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Global Pharmaceutical Black Market and Transnational Criminology: A Comparative Analysis of Legal and Crime Deterrence Strategies

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Abstract

The global pharmaceutical black market is an existing threat to public health, economic security, and transnational security through counterfeit and substandard drugs. The analysis applies a transnational criminology framework to evaluate potential legal frameworks and crime deterrence strategies in four jurisdictions (India, the US, the EU, and China). The paper examines these jurisdictions in terms of their variable regulatory frameworks and enforcement challenges. The analysis identifies three pillars for effective deterrence: technology, international cooperation, and public-private partnerships. Taken together, the comparative analyses show that transnational criminal organizations operating in the pharmaceutical crime sector can leverage regulatory variance, and this highlights the need for global standards, through bodies like the WHO and INTERPOL, to establish unified norms across jurisdictions. By integrating lessons learned from the comparative legal analysis, this paper has yielded concrete suggestions to make improvements to regulatory frameworks, particularly through employing technology and cross-border cooperation to build a transnational response to pharmaceutical crime.

Keywords: Pharmaceutical Black Market, Counterfeit Drugs, Substandard Medicines, Transnational Criminology, Crime Deterrence Strategies, Cross-Border Enforcement.

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1. Introduction

The global pharmaceutical black market represents a complex, escalating, and hazardous threat to public health, economic stability, and international security (World Health Organization [WHO], 2017). The illicit production, distribution, and sale of counterfeit, substandard, and illegally trafficked pharmaceutical products fuel an underground industry that thrives in secrecy. Dissatisfactory pharmaceuticals that are not quality compliant, counterfeit products that pass themselves off as genuine pharmaceutical agents, and illicitly diverted controlled substances from a legitimate source all comprise this illegal market (United Nations Office on Drugs and Crime [UNODC], 2020). The illegal trade in unsafe pharmaceuticals is occurring in an almost entirely unregulated and fragmented market that is mostly dominated by criminal organizations and unscrupulous individuals in a new digital part of this space, creating abstract challenges for governments, regulators, and law enforcement agencies worldwide (Bouchard et al., 2011).

This issue is broad, as the WHO (2017) estimates that 10% of medicines sold in low and middle-income countries are substandard or falsified (World Health Organization [WHO], 2018). These unsafe products represent a significant public health risk, including treatment failure, adverse drug reactions, and the emergence of resistance to important treatment courses, including antibiotics (WHO, 2017). This situation is equally harmful economically, as counterfeit and illegal drug trade threatens legitimate businesses, reduces consumer confidence, and increases healthcare costs due to avoidable complications (European Medicines Agency [EMA], 2019). The challenge has intensified with the unprecedented growth of digital marketplaces, including the dark web, which is an open conduit for illegal trade of coca leaves, weaponry, and cybercriminal activity, as well as transnational numerous web platforms that facilitate illicit transactions, thereby avoiding observation, circumventing regulations, and taking advantage of poor enforcement and regulatory gaps (UNODC, 2020).

The global pharmaceutical black market provides insight into why we must consider transnational criminology as an analytical structure for comparative or interest-based interventions (Passas, 2003). Unlike conventional criminology, which attends strictly to localized or nationalized criminal acts, transnational criminology attends crimes that exist in more than one jurisdiction and involve networks of actors (Passas, 2003). This would lend well to the pharmaceutical black market because counterfeit production, packaging, and distribution span a vast array of geography and legality. The transnational nature of the illicit trade

necessitates a coherent global response as opposed to an organic or block national response (UNODC, 2020).

The interconnectedness of the pharmaceutical black market requires a cross-border approach (EMA, 2019). For instance, a country with lax regulatory oversight could produce a batch of counterfeit medication, package it elsewhere to conceal its origin, and distribute it worldwide through smuggling networks or online platforms (FDA, 2020). National enforcement efforts aimed at combating this diffuse and complex threat within territorial boundaries are insufficient (Passas, 2003). As black-market drug supply chains extend across international borders, an international framework is needed to harmonize intelligence sharing and cooperative enforcement strategies to disrupt global supply chains fuelling the black market (McLean, 2009; UNODC, 2020).

