

**Forum:** The Commission on Crime Prevention and Criminal Justice

**Issue #11-01:** Measures to eradicate illegal fraudulent medicine trafficking

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## Introduction

Since the introduction of penicillin in 1928 by Alexander Fleming, medicine has been playing a critical role in human society. As a means to survive, humans have developed different types of antibiotics and vaccines that can cure lethal and virulent diseases. Subsequently, human's reliance on medicine has increased over the past decades to the point where people are vulnerable without the existence of medicine. By the end of 2017, global spending on medicine has risen by approximately 300 billion U.S dollars from 2010 and is estimated to increase up by another 300 billion U.S dollars in 2020.

However, despite the fact that medicines are purposefully developed for the benefits of human beings, recently, there has been major issues regarding the counterfeit of these medications for the purpose of harming public health. According to UNODC, these fraudulent medicines are often times very appealing to the criminals as there has been lack of regulations, gaps in legal and regulatory frameworks, and difficulties in international cooperations. Furthermore, not only is the counterfeit medication traffic difficult to detect, but they also have less physical and financial detriment or cost allowing criminals to earn greater profits. The illegal production of fake medicine combined with other various forms of crime such as theft, smuggling, trafficking, illegal trade, and money laundering has been the source of the hardship. With these crimes increasing over the past years, patients are at a risk of potentially consuming unknown chemicals that may put their health and lives at risk. There has been a drastic increase in the pervasiveness of fraudulent medicine as crimes tend to combine with internet trade where

these medications can be bought cheaply and easily without having to worry about the prescription. It has been proven by statistics that in some parts of Asia, Africa, and Latin America, these counterfeit medications take up about 30 percent of the market goods. The World Health Organization (WHO) estimates that about 1 in 10 medical products in low and middle-income countries are falsified or inadequately used and states that approximately 10.5 percent of medications fail to accomplish their purpose.

Taking into account the fact that organized crimes of counterfeit medicine are expanding globally with criminals operating across the national borders through exports and imports, there exists an essential need for cooperation in terms of the accurate coordination and cross-sector actions in international scales. With illegal trafficking of fraudulent medicine, there could exist more consequences regarding patients' health and may even go to an extent where diseases aggravated by counterfeit medicine may overrun the effects of prescribed vaccines and medications. Although there have been a recent step forwards to facing these problems, precise measures to effectively eradicate these pharmaceutical crimes are necessary for the future public health.

## **Definition of Key Terms**

### **Counterfeit Medicine**

These are fabricated medicines that are possibly contaminated or may not have active ingredients/substances. These medications may consist of the right substances, but with the wrong dose. FDA (Food and Drug Administration) are taking in reports and are cooperating with agencies to combat these counterfeit medicine issues (FDA).

### **Substandard Medications**

Authorized medications that do not hold the proper quality standards, specification, or both. These medications, although being legal, may influence the patients negatively as the wrong prescription may lead to worse health conditions (WHO).

### **Unregistered/Unlicensed Medications**

Unauthorized medications that have not undergone evaluation by the National or Regional Regulatory Authority (NRRA) in the market. These medications are also considered illegal as there currently exists no details on whether this medication is safe to utilize (WHO).

### **Falsified Medications**

Medications that are deliberately counterfeited with their identity, substance composition, and source. Whether or not these medications are approved, they are purposefully counterfeited for deceiving the patients (WHO).

### **Drug Trafficking**

A global trade that involves cultivating, manufacturing, distributing, and selling of substances that go against the drug prohibition law. Fraudulent medicine trafficking involves the same process with a variety of drugs and medical products (UNODC).

### **Money Laundering**

The European Commission defines this term as, “Process where criminal proceeds are cleaned so that their illegal origins are hidden”. This process allows criminals to conceal illegal fraudulent medicine in a way that it becomes challenging for efficient regulation.

## **General Overview**

Illegal Fraudulent Medicine and drug trafficking have long been a problem since the development of antibiotics and people’s reliance on these treatments. The manufacturing process of these immoral pharmaceutical products vary from product to product as different doses of substances or different types of substances may be embedded to create a completely different effect. With the alluring profits, the organized criminal network surrounding the trade of fraudulent medicine has recently increased in numbers. Furthermore, the fact that these crimes involve trade across the border, it becomes harder for the government or agencies to detect the origin of these counterfeits. In every scenario, the deceptive nature of these counterfeits puts a patient’s life at a considerable risk and therefore indicates the need for a coordinated and

organized investigation.

