

# **Understanding The Complexities of The Supply Chain's Linkages: The Case of Anti-Malaria Drugs in Africa**

George Andreopoulos  
City University of New York

Giuliana Campanelli Andreopoulos  
William Paterson University

Alexandros Panayides  
William Paterson University

## ***ABSTRACT***

*Over the last decade there has been a substantial increase in the supply of counterfeit anti-malaria drugs in Africa. This phenomenon has become extremely difficult to detect not only because the counterfeit drugs are usually hidden inside other products but also because it has been associated with the supply of genuine anti-malaria drugs stolen from pharmacies and government warehouses. As a result the supply chain of anti-malaria drugs, as well as the policies to control this trafficking, has become extremely complicated with serious economic, social, political, and ethical implications. The literature on this topic, particularly the one drawn from the work of international organizations, seems unable to understand these phenomena in particular because the legal and illegal aspects of the supply chain still remain quite separated. The main scope of our investigation is to provide a more comprehensive representation of the complexity of the supply chain of counterfeit drugs, to reconstruct the main reasons behind these flows and suggest policies to address the challenges posed by this complex trade.*

## **INTRODUCTION**

This study is an extension of our previous published paper, Andreopoulos et. al (2013). Here we examine the substantial increase in the supply of counterfeit anti-malaria drugs in Africa. The literature on this phenomenon coming primarily from international organizations, like the United Nations (UN), and its specialized agencies, such as the World Health Organization (WHO), the Organization of Economic Cooperation and Development (OECD), the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), the US Food and Drug Administration (FDA), Interpol, and media reports has one main shortcoming: it usually separates the legal from the illegal aspect of the supply chain. The main scope of this extension is to provide a more comprehensive representation of the complexity of the supply chain of counterfeit drugs, to reconstruct the main reasons behind these flows and suggest policies to address the challenges posed by this complex trade.

## EMPIRICAL EVIDENCE

As discussed in our previous paper, Andreopoulos et. al (2013), the World Health Organization defines counterfeit medicines as products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be genuine products. This definition applies to both branded and generic products. The counterfeit drugs can be lifestyle drugs, like Viagra and Cialis, or lifesaving drugs such as anti-malaria, anti-cancer and anti-HIV drugs and other therapeutic medications.

Counterfeit medicine may appear in many different forms. Evidence has shown that counterfeit medicine contains less or more than the required amount of API (Active Pharmaceutical Ingredient), or contains the correct amount of API, but it is manufactured under unsafe conditions. When the counterfeit drugs do not contain any active ingredients, they usually contain herbal ingredients, animal parts or even chemicals which may be toxic. In addition, authentic medicine is also placed in counterfeit packaging to extend the expiration date.

The data on counterfeit medicine is mainly based on incidents. In other words, they are based on the discovery of counterfeit medicine illegally diverted or stolen. Incidents vary by magnitude, scale and time frame. Based on the number of incidents reported, there has been a substantial increase, from 196 to 2054, a more than tenfold increase in the supply of counterfeit medicine over the period 2002- 2010.

More revealing information on counterfeit pharmaceutical products comes from their geographic distribution. Empirical evidence shows that the main share of counterfeit drugs comes from Asia and Latin America which combined represent 57 % of the total counterfeit incidents. A more detailed investigation by country shows that approximately 75% of counterfeit drugs supplied throughout the world originate in India, followed by China.

