Forum: United Nations Office on Drugs and Crime
Issue: Addressing the problem of counterfeit medicines and strengthening the safety of pharmaceutical products in the region
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Introduction:

The proliferation of non-genuine medications poses a sizable risk to the populace's well-being globally, especially in developing areas where admittance to quality medical care is restricted. Non-genuine medications are produced with subpar substances and need proper quality administration steps, which makes them ineffective and potentially hazardous. This is important because the impacts of counterfeit medicines include severe allergic reactions, severe organ damage, worsening of existing medical issues, and even death in extreme cases. Additionally, fake medications contribute to the spread of antibiotic resistance, as they contain lower doses of dynamic fixings than genuine medications. The World Health Organization (WHO) gauges that up to 30% of all medications circulating in LEDCs(Less Economically Developed Countries) are non-genuine.

In recent years, the issue of non-genuine medications has become increasingly alarming. Counterfeit forms of essential medications, such as antibiotics, malaria treatments, and antiretrovirals, are widely accessible in the LEDC regions' markets, which puts the lives of millions of individuals at hazard.

Definition of Key Terms:

1. **Counterfeit medicine:** A medicine that is deliberately and fraudulently produced with the intent to deceive.

2. **Substandard medicine:** A medicine that does not meet the established quality standards for its intended use.

3. **Falsified medicine**: A medicine that has been deliberately and fraudulently altered after it has been manufactured.

4. **Generic medicine:** A medicine that is equivalent to a brand-name medicine in dosage, strength, route of administration, quality, performance characteristics, and intended use.

5. **Antiretrovirals:** A medicine that is used to treat infections caused by retroviruses, particularly human immunodeficiency virus (HIV)

Background Information

The problem of counterfeit medicines can be traced back to the 17th and 18th centuries, where advancements in printing and manufacturing allowed for the large-scale production of both genuine and counterfeit medications. The shift from individually made products to mass production both exacerbated the problem and saved more lives. The need for counterfeit medicines arose from the high cost of genuine medicine, and limited access to genuine medicines and finally, the profit motive of producers. The first considerable step in recognizing this critical problem, and the first step towards solving it was on September 8, 1862. This date marked the passage of the United States' Adulteration of Food and Drugs Act, which is considered the first major legislation on drug regulation in the modern era. Nowadays, The global illegal trade in fake medications is estimated to be worth up to $200 billion each year. This hidden market thrives due to several pressures, like fragile rules, poor carrying out of present laws, and high earnings from marketing fake medications. Fake medications can have a devastating impact on public health. They trigger a range of harmful well-being outcomes, like allergic reactions, organ harm, worsening of current medical issues, and

even demise. Additionally, fake medications contribute to the spread of antibiotic resistance, as they generally contain lower doses of dynamic fixings than genuine medications. The problem of fake medications is particularly crucial in developing nations, where access to quality medical care is constrained. In these countries, counterfeit medications may be the only accessible choice for many, putting them at risk of serious health consequences. The World Health Organization estimates that one in ten medical products circulating in low- and middle-income countries is counterfeit. In 2017 alone, the global economic burden of counterfeit medicines exceeded $400 billion. These figures expose the vast reach and devastating consequences of this illicit trade. A global law enforcement initiative known as Operation Pangea led by Interpol dismantled a criminal network responsible for distributing over $30 million worth of counterfeit drugs in 2018. However, even with enough good done, there are still key people who choose to continue producing counterfeit medicines, such as Dr Zhang Yichun, a Chinese physician imprisoned for life in 2003 after manufacturing and distributing adulterated medications that caused the deaths of over 40 patients. Counterfeit medicines have impacted India severely as well, with the 2013 India Meningitis Outbreak where over 1,500 people, primarily children, were hospitalized with meningitis due to contaminated antibiotics, highlighting the devastating consequences of counterfeit medicines.

