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Counterfeit Pharmaceuticals as Organized Crime: A Threat to Public Health and Safety

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ABSTRACT

When we were children ago, our moms would usually rely on home drugs for fever, the flu, or similar remedies. These days, when someone reports having a headache or other comparable symptoms, we frequently recommend taking medicine, much like doctors do. Examples of recommended meds include paracetamol and Dolo 650. In accordance to the National Library of Medicine, diabetes prevalence is second highest in India. It is estimated that 124.9 million individuals in India would develop diabetes by 2025. The increased demand for pharmaceuticals opens up the potential of counterfeit drugs, one that could infiltrate syndicated crime in violation of consumer rights. The rise in the prevalence of e-medicines, on the flipside, is a further reason why there are more numbers cybercrimes. Intentional falsification and counterfeiting of pharmaceutical products are advocated by organized crime syndicates that profit greatly from these activities thereby endangering public health across the globe. Such illicit operations exploit regulatory gaps, poor enforcement and a heavy demand for cheaper medicines especially in low- or middle-income countries. Counterfeit pharmaceutical drugs which include mislabelled, low-quality, and unlicensed medication not only do not alleviate the claimed illnesses but also often lead to severe health problems or loss of lives.

Keywords: *Organized crime, Counterfeits Medicines, Public Health Concern's, E-Medicines.*

I. INTRODUCTION

Organized crime, due to extending far beyond the traditional criminal enterprises, presents an important risk to public health. The trafficking of counterfeit pharmaceuticals and illegal drugs are two of the most troubling concerns regarding organized crime that are out there, which are, in turn, directly linked to the health and well-being of populations across the globe. Counterfeit pharmaceuticals, generally produced in unregulated environments, can cause treatment failures, increased resistance to medications, and even death.² Also, the illegal drug trade does not only

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² Organised crime and the efforts to combat it: A concern for public health. Globalizationandhealth.Biomedcentral.com.

<https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-6-21>

cause addiction but also the spreading of infectious diseases and has been a burden to healthcare systems too. The worldwide spread of organized crime brings with it profound impacts that go beyond borders and as a result, such situations are hard to tackle.³ Across the world, criminal organizations abuse the vulnerabilities in regulatory settings, bribe officials, and online networks to sustain their business models at the expense of public health.⁴ The intersection of organized crime and public health means that the problem needs a thorough approach, including tough law enforcement, international collaboration, and the development of public health policy to reduce the negative impacts on public health.⁵ This paper will explore the impact of organized crime on public health from many different views, focusing on the smuggling of fake drugs and illegal substances. It will review the channels through which the activities hurt people and societies, and discuss options for overcoming these.

(A) Definition:

The meaning of counterfeit drugs varies largely from one country to another. There is no consensus on the definition of counterfeit drugs. As per the Black's law dictionary, counterfeit drugs are "drugs made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or right, with a view to deceive or defraud, and then marketing the copied or forged drug as the original".⁶

The World Health Organization (WHO) provides counterfeit drugs as "A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct or the wrong ingredients, without active ingredients, insufficient active ingredients or fake packaging."⁷

The United States definition by the Drug and Cosmetic Act is, "A drug which, or the containers or labelling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed,

³ Transnational Organized Crime: A Growing Threat to National and International Security. [Obamawhitehouse.Archives.gov. https://obamawhitehouse.archives.gov/administration/eop/nsc/transnational-crime/threat](https://obamawhitehouse.archives.gov/administration/eop/nsc/transnational-crime/threat)

⁴ Transnational organized crime: A threat to global public goods. [Sipri.org. https://www.sipri.org/commentary/topical-backgrounder/2022/transnational-organized-crime-threat-global-public-goods](https://www.sipri.org/commentary/topical-backgrounder/2022/transnational-organized-crime-threat-global-public-goods)

⁵ Drug trafficking. [Unodc.org. https://www.unodc.org/e4j/en/organized-crime/module-3/key-issues/drug-trafficking.html](https://www.unodc.org/e4j/en/organized-crime/module-3/key-issues/drug-trafficking.html)

⁶ WHO | General information on counterfeit medicines: World Health Organization; 2014 Available from: <http://www.who.int/medicines/services/counterfeit/overview/en/>.

⁷ WHO | General information on counterfeit medicines: World Health Organization; 2014 Available from: <http://www.who.int/medicines/services/counterfeit/overview/en/>.

packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.⁸

The WHO categorizes counterfeit drugs into 6 categories based on type and prevalence:

1. No active ingredients (32.1%).
2. Incorrect amounts of active ingredients (20.2%).
3. Incorrect ingredients (21.4%).
4. Correct quantities of active ingredients but fake
5. packaging (15.6%).
6. An original product that has been copied (1%).
7. High levels of impurities and contaminants (8.5%).

India does not have a legal definition for counterfeit drugs. However, its existing drug regulatory laws have made a reference to drugs which are spurious. The word spurious was introduced into the Indian statute for the first time by the Medicinal and Toilet Preparations Act 1955. Section 17-B of Drugs and Cosmetics Act, 1940 has defined spurious drugs as "A drug shall be deemed to be spurious if it is manufactured under a name of another drug, if it is an imitation of another drug or if it has been wholly or partly substituted by another drug or if it is wrongly claimed to be the product of another manufacturer."⁹

(B) Historical Perspective of Pharmaceutical Drugs On An Organized Crime

The pharmaceutical market in India has a complex history, especially when viewed through the lens of organized crime.

Early Development and Challenges

- **Post-Independence Era:** After gaining independence in 1947, India's pharmaceutical market was dominated by Western multinational corporations (MNCs), which controlled 80-90% of the market. The Indian government took steps to reduce foreign dominance and build indigenous capacity, such as establishing the Justice Bakshi Tek Chand Committee in 1949 to examine patent laws.¹⁰

⁸WHO | General information on counterfeit medicines: World Health Organization; 2014
Available from: <http://www.who.int/medicines/services/counterfeit/overview/en/>.

⁹ Khan AN, Khar RK. Current scenario of spurious and substandard medicines in India: A systematic review. *Indian journal of pharmaceutical sciences*. 2015.