In addition, transnational criminology widens the analytical lens beyond the economic and political constructs that sustain the pharmaceutical black market (Passas, 2003). There are numerous instances in which the affordability of medicines, as well as variation in the level of regulatory enforcement, will seem nonsensical or unfair, leaving the market for counterfeit drugs rife with demand and supply (WHO, 2017). There are also both prospects and issues with respect to all the new technology; while the same technologies that afford anonymity and the ability to operate on the Dark Web can be detrimental, they also afford advantages for drug tracking and regulation (EMA, 2019). Technologies such as blockchain may help the supply chain become more transparent, and AI may assist in predicting demand and intelligence-led regulation (FDA, 2020).

This paper adopts a transnational criminology perspective to examine crime deterrence strategies aimed at the global pharmaceutical black market (Passas, 2003). The paper evaluates the effectiveness of existing regulatory frameworks in India and compares them with strategies in the United States, European Union, and China (CDSCO, 2021; FDA, 2020; EMA, 2019). The paper seeks to address three primary questions:

1. What are the key drivers and operational mechanisms of the pharmaceutical black market globally and in India?
2. How effective are existing crime deterrence strategies, including legal frameworks and technological interventions, in curbing this trade?
3. What lessons can be drawn from international regulatory systems to enhance India's approach to combating pharmaceutical crime?

2. The Scope and Impact of the Pharmaceutical Black Market

The black market for pharmaceuticals, run by organized criminals, is a large and lucrative part of the market that generates billions of dollars in sales revenues each year (World Health Organization [WHO], 2017). The black market continues to exist

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due to demand for cheaper medical treatments, companies seeking better profits by using loopholes in their own country, and a general lack of oversight by regulators globally (United Nations Office on Drugs and Crime [UNODC], 2020). This illicit industry operates via counterfeit medicines, diversions of legitimate pharmaceutical products intended for sale, and the distribution of stolen pharmaceuticals into the legitimate marketplace (INTERPOL, 2019).

The black market includes counterfeit medicines as its primary commodity, as counterfeit medicines include spurious, misbranded, or substandard medicines (World Health Organization [WHO], 2018). These products are predominantly either not containing the active ingredient, containing the wrong amount of active ingredient, or include harmful substances to such an extent that patient safety and public health are being compromised on a global scale (International Criminal Police Organization [INTERPOL], 2021). Counterfeit medicines have huge negative consequences, leading to common issues like therapeutic failure, serious health effects, or even death (United Nations Office on Drugs and Crime [UNODC], 2020).

The other major element of all this illicit trade is managing controlled substances, specifically opioids and benzodiazepines (U.S. Drug Enforcement Administration [DEA], 2022). Instead of being diverted into the illegal market, these controlled substances are being transferred into the illegal market most consistently via the legal production channels to the market as they are being brought to those populations that are desperate and increasingly addicted in North America and Europe, respectively (European Monitoring Centre for Drugs and Drug Addiction [EMCDDA], 2021). Thefts of oncology drugs and key vaccines out of supply chains and then sold for illicit distribution have equally damaged legitimate supply chains; both by removing potentially vital medicines to patients and reducing the controlled substances assets of the legitimate health system they originally came from (Fyan, 2010).

The illicit trade of controlled substances, such as opioids or benzodiazepines, involves legal controlled substances in an illegal supply chain, which is compounding the addiction crisis in North America and Europe (U.S. Food and Drug Administration [FDA], 2021). Loss of oncology drugs (in the form of theft and diversion) and illegal distribution of vaccines further disrupt the legitimate supply chain and, in some cases, can cause shortages of essential medicines, which affects patient care (European Medicines Agency [EMA], 2020; Fyan, 2010).

Weak regulatory oversight and porous borders mean counterfeit anti-malarial drugs will continue to be a prime contributor to preventable or avoidable deaths. In Europe, the outcomes of Operation MISMED exposed major trafficking networks via online platforms that disseminated counterfeit medicines with a monetary

turnover of an estimated €64 million (Europol, 2024). In the case of North America, the current opioid crisis has been aggravated by the illegal distribution of fentanyl, which was either legally manufactured or mostly derived through transnational black markets (Klobucista & Ferragam, 2023).

