

# Lessons from Nigeria:

## the fight against

## counterfeit drugs in Africa

✉ Dora Akunyili

*The sale of counterfeit products is a problem in most countries. Every year, about 7% of world trade, valued at about 280 billion USD, is lost due to counterfeiting. In the information technology sector, products worth an estimated 20 billion USD are currently in circulation. But the huge financial losses incurred by manufacturers and individual customers as a result of the trafficking of fake goods are overshadowed by the tragic human costs: the pharmaceutical industry, and consequently the marketplace, are flooded with counterfeits. In this article, Dora Akunyili warns of the dangers of low public awareness of these potentially lethal products and describes the campaigns and strategies to protect the public in Nigeria and other countries in Africa.*

>>

Until recently, counterfeit pharmaceutical products were thought to be a substantial and increasing problem only in low-income countries, where traffickers of illicit goods have traditionally enjoyed the liberty of action

afforded by weak administrative systems. However, at the 2002 Global Forum on Pharmaceutical AntiCounterfeiting in Geneva, which brought together anti-counterfeiting organizations, healthcare providers, industry

representatives and drug regulators, many participants from developed countries reported the influx into their countries of fake drugs, underlining the global nature of this problem.

In 2003, the World Health Organization (WHO) estimated global sales of counterfeit medications at 32 billion USD – 10% of all medicines sold worldwide. The risks for those involved in the business of counterfeit drugs in terms of either legal or financial penalties are minimal. Huge profits can be made through the trafficking of pirate products, regardless of the damage and destruction to human life. Moving freely among today's virtually anonymous distribution channels, the traffickers reap the benefits of seemingly endless price-driven consumer demand.<sup>1</sup>

### The African experience

For various reasons, it is difficult to estimate the extent of the counterfeit drug business in Africa. Around the world,

there is a long tradition of smuggling, and African countries are no exception. There are few obstacles to the movement of contraband drugs in a region where smuggling is rife, communications within the continent are poor, and the drug regulatory authorities are for the most part impotent or inactive.

**Smuggling is rife and the drug regulatory authorities are impotent or inactive.**

In many African countries, long-standing political instability has given rise to poor drug procurement practices by the healthcare administrations. Furthermore, with widespread low literacy, public awareness of the existence of fake drugs is low. Many poor people who are unwell cannot afford costly authentic medications and are unaware of the danger of procuring an apparently cheaper alternative. They represent an ideal 'target market' for the unethical strategies of the entrepreneurs who profit from this illicit trade.

**Poor people make an ideal target for those who profit from the trade of counterfeit drugs.**

A recently published report on the status of drug supply in Dar es Salaam, Tanzania, painted a depressing picture of the dire circumstances of the health services, one which is all too familiar throughout the continent. The chronic shortage and erratic supply of drugs was compounded by irregular government funding and poor drug management. Notably, the quality of the

drugs was reported as questionable, some of them expired and often stored in unsuitable conditions.<sup>2</sup>

There is extensive trade in pharmaceuticals between countries in West Africa. Many of these – Togo, Benin, Chad, Niger and Cameroon – buy drugs from Nigeria, the country with the most important drug market in the region. Given this flow of trade, the status of drug supply in Nigeria, in terms of quality and security, is to some degree mirrored in many of the other West African countries.

### **The situation in Nigeria**

Despite the global presence of fake drugs, the international community has been slow to act. To date, there is no consensus on an internationally recognized definition of counterfeit drugs. At the turn of the last century, the problem reached dramatic proportions. The impact in terms of human suffering was incalculable; the sale of Nigerian-manufactured pharmaceutical products was banned in other African countries; investment fell and the Nigerian economy was significantly weakened as a result.

The National Agency for Food and Drug Administration and Control, Nigeria (NAFDAC) works under the auspices of the Ministry of Health to regulate and control quality standards for drugs, chemicals and medical devices, detergents and bottled water. The Agency identified a number of different types of counterfeit drugs in Nigeria, including those with insufficient – or an absence of – active ingredients, fakes and copies, orthodox medicines mixed with herbal preparations, and expired drugs.

