Introduction

The consumption of counterfeit medicines have been detrimental to public health in both developed and undeveloped countries. The manufacturing, distribution, and consumption of counterfeit medicines have resulted in deadly outcomes. While the issue is more widespread in countries whose regulating bodies are weaker, the lethal effects of the consumption of unregistered drugs also reach the developing world in areas such as the US and UK.

The overall rise in popularity of prescription drugs and certain market’s inability to gain access to these drugs has given way for a flood of counterfeit medicine businesses to flourish. While factors allowing for this illegal trade vary nation by nation, the most common factors are: lack of proper legislation, weak penal sanctions, weak or non-existent drug regulators, weak enforcement of drug laws, shortage in supply of drugs, poor control of drug export, and corruption.

The World Health Organization has reports of falsified products from all main therapeutic categories including medicines, vaccines and in-vitro diagnostics. The WHO also reports one out of ten drugs in undeveloped economies are not authentic. The total sales of counterfeit medicines have reached above $75 billion in 2010 which was a 90% increase from 2005. The World Customs Organization has released that 140 countries have been influenced by counterfeit products. This means that 140 countries are either involved in the production or consumption of illegal drugs resulting in over thirty billion USD being spent on counterfeit drugs.

The manufacturing and distribution of counterfeit drugs is unethical and immoral. It is critical to the health of our future generations that the people and markets facilitating the success of this deadly industry must be targeted and eradicated. As causes vary depending on markets, geography, and governments, the necessary solutions also must adapt to specific situations. A holistic approach
including cross governmental and organizational cooperation is necessary to target and eliminate one hundred percent of all facilitators in this deadly industry.

**Definition of Key Terms**

**Trafficking**

The act of dealing or trading in something illegal. It can involve one of numerous illegal trades including illegal drugs, sex slaves, or weapons. Trafficking is most commonly referred to when speaking about human trafficking, the trade of humans for the purpose of forced labour, sexual slavery, or commercial sexual exploitation for the trafficker or others but also applies to the trade of counterfeit drugs.

**Substandard**

Medical products that fail to meet either quality standards or specifications. These medical products are authorized and therefore accessible to doctors and patients while not having any real potency. Substandard medical products lead to patients not getting the treatment they need and can end lethally.

**Unregistered/unlicensed**

Medical products are required to go through the approval of National or Regional Regulatory Authorities to be able to be purchased by consumers. Unregistered or unlicensed medical products are those that have not been evaluated or approved for the markets in which they are being distributed in

**Counterfeit Medicines**

By which the counterfeiter creates confusion between the original product and the counterfeit product at the expense of the party who owns the intellectual property rights. Counterfeit medicines entail any substance or compound presented to having curative or preventive properties. The term counterfeit medicines applies to falsified medication of all animals in addition to humans.

**Pharma Fraud**

A term used in the description of several illegal activities including the manufacturing, marketing, and distribution of pharmaceuticals. Pharma fraud has escalated to a multi-million

dollar industry where illegal drug manufacturers are able to exploit a part of the consumer market into buying their illegal drugs that generally do not have the proper ingredients.

**Antimicrobial Resistance**

AMR is when a microorganism like bacteria, viruses, and some parasites, try to stop an antimicrobial such as antibiotics, and antivirals antimalarials from working against it. As a result, standard treatments become ineffective, infections persist and may spread to others.

**Active Ingredients**

An active ingredient is the ingredient in a pharmaceutical drug or a pesticide that is biologically active. Similar terms active pharmaceutical ingredient and bulk active are also used in medicine and the term substance may be used for natural products.

**Background Information**

The need for proper medication worldwide has not decreased. In particular, underdeveloped regions in Africa and Asia, are in dire need of vaccinations and antibiotics to combat wide-spread disease. Economic insecurity and lack of better options has led to the rise of counterfeit, substandard, or falsified drugs. Such drugs are typically produced in manufacturing facilities in China or India where there is a major lack of regulation in drug production. The drugs are illegally imported generally into areas of Africa and other underdeveloped regions and make their way into unregulated street markets or on the online illegal drug market. Consumers of these counterfeit drugs are generally victims of economic insecurity and ignorance. If an individual cannot afford the real drugs at a proper pharmacy, he or she will turn to the illegal street or online market where they can unknowingly purchase falsified or counterfeit drugs and suffer the consequences.