3. Crime Deterrence Strategies: A Comparative Legal Analysis

The battle against pharmaceutical crime worldwide requires strong legal frameworks suited to the complex, transnational nature of counterfeit drug manufacture and distribution. This section compares crime prevention measures across four different jurisdictions—India, the United States, the European Union, and China—representing different regulation regimes and enforcement issues.

3.1 Indian Legal Framework

India's experience illustrates the magnitude of the issue in one of the world's largest pharmaceutical-producing nations (Central Drugs Standard Control Organization [CDSCO], 2021). Despite being a major global producer of affordable generic drugs, India faces a serious counterfeit medicine problem that threatens both its domestic and export markets (CDSCO, 2021). While a legal apparatus exists through the Drugs and Cosmetics Act, 1940 (DCA), enforcement is patchy and hampered by structural issues such as shared jurisdictional powers, limited technology, and resources (Food and Drug Administration [FDA], 2020). The significant problems these challenges present are universal and reflective of a larger world of uneven regulatory and enforcement capacities among geographical jurisdictions, which are highly advantageous to agency leaders in criminal networks (UNODC, 2020).

Known as the "pharmacy of the world" for its large pharmaceutical industry and its global exports of generic medicines, India has a problem with counterfeit and sub-standard drugs infiltrating its systems of distribution (Central Drugs Standard Control Organization [CDSCO], 2021). According to the CDSCO (2021), where a little over 50 drugs were classified as "Not of Standard Quality (NSQ)," the question remains whether medicines in India can be considered safe or reliable. The ambiguity around terms like counterfeit and spurious complicates India's struggle against counterfeit pharmaceuticals, as this vagueness confuses consumers, as well as other stakeholders who can assure the quality of medicines (CDSCO, 2021; "Paracetamol to PAN-D", 2024).

The Indian market is saturated with products that can be deemed counterfeit, from low-priced generics that do not meet acceptable quality standards to extremely well-documented branded drugs that are labelled to mislead the consumer on purpose ("Paracetamol to PAN-D", 2024; Pharmaceutical Export Promotion Council of India, 2020).

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India has a formal legal framework for combating pharmaceutical crimes such as counterfeit drugs, illicit drug traffickers, and illegal distributors of controlled drugs-it is clear that problems exist (Ministry of Health and Family Welfare, 2023). The primary legislative framework for the manufacture, distribution, and sale of pharmaceutical products and cosmetics is the Drugs and Cosmetics Act, 1940. Section 17B specifically criminalizes the manufacture or sale of adulterated, spurious, or counterfeit drugs and contains strong penalties for offenders (e.g., imprisonment and fines) to ensure that the only medicines available on the market are associated with public health and are safe and effective (Drugs and Cosmetics Act, 1940). However, implementation of these laws is uneven because of loopholes in various statutes, a lack of resources to monitor, and counterfeit drugs that have been expertly composed to fill their place.

The Drugs and Cosmetics Act has been amended several times, but in an ad-hoc manner, without a central mandate, synchronization, or coordination between different states (Central Drugs Standard Control Organization [CDSCO], 2022). Local entities do not have the technical abilities and financial resources to identify and seize fake drugs, nor to build evidence for prosecution. The Narcotic Drugs and Psychotropic Substances Act, 1985, also attempts to tackle drug traffickers involved in illicit trades of narcotic substances and psychotropic drugs as well as to discourage unregistered transition of legitimate pharmaceutical products to the illegal drug trade (Narcotic Drugs and Psychotropic Substances Act, 1985). Law enforcement has encountered challenges relating to jurisdiction, particularly in respect of traffickers crossing international borders. Notably, India shares borders with Pakistan, Bangladesh, and Myanmar—countries that are also major hotspots for narcotic smuggling (Barnes, 2002–2003).

