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ELIMINATING THE SPREAD OF COUNTERFEIT DRUGS

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INTRODUCTION

In the current times of massive progress in the field of medicine, new drugs for various diseases are made available for consumers globally each year. And more of them are sold to consumers each year, as their price decreases and the market size increases. However, according to the World Health Organization (WHO), 10% of all drugs available in low and middle-income countries are substandard or falsified, with some regions reaching a staggering 30% or more. The main misconception about this problem seems to be that it only affects poor regions of the world. But this could not be further from the truth, as the amount of counterfeit drugs is on the rise in every region of the world and is becoming a massive problem for the medical industry (i.e. pharmacies and pharmaceutical companies). The spread of these counterfeit drugs actively undermines the effort of the United Nations in reaching the third Sustainable Development Goal of Good Health and Well-Being.

In today's globalised world, the pharmaceutical market is growing in complexity and this complexity leads to error. There is a growing number of pharmacies in the world, which the pharmaceutical companies have to provide with medicines. But the complicated routes and the increasing use of the Internet makes it easier for counterfeiters to infiltrate this market and supply pharmacies and other vendors with their own falsified or substandard goods. This aids the dealers of counterfeit drugs in their business and so does the rapidly growing use of e-commerce. E-commerce allows vendors to sell drugs over unofficial websites to larger masses of people with a larger demand for pharmaceuticals than ever before. The World Health Organization (WHO) estimates, that around 1 million people die each year due to substandard and falsified drugs, with counterfeit malaria and tuberculosis drugs being the biggest killer.

The combined profits of the sale of counterfeit drugs are estimated to be somewhere between 150 to 200 billion Euros per year, and this number is expected to only increase. The solution of this problem requires the cooperation of all member states, as this issue by its definition involves multiple nations in the production, distribution and marketing of falsified drugs, in all regions of the world.

DEFINITION OF KEY TERMS

Substandard drugs

Genuine medicines produced by manufacturers authorised by the NMRA (national medicines regulatory authority) which do not meet quality specifications set for them by national standards

Unregistered/unlicensed drugs

Drugs that have not undergone the evaluation of the NMRA (national medicines regulatory authority) for the market they are being distributed or used in.

Falsified medicines

Fraudulent medicines disguised as authentic medicine, but may contain ingredients of bad or toxic quality, or in the wrong dosage.

E-commerce

The activity of buying and/or selling goods over online services or the internet.

Generics

Copies of brand-name drugs, identical in terms of dosage, intended use, effects, side effects, route of administration, risks, safety and strength as the original brand-name drug.

Counterfeit

To make something in an exact imitation of something valuable with the intention to deceive or defraud; or a product made in such manner.

GENERAL OVERVIEW

Historical Background

Counterfeiting genuine products is a problem we all face during our day-to-day lives. For centuries, products ranging from clothes, money or even foodstuff have been counterfeited and falsified. These products are increasingly affecting the economy and the companies the products of which are being counterfeited. With time, these products got closer and closer to completely replicating the original product. The hotspots for the manufacturing of counterfeit products are to be found in Asia, and counterfeit medicine is no different. The difference when it comes to counterfeiting drugs, though, is the direct risk it poses to the health of the individuals that consume it.

The issue of counterfeit medicine did not majorly affect the pharmaceuticals market and risk of peoples' lives until globalisation and the use of the Internet to sell products became so prominent. Now, these drugs are very easily introduced into the market with pharmaceuticals and make up around 50% of the stock in unauthorised internet pharmacies. With the spread of the free market all across the globe, the costs of producing as well as buying these products when compared to their genuine counterparts has decreased dramatically, resulting in a boom in sales of these falsified or substandard medicines.

Statistics And Estimates

- According to the WHO, the sales of counterfeit medicines reached \$75 billion in 2010, and increase of 90% since 2005.
- At least 140 countries are affected by these counterfeit products, according to the WCO.
- Antimalarials and antibiotics are the most popular to counterfeit.
- Since 2013, the WHO has received over 1500 reports of fake or low-quality medicines, with the sub-Saharan region in Africa accounting for around 42% of these reports.
- Around 50% of medicines sold by internet pharmacies that hide their physical location are estimated to be fraudulent.

Current Situation And The Problem

Nowadays, our globalised world and liberalised trade routes as well as the use of the internet to sell falsified products contribute to the problem, as it is simpler than ever to produce and sell the substandard and falsified drugs globally. The use of unregulated e-commerce has largely impacted the problem, by offering the criminal organisations a way to conceal their identity, location and actively advertise their products through spam emails or paid promotions. Street vendors are also used to sell counterfeited medicines, but this occurs mainly in less economically developed countries (LEDCs), but they do impact more economically developed countries (MEDCs) through tourism. People travelling from MEDCs to LEDCs tend to buy medicines there, because of the difference in price and take these medicines back home with them regardless of laws regarding these products. These people have a high chance of taking back substandard and falsified medicines with them, exposing themselves, their families and friends to these fraudulent products or even selling them for a low price.

Unlike many other problems our world faces, this is not unique to any region or country and affects all regions. These products are being manufactured in many different countries around the globe and supplied to other using different methods, with the e-commerce being the

most prominent. Criminals that manufacture these pharmaceuticals use inexpensive ingredients, with some fraudulent medical products containing different doses of active ingredients from the original and different products not containing any active ingredients at all. These products commonly contain corn starch, potato starch and chalk, to mimic the appearance of the original product – that is the main goal of the manufacturers. The medical products can also contain completely different active ingredients, sometimes in fatal doses as well as toxic ingredients. They are commonly produced in low-income countries in unhygienic and very poor conditions, adding to the harmfulness of the drug produced.