NAFDAC has identified numerous counterfeit versions of life-saving drugs in Nigeria, including anti-diabetes medications. These include 'copies' of some of the most widely used insulins, blood glucose-lowering oral medicines (sulfonylureas) and cholesterol-lowering drugs (statins).

### *The implications*

In financial terms, the business of counterfeiting drugs constitutes economic sabotage. But the human costs are high and the consequences often irreversible. The use of poor-quality or fake medications often provokes serious complications, and in many cases premature death.

### *An ideal environment for counterfeiting*

Medicines make an attractive target for unscrupulous entrepreneurs. Drugs are low-bulk, high-value items and demand for them is high – and growing, particularly given Nigeria's increasingly urbanized population. In Nigeria and other low-income nations, a number of factors, including widespread corruption and conflicts of interests, facilitate the existence of networks that promote drug counterfeiting.

**Importers freely make false declarations about products, which slip easily into chaotic distribution systems.**

Internationally, there is a lack of consensus on the issues surrounding the production, exportation and importation of these potentially lethal products. Consequently, effective cross-border legislation to control the piracy of medicines is non-existent or

inadequate. Indeed, regulations exist in some exporting countries which ease the way for the producers and exporters of fake drugs; importers are free to make false declarations about products and these slip easily into chaotic drug distribution systems.

### NAFDAC strategies

#### *Empowering the public*

Public-awareness campaigns currently represent the most effective strategy against the use of counterfeit drugs. NAFDAC works to empower the potential victims of fake medicines by engaging the public through local and national media and at educational events.

#### *At source*

Other strategies are being employed abroad in an attempt to stem the importation of counterfeit medicines into Nigeria at source. To this end, NAFDAC drew up and implemented a number of administrative guidelines, including the inspection of manufacturing plants in producing countries, and the appointment of foreign analysts in India, China and Egypt to re-certify drugs before exportation to Nigeria.

Domestically, authorized drugs are required to carry a NAFDAC registration number, enabling the public to identify trustworthy medications. The Agency also monitors local drug manufacturers to ensure compliance with guidelines.

#### *At points of entry*

NAFDAC reinforced the directorates of inspection and enforcement to collaborate effectively with authorities at the ports of entry. These require

implementation of tighter and more effective surveillance at all ports of entry and enhance enforcement activities.

#### *In the marketplace*

Despite the improved control at sea ports, many of Nigeria's land borders remain insecure; achieving 100% prevention of entry is not a realistic option. NAFDAC therefore engages in coordinated surveillance operations at markets and retail outlets.

**The incidence of fake drugs in Nigeria has been reduced by about 90% since 2001.**

### Achievements of the campaign

As a result of the campaign to promote food and drug regulation in Nigeria, public awareness was raised in Nigeria and internationally. According to NAFDAC, the reported incidence of fake drugs in the country has been reduced by about 90% since 2001. The benefits of the campaign in terms of human safety are immeasurable.

The economic benefits are tangible. The ban on drugs manufactured in Nigeria was lifted by other West African countries. The production capacities of domestic pharmaceutical industries have increased, and 24 new drug manufacturing outfits were established during the last five years. From April 2001 to January 2006, NAFDAC seized and destroyed substandard products valued at around 100 million USD.

### Conclusions

Counterfeit drugs are no longer a problem only in developing countries. Copies, fakes and clones are sold

widely on the Internet. The potential negative impact of these is not limited by national borders: resistant strains of micro-organisms induced by substandard antibiotics do not need a visa to travel from country to country!

The experience in Nigeria demonstrates that the counterfeiters can be effectively overcome and society protected. But there is clearly a need for a more active response by the international community, including the United Nations. NAFDAC advocates for the international regulation of pharmaceutical products, and calls for an international summit to address the counterfeiting of pharmaceuticals.

#### ✉ **Dora Akunyili**

*Dora Akunyili is Director at the National Agency for Food and Drug Administration and Control, Nigeria (NAFDAC).*

### References

- 1 Ronald W Buzzeo. Counterfeit Pharmaceuticals and the Public Health. *Wall Street Journal* 20 October 2005.
- 2 Wiedenmayer K, Mtasiwa D. Transforming drug supply in Dar es Salaam. *Essent Drugs Monit* 2000; 28-29: 25-7.