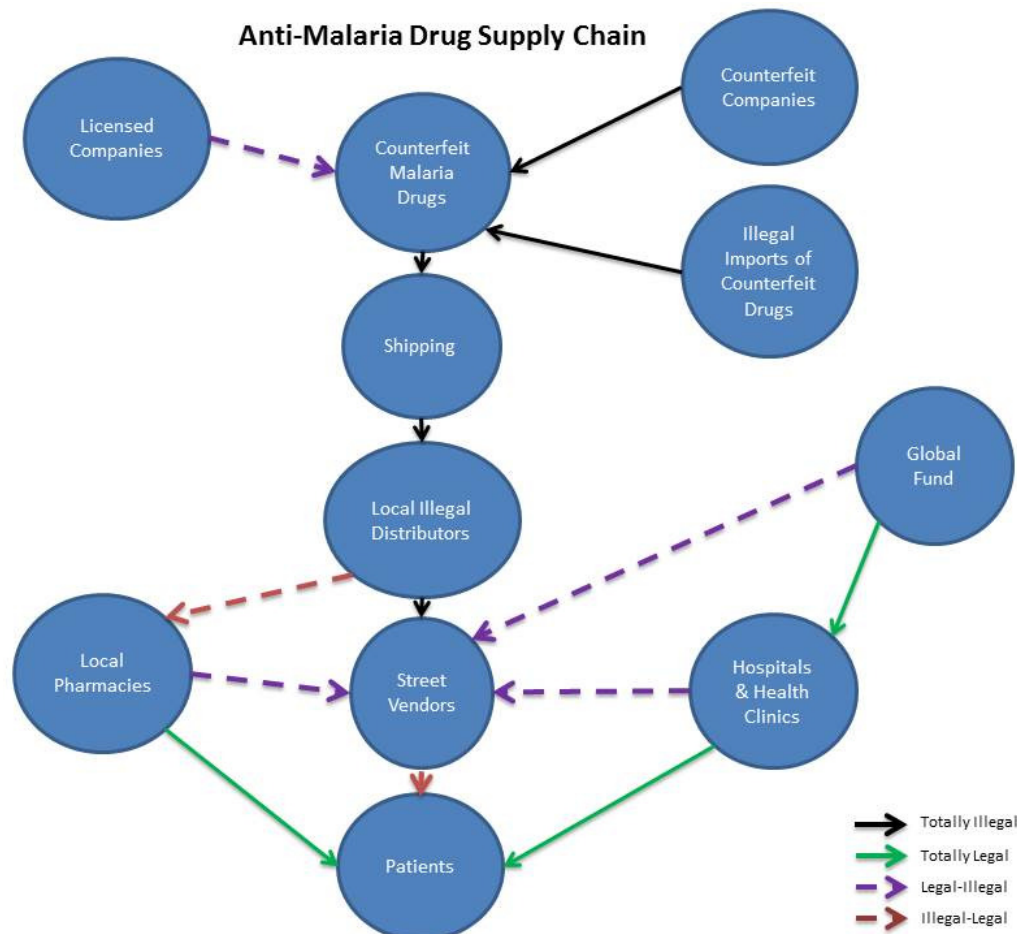
One of the most interesting cases is represented by anti-malaria drugs since the empirical evidence suggests that one third of these drugs used around the world are counterfeit. This phenomenon is particularly severe in Africa and more specifically in Angola, Burundi, and The Democratic Republic of Congo where more than 46 percent of drugs have been incorrectly formulated. Additional cases are provided in Andreopoulos et. al (2013).

The main reasons for the counterfeit trade are well known. For the supplier, the driving factors are the high price of drugs associated with high demand; since the cost of producing counterfeits is quite low, profits are extremely high. In the case of malaria we should remember one important factor: the price of anti-malarial products has increased over time making it a very profitable business.

## THE SUPPLY CHAIN

The literature on counterfeit drugs has three main shortcomings: it is based on limited empirical evidence, pays little attention to the trade of counterfeit drugs among developing countries, and more importantly, is unable to understand the real trafficking because it usually separates the legal from the illegal aspect of the supply chain. The scope of this section is to overcome these limitations and to provide an alternative representation of the anti-malaria drug supply chain considering both, the counterfeit and stolen drugs, based on empirical evidence derived from African countries. The suggested supply chain is shown in the graph below.