The Indian Penal Code, 1860, was superseded by Bharatiya Nyaya Sanhita, 2023, which has provisions designed to fight pharmaceutical crime in the form of fraud and forgery (Ministry of Home Affairs, 2023). Both animate and inanimate legal entities are now criminalized for engaging in various acts related to the manufacture, sale, and distribution of counterfeit or substandard drugs, as well as for the provision of fraudulent misrepresentation. The realization of a domestic counterfeiting industry in India has provoked pharmaceutical reforms designed for compliance and enforcement; however, enforcement is difficult due to procedural obstacles in the counterfeit supply chain (CDSCO, 2022). Unfortunately, in India, the criminal enforcement of falsified drugs involves the operation of multiple jurisdictions with several layers of enforcement.

India's criminal enforcement of forgeries is also complicated because there is little or no sharing of information or inter-agency coordination among national

regulators and state-level authorities, local enforcement agencies, and border security regulations (Directorate of Revenue Intelligence, 2023). This lack of coordination results in porosity of India's borders, which facilitates international trafficking of counterfeit and illicit pharmaceutical products. The challenges to enhancing law and strengthening enforcement as it relates to drugs in India would be made simpler with improvements in coordination; however, all national and regional level agencies must be unified in both their action and coordination to effectively respond to the complexities of logistics and operations associated with successfully enforcing drug laws in India.

3.2 US Legal Framework

The United States has developed a comprehensive legal structure to address the illicit pharmaceutical market, including counterfeit drugs, trafficking, and illegal online pharmacies (U.S. Food and Drug Administration [FDA], 2023). The FDCA (Food and Drug Cosmetics Act of 1938) is enforced by the FDA, responsible for regulating the safety, efficacy, and marketing of drugs and medical devices (Food, Drug, and Cosmetic Act, 1938). The FDCA regulates counterfeit or unapproved/misbranded drugs, and methods of regulation apply to counterfeit drugs that are both criminal enforcement measures and civil enforcement measures. The FDA is responsible for more than just pharmaceutical products. It is important to note that it is also essential in investigating and regulating cases that fall under counterfeit drugs (FDA, 2023). The FDA monitors the activities, raises public awareness, and collaborates with various U.S. agencies and organizations both nationally and internationally to block the pathway of illicit pharmaceutical products, counterfeit drugs, and drug trafficking in the U.S. and being sold in the U.S. (Gathii, 2003).

The Drug Enforcement Administration (DEA) enforces controlled substance law in the US and is an important part of the effort to prevent the diversion of legitimate controlled substances to the illegal market (Drug Enforcement Administration, 2023). To combat the illegal flow of controlled substances and dangerous drugs, including opioids, the DEA partners with the FDA and local law enforcement, as well as international stakeholders. A notable recent piece of legislation is the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, which attempts to address the issue of online pharmacies that provide ease of access to controlled substances (Ryan Haight Act, 2008). Meanwhile, the emergence of unregulated "dark web" pharmacies poses an enormous challenge, since law enforcement has few means to contain their operations, and they use many techniques to anonymize their operations and evade law enforcement (DEA, 2023).

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3.3 EU's Legal Framework

The European Union (EU), through numerous legislative frameworks on counterfeiting, has introduced specific legislation to protect the pharmaceutical supply chain from counterfeiting (European Medicines Agency [EMA], 2023). Arguably, the most essential piece of legislation is the Falsified Medicines Directive (FMD) of 2011, which lays out strict regulations that protect the pharmaceutical supply chain throughout the EU jurisdiction (Falsified Medicines Directive, 2011). Pharmaceutical Companies, Wholesalers, and Distributors now must implement adequate protections to track and verify the medicines within the supply chain, including serialization (Pantea, 2011). On top of this, EU Regulations 2016/161 require that pharmaceutical products have safety features, such as serial numbers and tamper-evident packaging, which will help identify counterfeit drugs sold through the supply chain, especially at points of sale (European Commission, 2016).