¹⁰ *A Saga of 75 years journey of Indian Pharmaceutical Industry*. Pharmatutor.org. <https://www.pharmatutor.org/articles/saga-of-75-years-of-journey-of-indian-pharmaceutical-industry>

Rise of Organized Crime

- 1960s-1970s: During this period, organized criminal syndicates began to emerge in India, particularly in Mumbai. These syndicates engaged in various illicit activities, including the production and distribution of counterfeit drugs.
- Regulatory Gaps: The lack of stringent regulations and enforcement mechanisms allowed these criminal networks to flourish. Counterfeit drugs became a significant issue, posing serious health risks to the public.¹¹

Government Interventions

- 1980s-1990s: The Indian government introduced several measures to combat the problem. The Drug Price Control Order and the Indian Patents Act of 1970 were significant steps in regulating the pharmaceutical industry.¹² However, these measures were not always effective in curbing the activities of organized crime syndicates.
- Recent Efforts: In recent years, the government has intensified its efforts to tackle the issue of counterfeit drugs. This includes stricter regulations, better enforcement, and international cooperation to dismantle criminal networks involved in the pharmaceutical market.¹³

(C) Importance Of Addressing Counterfeit Pharmaceutical As Organized Crime

The threat posed by counterfeit drugs connected to organized crime is becoming more widely acknowledged. Drug counterfeiting carries serious dangers to public health and safety since it is sometimes manufactured with inferior or hazardous chemicals.

Because this unlawful trade is very profitable and low risk in comparison to other illegal activities like drug trafficking, organized criminal networks are involved in it. In order to disrupt these criminal groups, addressing this issue calls for more law enforcement operations, better regulatory frameworks, and international cooperation. In addition to eroding public confidence in healthcare institutions, the selling of counterfeit medications causes financial losses for respectable pharmaceutical businesses.

Increasing awareness, strengthening supply chain security, and enacting harsher punishments

¹¹ *LAWS FOR PREVENTION OF ORGANISED CRIMES IN INDIA: A COMPREHENSIVE ANALYSIS*. Ijirl.com. <https://ijirl.com/wp-content/uploads/2024/03/LAWS-FOR-PREVENTION-OF-ORGANISED-CRIMES-IN-INDIA-A-COMPREHENSIVE-ANALYSIS.pdf>

¹² M. A. S. (2023). Evolution of Indian Pharmaceutical Industry – Overview. *International Bulletin of Management and Economics, Volume - XI*(September 2019 (Special Issue)). <https://doi.org/23/09/2023>

¹³ *Historical Background and Current Status of Indian Pharmaceutical Industry and Indian Patents Regime*. Link.Springer.com. https://link.springer.com/chapter/10.1007/978-981-10-6790-7_2

for violators are crucial tactics in the fight against the issue.¹⁴

(D) Prevalence of Counterfeit Pharmaceuticals

Counterfeit pharmaceuticals are a significant issue in India. Here are some key points about their prevalence:

- High Prevalence; Approximately 20% of all pharmaceutical products sold in India are counterfeit.¹⁵
- Substandard and Falsified Medicines: According to a 2017 WHO report, about 10.5% of medicines sold in low- and middle-income countries, including India, are substandard and falsified.¹⁶
- Global Incidents: Nearly 6,000 pharmaceutical crime incidents were recorded in 2021, marking a 38% increase from the previous year.¹⁷
- Geographical Distribution: The highest number of counterfeit pharmaceutical seizures were recorded in North America, followed by the Asia Pacific, Latin America, the Near East, Eurasia, Europe, and Africa.¹⁸
- Online Pharmacies A significant portion of counterfeit drugs are sold online, often without prescriptions.¹⁹

II. ORGANIZED CRIME GROUPS AND COUNTERFEIT PHARMACEUTICALS

(A) Overview Of Organized Crime Groups Involved in Counterfeit Pharmaceuticals

In general, these criminal organizations will also typically continue their operations over time in order to increase earnings at the expense of an ever-increasing risk to their health. In the case of pharmaceutical counterfeiting, several categories of criminal organizations can be identified:

- Small-scale businesses;
- International organizations of moderate scale,

¹⁴ *The Concept of Infamy in Roman Law*, (June 10, 2019), <https://pdfs.semanticscholar.org/7754/68e1bcf1df9813142ebb3c1f46ce50908488.pdf>.

¹⁵ *Content Blocked*, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3353184.

¹⁶ Anna Fleck, *Infographic: Counterfeit Drugs on the Rise Globally*, Statista (May 24, 2023), <https://www.statista.com/chart/30067/worldwide-counterfeit-pharmaceuticals-incidents/>.

¹⁷ Anna Fleck, *Infographic: Counterfeit Drugs on the Rise Globally*, Statista (May 24, 2023), <https://www.statista.com/chart/30067/worldwide-counterfeit-pharmaceuticals-incidents/>.

¹⁸ September 16, *Dangerous Counterfeit Drugs are Putting Millions at Risk, a New Study Says*, UConn Today (June 3, 2022), <https://today.uconn.edu/2022/06/dangerous-counterfeit-drugs-are-putting-millions-at-risk-a-new-study-says/>.

¹⁹ *1 In 10 Medical Products In Developing Countries Is Substandard Or Falsified*, (Nov. 28, 2017), <https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified>.

- extensive, especially international organizations that may exist for a number of years and alter based on opportunities and limits,
- cybercriminal organizations.

Small-sized criminal organisations (two to five persons)

When someone imports fake medications from China or India, either by themselves or with two or three accomplices, they typically find themselves in a western nation. These organizations are frequently made up of individuals who see a chance to profit by recommending particular goods to a subset of the public, at competitive costs.

There is also the case of Mimi Trieu²⁰, the owner of a beauty salon in Philadelphia, who imported and sold slimming pills from October 2008 to May 2009 and continued to import them up to March 2010, even though she was well aware that these pills contained sibutramine and other dangerous substances. Almost four million pills were imported from China by post in this way: the parcels stated that the contents were gifts with a non-commercial value. According to the American authorities, Mimi Trieu sold 1,750,000 capsules of illegal medicines at a value of USD 245,000. Furthermore, she promoted these fake pills stating that they were manufactured in Japan and contained natural ingredients... All incriminating evidence.²¹

Medium-sized transnational criminal organisations (about 10 persons).

