

Forum: Economic and Social Council

Issue #30-02: Combatting the Counterfeit Pharmaceutical Drug Market

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Introduction

Counterfeit drugs are medications that are sold under a product name without meeting regulations or prior authorization. Often, these medicines include active ingredients, which may be harmful to health. The counterfeit pharmaceutical market has grown rapidly through the years, and this presents a great danger to public health. In recent years there have been several cases of counterfeit medicines being seized or presenting threats to public health. For example, in China around 20 million medicines in different forms (pills, bottles) which were identified as counterfeit by Interpol were seized and this led to over 100 retailers being shut down and 33 arrests. In 2016, a criminal network distributing these counterfeit drugs to the Middle East was exposed. These are just two of the many cases that counterfeit medicines have presented throughout the years. The issue has exceeded the expectations of many industry leaders, such as the commissioner of the European Union Guenter Verheugen who stated that this issue has “exceeded our worst fears”. The main problem originates with both government and industry, as both of them must come together to reduce the market.

Manufacturing this type of medications is very profitable. According to the World Customs organization, Drug Counterfeiting has become a \$200 billion business annually, often being part of organized crime. Most of the market share for these illicit drugs is in Asia, yet Interpol officer Aline Plançon states that there are several hubs in the world, and that there are products coming “from everywhere and going to everywhere”. These counterfeit drugs do not have their own market, they are sold within the pharmaceutical drug market.

Counterfeit drugs can be varied; however, the most popular ones are regarding weight

loss, influenza medicines, cardiovascular, nervous-system, and erectile dysfunction medicines. The main problem with counterfeit drugs is that manufacturers take advantage of the reputation that big companies have taken years to build with their medicines, their main focus is making the counterfeit medicines seem as close to the authentic ones from the outside and disregard what goes on the inside. By doing this, they create a perfect replica and this easily deceives consumers.

The main problem with these drugs are that they do not fulfill no legal requirements as they are being made, as opposed to the pharmaceutical companies who carry out several tests and follow legal procedures before their product hits the market. In many countries, there is also a very weak penalty for selling these drugs, thus it is more attractive for dealers. IMPACT in 2008, carried out an operation in which they targeted internet sites trading illicit or counterfeit medicines, and results were found in over 25 countries. Australia, Canada, Israel, New Zealand, Singapore, South Africa, USA, Thailand, and 16 other european countries were portals through where 1200 web sites engaged in illegal activity, 153 sites were shut down during this operation, nevertheless most of these web sites still remain. IMPACT leaders say enforcement remains at a standstill because of weak laws and regulations for stopping counterfeiters, there is no worldwide consensus on a penalty or what is defined as counterfeit, activities are illegal in some countries and are legal in others due to this.

Definition of Key Terms

Medication:

A substance used for medical treatment, this can be in the form of a medicine or a drug. Relates to the issue as it is the product causing health risks or presenting a threat to citizens.

Counterfeit:

Something that is made imitating something valuable or important with the purpose to deceive, or defraud. In this context it refers to the false or deceiving medications in the

market.

Market:

A medium that allows buyers and sellers of a good or service to interact in order to facilitate an exchange, it can also be an area in which dealings are conducted. Relates to the issue as counterfeit drugs are sold in a large market.

Health:

A person's mental or physical condition. It can also be defined as being free from illness or injury. Pharmaceutical drugs are severely affecting the health of citizens.

General Overview

The counterfeit market has presented a great threat to the health of the public. Counterfeit manufacturers conduct business disregarding law and patient safety, they also affect the pharmaceutical market, and operate unlicensed. According to the Center for Disease Control (CDC), an estimated 10%-30% of medicines sold in developing countries are counterfeit, but in developed countries such as, the United States, Canada, Japan, and many others, less than 1% of medicines sold are counterfeit. Therefore, it is clear to see how counterfeit drugs are not an issue of faulty detection techniques, but rather, that in developing nations there simply no restrictions put into place to stop the counterfeit drug crisis.

Health Issues

The most important aspect of this issue is a person's safety. Once an individual is in contact with a counterfeit medicine, they may experience extreme issues. These can include side effects, allergic reactions, and also the worsening of the disease or illness that is trying to be cured. In 50% of the cases, medicines purchased online where the sites hide their physical address are counterfeit. The main problem is patients, and hospitals that buy the pharmaceuticals, do not know if the drug is fake or not, and the only way to affirm that it is

counterfeit is through chemical analysis. Even if a counterfeit medicine has active ingredients they can cause a vaccination or test result to fail, or even lead to pathogens becoming resistant to the original active ingredient.

A big threat presented from counterfeit pharmaceuticals is poisoning. Poisoning has been presented in several cases, for example, this problem has been predominant in both Nigeria and Panama. According to NCBI, Between November 2007 and February 2009, 84 Nigerian children died from kidney failure which was due to industrial solvent glycol sold in counterfeit teething syrup. Inspectors then traced this to a fraud dealer in Lagos, which resulted in prosecutions. According to the same source, a similar tragedy unfolded on a larger scale in Panama, when a Chinese manufacturer sold the same glycol ingredient in antifreeze, this caused acute kidney failure in people who ingested the medicine, which was often in the form of cough syrup, and resulted in the death of 219 people. The main problem, however is not these active ingredients, it is the ineffectiveness of these medicines. In 2009, within an operation carried out by IMPACT, counterfeit coartem was found. Coartem is a medication that is used to treat malaria infections, often in adults and children. In the operation fake packaging of coartem was found, and the difference between packaging was simply a darker shade of yellow. This caused the public to be deceived and not recognize which one of the two packages was fake. Hence, this counterfeit medicine and many other similar ones do not work for the illness being treated. In other cases, some medicines include ingredients that disguise the disease, thus once the patient has died, his death will be due to natural causes as due to the ingredients that cover up the original illness, it won't be found when doing an autopsy or a similar study.

Major Parties Involved:

China

China is a big contributor to the issue of counterfeit pharmaceutical drugs. In 2007, there was a pharmaceutical trade show for ingredients in Milan. There were a handful of Chinese chemical companies attending this event. There were several manufacturers who

attended this event and had strong accusations against them, According to the New York Times, there was one manufacturer who was accused of supplying steroids, also there were two exporters who had sold poison mislabeled as a drug ingredient, which resulted in the death of various people including those In Panama mentioned above. This presents a huge problem, the companies that export the ingredients for the medicines are chinese companies that are not regulated, and these companies are not required to meet drug-manufacturing standards by the government, thus stopping them from exporting is hard. According to the same source, the times identified at least 82 Chinese chemical companies that said they made and exported the pharmaceutical ingredients, none of them were certified by the Food and Drug administration in China. This presents a huge threat as China is one of the largest exporters for ingredients in the world, and government pressure on regulations to prevent such diseases and harmful ingredients should be stronger.

India

In India patients receiving authentic drugs has become a great problem. According to the World Health Organisation, 35 percent of the fake drugs sold all over the world comes from India, and 20 percent of all drugs sold in India are fake. The reason for this is that the Drug administration in India provides very little guidelines and low standards for manufacturers of these drugs to set up shop, along with that thousands of other manufactures operate illegally and violate regulations, they often do not get caught as there is a lack of Government pressure. The Government of India must pressure manufacturers and implement stronger regulations to prevent the flow of these fake pharmaceutical drugs, India accounts for a large market share and to combat this issue it is key to focus on India.

United States:

In the United States, counterfeit drug manufacturing happens less often than in other countries. The reason for this is high regulations imposed by the FDA(U.S. Food and Drug Administration). Nevertheless over the past couple of years there have been cases of counterfeit drugs in the United States, According to the FDA some of them are Lipitor

tablets, which lower cholesterol, Procrit, stimulates red blood cell growth, and Alli, an over-the-counter weight loss drug. Even though these drugs may seem helpful to the public, they are not, they contain active ingredients which are hazardous to public health. Despite this the United States is a country which has been combatting the pharmaceutical drug market for years.

World Health Organization:

The World Health Organization(WHO), is the main organization participating in combatting the counterfeit pharmaceutical drug market. The WHO has employed taskforces on this issue, provided several guides detailing how to know if the drug you are consuming is fake, and have attempted to implement stricter regulations to prevent the export of these drugs. They are also launching a WHO Surveillance and Monitoring System which will oversee emergencies regarding this issue and help identify trends in the market.

Timeline of Events:

Date	Event
2005	4 deaths tied to Counterfeit Drugs Dispensed in Canada.
2005	109th Congress discusses death of Missouri patient given Counterfeit drugs
2006	4 Arizona dealers are convicted after Fake Botox medicine results in several tragedies.
2007	219 Deaths in Panama due to Kidney failure caused by counterfeit medicines.
2008	84 Nigerian children die from diethylene glycol counterfeit drug case.
2009	2 million counterfeit needles are found in Europe.
2009	Southern California Doctor is convicted on Cancer causing drug scheme.
2010	12 million dollars in Counterfeit Drugs seized in Asia.

- 2010** Israeli Authorities catch smuggler with 5,000 counterfeit pills.
- 2012** Counterfeit Cancer treatment drugs are found in the United States.
- 2015** Canadian Company involved in a massive counterfeit drug case pays \$75 million in fines and 5 managers are prosecuted, Company that acted as Drop-Shipper pays \$33 million fine.

UN Involvement:

The United Nations has launched several campaigns against the trafficking of counterfeit drugs. One of them for example is that of “Don’t Buy into Organized Crime”. The purpose of this campaign is aimed at educating customers and that colluding with these traffickers place their health at risk and the health of others at risk. The United Nations has adopted resolution 20/6 to address this issue, This concurs that major organizations and UN bodies will come together and combat the threat posed by counterfeit drugs. Some organizations include, Interpol, World Health Organization, World Customs Organization, and many member states.

- **United Nations, Fraudulent Medicines and their Trafficking, 2017 (Resolution):**
Resolution passed by the United Nations, includes different regulations and goals to combat the threat of the counterfeit drug market. States that various entities, such as those mentioned above, will cooperate with each other to combat this issue.

Evaluation of Previous Attempts

There have been many previous attempts to solve this issue, nevertheless the problem of lack of enforcement and awareness on this issue persists. Governments around the world, have tried to enforce policies against this pressing issue, yet this is the root of the problem. Governments do not have strong regulations in such and that is why in some countries dealing may be illegal and in some it is not. Moving forward, Governments have to strengthen their penalties. Secondly, evaluating previous resolutions passed by the United

Nations, more specifically the resolution passed this year on Fraudulent medicines and their trafficking, is a good start, nevertheless it needs some work. The resolution mainly focuses on setting goals, yet does not state how these goals will be accomplished, it is more focused on bringing different organizations together and forming a coalition. Moving forward there needs to be a more detailed resolution explaining how the trafficking will be reduced and in what ways specifically.

Possible Solution:

Counterfeit medications remains a big issue, yet there are some possible solutions to combat this growing threat. The fight against this should be divided in three ways, Education, Government, and Technology. Firstly, looking at education. A big reason why the counterfeit drugs are still a threat is that the citizens are unaware on how they look or how to prevent consuming them. Educating the citizens is key, a identifying guide with steps to know if the medicine you are ingesting is fake or not should be prioritized by organizations. Creating awareness on this issue will help diminish it, as most cases happen due to lack of education on the Subject. Secondly, looking at Government. Looking at China, India, and the United States as examples, the biggest issue in China and India is that these drugs keep being exported due to lack of government pressure. In the United States, the FDA has implemented strong regulations against such, which has reduced the market share of these drugs, thus it must be a priority to implement stronger regulations in order to diminish the threat. Finally, regarding technologies, a counterfeit identifying machine can be created that scans each drug and identifies if it has ingredients that make it counterfeit. These machines can be government mandated to be used for every sale of any drug in every pharmaceutical shop, and penalties can be implemented if they are not used. This will speed up the process and keep potential harmful drugs out of the hands of the public.

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