterfeit medicines in Kenya is indeed a real threat. There is little evidence the situation will improve in the near future but feasible measures can be put in place to reduce the level of counterfeit medicines. An enforceable anti-counterfeit law is urgently needed to promote better registration and enforcement of intellectual property rights in Kenya.

Meanwhile, it's important for legitimate pharmaceutical companies to develop and/or maintain a strong presence and reputation in Kenya as there is a growing medicine market created by Kenya and the entire central and eastern Africa region (Uganda, Tanzania, Rwanda and Burundi).

The international pharmaceutical industry must continue to play an important role in developing countries experiencing medicine counterfeiting by seeking partnership with qualified local distributors and retailers, enforcing the use of security-tamper-proof seals, working with government bodies to roll out anti-counterfeit mechanisms/programs and sponsoring campaigns to educate the public on risks of counterfeit medicines.

As discussed earlier, the pharmaceutical companies may consider going a step further by manufacturing generic medicines in the developing countries. In the long term, these generic medicines fulfill the four-pronged strategy and help to reduce the demand for counterfeit medicines.

As a Supply Chain Fellow, I learned that a strong quality assurance system is important to serve as a last gate of defense in detecting counterfeit medicines in the supply chain. The quality assurance system ensures that the procured medicines meet the acceptable quality attributes related to supplier prequalification, storage and distribution. However, the established quality assurance system is only as robust as the personnel in the organization who committed to uphold their responsibilities and do not succumb to corruption practices.

#### References

1. [Drug firms fight spread of counterfeit drugs in East Africa \(VOA News.com dated June 29, 2011\)](#)
2. [Kenya Pharmacy and Poisons Board seeks Kenya Anti Corruption Commission \(KACC\) partnership to stop fake drugs \(Business Daily dated July 4, 2011\)](#)
3. [Pharmacist tells how to identify fake drugs shop \(Daily Nation Online dated June 29, 2011\)](#)
4. World Health Organization website ("[General information on counterfeit medicines](#)")
5. Presentation by Dr. Jayesh M. Pandit, Head of Department for Pharmacovigilance in Pharmacy and Poisons Board of Kenya, "*Scope of Local (Anti?) Counterfeit Problem in Kenya*" (February 13, 2008).
6. Business section of Kenya's newspaper entitled "*Drug company opens new hub to fight cheats*" (Daily Nation dated July 20, 2011)
7. Business section of Kenya's newspaper entitled "*East African Community (EAC) Common Market pulls Pfizer back into the region*" (The Standard dated July 20, 2011)