Arnaud B is suspected of disposing of over 4 tonnes of counterfeit medicines manufactured in China through official pharmacies in the UK, Germany, Belgium, Switzerland, the US, and the UAE. The drugs were intended to combat cardiovascular diseases and treat bipolar disorder patients. The damage to pharmaceutical companies, including Sanofi, was several million euros. The suspect, who bought EUR 14 billion in cash, was served a European arrest warrant and is expected to be handed over to an examining magistrate in the specialized inter-regional court in Marseilles. The case was made possible thanks to collaboration between investigators of the Guardia Civil and the gendarmes in the OCLAESP.²²

Large-scale and transnational criminal organisations.

Peter suggests that globalization leads to crime based on professionalized disinhibition, exploiting loopholes in markets and laws, fostering transnational criminal organizations.

But it should also be made clear that studying transnational crime comes up against three major

²⁰ FDA, Philadelphia Woman Pleads Guilty to Importing Illegal Diet Pills, December 17, 2010.

²¹ Source of information, Website: http://www.justice.gov/usao/pae/News/Pr/2010/may/trieu,m_indictment.pdf

²² <https://globalinitiative.net/wp-content/uploads/2017/12/IRACM-Counterfeit-Medicines-and-Criminal-Organizations-Oct-2013.pdf>.

obstacles²³

- the lack of any sound data,
- the difficulty in defining these transnational activities,
- ambiguity in trying to identify these transnational criminals and their organisations.

(B) Alterations in Organized Groups Activities During Covid-19 Pandemic

Under a criminological perspective, the evolution and psychology of organized crime are greatly influenced by the COVID-19 epidemic. A decline in both violent and non-violent crime was observed in 2020 with the start of the crisis and the implementation of social distance and quarantine protocols. Criminal organizations often adapted immediately to possibilities for financial gain, and the pandemic created new ones because of the sharp rise in the market for some medical supplies.²⁴

A health crisis emerged which did not only demand an adaptation only from many legal companies but also from criminal associations.²⁵ The use of the Internet as the main route for the distribution of counterfeit medications, with its large customer base and little detection risk, was immediately identified by organized crime. The dark web provided a flexible, distributed structure with liberal entry into the internet market, enabling anonymous transactions between producers, distributors, and consumers, hence providing substantial support for illicit activities.²⁶ Advanced digitalization increased potential for cybercrime e.g. online fraud, and higher profits.²⁷

Furthermore, the only way counterfeit medicines could reach consumers in wealthy nations was through the Internet. Since the turn of the century, online pharmacies that is, retail pharmacies that conduct all or part of their business online (primarily via social media platforms and messaging apps and deliver goods directly to customers—have been associated with the sale of counterfeit medications over the internet.

While fake e-pharmacies appear to be legitimate businesses selling only pharmaceuticals, they

²³ Robert Mandel, *Dark Logic, Transnational Criminal Tactics and global security*, Stanford Security Studies, Stanford University Press, 2010, p. 7.

²⁴ Dellasega, M.; Vorrath, J. A., *Gangster's Paradise? Transnational Organised Crime in the Covid-19 Pandemic*, SWP Comment 66, December 2020, p. 1.

²⁵ Muggah, R., *op. cit.*, note 23.

²⁶ Khan, D.; Rafiqi, F. A., *E-Pharmacies & Fake Medicines: Threat to Public Health*, Indian Journal of Law and Legal Research, 2022-2023, 4, p. 2. According to WHO 50% of medicines are purchased on websites showing their physical address according to the studies carried out by European Federation for Accessing safe medicines 62% of medicines bought over the Internet are counterfeit (50% according to WHO-u). Przynska E., *op. cit.*, note 6, p. 19

²⁷ Dellasega, M.; Vorrath, J. A., *op. cit.*, note 25, p. 2

actually steal identities and copy credit card numbers. Illegal online pharmacies, on the other hand, are the primary means through which counterfeit drugs are supplied to Western customers. Legal e-pharmacies adhere to the nation's legal framework.²⁸ In the virtual illegal trade of counterfeit medicines, there is trade taking place on superficial websites accessible via standard search engines (e.g. Google), and the sale on deep web (a hidden part of the Internet not accessible by conventional web browsers, which can be reached, for example, by special software like Tor browse engine.²⁹ Internet is a new powerful instrument which organized crime uses as an important channel to offer counterfeit medicines at both wholesale and retail level, creating independent distribution processes which directly aim at distributors and finally consumers.³⁰

(C) Methods of Production, Distribution, and Sale

The counterfeit pharmaceutical industry employs various methods for production, distribution, and sales, often exploiting gaps in the legitimate supply chain. Here are some key aspects:

Production

1. **Illegal Laboratories:** Counterfeit drugs are often produced in unregulated, unsanitary conditions using substandard or inert ingredients³¹. These labs can be located anywhere, from residential homes to industrial warehouses.
2. **Diversion:** Some counterfeit drugs are diverted from legitimate supplies, either stolen or illegally obtained at various stages of the supply chain.³²

Distribution

1. **Complex Networks:** Counterfeiters use intricate distribution networks to disguise the origin of fake drugs. These networks can span multiple countries, making it difficult to trace the source.³³
2. **Online Markets:** A significant portion of counterfeit pharmaceuticals is sold through online

²⁸ According to Lavorgna, A., The online trade in counterfeit pharmaceuticals: new criminal opportunities, Trends and challenges, *European Journal of Criminology*, 2015, Vol. 12, No. 2, p. 233. Fake and illegal e-pharmacies are promoted by spam messages, very powerful instruments which have become one of the favorite tools of organized groups for advertising their illegal products, which reach a large number of addresses worldwide and is even adapted to the needs of certain geographical regions. Negri, S., *op. cit.*, note 22, p. 358

²⁹ *Ibid.*, p. 228

³⁰ Khan, D.; Rafiqi, F. A., *op. cit.*, note 34, p. 7

³¹ Hannah Balfour, *The latest on pharmaceutical counterfeiting*, (May 3, 2022), <https://www.europeanpharmaceuticalreview.com/article/170913/the-latest-on-pharmaceutical-counterfeiting/>.