The World Health Organization has stated that ten percent of medical products circulating in low and middle income countries is either substandard or falsified. The purchase and consumption of such drugs has led to tragedies such as in Pakistan in 2011; where 200 people died after taking a contaminated heart medication. Or when over a thousand people were hospitalized in the Democratic Republic of Congo after taking a falsified drug in 2014-2015. The WHO estimates that at least 72, 000 children die of pneumonia and 69, 000 people die of malaria each year as a result of falsified or substandard treatment. Additionally, these drugs have contributed to the global problem of bacterial resistance.
The manufacturing of these fake drugs, while being extremely illegal and immoral, has been an extremely profitable business for people in underdeveloped markets with poor economic alternatives. A 2003 World Health Organization estimate of total annual earnings from substandard drugs reached over USD 32 billion. Counterfeit drug businesses thrive during times of drug shortages. During a meningitis outbreak in 2015, pharmacies in Niger unknowingly bought expired vaccines from wholesalers. The crisis also affects the developing world. When several US insurance companies stopped their coverage of specific cancer medications, a Canadian website took hold of demand with fake versions. Michael Deats, a WHO expert on medicine safety and vigilance states that, “if there is insufficient product on the market, within days, the vacuum is filled with falsified versions.” Location does not matter as is its just as risky to purchase medication from a street market in Africa as buying from an unregulated website in North America.

Cultural stigmas are also causes that widen the entrance of counterfeit drugs. Weight loss, erectile dysfunction, and addiction are examples of conditions that patients would be ashamed to see a physician for. Instead of going to a professional, patients go directly to the illegal market to purchase the fake product. For these reasons, counterfeit drug production is a global problem that while being more pronounced in underdeveloped regions, impact the developed world as well. The various bodies involved in the fight against counterfeit drug production include but are not limited to the International Institute of Research Against Counterfeit Medicines, The World Customs Organization, Interpol, European Commission, The World Health Organization, and the International Federation of Pharmaceutical Manufacturers and Associations.

**Major Countries and Organizations Involved**

**Sub-Saharan Africa**

There are tens of thousands of deaths in Africa reported each year due to the consumption of fake and counterfeit medication. African consumers without the means to pay for medication in pharmacies turn to unregulated street vendors that are less expensive. The selling of these counterfeit drugs, typically originating from China or India, have resulted in the hospitalization of thousands of individuals. The World Health Organization reported that between 2013 and 2017 almost half of the fake and low-quality medicines reported were found in sub-Saharan Africa. Fake antimalarial medications have caused the deaths of between 64,000 and 158,000 people per year in sub-Saharan Africa. Africa as a continent is arguably the most in need for proper vaccinations, antibiotics, and other vital medications. Uneducated consumers are being exploited by drug trafficking in their most vulnerable moments.

**India**
Around a quarter of India’s total drugs are fake, counterfeit or substandard. The main causes of the trade of the counterfeit drugs include lack of sufficient regulation, shortage of drug inspectors, and shortage of lab facilities to check purity of drugs. Other facilitators in the billion dollar market include storage of spurious drugs by chemists, poor medication distribution systems, and lastly the awareness among consumers and weak enforcement of the law. In general, India has a larger problem with substandard drugs rather than outright fake or counterfeit products. According to Outsourcing Pharma in 2012, 75% of counterfeit drugs supplied worldwide had some origins in India.

Interpol

The International Crime Police Organization has lead several operations with the goal to target illegal drug trafficking and eradicate the market worldwide. Operation Pangea is the Interpol’s most recent project which targeted the online sale of counterfeit and illicit medicines and medical devices. Operation Pangea was Interpol’s largest operation. In addition to removing illegal pharmaceutical products from circulation, Operation Pangea raises awareness of the risks in buying medicines from unregulated websites. Over the past decade, accumulating from the participation of 8 countries in its launch in 2008 to 123 in 2017. In 2018 Operation Pangea recorded the seizure of 10 million units valued at USD 14 million, making 859 arrests and 3,671 websites being taken down. Other Interpol operations in the past targeting the sale of counterfeit and illicit medicines include Operation Rainfall, Qanoon, and Heera.