### ***Background of Illegal Fraudulent Medicine***

Although no one is to be certain as to who initiated the production of Illegal Fraudulent Medications, the recognition of the issue has only been addressed recently.

The concern regarding the quality of the drugs has long been discussed since the ancient times. It goes back as early as the fourth century B.C where people warned about the contamination of drugs and medications. However, until now, this notion of drug quality dangers is increasing as more pharmaceutical industries advance.

Counterfeiting, as the main example of potential dangers of drug qualities, has been internationally addressed relatively recently in 1985 at the Conference of Experts on the Rational Use of Drugs in Nairobi. The meeting advocated the World Health Organization (WHO) along with international and non-governmental organizations (NGO) to collect data on the nature and background of counterfeit medications for the governments.

Counterfeit Medicine is unknowingly approached as just mislabelled or disproportionated medications. However, types of counterfeit medicine vary and include products that: do not consist of labeled ingredients, consist of active substances that are not labelled, have not been approved by listed organizations, or contain different doses or impurities of substances. Although laws have created national drug distribution channels as a means to produce quality medications, these are often times blunted and therefore infiltrated. In other words, counterfeit medicine still possesses a significant threat of getting trafficked by criminals regardless of strict laws. Alongside, black markets or illegal markets exist to distribute these medicines worldwide, creating consumers with disorders while generating significant profits.

When addressing issues regarding counterfeits and fraudulent medications, it is important to acknowledge the fact that there exist a shortage of valid information and accurate data that prevents the government and international organizations from effectively addressing the issue.

### *Processes Utilized by Organized Criminal Groups (OCG) of Counterfeit Medicine*

An organized criminal group (OCG) is determined mainly by the four criteria established by Interpol Pharmaceutical Crime Sub-Directorate. First, they should have collected an element where criminals usually work together in groups. Second, they contain structure or hierarchical systems and roles within the group. Third, they should be associated with criminal activities continuously. Lastly, they aim and obtain large amounts of profit from their activities.

The reason for the increase in counterfeit medications lies within the significant profit the criminals may earn with simple methods. The main problem arises when these medications cross the borders of different countries, importers, retailers, and distributors. As mentioned previously, criminal organizations may infiltrate these systems to implant fraudulent products.

One of the main sources of introduction of counterfeit medication lies within the process of repackaging. This term refers to a process where, apart from the original container that held the medications, the criminals are able to change the substance or the product and redistribute to the next importer. The repackaging process that occurs while shipping and distributing create a significant loophole for these fake medicines to infiltrate in the legal supply channels. The extended process of redistribution may mask the existence of the counterfeit products' provenance and therefore makes it nearly impossible to trace its origin. Furthermore, the original packages that held the medications, instead of getting wasted, become the source of new counterfeit products where criminals may insert non-original products and therefore allowing an easy marketing of these products.

Another strategy that criminals may employ is the use of intermediaries and parallel distributors. Intermediary and parallel distributors create quick changes in demand and incorrect storage levels, ultimately leading to multiple transfers before it reaches the patient/consumer. In simple terms, these distributors are independent of the marketing authorization holder and therefore may operate without commercial agreement. The fact that there exist no commercial agreement creates great uncertainty. Criminals use these distributors as they are able to obtain medications at a cheaper price and may re-sell them at markets that offer the greatest profit. Apart from these distributors, the criminals may use "diversion", in which these medications are

sent to hospitals or humanitarian experiments. Diversions create significant profit as these counterfeit medications are paid for full price.

Through these different types of distributions, an interconnected chain of profits is formed. Criminals selling to the subsequent distributor earn profits and as these processes of selling and paying continues on, the leakages from the microeconomics circular flow model would accumulate. Not noticing the existence of these complex systems, a simple consumer, often times lacking in money to afford adequate medications, would easily become vulnerable to these type of counterfeits.

### *Online Pharmacy and Counterfeits*

Although physical trades and smugglings of these fake pharmaceutical products exists, recent trends of online marketing have created new pathways for the criminals. Nowadays, a quick search on the web allows one to obtain a lot of information on different medications or products they wish to purchase. The deals for particular pharmaceutical medications are sometimes low-priced and may indicate a possibility of fake products. Subsequently, the consumers are attracted by these online pharmacies as it offers convenience, broader and wider choice of products, and the anonymity the internet provides.