³² Scott Deakins, *Serialization: Reducing Counterfeit Drugs and Increasing Sales*, (Aug. 3, 2021), <https://www.pharmtech.com/view/serialization-reducing-counterfeit-drugs-and-increasing-sales>.

³³ Hannah Balfour, *The latest on pharmaceutical counterfeiting*, (May 3, 2022), <https://www.europeanpharmaceuticalreview.com/article/170913/the-latest-on-pharmaceutical-counterfeiting/>

pharmacies and social media platforms, which are harder to regulate.³⁴

Sales

1. Open-Air Markets: In some regions, counterfeit drugs are sold openly in markets, often without proper storage conditions, leading to further degradation of the product.
2. Sophisticated Packaging: To avoid detection, counterfeiters often invest more in the appearance of the packaging than the quality of the product itself. This can include using advanced printing techniques to mimic legitimate products.³⁵

(D) Procedure and Strategies Foe Anti Counterfeit; India

India has several laws and regulations aimed at combating counterfeit pharmaceutical products. Here are some key legal frameworks and measures:

1. Drugs and Cosmetics Act, 1940

- Drugs and cosmetics in India. It empowers government agencies to:
- Inspect: Conduct inspections of manufacturing facilities and distribution channels.
- Seize and Confiscate: Seize and confiscate products found to be adulterated, spurious, or misbranded.³⁶

2. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

This act prohibits misleading advertisements of drugs and remedies that claim to have magical properties. It aims to protect consumers from false claims and ensure that only genuine products are marketed.³⁷

3. Intellectual Property Rights (IPR) Enforcement

India has strengthened its IPR laws to protect against counterfeit pharmaceuticals. This includes:

- Patents Act, 1970: Provides patent protection for pharmaceutical inventions.
- Trademarks Act, 1999: Protects brand names and logos from being copied.

4. Anti-Counterfeiting Measures

³⁴ Scott Deakins, *Serialization: Reducing Counterfeit Drugs and Increasing Sales*, (Aug. 3, 2021), <https://www.pharmtech.com/view/serialization-reducing-counterfeit-drugs-and-increasing-sales>

³⁵ Hannah Balfour, *The latest on pharmaceutical counterfeiting*, (May 3, 2022), <https://www.europeanpharmaceuticalreview.com/article/170913/the-latest-on-pharmaceutical-counterfeiting/>.

³⁶ <https://journalofsocialsciences.org/vol6no1/combating-counterfeit-and-substandard-medicines-in-india--legal-framework-and-the-way-ahead/>.

³⁷ *Procedures and strategies for anti-counterfeiting: India*, Lexology (May 14, 2019), <https://www.lexology.com/library/detail.aspx?g=3044c5a2-8329-4468-811c-649e523ee1e2>.

- Serialization and Track-and-Trace: Implementing unique identification codes on drug packaging to ensure traceability throughout the supply chain.
- Digital Solutions: Use of QR codes, RFID tags, and blockchain technology to authenticate products.³⁸

5. Regulatory Bodies

- Central Drugs Standard Control Organization (CDSCO): The national regulatory body responsible for drug approval and regulation.
- State Drug Control Organizations: These bodies work at the state level to enforce drug regulations and conduct inspections.

6. Recent Initiatives

- Pharma Jan Samadhan Scheme: A grievance redressal system for consumers to report issues related to counterfeit drugs.
- National Drug Survey: Conducted periodically to assess the quality of drugs available in the market.³⁹

These laws and measures are crucial in the fight against counterfeit pharmaceuticals, ensuring the safety and efficacy of drugs available to consumers in India.

(E) Categories of drugs being counterfeit

Drugs belonging to different therapeutic categories are counterfeited across the globe. Different reports corroborate that the anti-infective drug category, which consists of antibiotics, antivirals, antifungals, antimalarials, etc., makes up the bulk of drugs being counterfeited, with the percentage ranging anywhere from 10% to as high as 50%.⁴⁰ This is followed by genitourinary drugs, especially drugs for male sexual health, including department of Pfizer for its blockbuster PDE5i, Viagra, showed that 77% of the tablets ordered online were counterfeit.⁴¹

The PSI roughly follows the regional categories established by the U.S. Department of State. Using these categories, incident data was analysed with respect to seven regions of the world. Within the 6,897 pharmaceutical crime incidents, the Institute found:

- A four percent increase (+4%) in the worldwide incident total

³⁸ Cloudflare <https://bytescare.com/blog/anti-counterfeiting-in-india>.

³⁹ <https://blogs.deloitte.co.uk/health/2018/04/tackling-counterfeit-medicines-in-india.html>.

⁴⁰ Newton PN, Green MD, Fernández FM, et al. Counterfeit anti-infective drugs. *Lancet Infect Dis*. 2006;6(9):602–13.

⁴¹ Campbell N, Clark JP, Stecher VJ, et al. Internet-ordered viagra (sildenafil citrate) is rarely genuine. *J Sex Med*. 2012;9(11):2943–51.

- All seven regions experienced an increase in new incidents in CY 2023
- 154 countries were impacted by pharmaceutical crime.⁴²

The number of arrests made by the police is often viewed as a key measure of law enforcement's productivity and effectiveness in addressing crime. However, law enforcement practices and reporting of arrests can differ significantly from country to country. PSI collects information concerning arrests as one indicator of a government's commitment to addressing pharmaceutical crime. A small number of arrests may indicate that the government has not assigned a high priority to enforcement.

There are 4,894 persons were arrested for counterfeiting, illegally diverting, or stealing pharmaceuticals. The number of arrests increased seventeen percent (+17%) over that documented in CY 2022, On a percentage basis, the largest number of arrests were in the Asia Pacific region.⁴³

III. CRIMINAL INVESTIGATION AND PROSECUTIONS

(A) Challenges in investigating and prosecuting counterfeit pharmaceutical cases

1. Complex Supply Chains: Counterfeit drugs often pass through intricate and opaque supply chains, making it difficult to trace their origins and identify the perpetrators.⁴⁴
2. Global Nature of the Crime: Counterfeit pharmaceuticals are a global issue, with production and distribution often spanning multiple countries. This international scope complicates jurisdiction and enforcement.⁴⁵
3. Low Risk of Prosecution: The risk of prosecution for counterfeiters is relatively low. Many counterfeit drugs are only detected at the retail level or by patients, making it hard to gather sufficient evidence for prosecution.⁴⁶
4. Technological Challenges: Counterfeiters use sophisticated methods to replicate packaging and labelling, making it difficult to distinguish fake drugs from genuine ones. Advanced technology is required to detect these counterfeits.⁴⁷

⁴² *Geographic Distribution*, PSI <https://www.psi-inc.org/geographic-distribution>.