China

China has a worldwide reputation for producing counterfeit goods. The production of counterfeit drugs in China has led to the fatal deaths of thousands of innocent people. The lack of regulation has allowed for counterfeit drug manufacturers to be able to operate. Thousands of these counterfeit drugs from China find their way to the African Continent where there is a large market of people without access. Along with India, 97% of fraudulent pharmaceutical products are from China. Counterfeit Drugs from China commonly are stuffed with chalk, flour, pollen, and other non-effective ingredients that patients desperately need. The manufacturing of counterfeit drugs in China is also being distributed in Chinese street markets and online stores where. The China Food and Drug Administration has released a draft regulation to ban online drugstores from selling prescription medicines as well as drugs that have reported quality problems.

World Health Organization
The WHO is an agency within the United Nations that is primarily focused on the status and improvement of international public health. WHO effort in fighting falsified and substandard medical products include the launching of the Global Surveillance and Monitoring System which helped develop a more accurate and effective problem assessment by encouraging countries to report incidents. Beginning in November 2017 the WHO has issued over 20 global medical product alers and numerous regional warnings, while providing technical support in over 100 cases. A global network of over 550 regulatory staff in 141 Member States has been trained by the WHO to report substandard medical products. WHO has worked in conjunction with Interpol to seize and arrest counterfeit traffickers. In their success accounted for 20 million pills, bottles and sachets of counterfeit medicines were seized in a five month operation in 2009 spanning over China and several other south-east Asian countries.

International Institute of Research Against Counterfeit Medicines

The IRACM was created in 2010 in response to the surge of counterfeiting of pharmaceuticals. the IRACM is the sole existent international organization independently focused to combat the presence of counterfeit and falsified drugs, primarily through information, prevention and training. Actions taken by the IRACM are considered complementary to other enforcement agencies such as Interpol and The WHO. The IRACM is a French organization established by the 1901 ACT.

Pakistan, United States of America (USA), United Kingdom (UK), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), World Customs Organization

Timeline of Events

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<th>Date</th>
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<tr>
<td>1848</td>
<td>The US Congress passed legislation on medication imports to strengthen control through customs control.</td>
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<td>1985</td>
<td>The Nairobi conference brings the issue of counterfeit drugs to the international eye.</td>
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<td>1992</td>
<td>The first official definition of counterfeit medication is produced as a result of an international meeting Geneva.</td>
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<td>2006</td>
<td>The World Health Organization creates the Rome Conference where the counterfeiting of medicines were officially recognized as a serious and vile criminal offense that is detrimental to the lives of the public and undermines the</td>
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50 heads of States sign an appeal to pronounce their fight against counterfeit medicines, led by Jacques Chirac in Cotonou, Benin.

The World Health Organization held their 63rd meeting where they focused on substandard or counterfeit medical products.

The Resolution to fight against the production and marketing of fake drugs was adopted in the 92nd session of the Council of Ministers of the African, Caribbean and Pacific group.

The resolution AG-2010-RES-06 was adopted by Interpol for improved international cooperation and calls on member states to prioritize the fight against medicine counterfeiting.

Inaugurated the 20th session of the United Nations Commission on Crime Prevention and Criminal Justice. Adoption of 20/6 which defined the role of the UN Office on Drugs and Crime.

The Medicrime convention gets adopted by the Council of Europe, the first international legal tool to properly combat pharmaceutical crime.

The European Parliament validated directive 2011/62/EU which strengthened the instruments to combat counterfeiting through securing pharmaceutical distribution channels specifically on the internet. The directive created logo o distinguish legal pharmacy websites and product’s traceability while strengthening repression for offenders.
111 countries shuts down 10,600 illegal websites, seized 20,000 packages and arrested 239 offenders because of Pangea VII.