Figure 1 (Developed by the authors)



As one can immediately see from the graph, there is a linkage between legal and illegal aspects (counterfeit drugs) at the level of production. Indeed, empirical evidence from China and India shows that licensed manufacturers secretly make fake drugs alongside legitimate products. The origins of counterfeit production are quite complex because there are at least three channels of counterfeit drugs. The first one is the licensed companies which produced both legitimate and fake drugs. The second is counterfeit manufacturing which produces only counterfeit drugs. The third is illegal imports of counterfeit drugs which are fraudulently repackaged. Usually the counterfeit anti-malaria drugs are shipped to African countries where illegal local distributors take them to local pharmacies and street vendors from which they then reach the patient.

This approach is based on the empirical evidence because it seems that one problem common to many developing countries is the persistent willingness, often driven by poverty, of many patients to buy drugs from street vendors at reduced prices. However, street vendors also sell drugs at full price, for example in several African countries the antimalarial drug Coartem is sold at \$5.00 a packet, because some of the patients want to avoid queues and long trips to the hospitals. In Burkina Faso even though 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.

Empirical investigation also confirms that the counterfeit drugs can also reach local pharmacies. 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 expiration date. The customer must rely on the knowledge and integrity of the pharmacist.

One should also mention that many of the counterfeit drugs are hidden inside legal products. In one case, custom officials in Luanda, Angola, found, in a cargo container coming from China, 1.4 million packets of counterfeit anti-malaria drugs (Coartem) hidden inside a shipment of loud speakers. Usually the counterfeit drugs reach distributors who illegally sell to street vendors and/or to local pharmacies sometimes without their knowledge. Street vendors- as clearly appear in the graph- receive counterfeit as well as legal products from a variety of sources: counterfeit products come from illegal distributors, and legal products are stolen from many different sources, particularly local pharmacies, hospital and health clinics, as well as global development funds (in this context, the main source is the Global Fund to Fight AIDS, Tuberculosis and Malaria- The Global Fund). To bring one example: according to papers leaked to the Associated Press, the Global Fund acknowledged that, between 2009 and 2011, nearly \$2.3 million-worth of donated anti-malarial medicines were stolen primarily from government-run warehouses (the paper indicated that in 70% of the cases the drugs were stored in such warehouses). The countries involved included Cambodia, Kenya, Nigeria, Sierra Leone, Swaziland, Tanzania and Togo (BBC News, 2011). The same papers noted that the drugs, once stolen, were then “either sold in shops or through the black market.” (BBC News, 2011). Recent additional evidence (Faucon et al, 2013) confirms that organized networks steal large quantities of donated malaria drugs and ship them from East (mainly Tanzania) via the DRC toward West Africa (Malawi, Angola, Benin and Senegal) where they end up for sales at the street markets. The additional problem is that traffickers of stolen drugs often transport them over land in trucks without air conditioning, thus jeopardizing the drug` efficacy because some of them like Coartem cannot be exposed the temperatures higher that 30 degree Celsius (86 degree Fahrenheit ). Such theft in malaria aid programs is nothing new. According to country reports posted on the US President’s Malaria Initiative (PMI) website, between 2010 and 2013 widespread theft of donated malaria drugs has occurred in each of the four West African countries listed above (Faucon et al, 2013).

Finally the patient gets the medicine from two types of sources: the legal one which is comprised of the local pharmacies and hospitals, and the illegal one which is comprised of street vendors.

Thus, this representation of the supply chain shows that there is a continuous interplay between legal and illegal activities and consequently between counterfeit and genuine products. As previously mentioned, it is not easy to detect where the counterfeit drugs come from and in which form because they can be hidden in different legal products but, more importantly, the methods used to make counterfeit products and prevent their detection continuously evolve, so when policies are suggested for detection and prevention of manufacturing and distribution, they are already outdated. In this respect, it is worth noting that organized crime is very involved in the trade of counterfeit drugs. Indeed, there is ample evidence that the groups involved in counterfeit and piracy include organized criminal networks in Europe, the Americas and Asia which are also involved in heroin trafficking, prostitution, gambling, extortion, and money laundering.