⁴³ *Arrest Data*, PSI <https://www.psi-inc.org/arrest-data>.

⁴⁴ Ranjana Pathak, *Tackling Counterfeit Drugs: The Challenges and Possibilities*, SpringerLink (May 15, 2023), <https://link.springer.com/article/10.1007/s40290-023-00468-w>.

⁴⁵ The push factors behind counterfeit pharmaceuticals - OECD iLibrary. <https://www.oecd-ilibrary.org/sites/88de56c2-en/index.html?itemId=/content/component/88de56c2-en>.

⁴⁶ Ranjana Pathak, *Tackling Counterfeit Drugs: The Challenges and Possibilities*, SpringerLink (May 15, 2023), <https://link.springer.com/article/10.1007/s40290-023-00468-w>.

⁴⁷ *Tackling Counterfeit Drugs: The Challenges and Possibilities* - Springer. <https://link.springer.com/article/10.1007/s40290-023-00468-w>.

5. Regulatory Gaps: Inconsistent regulations and enforcement across different countries create loopholes that counterfeiters exploit. Strengthening global health governance and harmonizing regulations are essential steps to combat this issue.⁴⁸

6. Public Awareness and Education: Many consumers are unaware of the risks associated with purchasing medications from unverified sources, such as online pharmacies. Increasing public awareness is crucial to reducing demand for counterfeit drugs.

7. Resource Constraints: Law enforcement agencies and regulatory bodies often lack the resources and expertise needed to effectively combat counterfeit pharmaceuticals. Enhanced training and funding are necessary to improve their capabilities.⁴⁹

(B) Successful investigations and prosecutions

There have been several successful investigations and prosecutions of counterfeit pharmaceutical cases, highlighting the efforts of various agencies and international cooperation. Here are a few notable examples:

1. **Operation Pangea**: Coordinated by INTERPOL, this annual operation targets the online sale of counterfeit and illicit medicines. In 2020, Operation Pangea XIII resulted in the seizure of over 4.4 million units of illicit pharmaceuticals and the arrest of 121 individuals worldwide.⁵⁰
2. **FDA Enforcement Actions**: Between 2016 and 2021, the U.S. Food and Drug Administration (FDA) took 130 enforcement actions against counterfeit medication rings. These actions included arrests, product confiscations, and the dismantling of counterfeit rings.⁵¹
3. **Operation Shield**: This global effort, involving 27 countries, led to the disruption of 25 criminal networks and the seizure of 25 million units of counterfeit drugs valued at €73 million. The operation also shut down 453 websites and seized 10 illegal laboratories.⁵²

⁴⁸ Strategies To Combat Counterfeit Drugs and Other Pharma Supply Chain <https://www.pharmaceutic.alonline.com/doc/strategies-to-combat-counterfeit-drugs-and-other-pharma-supply-chain-threats-0001>

⁴⁹ Improving global health governance to combat counterfeit medicines: a <https://bmcmmedicine.biomedcentral.com/articles/10.1186/1741-7015-11-233>.

⁵⁰ September 16, *Dangerous Counterfeit Drugs are Putting Millions at Risk, a New Study Says*, UConn Today (June 3, 2022), <https://today.uconn.edu/2022/06/dangerous-counterfeit-drugs-are-putting-millions-at-risk-a-new-study-says/>.

⁵¹ Hannah Balfour, *The latest on pharmaceutical counterfeiting*, (May 3, 2022), <https://www.europeanpharmaceuticalreview.com/article/170913/the-latest-on-pharmaceutical-counterfeiting/>.

⁵² September 16, *Dangerous Counterfeit Drugs are Putting Millions at Risk, a New Study Says*, UConn Today (June 3, 2022), <https://today.uconn.edu/2022/06/dangerous-counterfeit-drugs-are-putting-millions-at-risk-a-new-study-says/>.

4. **Europol Operations:** Europol has been actively involved in combating pharmaceutical counterfeiting. In 2020, they reported a significant increase in customs procedures related to counterfeit drugs, with the majority originating from China and Turkey.⁵³

These operations demonstrate the importance of international collaboration and the need for robust regulatory frameworks to combat the global issue of counterfeit pharmaceuticals. Enhanced surveillance, stricter regulations, and public education are crucial in addressing this challenge.

(C) International cooperation and law enforcements efforts

International cooperation and law enforcement efforts are crucial in combating the global issue of counterfeit pharmaceutical drugs. Here are some key initiatives and collaborations:

1. WHO, UNODC, and Interpol Collaboration:

A proposed trilateral mechanism between the World Health Organization (WHO), the United Nations Office on Drugs and Crime (UNODC), and Interpol aims to leverage their respective strengths in public health, transnational crime prevention, and law enforcement.⁵⁴ This collaboration focuses on enhancing global health governance to address the counterfeit medicines threat effectively.

2. Global and Local Efforts:

Efforts to combat substandard and falsified medicines include legislation, manufacturing practices, supply chain management, and detection and reporting methods.⁵⁵ These efforts are tailored to address the specific challenges faced in different regions, emphasizing that a one-size-fits-all approach is not effective.

3. Pharmaceutical Companies and Interpol:

More than two dozen of the world's largest pharmaceutical companies have agreed to provide funding and other support to Interpol's battle against counterfeit prescription drugs.⁵⁶ This

⁵³ September 16, *Dangerous Counterfeit Drugs are Putting Millions at Risk, a New Study Says*, UConn Today (June 3, 2022), <https://today.uconn.edu/2022/06/dangerous-counterfeit-drugs-are-putting-millions-at-risk-a-new-study-says/>.