Relevant UN Treaties and Events

- Countering fraudulent medicines, in particular their trafficking, 14-15 February 2013 (A/RES/20/6)
  
  Urges Member States and international institutions to strengthen measures and mechanisms to prevent trafficking fraudulent medicines.

- Follow-up on strengthening the systems of control over chemical precursors and preventing their diversion and trafficking, 20 December 2004 (A/RES/59/162)
  
  Urges all Member States to place systems and procedures to aid in the information sharing of international trafficking to help identify such activity in the future.

- Strengthening international cooperation and comprehensive regulatory and institutional frameworks for the control of precursors used in the illicit manufacture of narcotic drugs and psychotropic substances, 2019 (A/RES/62/1)
  
  Confirms to Member States that they bear the expenses of the counter counterfeit drug operations and organization to continue contributing to the efforts of the International Narcotics Control Board.

- Advancing effective and innovative approaches, through national, regional and international action, to address the multifaceted challenges posed by the non-medical use of synthetic drugs, particularly synthetic opioids, 14-15 March 2019 (A/RES/62/4)
  
  Highlighting the negative impacts of fake drugs, synthetic opioids in particular, The Commission on Narcotic Drugs encourages international cooperation stressing the grave concern toward public health and welfare and law enforcement.

- Developing an international electronic import and export authorization system for licit trade in narcotic drugs and psychotropic substances, 16 March 2012 (A/RES/55/6)
  
  The Commission on Narcotic Drugs encourage the technological advancement in the law enforcement to crack down on the illegal industry. In particular, to develop and utilize national systems for issuing import and export authorizations electronically.

Previous Attempts to solve the Issue

Interpol’s Operation Pangea
Launched in 2008, Pangea is an Interpol operation that is focused on disrupting the online counterfeit drug market. Secondly, Pangea functions to raise awareness of the risks associated with the consumption of drugs from unregulated websites. They have successfully removed more than 105 million units of pills, shut down 82,000 websites, and have made over 3,000 arrests. The success of the operation has led to organized criminal groups taking increasingly complex measures to avoid detection such as using complicated shipping routes, or concealing illicit medicines with sophisticated packaging.

**Interpol's Operation Qanoon**

Operations Qanoon is an Interpol multi-year project focused on illicit medicines specifically in the Middle East and North Africa region. The operation is positioned to collect and share data to identify transnational issues, support investigations, and dismantle criminal networks. In 2018, Qanoon had successfully seized 1.4 million units at an estimated value of USD 1.4 million dollars as well as identifying 39 suspects.

**Possible Solutions**

In order to strengthen the grip on the manufacturing and distribution of counterfeit medication around the globe several actions must be taken by cross governmental and national regulatory bodies. Organizations such as Interpol, who have sufficient resources at their disposable must focus on the crackdown of illegal trafficking as well as the proper education of its consequences. More importantly, it is vital to educate the developing world, such as regions in Africa, the perils of buying from unregulated markets. The developed world is fortunate enough to have the resources to prioritize the eradication of the counterfeit market industry. Affluent markets must aggressively apply themselves towards the issue so that developing communities will follow in their footsteps to result in the holistic prevention of this terrible business.

An international pharmaceutical cooperation to enforce a sticker of authenticity such as found in currency to identify fraudulent products would make it easy to distinguish fake from authentic medications. Campaigns funded by the UN could be run through television and billboards to educate the public of the sticker of authenticity and portray the dangers of buying drugs that do not contain it. The awareness of consumers to not buy counterfeit drugs would extremely cripple the profitability of the illegal drug manufacturing and deeming it an unattractive market to invest in.

Additionally, the governments in India and China must prioritize the crackdown of illegal manufacturing and online distribution of counterfeit medicines. International penalties should be applied if these governments cannot finally put a stop to manufacturing of counterfeit medicines. It is the duty of
these federal governments to uphold a standard for products containing their country of origin. The history of counterfeit medications coming out of these countries has negatively impacted the integrity of those country’s products. If these countries would like to protect their industries, they need to invest in the crack down on the illegal activities or suffer the consequences.

Bibliography