According to the World Health Organization (WHO), the reports estimate that there exists as many as 50% of illicit online pharmacies that supply and sell counterfeit medicines. Furthermore, in a 2014 annual report conducted by the National Association Boards of Pharmacy (NABP) in the United States, out of 11,000 sampled online pharmacies, 96 percent of them did not comply with NABP patients and pharmacy practice standards or state and federal laws. John Clark, a chief security officer and vice president of global security for Pfizer pharmaceuticals have found that 78 different types of fraudulent Pfizer medications have been found over the 109 countries.

As previously mentioned, as online pharmacies advance and increase in numbers, incidents associated with counterfeiting medications also tend to increase. The attractive factor mentioned in the beginning, such as anonymity and low price also attracts the criminals. With

the significant use of anonymity, the criminals are able to create logos and fake websites that now attract the consumers through showing aspects of authority within the market. Additionally, these criminals have advanced in their methodology and some request prescriptions as a means to reassure patients with their doubts. Apart from these, other ways such as spamming exist to create even more attraction for these fraudulent medications.

### *Consequences of Fraudulent Medicine*

Fraudulent Medications not only fail in treating the patients' diseases, but it may also worsen it by creating other potential threatening disorders. The consequences of these products may far exceed the intensity of just a normal crime. The WHO estimates that about 10 percent of medications available globally are counterfeited and that in some countries such as Asia, Africa, and Latin America, 30 percent of the markets are counterfeited. This report indicates that the extent of the problem may be far beyond a country's reach and requires an international cooperation.

The Interpol suggests that counterfeiting does not only apply to "lifestyle" medications, but includes erectile dysfunction, weight loss medications, and also "life-saving" medications that may treat cancer or heart diseases. Apart from simple pills and powders, these counterfeiting extends to medical products that include contact lenses, condoms, a syringe for surgeries, and wheelchairs.

Some of the major consumer health issues lie within the types of counterfeit product one is dealing with. A patient, when dealing with medications with inactive substances, may just harm themselves through failing to treat their diseases. However, this may extend to scenarios in which patients may have to deal with medications that contain harmful substances that include bacteria-laced water, toxic yellow paint, floor wax, colored dye, powdered cement, boric acid, and antifreeze. Worldwide, approximately 500 children die every year due to counterfeit cough syrup which was contaminated with ethylene glycol. Furthermore, there existed incidents where a patient with cancer had bacteria-contaminated water injected into their bodies and lungs of

children.

Apart from health issues there also exists economic issues. The National Association of Boards of Pharmacy (NABP) estimates that counterfeit drugs created 75 billion dollars of revenues in 2010. These estimates show the fact that counterfeit medications have created a substantial damage to the pharmaceutical industries. The cost for society becomes relatively high and these markets deter innovation and programs within the country.

## **Major Parties Involved and Their Views**

### **China**

As one of the largest countries in Asia, illegal pharmaceutical issues are common in China. Although China has implemented strict laws, set up multi-ministerial cooperation, and collaborated with local governments in preventing illegal counterfeit medicine trafficking, fraudulent medicine manufacturing industries are still quickly expanding. On July 25th of 2012, China arrested 1,900 people associated with a fake drug dealing organization where about 180 million dollars worth of illegal fraudulent medicine had been found. These medicines consisted of toxic, sedative, or hallucinatory substances that the State Food and Drug Administration has banned. With criminals creating new methods for decisively trading illegal medicine, the ministry of China has recently suggested the consumption of medicine only within hospitals or pharmacies. However, currently, China is one of the leading countries that have contributed to international cooperation on preventing illegal counterfeit medicine (including cooperation between the U.S through MOU in 2007).

### **United States of America**

The United States of America, with organizations such as the FDA (Food and Drug Administration) and DEA (Drug Enforcement Administration), is one of the most active parties in issues regarding counterfeit medicine trade. Recently, the Justice Department has been concerned with statistics that indicated an increase in Americans purchasing drugs from foreign countries and therefore increasing the number of counterfeit medicine entering the United States.



Following the innovations in healthcare and US competitiveness in the global market, hazardous drugs are increasingly growing in numbers. Some problems regarding these illegal trades include criminals falsely portraying themselves as Canadian in order to increase consumer acceptance and trust. The Department of Homeland Security has stated that “counterfeit and pirated goods pose a serious threat to America’s economic vitality, the health and safety of American consumers, and our critical infrastructure and national security.”