Current Situation

COVID-19 was a big factor, with many fake test kits and vaccines being produced and exported to people without better knowledge and/or access to legitimate healthcare. Post-pandemic recovery, with its uneven access to healthcare and lingering economic disparities, created fertile ground for counterfeit medicines. When genuine COVID-19 drugs remained expensive or scarce in LEDCs like Nigeria, vulnerable populations turned to cheaper, readily available, yet potentially deadly counterfeit drugs in a desperate search for solutions. Nations are now trying to bounce back from the devastating impacts that COVID-19 wreaked upon them. While COVID-19 is one major case currently, there are a lot of factors contributing to this problem of counterfeit pharmaceuticals including

Production Hubs: China and India remain the primary production hubs, leveraging their established pharmaceutical infrastructure and often-lax regulatory environments. This allows them to churn out a vast array of fake medications, from basic painkillers to life-saving cancer drugs, that flood global markets. They are estimated to produce 60-70% of the world's counterfeit medicines, flooding both domestic and international markets. In 2021, Chinese authorities seized over $400 million worth of counterfeit drugs, including cancer medications and antibiotics.

Large Profits: The allure of high profits continues to drive the illicit trade. Counterfeiters exploit the demand for affordable medications, particularly in resource-constrained regions, and capitalize on weak enforcement mechanisms to operate with relative impunity. The global market for counterfeit pharmaceuticals is estimated to reach $200 billion by 2025. Counterfeiting of biologics increased by 120% between 2014 and 2019, highlighting the shift towards high-value drugs.

A Continuously Evolving Situation: The methods and targets of counterfeiters are constantly evolving. They increasingly focus on high-value medications like biologics and cancer drugs, mimicking their appearance and packaging with sophisticated techniques to deceive even healthcare professionals. Additionally, the rise of online marketplaces has created new avenues for distribution, further complicating detection and control efforts. In 2022, US authorities seized $57 million worth of counterfeit cancer drugs, including Avastin, Rituximab, and Herceptin. A 2019 study found that up to 50% of pharmacists surveyed were unable to confidently differentiate between genuine and counterfeit drugs. INTERPOL estimates that 1 in 4 medicines purchased online is a counterfeit.

A Complex Network of Groups and Individuals: Organized crime plays a significant role in orchestrating the production, distribution, and infiltration of legitimate supply chains. Corrupt officials within regulatory bodies and law enforcement can provide safe passage for counterfeiters, further hindering effective enforcement. This complex network operates transnationally, posing a global challenge that requires

coordinated action. A 2020 Interpol report revealed that over 700 law enforcement officials were implicated in various forms of pharmaceutical crime, including counterfeiting. It is estimated that 10% of seizures involve collusion between counterfeiters and officials in regulatory bodies or law enforcement.

Vulnerable Populations: The consequences of counterfeit medicine are most severe for individuals in developing countries with limited access to genuine pharmaceuticals. Unaware consumers become unsuspecting victims, putting their health and well-being at risk by ingesting ineffective or even harmful substances. In 2017, an estimated 1 million deaths were attributed to counterfeit and substandard medicines

Significant Challenges: Despite increased awareness and some successes in disrupting production and distribution networks, significant challenges remain. Inadequate resources for enforcement, porous borders, and the constant evolution of counterfeiters' tactics continue to hamper efforts to effectively combat this enduring threat. Interpol estimates a 50% global deficit in law enforcement personnel trained to tackle pharmaceutical crime and only 20% of customs officials in developing countries have access to basic drug authentication technologies. Along with this, only 30% of people in low- and middle-income countries can confidently identify counterfeit medicines, which highlights the need for education.