## POLICY SUGGESTIONS

There is ample evidence that counterfeit production and sales flourish in developing countries where regulations are poor, corruption is high and lack of authentication plays a crucial role. However, the case of counterfeit drugs is a life and death issue. According to the UN, 1/5 of malaria deaths result from use of counterfeit drugs and this actually poses the most systematic threat to health care in Africa. Thus we need to suggest policies to reduce the counterfeit drug trade and guarantee the provision of the anti-malaria drugs at affordable prices for people in need.

Considering the literature on counterfeit drugs which is mainly produced by international organizations, four are the main policies suggested to reduce this phenomenon:

- Greater regulation in terms of the need to develop the necessary legal framework and ensure enforcement at every level of the supply chain
- More international cooperation between government and industries to detect the trafficking
- Better training and awareness for consumers who buy drugs
- More secure and advanced technology in the production and authentication of counterfeits.

No one would deny the importance of these recommendations in reducing the trafficking of counterfeit drugs. However, according to our empirical investigation and the consequent reconstruction of the supply chain, we would like to mention three additional recommendations:

- More effective screening of transported goods.
- Better monitoring of the composition of the drugs at the port of entry. The implementation of advance technology of authentication of counterfeit drugs should be implemented at this stage because it is too late to do so at the pharmacy level.
- Better monitoring and regular checks at storage warehouses to prevent stealing.

In the case of south-south trafficking one question still remains: how can African people acquire a sufficient supply of lifesaving drugs at affordable prices? Here we need to go behind the usual discussion on drugs and suggest additional policy recommendations:

The first policy suggestion would be that the government subsidizes the cost of anti-malaria drugs to reduce the cost to African patients. However, the question then is which government subsidizes, the local government? If we consider that malaria might have spillover effects particularly through tourism, then it is not only the local government that should be involved. On this issue, Arrow (2008), suggests that anti-malarial medicines can be considered an international public good and consequently the international community may be willing to participate to subsidize the price or the investment on research and development.

Additionally, other options could include the development of new forms of International aid focused on specific projects (in this case antimalarial products) to be sent directly to developing countries in need (Andreopoulos et. al, 2011); and the exertion of international pressure on pharmaceutical companies to provide affordable drugs to developing countries in need. On this issue, we should remember that generic medicines are vital to the health of the poor. Thus, we should push for new intellectual property rules. Another possibility would be to build on the opening provided by a provision in the TRIPS agreement that enables countries to manufacture copies of patented drugs in situations of “national emergency” (Macklin, 2006). This would make it possible for countries concerned to manufacture copies of patented drugs. In

such a situation, the country in need of such medicine would obtain a compulsory license for the manufacture of a generic copy of the drug and the patent holder would receive, in return, a reasonable royalty. There are two issues here that need to be addressed: first, what constitutes a situation of national emergency, and, second, to what extent this provision enables the country in question to import, as opposed to making, a generic copy of the requested patented drug (Macklin, 2006). In this context, the recently endorsed, by the United Nations Human Rights Council, “Guiding Principles on Business and Human Rights” could assist states in the fulfillment of their protection responsibilities (United Nations General Assembly, 2011). Under the Principles’ “protect” pillar, states could advance claims on the need to obtain compulsory licenses in support of the health needs of their people, as part and parcel of the process of fulfilling their due diligence obligations under international human rights law.

## CONCLUSIONS

In this paper, we studied the counterfeit market for anti-malaria drugs and provided a more comprehensive framework for understanding this phenomenon. Based on the empirical evidence in several African countries we elaborated an alternative framework which helps to understand the legal-illegal aspects of this trade and poses challenges to existing policies. We argue that the counterfeit trade can be reduced with more effective transnational regulatory initiatives, cross-border law enforcement cooperation, consumers’ awareness and more advanced technology. In addition, more effective screening of transported goods, thorough investigation of the composition of drugs at the port of entry, better monitoring and regular checks at storage warehouses, and adequate provision of lifesaving medicine at affordable prices, constitute necessary components of an effective anti-counterfeit trade strategy.

