

**Forum:** Special Conference  
**Issue:** Preventing the distribution of counterfeit medicine  
**Student Officer:** Ashley Zhou  
**Position:** Chair of Special Conference

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## Introduction

Since its invention, medicine has always been inextricably intertwined with lives. With the recent advent of globalization, medicine is able to be distributed to every corner of the globe; however, this has also led to an increase in the distribution of counterfeit medicine. The use of such medicines may lead to adverse effects on an individual's health, ranging in severity from toxicity to treatment failure to resistance and even, in the most serious cases, to death. The dangers that counterfeit medicine brings are dire, and millions of lives around the globe are potentially threatened by the pressing issue of counterfeit medicine distribution. In the past decade, huge amounts of the counterfeit medicine were discovered in parts of the world. For example, 20 million bottles, pills, and sachets of counterfeit medicines were seized in a five-month operation coordinated by the International Criminal Police Organization across China and seven of its southeast Asian neighbors in 2007; a total of thirty-two people were arrested, and one hundred retail outlets were closed. According to the Pharmaceutical Security Institute, Asia accounts for the biggest share of the counterfeit medicine trading; however, Interpol officer, Aline Plancon, states that there are counterfeit medicine flows in every part of the world.

A profile of the trade in counterfeit medicine is slowly accumulating, using information from an array of different law enforcement operations by different world governments. These operations have shown that counterfeit medicine is a serious problem. For instance, in the United States in 2008, 81 deaths and many more adverse health reactions were either associated indirectly with or caused directly by counterfeit heparin tablets that reached the legal supply chain. According to WHO, the World Health Organization, health experts believe that such operations have only scratched the surface of a thriving, industry in the field of counterfeit medicine that poses a growing threat to the public health around the world. More actions and investigations will need to be take in order to gain a deeper understanding of the field of counterfeit medicine.

## Definition of Key Terms

### Counterfeit Medicine

Simply worded, counterfeit medicine is defined as “fake” medicine, which can refer to medicines that are contaminated or contain the incorrect or non-active ingredient. Counterfeit medicine can also refer to medicines that have the right and active ingredient but at the wrong dose. Counterfeit medicines are illegal and may be harmful to an individual’s health; these medicines do not comply with quality standards, are not approved by health authorities, have not been tested, and their effectiveness in curing the diseases they claim to treat has not been proven. The World Health Organization (WHO) defines counterfeit medicines as those which are ‘deliberately and fraudulently mislabeled with respect to identity and/or source.’



*Caption 1: Comparison of sample counterfeit and authentic medicine*

## The World Health Organization (WHO)

As its title implies, the World Health Organization (WHO) is primarily associated with direct international health within the United Nations’ system and leads partners in global health responses. The organization is a specialized agency of the United Nations and was established on April 7<sup>th</sup>, 1947. It is headquartered in Geneva, Switzerland. Counterfeit medicines have been recognized by the WHO as a serious threat to public health since 1985, but manufacture of the products appears, however, to be currently at an increase.

## Distribution

Distribution can be defined as the process of supplying a product to the individuals that desire such products. In other words, distribution is the delivery process of a good to its customers. The distribution process can take place through many different methods, including self-distribution and cooperating with wholesalers and distributors; however, the distribution of counterfeit medicine would involve itself in more of the business of black markets, and thus will inevitably function slightly differently, as it is not a process acknowledged by the laws enforced by the majority of nations.

## General Overview

### History & Developments

The threat posed by counterfeit medicine is severe. WHO has been tackling the problem of counterfeit medicine ever since its first discussion about the issue at the World Health Assembly in the May of 1998. Since then, an International Medical Products Anti-Counterfeiting Task Force (IMPACT) has been an attraction to different organizations, ranging from international to industrial to nongovernmental. Despite the of IMPACT, the manufacture and distribution of counterfeit medicine is nowhere near being eliminated.

Developing countries have become the obvious target for counterfeit medicine manufacturers, partly because the price of real medication may be too expensive for most of the population, and also because their governments have less stringent or less effectively enforced laws relating to counterfeit medicine. IMPACT's 2009 'Operation Storm 2' found that the variety of counterfeit medicine in Egypt ranges from organ transplant drugs to medicines for heart diseases, and more.



*Caption 2: More than 260 premises were visited during IMPACT's Operation Zambezi in November 2009.*  
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### Effects on the world

#### *Facts and statistics*

In estimation, 10% of all products from less economically developed countries are found to be counterfeits, and distribution of counterfeit medicine in these countries can be attributed towards the “deaths of tens of thousands of children from diseases such as malaria and pneumonia every year,” according to the World Health Organization. After their review of more than 100 studies and 48,000 medicines, WHO have declared to have that 65% of counterfeit medicine on the market for medicines in poor nations that treat malaria and bacterial infections is counterfeit.

In addition, it also found that counterfeit medicine might be contributing to 116, 000 deaths from malaria, with the majority of deaths in Africa, as reported by scientists working at the University of Edinburgh and London School of Hygiene and Tropical Medicine commissioned by WHO.