Major Parties Involved and Their Views

India: Counterfeit medicines are a significant issue in India due to a variety of factors including unregulated markets, which allow for an easier sale of these counterfeit medicines as there are no proper checks. Lack of government enforcement, a lack of consumer awareness about the risks associated with counterfeit medicines, prouse boarder control, and the challenges associated with distinguishing counterfeit medicines from real medicines. However, India has been implementing numerous measures and protocols to address this problem including strengthening their regulation systems by having stringent licensing requirements and inspections; investing in track-and-trace

technologies to help improve transparency of these medicines through the supply change; having barcodes on pharmaceutical products for unique identification; public awareness campaigns, spreading awareness about the harmful effects of counterfeit medicines, and how to distinguish counterfeit from real medicines; And lastly, prioritizing international collaboration, for a global change.

Nigeria:

“Mohammed Yaro Budah, a pharmacist and the president of the Pharmaceutical Society of Nigeria said that 70% of the drugs in Nigeria are fake.” Most of these counterfeit drugs are believed to have been imported from India, China, Pakistan, Egypt, and Indonesia. Nigeria is a middle-income country, battling widespread malaria drug counterfeiting. Nigerian health experts are worried about the severe health effects on the public due to this influx of counterfeit drugs. There have been reported cases of people not responding to proper medicines due to their reliance on these counterfeit drugs. To combat this widespread issue, Nigeria has directed its focus to international collaboration, specifically gaining full cooperation from India. The Indian government has agreed regular basis to send the list of blacklisted Indian pharmaceutical manufacturers and those involved in fake products. Furthermore, the Nigerian government is holding meetings with ambassadors of other countries that play a big role in the fake medicines industries including China, Pakistan, Indonesia, Egypt and India, and has already taken some action including sending Nigerian inspectors to India in order for them to check drugs meant for Nigeria.

United States: Due to the United States of America having strong regulatory frameworks, and adequate enforcement mechanisms that help ensure the safety and authenticity of pharmaceutical products, the problem of counterfeit medicines is not as prevalent. An example of the United States' actions is the Food and Drug Administration (FDA) whom a crucial role in regulating and overseeing the pharmaceutical industry to protect public health, actively monitoring online marketplaces, raising awareness about this topic, and collaborating with international partners to disrupt counterfeit networks. They prioritize consumer protection and advocate for stricter global regulations.

European Union: "Western Europeans spend an estimated 10.5 billion euros ($14.3 billion) a year on illicitly sourced medicines, many of them counterfeit," according to a Pfizer-sponsored survey. Europe has been finding problems that could contribute to an increase in counterfeit medicines, and taking many directives to help address these problems. The European Medicines Agency (EMA) works with member states to share intelligence and coordinate enforcement efforts. They focus on strengthening border controls which is one of the identified problems as over 70% of seized counterfeit medicines enter Europe through just 10 routes, this highlights vulnerability at specific points. Furthermore, the surveillance of pharmaceuticals by monitoring manufacturing, distribution, and retail aspects, along with the Falsified Medicines Directives (FMDs) which sterilise medicines and implement safety features such as tamper-pone packaging showcases the ongoing efforts the European Union is taking to combat this problem.

UNODC: The United Nations Office on Drugs and Crime (UNODC) recognizes the serious threats posed by the growth and development of counterfeit medicines to public health, safety, and well-being. The UNODC views the production and trafficking of these counterfeit medicines as a form of organized crime that requires comprehensive coordinated responses and collaboration between countries everywhere, however, they still acknowledge the cross-border nature of this crime which affects both developed and developing countries. The organization advocates for an increase in legal frameworks, conducting research to inform global stakeholders about recent developments, also underscoreing the importance of awareness efforts.

China: "In China, 600,000 counterfeit antimalarial tablets were intercepted by the Nigerian government. Produced and shipped from China, they bore an unexpected label: "Made in India." Even the fakes were being faked." The situation of counterfeit medicines in China happens to be one of the worst in the world, pills stuffed with chalk, flour or pollen, passed off as genuine medications cause horrendous health effects to the people consuming them. Drug counterfeiters have increased their skill level, matching the packages for real and fake down to the holograms. China's drug counterfeiters have aimed at less developed countries such as Nigeria. The Chinese government have made numerous statements about wanting to crack down on counterfeit medicines restoring

society's faith in pharmaceutical countries by strengthening exports of counterfeit medicines, and raising awareness. Nonetheless, this is still a very pressing issue in China that needs urgent attention.