⁵⁴ Tim K Mackey, *improving global health governance to combat counterfeit medicines: a proposal for a UNODC-WHO-Interpol trilateral mechanism*, Full Text (Oct. 31, 2013), <https://bmcmmedicine.biomedcentral.com/articles/10.1186/1741-7015-11-233>.

⁵⁵ <https://pharmaceutical-journal.com/article/research/substandard-and-falsified-medicines-global-and-local-efforts-to-address-a-growing-problem>

⁵⁶ Stephen Noguera, *With the World in Turmoil, Transnational Organized Crime Sees Opportunity in Counterfeit Pharmaceuticals and Medical Supplies during the COVID-19 Pandemic*, George C. Marshall European Center For Security St (Apr. 17, 2020), <https://www.marshallcenter.org/en/publications/perspectives/world-turmoil->

partnership enhances the resources available for international law enforcement operations targeting counterfeit pharmaceuticals.

4. International Treaties and Conventions:

Various international treaties and conventions, such as the Medi crime Convention, provide a legal framework for international cooperation in combating counterfeit medicines.⁵⁷ These agreements facilitate the sharing of information, joint investigations, and coordinated actions among countries. These collaborative efforts are essential in addressing the complex and widespread issue of counterfeit pharmaceuticals, ensuring safer medicines for all.

IV. PUBLIC HEALTH IMPACT

(A) Health consequences of consuming counterfeit pharmaceuticals

Consuming counterfeit pharmaceuticals can have severe health consequences, including:

1. Therapeutic Failure: Counterfeit drugs often contain incorrect or insufficient active ingredients, leading to ineffective treatment. This can result in the progression of diseases like HIV, tuberculosis, and malaria.⁵⁸
2. Adverse Reactions: These drugs may contain harmful substances such as mercury, arsenic, or even rat poison. This can cause unexpected side effects or severe health issues.
3. Drug Resistance: Substandard medications can contribute to antimicrobial resistance. For example, counterfeit antibiotics with low doses of active ingredients can allow pathogens to survive and mutate, making infections harder to treat.⁵⁹
4. Toxicity: Some counterfeit drugs contain toxic ingredients that can cause poisoning. In extreme cases, this can lead to death.

(B) Impact on vulnerable populations

Counterfeit pharmaceuticals disproportionately affect vulnerable populations, leading to severe health and socio-economic consequences:

1. Increased Mortality and Morbidity: Vulnerable groups, such as those in low- and middle-income countries, often rely on counterfeit drugs due to limited access to genuine medications.

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⁵⁷ Michele Forzley, *Combating counterfeit drugs: a concept paper for effective international collaboration*, Academia.edu (Feb. 7, 2022), https://www.academia.edu/70845654/Combating_counterfeit_drugs_a_concept_paper_for_effective_international_collaboration.

⁵⁸ *Fake Drugs, Real Dangers*, Hopkins Bloomberg Public Health Magazine <https://magazine.publichealth.jhu.edu/2024/fake-drugs-real-dangers>.

⁵⁹ Pfizer Staff, *Fake Drugs 101: Facts on Illegal, Counterfeit Drugs*, https://www.pfizer.com/news/articles/fake_drugs_101_facts_on_illegal_counterfeit_drugs.

This can result in treatment failures and increased mortality rates, particularly for diseases like malaria, tuberculosis, and HIV.⁶⁰

2. Economic Burden: The financial strain of purchasing ineffective or harmful medications can exacerbate poverty. Families may spend their limited resources on counterfeit drugs, leading to further economic hardship.⁶¹

3. Exacerbation of Health Inequities: Counterfeit drugs are more prevalent in regions with weak regulatory systems and poor healthcare infrastructure. This exacerbates existing health inequities, as these populations already face significant barriers to accessing quality healthcare.⁶²

4. Drug Resistance: Substandard medications contribute to the development of drug-resistant strains of diseases. This is particularly dangerous for vulnerable populations who may not have access to alternative treatments.⁶³

5. Psychological Impact: The fear and uncertainty associated with counterfeit drugs can lead to psychological stress and decreased trust in healthcare systems.⁶⁴

(C) Economic burden on healthcare systems

Counterfeit pharmaceuticals impose a significant economic burden on healthcare systems, affecting various aspects:

1. Increased Healthcare Costs: Treating the adverse effects of counterfeit drugs often requires additional medical interventions, hospitalizations, and prolonged treatments, leading to higher healthcare expenses.⁶⁵

2. Lost Revenue: The global economy loses an estimated \$75 billion annually due to counterfeit drugs.⁶⁶ This includes lost income from prolonged illness and decreased productivity.

3. Impact on Research and Development: Counterfeit drugs can result in substantial losses in

⁶⁰ September 16, *Dangerous Counterfeit Drugs are Putting Millions at Risk, a New Study Says*, UConn Today (June 3, 2022), <https://today.uconn.edu/2022/06/dangerous-counterfeit-drugs-are-putting-millions-at-risk-a-new-study-says/>.

⁶¹ *Fake Drugs, Real Dangers*, Hopkins Bloomberg Public Health Magazine <https://magazine.publichealth.jhu.edu/2024/fake-drugs-real-dangers>.

⁶² Diane McCarthy, *The Human Impact of Counterfeit and Substandard Medicines*, U.S. Pharmacopeia Blog <https://qualitymatters.usp.org/human-impact-counterfeit-and-substandard-medicines>.

⁶³ *Identifying Vulnerable Populations to Substandard or Falsified Drugs: A Global Health Challenge*, (Aug. 26, 2024), <https://www.hhmglobal.com/health-wellness/identifying-vulnerable-populations-to-substandard-or-falsified-drugs-a-global-health-challenge>.

⁶⁴ *Fake Drugs, Real Dangers*, Hopkins Bloomberg Public Health Magazine <https://magazine.publichealth.jhu.edu/2024/fake-drugs-real-dangers>.

⁶⁵ *Substandard and falsified medical products: bibliometric analysis and mapping of scientific research*, Full Text (Sept. 23, 2021), <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-021-00766-5>.

⁶⁶ <https://truemedinc.com/news/the-economic-impact-of-counterfeit-healthcare-products/>.

research and development (R&D) resources. Estimates suggest up to \$73.3 billion in lost R&D resources and \$162.1 billion in lost revenue to the U.S. industry alone.

4. Job Losses: The economic impact extends to employment, with counterfeit drugs potentially causing up to 247,803 lost jobs.⁶⁷

5. Public Health Expenditure: Governments and healthcare systems must allocate significant resources to combat counterfeit drugs, including regulatory enforcement, public awareness campaigns, and quality control measures.⁶⁸

V. PREVENTION AND DISRUPTION STRATEGIES

(A) Role of various stakeholders in protecting against counterfeit of drugs

a. Role of The Consumer and Pharmacist;

Pharmacists as well as end consumers are vital players in the war against drug counterfeiting. They are the individuals who are in direct contact with the drug suppliers. It thus becomes essential to ensure that pharmacists and patients are aware of the problem of counterfeiting and the ways to identify genuine medicines from counterfeit medicines. A patient must buy the medicines from a trusted source and avoid using shady online pharmacies since reports suggest that most counterfeit products are sold via untrusted online pharmacies.⁶⁹ The patient must immediately contact the pharmacist or the doctor if he/she notices any discrepancy in the appearance, taste, or effect of the consumed drug. Pharmacists must ensure that they are buying their medicines from a trustworthy source that has been approved by the respective drug regulatory agencies. Pharmacists are advised to keep records of products to ascertain the traceability of the medicine or medical device. This becomes necessary for patient safety. Another important task for the pharmacist is to notify the relevant authorities regarding any suspicious or confirmed case of drug counterfeiting.⁷⁰

b. Role of pharmaceutical companies;

As per available reports, pharmaceutical companies lose almost \$200 billion annually to drug counterfeiting.⁷¹ Pharmaceutical companies spend many years and huge budgets to research and

⁶⁷ <https://medecon.org/new-brief-counterfeit-drugs-harm-patients-economy-innovation/>.

⁶⁸ Faris El-Dahiyat1*, *Frontiers | Combatting Substandard and Falsified Medicines: Public Awareness and Identification of Counterfeit Medications*, *Combatting Substandard and Falsified Medicines: Pu* <https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2021.754279/full>.

⁶⁹ Chambliss WG, Carroll WA, Kennedy D, et al. Role of the pharmacist in preventing distribution of counterfeit medications. *J Am Pharm Assoc.* 2012;52(2):195–9.

⁷⁰ Ziance RJ. Roles for pharmacy in combatting counterfeit drugs. *J Am Pharm Assoc.* 2008;48(4): e71–91.

⁷¹ Blackstone EA, Joseph PF, Pociask S. The health and economic effects of counterfeit drugs. *Am Health Drug Benefits.* 2014;7(4):216.

develop innovator and generic drugs. Randomized controlled trials ensure rigid safety measures are taken. Therefore, the loss of income to pharmaceutical companies is but one of the consequences of drug counterfeiting. In order to prevent the same, companies need to prevent counterfeiting at the source, such as the wholesalers, distributors, the pharmacist community, and regulatory agencies. Pfizer alone has 103 counterfeited medicines being sold in 116 countries.⁷²

Drug manufacturing companies and/or packagers, regulatory bodies, primary and end consumers have the collective responsibility of preventing falsification of drugs. There are certain steps that could be put into practice to fight this menace of drug counterfeiting. First and foremost, companies could focus on raising awareness amongst the pharmacists, doctors, and the end consumers. It has launched a counterfeit awareness campaign to detect, disrupt and deter leading producers and sellers of their drug imitations.⁷³

The companies should ensure that their supply chain is not susceptible to penetration by the counterfeiters. A specify team must be formed within the company, which will be responsible for monitoring the sanctity of the supply chain to protect the products at manufacturing sites, warehouses, during shipment, and at the end customer level.⁷⁴

This process must be audited in sufficient detail to ensure supply chain security. The companies could also utilise intelligent packaging with artificial intelligence (AI)-embedded quick-response (QR) codes. Also, common digital tags, such as radiofrequency identification (RFID) and near-field communication (NFC), can give a drug a distinct identity. These identities carry information about the product, and they facilitate a track-and-trace element that aids drug companies in gaining product visibility throughout the supply chain.⁷⁵

c. Role of regulators;

It is the responsibility of the regulators in different countries to ensure that their people are receiving genuine medicines. The International Medical Products Anti-Counterfeiting Taskforce was established by the WHO in 2006 with the objective of bringing together pertinent parties such as national governments, the pharmaceutical sector, nongovernmental organisations (NGOs), and law enforcement organisations such as Interpol to combat the spread

⁷² *Counterfeiting*, Pfizer <https://www.pfizer.com/products/medicine-safety/counterfeiting>.

⁷³ *Counterfeit Awareness Campaign*, Pfizer, <https://www.pfizer.com/counterfeiting/counterfeitawarenesscampaign>.

⁷⁴ *Pharma Industry News*, Latest Healthcare Sector & Healthcare Industry new, <https://health.economictimes.indiatimes.com/news/pharma/three-strategies-to-combat-counterfeit-drugs-and-other-pharma-supply-chain>.

⁷⁵ Burns W. WHO launches taskforce to fight counterfeit drugs. *Bull World Health Organ*. 2006; 84:689–90

of counterfeit medicines.⁷⁶

The European Parliament and European Council released the Falsified Medical Directive (FMD) to fight against the spread of drug counterfeiting.⁷⁷ The FMD 2011/62/EU requires marketing authorisation holders and manufacturers to put in place a system to prevent falsified medicines from entering the legal supply chain. It also aims to improve patient safety. The FMD directive recommends the placement of safety features, including a unique identifier and an anti-tampering device, on the packaging of specific medicinal products for human use. Additionally, the FMD offers a tool to help with security while purchasing medications online.⁷⁸

The United States Food and Drug Administration (USFDA) has a Drug Supply Chain Security Act (DSCSA) in place to prevent the circulation of counterfeit medications. The act describes how to implement electronic tracing that is compatible at the packaging level to identify and track specific prescription medications as they are supplied in the USA. This improves the FDA's capacity to assist in preventing consumer exposure to medications that might be fake, stolen, tainted, or otherwise hazardous. Furthermore, the FDA conducts an electronic evaluation of each imported shipment of a product subject to FDA regulation.⁷⁹