## Ghana

Recently Ghana has risen to 6th place in the list of countries with the greatest production of counterfeit drugs. These illegal medicines have flooded into Ghana’s market, including government hospitals, over the past few years. Drug regulators are currently having a hard time filtering out these illegal trades. President Alex Dodoo has stated that the FDB (Food and Drugs Board) is a weak regulating system that can not control the care and management of medical resources. The gangs involved in these trades have gone to an extent where they have been able to easily infiltrate into local hospital supply chains. Even worse, Ghana’s president states that there exists no statistical number of these crimes and therefore it is not possible to act effectively towards these matters. According to Gyansa-Lutterodt, the Health Director of Pharmaceutical Services, a lot of fake medicines are imported from Nigeria and due to lots of loopholes in laws and gaps within national borders, these trades are becoming more frequent.

## Nigeria

Similar to problems in Ghana with counterfeit medicines, Nigeria is also one of the major exporters of these fake drugs. A study from the National Agency for Food and Drug Administration and Control (NAFDAC), in 2002, nearly 41 percent of the pharmaceuticals were counterfeit and 70 percent were unregistered in Nigeria. In this nation, the informal drug dealers are present in places such as kiosks, open markets, and general stores where most of these medications are sold for nearly half the price and are almost all fake or improperly stored, which reduces the overall quality. Although Nigeria is having regulated medicines sold as a means to combat the issue, a lot of people/citizens in rural areas are struggling to afford these drugs and as

a result are more interested in purchasing counterfeit products, especially in black markets.

## India

India, a developing country, consists of more than 40 percent of its citizen surviving with less than 1 U.S dollar per month. Due to this, people in India suffer from not being able to purchase medication necessary for their own survival and health. Although India's government has been distributing free generic medicines, these are limited to only some patients in a particular category of the diseases. Citizens who are unable to gain these aids prefer counterfeited products and medications that are often times much cheaper. In India, acts such as 1940's Drugs and Cosmetic Act, under section 17 has regulated some misbranded or other types of counterfeit medications. Out of these medications that India exports, 12-25% are contaminated or counterfeit. In reports from the European Commission, it has been analyzed that about 75% of global cases of SFECs (poor quality drug cases) are originated in India.

## Russia

In Russia, approximately 3.6 percent of drugs are fake and in a recent conference at Moscow, the deputy minister of health, Anton Katlinsky, has reported that there exist 56 different types of drugs that have been counterfeited in 2000. The Russian judicial systems are unable to effectively punish these crimes as they are underpaid and understaffed. Even when an organized gang has been convicted of the crime or trade of illegal fraudulent medicine, there exists only a mere fine of 5000 dollars. These drugs, with the use of bribing, flow into the open markets without getting detected.

## Timeline

Date	Description of event
2nd Century B.C	First Counterfeiting Medication has been detected
1820	With the help of the Industrial Revolution, medications were much more rapidly produced and the industries were able to mass produce medications. This

increased the chance of infiltration of counterfeit medications.

1948	Establishment of World Health Organization. Concerns regarding the quality of medications in international commerce.
1985	The problem associated with counterfeit medications were first addressed at an international level at the Conference of Experts on the Rational Use of Drugs in Nairobi.
1992	Counterfeit Medicine was officially defined at an international meeting on Geneva
1999-2002	WHO received barely any reports after 2002, and only 84 reports during this period.
2003	United States pharmaceutical companies made an agreement with the U.S Food and Drug Administration (FDA) on the immediate reports (within 5 days) of counterfeit medications.
2008-2009	European customs officials seized the distribution of generic medications in transit from India to Latin America and sub-Saharan Africa.
2009	The plans to address the issue at the World Health Assembly were preempted by the H1N1 influenza pandemic.
2011	In July of 2011, the European Union has advanced on the protection of patients by creating new directive on the counterfeit medications
2014	Operation Pangea VII initiated Interpol against fraudulent medicine which involved 111 countries, shutdown of 10,600 websites, 20,000 packages detection, and 239 criminals arrested.

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

Regarding issues with Fraudulent Medicine, several but minor resolutions and proposals

were made to counter the severity of the issue. Despite these efforts, not much of these resolutions have shown significant outcomes as counterfeiting drugs involve high costs, time, anonymity, and diversions. Currently, the United Nations is seeking methods to reduce or prevent this issue on fake medicine. However, the issue of fraudulent medicine becomes significantly difficult and requires vital coordination. It extends internationally and communities should be well aware of what and how to counter the use of these pharmaceutical products. Though acts on creating awareness and policies set forward by the UN and governmental/non-governmental organizations are diverse, it is not yet enough to prevent this issue.