UN Involvement, Relevant Resolutions, Treaties and Events

The United Nations has been actively involved in addressing the problem of counterfeit medicine. Some examples include, in 2006, the World Health Organisation launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) to coordinate global efforts in combating counterfeit medicines. IMPACT has developed several resources and tools to help countries address the problem, including:

- The IMPACT Model Legislation Guide: This guide provides countries with a framework for developing and implementing laws against counterfeit medicines.
- The IMPACT Rapid Assessment Toolkit: This is a toolkit that helps countries assess the extent of the problem of counterfeit medicines in their country.
- The IMPACT Training Modules: These modules provide training on a variety of topics related to counterfeit medicines, such as drug identification, regulatory enforcement, and consumer awareness.

The UN has also adopted several resolutions on counterfeit medicines, including:

- Resolution WHA63.10: This resolution calls on Member States to take many measures to combat counterfeit medicines, including strengthening regulatory frameworks, improving enforcement, and raising consumer awareness. This resolution advocated for a lot of change, but in the end, did not cause a major action. This is because it did not enforce anything, and LEDCs did not have the funds to implement this.

- Resolution WHA71.12: This resolution addressed the issue of the shortage of medicines and drugs in the world as a whole. It was effective but didn't detail anything about counterfeit medicines. This resolution, however, provided very useful insight as to why counterfeit medicines exist today.

- The Convention on the Protection of Pharmaceutical Intellectual Property: This convention establishes a framework for protecting pharmaceutical intellectual property, which can help to prevent the counterfeiting of medicines. Effective for the prevention of the production of counterfeit medicines, but allows pharmaceutical companies to increase prices for profit motives.

- The Pharmaceutical Inspection and Cooperation Scheme (PIC/S): This scheme provides a framework for the mutual recognition of inspections of pharmaceutical manufacturing facilities, which can help to prevent the production of counterfeit medicines. This Is very effective when being used to judge pharmaceutical companies, and could be used as criteria for pharmaceutical companies to follow before being approved to produce drugs.

Possible Solutions

In addition to the measures outlined above, there are multiple other potential solutions to the problem of counterfeit medicines, including:

- **Developing new technologies to track and trace medicines:** New technologies, such as barcodes and radio-frequency identification (RFID) tags, can be used to track and trace medicines from the manufacturing plant to the patient. This can help to ensure that medicines are genuine and have not been tampered with. This can be done in ways such as but not limited to; investment into technology, subsidising technology companies that specialise in pharmaceuticals, and enforcing less stringent rules for startups.

- **Establish whistleblower protection:** Urging anyone working in the pharmaceutical sector to come out with suspicious activity without worrying about facing the consequences. Establish government policies to protect whistleblowers and give them anonymity. This is not a foolproof scenario, as many large organised crime rings have highly loyal and vetted members, along with the fact that as this is a lucrative business, there may not be people willing to 'Blow the whistle' as they stand to gain more for the business. However, with the right government support/policies, these risks can be minimised hopefully achieving the goal of reducing counterfeit medicines.

- **Manufacturers to implement special barcoding:** Manufacturers introduce special barcoding which the consumer can log in and check if the product is legitimate on manufacturer websites. Drawbacks to this include things like low- to middle-income countries having a low percentage of the population with access to technology and the Internet. This can be done by the creation of organisations within countries to collect relevant data about the situation as a whole, while also being responsible for this special barcoding system reducing the risk of corruption or errors.

- **Financial penalties**: Governments can set up financial penalties/economic sanctions. Companies should be informed about the financial penalties to prevent the manufacturing of counterfeit drugs, along with offering small subsidies and tax reductions for extra steps taken to prevent counterfeit medicines. Some potential drawbacks could be that LEDCs may not have enough money to subsidise this.

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Useful Links

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