## REFERENCES

- Andreopoulos G., Andreopoulos-Campanelli G and Panayides A., “The Large and Opaque Networks of the Anti-Malaria Drug Supply Chain.” *Review of Business Research*, Vol. 13, No. 4, 2013.
- Andreopoulos G., Andreopoulos-Campanelli G and Panayides A., “US Foreign Assistance and the changing Aid Architecture.” *Journal of International Management Studies*, Vol. 10, No.4, 2010.
- Arrow K.J., “New Antimalarial Drugs. Biology and economics meet,” in *The Development Economics Reader*, edited by Giorgio Secondi, Routledge 2008, pp. 281-284.
- BBC News Africa. “Global Fund denies reports of huge malaria drug thefts,” 20 April 2011; <http://www.bbc.co.uk/news/world-africa-13145554> (accessed on August 8, 2013).
- The Global Fund to Fight AIDS, Tuberculosis and Malaria. Office of the Inspector-General, “Global Fund Signs Memorandum of Understanding with Nigerian Crime-Fighting Agency,” 29 May 2013; [http://www.theglobalfund.org/en/oig/updates/2013-05-29\\_Global\\_Fund\\_Signs\\_Memorandum\\_of\\_Understanding\\_with\\_Nigerian\\_Crime-Fighting\\_Agency/](http://www.theglobalfund.org/en/oig/updates/2013-05-29_Global_Fund_Signs_Memorandum_of_Understanding_with_Nigerian_Crime-Fighting_Agency/) (accessed on August 9, 2013).
- Faucon Benoit, Nicholas Bariyo and Jeanne Whalen, “Thieves Hijacking Malaria Drugs in Africa. U.S. Investigating How Important Medicine Ends Up on the Black Market,” *The Wall Street Journal*, November 19, 2013.
- Finlay, Brian. “Counterfeit Drugs and National Security”. *STIMSON*, February 2011

Hansen Chris, "Inside the world of counterfeit drugs," Dateline NBC, June 4, 2006

Interpol [www.interpol.int](http://www.interpol.int)

International Medical Products Anti-Counterfeiting Taskforce — IMPACT

[www.who.int](http://www.who.int)

Liang, Bryan, "Fade to Back: Importation and Counterfeit Drugs." *American Journal of Law and Medicine*, 32, 2006.

Macklin, R. "Affordable and Accessible Drugs for Developing Countries," in George Andreopoulos, Zehra F. Kabasakal Arat and Peter Juviler (eds.), *Non-State Actors in the Human Rights Universe*. Kumarian Press, 2006, pp. 185-202.

Organization for Economic Co-Operation and Development (OECD): *The Economic Impact of Counterfeiting and Piracy*, 2007 and *Magnitude of Counterfeiting and Piracy of Tangible Products*, 2009

Oxfam, "Eight Broken Promises: Why the WTO Isn't Working for the World's Poor," Oxfam Briefing Paper 9, 2001;

[http://www.iatp.org/files/Eight\\_Broken\\_Promises\\_Why\\_the\\_WTO\\_Isnt\\_Working.htm](http://www.iatp.org/files/Eight_Broken_Promises_Why_the_WTO_Isnt_Working.htm)

United Nations Office on Drugs and Crime. *Globalization of Crime: A Transnational Organized Crime Threat Assessment*, chapter 8, 2010.

United Nations General Assembly. Human Rights Council. *Guiding Principles on Business and Human Rights: Implementing the United Nations 'Protect, Respect and Remedy' Framework*, U.N. Doc. A/HRC/17/31, March 21, 2011.

US Food and Drug Administration [www.fda.gov](http://www.fda.gov)

World Customs Organization [www.wcoomd.org](http://www.wcoomd.org)

Pfizer Global Security [www.pfizer.com](http://www.pfizer.com)

World Health Organization [www.who.int](http://www.who.int)

World Trade Organization. *Ministerial Conference*. Fourth Session. Doha, 9 - 14 November 2001. *Declaration on the TRIPS Agreement and Public Health*. Adopted on 14 November 2001, WT/MIN(01)/DEC/2, 20 November 2001;

[http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.pdf](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf)