Forum: The United Nations Office of Drugs and Crime

Issue: Establishing Measures to Reduce the Proliferation of Fraudulent Medicines

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Introduction

The proliferation of fraudulent medicines is a demanding international issue that affects many nations across the world. Fraudulent medicines pose public health threats as they are known to fail to cure, harm or even kill consumers. These threats to global public health are only worsening with an increase in the trade of fraudulent with the advent of the 21st century. New counterfeit technologies, new trade relations, and increasing digital connectivity are all factors that are fueling the circulation of fraudulent medicines in the global marketplace.

Due to these concerns, the international community has been led to call for a more comprehensive and coordinated response to this issue. Making matters more demanding is the fact that the supply chain for medicines operates on a global scale; therefore, a focused effort on an international level is required to effectively detect and prevent the entry of fraudulent medicines into the global supply chain.

As an initiative, the Commission on Crime Prevention and Criminal Justice (CCPCJ) has adopted resolution 20/6 due to second-hand concerns, specifically the involvement of organized criminal groups in the trafficking of fraudulent medicines. The resolution highlights the potential to utilize the United Nations Convention against Transnational Organized Crime (UNTOC), which is guarded by UNODC, in the strengthening of international cooperation on preventing the trafficking of fraudulent medicines.

Definition of Key Terms

Counterfeiting

The act of imitating something authentic, with the intention of stealing, destroying, or replacing the original, for use in illicit transactions, or to deceive consumers on its authenticity. Counterfeiting is usually performed for financial gain and is a punishable crime in many nations. The counterfeiting of pharmaceuticals is performed due to the potential for massive profit and the consistently high demand for pharmaceutical products in the global market.

Fraudulent medicines

Medication or pharmaceutical products that are counterfeit; in other words, fake medicine. These medicines might contain the wrong active ingredients, the right active ingredients but the wrong doses, or no active ingredients at all. They are sold with the intent of deceiving the buyer on its origin, authenticity or effectiveness. Fraudulent medicines include the subcategories of substandard, unregistered/unlicensed, and falsified medicines. These medications are illicit and potentially harmful to the consumer's health. Therefore, it is important to identify and address substandard medicines in the global market because they are found in all regions of the world, pose public health threats, and could potentially cause the loss of public confidence in healthcare systems.

Substandard medicines

WHO officially defines this as "authorized medical products that fail to meet either their quality standards or specification or both." Due to its failure to meet quality standards and specifications, substandard medicines would be of inferior quality and this poses many risks to consumers. Risks include the harming of consumers and the failure to treat the disease for which they were intended. The circulation of substandard medicines in the global market could result in pharmaceutical manufacturers and health care systems becoming less integrous and reliable.

Unregistered/Unlicensed medicines

Medical products that have not been evaluated or approved by the National or Regional Regulatory Authority (NRRA) for the market in which they are marketed, distributed or used.

Without being approved by the NRRA, these medicines can pose many health risks and create knowledge gaps on the intended use of the medicine. The reasons for the origin of unregistered/unlicensed medicines may include the pharmaceutical company not being able to afford the expensive clinical trials required for its use on different age groups and medical conditions. Due to this reason, many medicines for children are often unlicensed. In many cases, doctors may have to choose a medication that is unlicensed when options for other treatments are limited or unavailable, especially for younger age groups.

Falsified medicines

Unauthorized medical products that are deliberately replicated to seem authentic by misrepresenting the dosage and composition, and imitating the original packaging. Falsified medicines may contain no active ingredient, the wrong active ingredient or the incorrect amount of the correct active ingredient. Common constituents found in falsified medicines include potato starch, cornstarch, and chalk.

Organized Crime

Highly-centralized enterprises run by criminals to perform illicit operations generally with the aim to maximize profits. The UNTOC does not contain an official definition for organized crime, but it defines the term “organized criminal group” under four criteria:

1. A structured group of three or more persons;
2. The group exists for a period of time;
3. It acts in concert with the aim of committing at least one serious crime;
4. To obtain, directly or indirectly, a financial or other material benefits.

Organized crime is often the mechanism behind the mass trafficking and trade of fraudulent medicines in the current day, and its extensive nature of the activity is one of the very reasons why increased international coordination is needed on the issue of proliferating fraudulent medicines.

The United Nations Convention against Transnational Organized Crime (UNTOC)

A multilateral treaty signed by 193 signatories during the ninth session of the UNODC in Vienna (November 15, 2000) to re-enforce cooperation among member states in combating

transnational organized crime. The treaty contains nine points of action, and the ninth point requests the UNODC to cooperate with other UN bodies and international organizations such as the International Narcotics Control Board (INCB), the World Health Organization (WHO), the World Customs Organization (WCO) and the International Criminal Police Organization (ICPO/INTERPOL) to aid member states in combating criminal networks affiliated with the illicit supply chain. This treaty would later provide a basis for resolution 20/6 signed by the CCPCJ to initiate international efforts to fight the trafficking of fraudulent medicines.

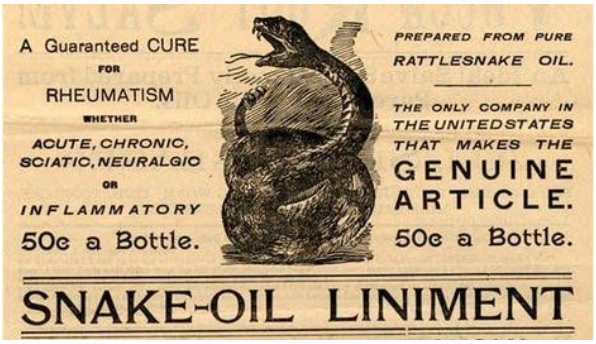
History

18th to 19th century (The Industrial Age)

The mass counterfeiting of medicine started during the Industrial Revolution when industrialization fueled mass production which led to the spike in the production of genuine medicines as well as in the production of fraudulent ones. Counterfeit medicines rapidly spread to multiple continents during this period despite the efforts of pharmaceutical manufacturers to contain the issue. As a result, the government of the United States set standards for the production, quality and chemical composition of pharmaceutical products and legislations were passed by Congress to tighten controls on imports and exports.

Patent medicines

Despite the increased regulations, a type of “pharmaceutical” product called patent medicine became extremely common in the United States from the 18th century into the early 20th century. Patent medicines were commercial products that were deceptively advertised as medical panaceas (products claiming to be a cure to all illnesses) and were sold as over-the-counter medications, without any proof of effectiveness. These medications often emphasized that they contained exotic ingredients without actually including the mentioned ingredients. Vendors would sometimes disguise addictive drugs such as cocaine, amphetamine, alcohol , and opium as patent medicines and advertise them as miracle cures. An example of an especially proliferant type of patent medicine was “snake oil”. Snake oil was a petroleum-based mineral oil that was advertised as containing pure oil extracted from snakes and was promoted as a panacea for all illnesses.



Caption #1: Snake-oil, a popular patent medicine from the 18th to early 20th century

20th Century

As a consequence of the proliferant patent medicines in the 18th and 19th century, organizations such as the Food and Drug Administration(FDA) and Federal Trade Commission(FTC) placed stricter regulations in the early 20th century to prevent further fraudulency, deceptive advertising and unintentional poisoning. Unfortunately, the downfall of patent medicines was not the downfall of fraudulent pharmaceuticals.

In the aftermath of World War II, American and British intelligence services captured an organized criminal group who were later charged for manufacturing, possessing, and distributing counterfeit penicillin. If this penicillin were to be reconstituted for injections, it would most likely have contained highly dangerous environmental pathogens. However, although this criminal network was able to be taken down, it was evident that the illegal penicillin trade had already spread throughout Europe.

In the 1980s, sub-Saharan was being plagued by economic crises and it went through the devaluation of currencies. Not reacting soon enough, the governments of African states allowed the trade of illicit medicines to proliferate. This led to the rapid increase in the circulation of fraudulent medicines and these drugs later spread to countries harboring traffickers. Also, with the rise of e-commerce, online trade channels appeared and consequently, drugs were able to make their way into American and European markets.

21st Century

With the phenomenon of organized counterfeiting reaching unprecedented highs, WHO now described this lucrative trade of counterfeit drugs as “organized crime”. Operating on global scales, higher levels of international coordination and vigilance were required. This led to the adoption of many successive resolutions, the founding of multiple organizations, and the establishment of new international cooperations.

Fraudulent medicines and the Internet

With the increasing ubiquity of the Internet, unregulated websites, social platforms, and smartphone applications have become direct channels for fraudulent medicines. The massive outreach of the Internet has also made an issue that was once limited to Low and Middle-Income Countries (LMICs) an issue for all. Exponentially-increasing digital connectivity has also increased the risk of consumers unintentionally purchasing fraudulent medicines, and illicit suppliers are now able to reach more consumers through spam email advertisements, social platforms, and unofficial websites. Also, a rise in the culture of self-diagnosis and self-prescription has led to the emergence of many websites providing unregulated access to fraudulent medicines.

Spread of Fraudulent Medicines in LMICs

Aside from many consumers being vulnerable to digital threats, LMICs with civil unrest, conflict, economic crises, and poorly-maintained or non-existent health systems are the ones carrying the greatest pressure of this issue. Consumers and patients living in countries with poor governance, low regulation, and limited access to healthcare are most likely to come into contact with fraudulent medicines. A 2017 estimate by WHO states that 10% of drugs in LMICs are counterfeit. Therefore, WHO states that counterfeit drugs are most likely responsible for the deaths of tens of thousands of children from diseases such as malaria and pneumonia. The first WHO assessment of 100 studies involving more than 48,000 medicines showed that drugs treating for malaria and bacterial infections accounted for 65% of all fraudulent medicines.

Key Issues

Public health concerns

Either from being substandard, unauthorized or falsified, all fraudulent medicines pose health risks as they can deceive consumers into consuming medications that may contain the wrong dosages, constituents, or production/expiry dates. A worrying statistic from the WHO states that counterfeit drugs could be responsible for the death of over hundreds of thousands of people annually. Out of these deaths, over 250,000 were the death of children. Most of the countries in which these deaths occur are countries with a high demand for drugs paired with poor surveillance, quality control, and regulations. It is absolutely imperative to address these public health concerns as it concerns the wellbeing of people in all regions of the world and is crucial to the reliability and efficacy of health systems and organizations worldwide.

Transnational organized crime (TOC)

TOC is one of the mechanisms that make the world wide illicit trade of fraudulent medicines possible because highly-centralized organized criminal groups would operate as a large network to coordinate international trade between regions. TOC hinders the international rule of law and this makes the issue of reducing the proliferation of fraudulent medicines more complex as it brings judicial, economic, and political factors into play. TOC is highly important to address as it harms genuine economic activity and threatens the national security of nations. In order to address transnational OC, the identification, breakdown, and prosecution of organized criminal groups are required. As initiatives the UNODC has adopted the UNTOC which provides a basis for many operations and resolutions against TOC.

GEOGRAPHIC BREAKDOWN OF PHARMACEUTICAL CRIME INCIDENTS IN 2015
An incident means that a region has been identified as the origin, point of seizure or transit, or destination of illegal pharmaceuticals

Source: Pharmaceutical Security Institute 2016

Caption #2: Geographic breakdown of pharmaceutical crime incidents in 2015

Loss of genuine economic activity

WHO states that the cases of fraudulent medicine found are only a "small fraction" of the real situation. Estimates by the agency show that countries may be spending over 30 billion USD on counterfeit drugs. This has drastic economic consequences as with more purchases made on counterfeit drugs, less of genuine medicines are purchased. This creates a loss of genuine economic activity that actually aid nations in development and costs targeted companies billions of dollars in profit loss.

Major Parties Involved and Their Views

The World Health Organization (WHO)

WHO is a UN organization which acts as a coordinating authority on international public health and it addresses health, sanitation, and diseases by sending medical teams to combat epidemics. WHO is governed by 194 member states through the World Health Assembly (WHA). As WHO is tasked with improving international public health, the issue of fraudulent medicines is very relevant to its cause. WHO believes in promoting the wellbeing of people world wide by addressing health issues from all possible perspectives.

The International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

IMPACT was a task force formed immediately after the Rome Declaration in 2006. Members of IMPACT would work closely with each other to investigate international crimes alongside the pharmaceutical industry to create high tech security packaging on pharmaceutical products. In Europe the UK, US and IMPACT are regarded to be the key roles in the fight against counterfeit drugs.

Caption #3: The IMPACT logo

The International Criminal Police Organization (ICPO/INTERPOL)

Interpol plays a key role in combating counterfeit drugs and it works closely with the WHO, especially through IMPACT. IMPACT has also initiated large-scale operations in 2008 through Interpol to combat pharmaceutical counterfeiting in East Africa and Asia. High-Income Countries (HICs) have also assisted in the crackdown operations by providing information gathered from the Internet.

The Medical Products Counterfeiting and Pharmaceutical Crime (MPCPC)

The MPCPC was a special unit formed in 2010 with the primary tasks of defeating transnational crime rings through field operations, providing major stakeholders with important information regarding pharmaceutical crime, and building partnerships between various sectors.

Operation Pangea

Operation Pangea is an international effort that was established to hinder the online sale of counterfeit drugs. Aside from crackdown operations, Operation Pangea has also raised awareness on buying risks of buying medicines from unregulated websites. Since its launch in 2008, Operation Pangea has removed 105 million units of fake drugs from the market and has made over 3,000 arrests.

Caption #4: Operation Pangea figures

Non-Governmental Organizations (NGOs)

Although the scale of the issue of fraudulent medicines is great, the aid of NGOs cannot be underestimated. Various NGOs such as RxAll and FarmaTrust have provided highly useful and high-potential solutions through the development of innovative technologies.

RxAll

RxAll is Nigerian start-up company that created a handheld device that scanned the composition of a pharmaceutical product in real time and compared it to a cloud-based database to check what the product should contain. The scanner connects to an app which shows the areas in which the product had already been tested to show the user the patches in the city where bad suppliers were. The app stayed up-to-date with artificial intelligence-generated algorithms.

Caption #5: The RxAll logo

FarmaTrust

FarmaTrust is a UK-based data company that lets users track the movement of medicine through the supply chain using block chain technology. This technology was originally created for the purpose of buying and selling Bitcoin. Through this technology, the purchase of genuine medicines can be facilitated, while avoiding the purchase of counterfeit ones.

Caption #6: The FarmaTrust logo

European institutions

The Council of Europe adopted the Medicrime Convention in December of 2010 that called for an international legal instrument to be used in the fight against pharmaceutical crime. As of the end of 2013, only the states of Ukraine, Spain, Moldova and Hungary ratified the convention. In order for the convention to take effect, at least five states and three member states of the Council of Europe was needed.

The European Union also made an amendment on June 8th, 2011 was validated by the European Parliament. The aim of this amendment was to combat counterfeiting by securing pharmaceutical channels, especially on the Internet.

Timeline of Relevant Resolutions, Treaties and Events

Date	Description of event
1760 to 1820-1840	**Industrial Revolution** During this period of rapid industrialization, the world saw the arrival of mass production and this caused a spike in the production of pharmaceutical products, both genuine and fraudulent.
1937	**The Elixir Tragedy in the United States** The deaths of 137 Americans as a result of a pharmaceutical containing poisonous solvent diethylene glycol.
November 25-29, 1985	**Conference of Experts on the Rational Use of Drugs in Nairobi** A conference arranged by the World Health Assembly to gather experts of relevant parties, governments, pharmaceutical industries, patients and consumer organizations. The highlights of the conference include discussions of how to ensure the rational use of drugs, especially in developing countries,

	through shared information and improved knowledge. This conference was the event that brought the issue of reducing the proliferation of fraudulent medicines to the international stage.
1998	**The Permanent Forum on International Pharmaceutical Crime** The forum was founded as an international enforcement forum aimed to share information and ideas on reducing pharmaceutical crime.
15 November 2000	**The United Nations Convention against Transnational Organized Crime (UNTOC)** The multilateral treaty signed by 193 signatories during the ninth session of the UNODC in Vienna to re enforce cooperation among member states in combating transnational organized crime.
2006	**Mass death from counterfeit cough syrup medicine in Panama** The lives of 100 children were claimed due to counterfeit cough syrup medicine containing poisonous solvent diethylene glycol**,** the same substance responsible for the Elixir Tragedy in 1937.
February 2006	**The Rome Declaration** This declaration was adopted at a WHO conference and this led to the immediate creation of IMPACT. The idea behind the declaration was to coordinate the efforts of 193 WHO member states and UN organs to combat medicine counterfeiting.
December 13, 2011	**The 20th session of CCPCJ adopts resolution 20/6** The resolution was adopted to re-enforce international cooperation on the issue of mitigating the transnational trafficking of fraudulent medicines. Highlights of

the resolution include the utilization of the UNTOC and this was a significant step towards combating transnational organized criminal groups who were responsible for illicit activities such as the trafficking of fraudulent medicines.

Evaluation of Previous Attempts to Resolve the Issue

The adoption of the UNTOC was one of the key steps that allowed many successive operations and resolutions to be established because the issue of fraudulent medicines is one that is deeply entangled with organized crime. The UNTOC later proved useful by being a core component of CCPCJ's resolution which was adopted to address the involvement of organized criminal groups in the trafficking of fraudulent medicines through the utilization of the UNTOC. Bringing the initiatives into action, the crackdown operations of Interpol such as Operation Pangea proved to be highly successful with a large number of arrests made and units seized since its founding.

The issue of ensuring the authenticity and inimitability of drugs was also effectively addressed by WHO's IMPACT taskforce which created packaging with high-tech security measures. Similar to this attempt, the efforts of NGOs such as that of RxAll and FarmaTrust have also been valuable assets to the issue. In future, higher coordination between main stakeholders, pharmaceutical manufacturers, governments, and NGOs could be established to merge the innovations from all sectors.

The attempts to resolve this issue have far been focused mostly on the health and regulatory aspects of this problem. More focus is needed on the criminal justice aspects of the issue. Given its ability, the UNODC could focus more on the aspects of criminal justice through the establishment of transparent criminal justice systems in member states.

Possible Solutions

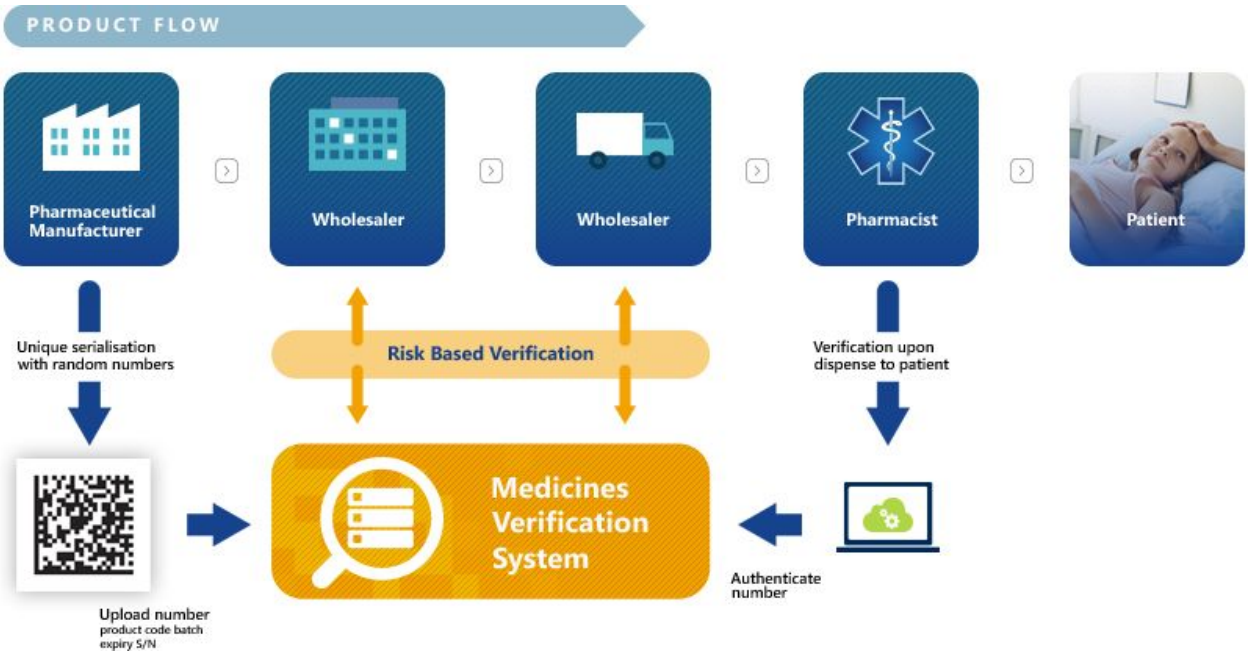
To effectively address the issue of establishing measures to reduce the proliferation of fraudulent medicines, the issue has to be considered and addressed from **all possible perspectives**. Intuitively, to prevent the recurrence of the issue, the cause of the issue will have to be tackled first. In this particular issue, that would be to target the **supply of fraudulent medicines.** Through more **international crackdown operations** carried out in **all regions of**

the world by task forces such as IMPACT and organizations such as Interpol, the sources, the manufacturers of fraudulent medicines, can be identified and extirpated.

Next to prevent recurrences of the crime, perpetrators and manufacturers involved in the organized crime could be brought to justice through the **establishment of transparent criminal justice systems**, given the UNODC's expertise in the area. Furthermore to widen the extent of the international operations, the identified criminal organizations could be used as sources of information to identify other drug rings. Also, to constrict the flow of fraudulent medicines in the global market, **stricter international regulations and supervisions** can be put into place. Also to preserve the authenticity and imitability of medicines, technologies such as **high security packaging, blockchain tracking and track and trace directives**, as used in the European Medicines Verification System (EMVS), can be standardized on a more international scale. In the instances of LMICs rampant with fraudulent medicines due to poor surveillance and regulation, an i**nternational trust** fund can be established to provide a source of funding dedicated solely to the **improvement of regulatory systems** in LMICs.

Another step in addressing this issue would be to target the demographic that is most at risk by the trade of fraudulent medicines: consumers. The only way to ensure customer awareness on the issue of is to **raise public awareness** on fraudulent medicines. This can be done by starting **public and digital campaigns** in member states to **educate the public** on the dangers of fraudulent medicines, guidelines on how to identify and avoid them, and to report to authorities if fraudulent medicines are found. To make methods on identifying the authenticity of medicines more accessible to consumers, **handheld composition scanner devices**, such as the one develop RxAll, to be more **readily available to consumers and pharmacies**. These devices could also be paired with a **public digital database** containing the data on the correct composition of the medications.

Through the combined implementation of solutions addressing multiple perspectives, demand for counterfeit drugs would decrease, manufacturers would be sapped of financial gain, fraudulent medicines would be prevented from entering the market, and consumers would be more aware of the risks of the issue. With these measures implemented, the proliferation of fraudulent medicines could be significantly reduced and future measures to eliminate counterfeiting could be more easily implemented.



Caption #7 The product flow map used by the European Medicines Verification System (EMVS)

Questions A Resolution Must Answer

1. How can global supply chains be regulated and monitored to prevent the circulation of fraudulent medicines?
2. What system will be used to set apart genuine and counterfeit medicines?
3. How will awareness on the risks of fraudulent medicines be raised?
4. What will be done to re enforce constant international coordination on addressing the issue?
5. How will regulation and supervision of pharmaceutical products be improved in LMICs?
6. What can be done to prevent the economic losses of manufacturers, industries, and nations?
7. How would a criminal justice system for perpetrators charged for counterfeit crimes established in all member states?
8. How will unauthorized pharmacy websites be regulated online and how will legal pharmacy websites be secured?

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