These fraudulent drugs are very difficult to detect, because the main focus of the criminal individuals and organisations is to mimic the appearance of the drug they are counterfeiting. They are perfectly manufactured to appear identical to the genuine drugs in question, but do not treat the conditions that the original drug is purposely intended for and can lead to fatal side effects.

Also, a change of trend recently occurred in the counterfeit drug industry, which changed their focus on different kinds of drugs. Before, the criminals focused on counterfeiting “lifestyle drugs” these drugs treat conditions such as erectile dysfunction, baldness etc. But recently, their focus shifted onto “life-saving drugs”, which treat conditions such as HIV/AIDS, tuberculosis, malaria, etc.

Consequences

- As the demand for drugs increases with the growing population of the world, the sales of the counterfeit drugs increase each year, allowing large scale manufacturing and selling, threatening the lives of people all over the world;
- The death toll (direct and indirect) as a result of taking counterfeit medicines is in the hundreds of thousands due to fraudulent antimalarials alone, with Africa being main region affected;

- This business is very lucrative for the sellers and manufacturers. As a result, it is becoming more popular every year, thus more counterfeit drugs enter the market every year, resulting in bigger sales each year.

MAJOR PARTIES INVOLVED

Africa

Africa has been the most affected by the spread of counterfeit drugs. Malaria was a large problem for healthcare even without counterfeit drugs being as prominent as they are today, mainly because of the cost of the medication needed for treatment, but with the spread of counterfeit drugs, many people do not seek further medical attention, as they believe the illegitimate drugs will cure them. However, these drugs do not aid the patients at all, sometimes even making their condition severely worse. But because of the high cost of legitimate drugs, economically disadvantaged individuals often turn towards street markets, where the sale of counterfeit drugs is most prominent. On top of this, the poor conditions of the African healthcare system sometimes causes genuine drugs becoming substandard, mainly because of their storage, also endangering the patient's life. The Food and Drugs Authority of African nations is on high alert and is periodically sending its staff to markets and pharmacies to check the authenticity of drugs. As well as that, the Ghanaian company, mPedigree, developed a mobile application, which allows people to scan the codes on the packets of drugs and find out if it is fake or original.

Eastern Europe

Post-soviet states in Eastern Europe have an extremely high number of counterfeit drugs circulating in them. The states present in this region are largely technologically developed, but aren't as economically developed as the states of Western Europe, which means that they are easily reached by unauthorised Internet pharmacies, leaving them vulnerable to their

advertisement. The combination of less economic development and higher technological development led to the fact that around 20% of drugs in some countries in the East are fraudulent. The states in this region are introducing stricter penalties for convicted dealers and smugglers of fake medicines. However, clear laws on the matter haven't yet been introduced, but are being discussed with the country representatives, law enforcement officials and the European Union.

Asia

It is suspected that most of the counterfeit drugs produced are made in Asia and then traded globally. These operations evolved from "basement operations" in ordinary households into full scale industrial operations. These counterfeit drugs were first bought from street contacts and unlicensed street vendors, but then entered the legitimate medicine flow and went into sale in licensed pharmacies and traded globally. The countries are not able to agree as to what legally constitutes a fake medicine, making this region being among the most affected and the hotspot for production. Since the 1990s, the ASEAN Pharmaceutical Product Working Group has been working on technical procedures and quality requirements to prevent the spread of fake drugs.

Latin America

The countries of Latin America are some of the most severely affected, with an estimated one in four drugs being fraudulent in Venezuela and a similar number in Argentina and Colombia. Latin American countries are introducing anti-counterfeiting laws and initiating crackdowns on counterfeiters and sellers.

United States of America

Although the issue of counterfeit drugs is most prevalent in less developed countries, the United States are riddled with black markets selling counterfeit drugs. These markets have the potential of rapidly spreading and affecting more and more people. There have already been many cases where fraudulent Botox has been used on patients by licensed doctors and the number of counterfeit drugs is on the rise in the USA as well as Canada. The USA is informing its citizens about the problem of counterfeit drugs through multiple mediums and the FDA is launching countless investigations into the spread and origin of these medications and the routes they take inside of the United States. However, it is difficult to persecute foreign suppliers. The USA is working towards securing its drug supply chain and implementing regulations to prevent the spread of the problem.

World Health Organization

The World Health Organization has taken steps to identify fraudulent drugs and has set up a system which monitors medicines in 141 countries in the world, offering quick responses to any threat, aiding all countries in identifying and dealing with the problem at hand.

TIMELINE OF KEY EVENTS

- **July 2013** – WHO launches the Global Surveillance and Monitoring System on medical products.
- **24th May 2018** – side event during 71st World Health Assembly on “Combatting the Challenges of Substandard and Falsified Medical Products: the Critical Role of Regulators”

- **26th September 2018** – United Nations General Assembly (73rd session) High Level Side Event “The fight for quality medicines in Africa – stopping falsified, substandard medicines”.

PREVIOUS ATTEMPTS TO SOLVE THE ISSUE

The World Health Organization (WHO) set up a Global Surveillance and Monitoring System on medical products, which is in effect in 141 countries in the world. With this system the WHO monitors drugs in different markets around the world and adds them to their database. They use this database to compare drugs found in other regions, possibly uncovering a trade path and saving lives by being able to quickly respond to alerts of counterfeit drugs in different areas – response time of 72 hours. Thanks to their database, they were able to uncover a fake drug in Paraguay, which contained the same ingredient as a drug found months earlier, when it killed 60 adults in Pakistan, saving several children. Along with this, several side events were held during assemblies of UN bodies, notably the 71st World Health Assembly and the 73rd session of the United Nations General Assembly (UNGA), where the problem was discussed with the support of the African Union.

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