### *The health and economic effects of counterfeit medicine*

As well as wasting the income of patients, counterfeit medicine seriously endangers the public's health and safety. For example, after completing a liver transplant, a patient was treated with injections for anemia; however, his health rapidly deteriorated, even after 8 weeks of continuous injections. It was at this point that his physicians realized that the medicine the patient used was counterfeit. As exemplified by this case, consequences of consuming counterfeit medicine may be very dire. Another example is the case of the blood thinner heparin which occurred in the United States in 2008. The active ingredient in the medicine was substituted with a cheaper substance, causing adverse reactions and symptoms from the patient. This counterfeit active ingredient of the medication came from China, which is a major source of counterfeit medicine in the 21<sup>st</sup> century. Consumption of the counterfeit heparin has been linked to as many as 81 deaths.

### **Practical difficulties when preventing the distribution of counterfeit medicine**

It is especially difficult to combat counterfeit medicines in the United States of America. This is partly because, as statistics have shown, 40% of medicine sold in the US is made in foreign lands, and 80% of medicinal components are imported; this mass exchange makes it increasingly difficult to control what substances are being bought and sold. In addition, due to the fact that the majority of medicine is relatively expensive, customers are inclined towards products of lower prices, which are more likely to be counterfeit and can be potentially life-threatening. Finally, it can be quite difficult to detect counterfeit medicine, because all medicines enter a long and complex supply chain which provides ample opportunity for counterfeit medicines to enter the distribution network.

### **UN Involvement, Relevant Resolutions, Treaties and Events**

WHO, being a specialized agency in the UN, is very involved with preventing the distribution of counterfeit medicines. For example, WHO has set up the world's first web-based system used to track down illicit drug traders' activities in the Western Pacific Regions last year. They have constructed a system named the 'Rapid Alert System', or RAS, a communications network which reports on the current distribution of counterfeit medicines to relevant authorities so appropriate responses can happen immediately. WHO has suggested that the system should be expanded to include all regions. Also, in 2006, WHO established the aforementioned International Medical Products Anti-Counterfeiting

Taskforce (IMPACT) to coordinate such efforts. This establishment seeks to bring together international, industrial, and nongovernmental organizations; this collaboration unites their efforts against the issue of counterfeit medicines, therefore resulting in more effective prevention of the problem.

## Possible Solutions

With the growing threat of counterfeit medicine at hand, it is absolutely paramount to find possible solutions to the problem. There are three crucial factors that come into play when it comes to preventing the distribution of these medicine: international bodies, the national government, and pharmaceutical manufacturers. The manufacture and distribution of counterfeit medicine needs to be recognized as an urgent and imperative problem and be given immediate attention at these three levels among authorities in different fields, including drug regulatory committees, securities, pharmaceutical companies, NGOs, and consumers.

All three parts (international, national, and manufacturing) are crucial to the prevention of the distribution of the counterfeit medicines. Typically operating across borders, medicine counterfeiters may manufacture counterfeit medicines in currently developing nations that do not have many regulatory controls on the matter, and then ship these products as cargo to other developing or developed nations. Therefore, international responses are needed to facilitate action against the manufacturing of counterfeit medicine in countries with poor regulations on the topic. More international cooperation and regulations should be made between member states, in order to prevent the manufacturers from distributing counterfeit medicines from nation to nation.

National governments also play a key role in combatting the issue of counterfeit medicine. The majority of developing countries have strictly enforced regulations regarding this issue. For example, in Australian law, the manufacture, sale, import, and export of counterfeits are prohibited by the Therapeutic Goods Administration. They also have assessment mechanism to prevent the distribution of counterfeits, including customs inspections. However, though some governments have taken counterfeit medicine seriously, others do not yet have legislature that adequately reflects the importance and urgency of the issue of counterfeit medicine. For example, in the United Kingdom (UK), the fines given to an individual who counterfeits a brand name T-shirt can sometimes be more severe than those given to an individual who has counterfeited medicine and drugs. It is important to urge member states to acknowledge the imperativeness of preventing the distribution of counterfeit medicine and to enforce stricter laws to discourage further distributions. Another strategy that can be used is public education. Education can be used to provide warnings to citizens on the danger of purchasing medicines from the internet and the health risks caused by counterfeit medicine. Also, citizens can be told to notify government officials



immediately when they know through any means that counterfeit medicines may be on the market, so an investigation can be held at an appropriate time. Product recalls can be declared when medicines are suspected or known for certain to be counterfeits. Only with the support and acknowledgement of a nation's government, can the problem be effectively stopped.

Finally, pharmaceutical manufacturers can also prevent the distribution of counterfeit medicine through measures such as placing a physical-chemical identifier in their products. Physical-chemical identifiers are compounds with unique physical properties which can be used to identify the medicine through laboratory testing after manufacture. Pharmaceutical manufacturers can employ technologies, such as the aforementioned physical-chemical identifiers, to track drugs throughout a drug supply chain, from the seller to the purchase, and quickly identify illegal counterfeit medicine as it enters the market. These cutting-edge methods have proven to be effective, and if further investigations and experimentations are made in this field by the pharmaceutical manufacturers, it can be a big step towards the prevention of the distribution of the counterfeit medicine.



*Caption 3: Pharmaceutical manufacturers in a company at work*

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