India, is home to the maximum number of drug counterfeiting cases. The Indian government formed a task force to tackle the issue of drug counterfeiting. The task force ultimately reached the conclusion that for track and trace to be effective, the following two systems must be put into place concurrently: first, a unique identification number for each primary pack to allow consumers to identify the medicine; and second, a 2-D bar coding that incorporates all product information for quick data retrieval at each stage of the supply chain.⁸⁰

Based on the recommendations of the task force, India has already implemented the suggestion of including a unique identification number and a bar code on each drug pack. One can also verify the authenticity by sending the unique code behind the bottle or package to the Drug Technical Advisory Board's (DTAB) number via SMS. The DTAB should respond with an authentication message from the medicine's manufacturer. Despite all these regulations by different countries, the threat of drug counterfeiting continues to increase in developing

⁷⁶ Merks P, Religion U, Castro NP, et al. Falsified medicines directive in a secondary care environment-impact on supply chain. *Int J Environ Res Public Health*. 2022;19(6):3276.

⁷⁷ <https://journals.sagepub.com/doi/10.5301/maapoc.0000010>.

⁷⁸ Le P, Grund L, Marwa J, et al. Combating substandard and counterfeit medicines by securing the pharmaceutical supply chain: the drug supply chain security act (DSCSA) of 2013. *Innova Pharm*. 2018;9(2):1.

⁷⁹ Chaudhry PE, Stumpf SA. *The challenge of curbing counterfeit prescription drug growth: preventing the perfect storm*. *BusHoriz*. 2013;56(2):189–97

⁸⁰ Report of the Task Force, Submitted to Ministry of Health & Family Welfare Government of India. 2012. <https://main.mohfw.gov.in/sites/default/files/5557266952.pdf>. Accessed 17 Sep 2024.

countries, particularly in Africa. Hence, there is a pressing need for global regulatory authorities to come together to devise a strategy to prevent drug counterfeit internationally.

VI. CONCLUSION AND RECOMMENDATIONS

One conclusion from the foregoing is that the absence of a robust legal framework is one of the factors militating against the eradication of substandard and falsified medical products. Domestic laws cannot by themselves effectively combat the manufacture, trafficking and dealing in substandard and falsified medical products. To facilitate detection of such products, support local and global surveillances, strengthen regulatory capacity and harmonize pharmaceutical governance in Africa, there is a need for a transnational action through transnational regional law to assist in the fight against substandard and falsified medical products.

1. Studies conducted by WHO, UNODC, OECD and other international bodies showed that the absence of a comprehensive legal framework is responsible for the flourishing of the adulterated medicines trade especially in low-income countries.⁸¹
2. If the laws are inadequate, legislation needs to be quickly strengthened in order to assist in the detection and eradication of fake pharmaceuticals and the criminal groups behind them.⁸²
3. On the other hand, due to globalization, it is also essential that both domestic and international law be engaged to combat counterfeit medical crime.⁸³
4. Another tool in combating fake drugs and pharmaceuticals is raising public awareness, through educational campaigns, regarding medicine quality and the risks generated from using counterfeit health products.⁸⁴
5. Moreover, the issue of weak governance in many countries causes the dangerous practice of allowing non-trained individuals who are not pharmacist or pharmacy technicians to be allowed to work in pharmacies and dispense medications. Therefore, it is very important people not only to be educated in safely purchasing medicines and

⁸¹ Odiase P.O. Recalibrating African health laws to combat substandard and falsified medical products: beyond Covid-19. *Int. J. Civ. Law Leg. Res.* 2021;1(2):1–9

⁸² . Noguera S., Ziavrou K. With the world in turmoil, transnational organized crime sees opportunity in counterfeit pharmaceuticals and medical supplies during the COVID-19 pandemic. *Perspectives.* 2020;12

⁸³ Odiase P.O. Recalibrating African health laws to combat substandard and falsified medical products: beyond Covid-19. *Int. J. Civ. Law Leg. Res.* 2021;1(2):1–9

⁸⁴ Tesfaye, W., Abrha, S., Simulated, M., Arnold, B., Brown, A., Matthew, C., Oguma, V. M., Peterson, G. M., & Thomas, J. (2020). How Do We Combat Bogus Medicines in the Age of the COVID-19 Pandemic? *The American journal of tropical medicine and hygiene*, 103(4), 1360–1363. <https://doi.org/10.4269/ajtmh.20-0903>

medical supplies but also in recognizing pharmacists as the best suited individuals to provide trusted advice regarding medications.⁸⁵

6. Guidelines for potential consumers as were given by the INTERPOL⁸⁶

Never buy

- From unknown websites or in a marketplace
- From pharmacies making promises like “too good to be true”, “cures all types” of a major illness, “money-back guarantee”, or “no risk”
- Substantially cheaper product, it is likely to be a fake
- If the product contains different ingredients, claims to have different properties, has a different shape, is not correctly labelled, has an out-of-date or missing expiry date, or the packaging looks badly made.

Only Buy

- Medicines prescribed by doctors
- From websites that require prescription and have authenticity certificate
- After checking the price against usually bought products from reputable providers
- After comparing the medicine against the usually prescribed one.

In achieving the goal of eradicating fake pharmaceuticals trade, one should take into consideration the implementation of appropriate detection technologies to enable easy, quick and accurate identification of counterfeit or authentic products.

These technologies are not only an effective tool in protecting public health through detection but also in generating useful data mostly needed to quantify and evaluate the problem.

⁸⁵ Leszkowicz P., Kryszynski J., Religion U., Merks P. Access to medicines via non-pharmacy outlets in European countries—a review of regulations and the influence on the self-medication phenomenon. *Healthcare*. 2021;9(2):123. doi: 10.3390/healthcare9020123.

⁸⁶ *Interpol*, <https://www.interpol.int/>.

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- out by European Federation for Accessing safe medicines 62% of medicines bought over the Internet are counterfeit (50% according to WHO-u). Przysta E., op. cit., note 6, p. 19
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