- In 1988, the World Health Assembly adopted a resolution (**WHA41.16**) that requested the Director-General of World Health Organization to create programs for the prevention of trades and smuggling of counterfeit pharmaceutical products.
- The 20th session of the Commission on Crime Prevention and Criminal Justice (CCPCJ) adopted (**Resolution 20/6**) on fraudulent medicine. This resolution makes emphasis on the potential use of the United Nations Convention Against Transnational Organized Crime (UNTOC) where the United Nations Office on Drugs and Crime (UNODC) is the guardian in recreating international cooperation that goes against counterfeit medicine trafficking. These committees are in plans to combat the issue through provisions, extraction and seizing, freezing, and penalties of the instrumentalities and proceeds of crime.
- After the conference in Nairobi of 1985, the World Health Organization advanced towards creating global standards and a definition for Counterfeit medications in the conference held at Geneva. In February of 2006, “The Rome declaration”, adopted by WHO at the international conference, became the major turning point, leading to the creation of International Medical Products Anti-Counterfeiting Taskforce (IMPACT), which involved all 193 countries involved in the WHO.

## Evaluation of Previous Attempts to Resolve the Issue

UN involvement and different attempts to combat counterfeit medications exist, though it

is certain that these actions are not enough to clear the issue. Including the creation of new programs, forces, and groups, these acts have been made to create significant awareness and possibly new policies. Even though these policies can prove effective in some ways, this also indicates that the United Nations will have to focus more towards the physical actions for the actual prevention of crimes within trades and online. Since counterfeiting businesses are global operations spread across the world, the committees should address the issue with significant planning and set base in order to coordinate the issue effectively. As these crimes often times involve trades beyond borders and the difficulties of illegally crossing these borders, these coordinations would allow each country to monitor and penalize these actions. Together with the United Nations Convention against Transnational Organized Crime (UNCTOC) and IMPACT which works as the center vein of this issue, the cooperation and implementation of new, feasible laws and regulations on counterfeit medications need to be carefully structured.

## Possible Solutions

Issues regarding the use of Fraudulent medicine is an ongoing yet difficult issue to combat against. While preventive actions should be put in place, it is also crucial to address issues regarding the current crimes with fake medical products. As issues on imports and exports and online pharmacies are one of the main problems with fraudulent medications, it is necessary for organizations to understand the criminal routes of illegal sellers while internationals should focus on the cooperation and coordinated plans that will increase awareness, simultaneously narrowing down to the origins of the initiators.

One simple solution that could assist in ceasing the distribution of fraudulent medications is education. The solution for education becomes necessary for the non-governmental or community-based organizations that require information on possible distribution channels and the methods for detecting these routes. These education programs may inform organizations about procedures on making reports on the distribution of counterfeits to the authorities. Apart from these organizations, the public and the citizens should also be well informed of the current situation through education. These platforms may consist of ways to avoid untrustworthy webpages and the specific color changes, shapes, or texture on frequently purchased medications

in order to prevent these issues.

A long-term solution is an increase in governmental funding in social services. Poverty is one of the main issues as to why people are purchasing cheaper medications online. Developing countries that lack social services creates insufficient education and as a result, healthcare becomes costly. Initiating programs and ultimately creating sufficient government funding that improves these social services may lead to breaking the poverty cycle and therefore reducing incidents where people would purchase cheap, but untrustworthy medications online.

Last but not least, the most important solution that needs to be addressed rapidly is the necessity of international cooperation and coordination. The strong commitment of all countries in terms of combating fake medications is the most crucial aspect. Countries or organizations should foster partnership and cooperation to discover infiltration in systems of markets while also working with drug authorities to ensure that all the drugs that are distributed among suppliers are authorized and have met global standards. As for the difficulties in tracking down the secretive system that influences the trade lines, it becomes crucial that the crimes would not be tackled by only one specific country, but from various active countries with simultaneous cooperation. The coordination of such action would have to be logically thought out before countries take action on such complex crimes.

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## Appendix

- General Overview of WHO on the issue

[www.who.int/bulletin/volumes/88/4/10-020410/en/](http://www.who.int/bulletin/volumes/88/4/10-020410/en/).

- General Overview of UNODC on the issue

[www.unodc.org/unodc/en/fraudulentmedicines/introduction.html](http://www.unodc.org/unodc/en/fraudulentmedicines/introduction.html).

- Video of introduction to counterfeit medications (CBS news)

<https://www.youtube.com/watch?v=6Djftj0bwus>

- Video of counterfeit medication trade on Pakistan (CNN news)

[https://www.youtube.com/watch?v=rqP\\_Pa\\_NgX0](https://www.youtube.com/watch?v=rqP_Pa_NgX0)

- International Law enforcement in Europe on Counterfeit medications

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