The FMD and its associated regulatory bodies have had a positive impact on counterfeit drugs (EMA, 2023). However, enforcement of such regulations continues to present challenges in the national jurisdictions of EU members. National strategies were supposed to complement EU regulations; however, the inability to harmonize from one member to the next has produced issues in enforcement (European Commission, 2023). There is a need for only the national strategies in those jurisdictions in the illicit drug trade in the EU, but discrepancies between national laws lead to overlaps in jurisdiction, which hinder enforcement. There continues to be substantial advancement in combating counterfeit drugs, but coordinating and enforcing the borders of the EU remains a challenge.

3.4 China

The legal basis for regulating the pharmaceutical market and tackling counterfeit drugs in China is mainly derived from two principal laws: the Drug Administration Law (2019) and the Pharmaceutical Administration Law (State Council, 2019). However, these laws have not fundamentally addressed the criminal elements of counterfeit drug production in China due to the sheer volume of pharmaceutical production in the country, in addition to limited capacity for delivery of regulatory enforcement (National Medical Products Administration [NMPA], 2022). At the state level, the State Drug Administration (SDA) has increased penalties on violators and created public awareness campaigns to address counterfeiting of products and drug distribution (NMPA, 2022). The fundamental challenge is not only upholding regulations but also the complexity of China's expansive pharmaceutical sector and the ineffectiveness of regulatory

enforcement in rural or remote regions (Chow, 2017; World Health Organization [WHO], 2021).

Another challenge in China is the issue of transnational illicit trade, which on occasion comes from outside the jurisdiction of China's government through cross-border smuggling violations primarily with Hong Kong, Malaysia, and Southeast Asia, where counterfeit drugs are trafficked for importation globally (INTERPOL, 2022). To ameliorate international regulatory enforcement, China has begun implementing track and trace systems and ramped up cooperation with multiple international organizations, such as INTERPOL, but the sophistication of pharmaceutical crimes far outpaces many of the domestic regulatory enforcement capabilities available (NMPA, 2022).

3.5 International Treaties and Guidelines

Several international treaties and guidelines deal with criminal activity related to pharmaceuticals and multinational cooperation (United Nations Office on Drugs and Crime [UNODC], 2021). The World Health Organization (WHO) has made several recommendations to combat the international trade in counterfeit drugs (WHO, 2021). In 2011, WHO adopted the MEDICRIME Convention, establishing an international treaty with explicit goals of criminalizing counterfeit medical drugs through international cooperation to combat pharmaceutical crime (Council of Europe, 2011). WHO is also providing technical assistance for national regulators and working directly with the private sector to facilitate the implementation of successful deterrent strategies against pharmaceutical crime (Negri, 2016; WHO, 2021).

The United Nations Office on Drugs and Crime (UNODC) assists in combating illegal drug trafficking around the world through the International Drug Control Conventions, which regulate illicit and licit production, supply, and consumption of narcotic drugs and psychotropic substances (UNODC, 2021). The provisions of the conventions serve as the legal basis for international cooperation in investigations and enforcement against drug smuggling. The conventions, however, have never been fully implemented because of jurisdictional issues, especially in cross-border trafficking scenarios (UNODC, 2021).

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is another vital international framework associated with pharmaceutical crime (World Trade Organization [WTO], 1994). The protection of Intellectual Property Rights (IPRs) under TRIPS is fundamental to preventing counterfeit medications. However, the protection of intellectual property itself is a contentious issue in developing countries because they need affordable access to medicines (WTO, 1994). Enforcement and public health conflict in these countries because it is

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difficult to enforce IP law (protect the rights of IP owners; provide restitution) while still permitting the public to access the medicines they need (WHO, 2021).

3.6 Comparative Legal Analysis

In India, the Drug and Cosmetics Act, 1940, established the legal framework for the regulation of pharmaceutical activity (Government of India, 1940). However, the framework cannot be effective due to structural deficiencies and needs to be regulated uniformly across all the states (Central Drugs Standard Control Organization [CDSCO], 2022). Fragmented enforcement by the States, limited technology use, and agency coordination failures create ineffective jurisdictions (Ministry of Health and Family Welfare, 2023). Different socio-economic conditions across India's geography further limit the uniform implementation of regulatory enforcement (CDSCO, 2022). Cross-border drug crime, created by disparity of regulatory enforcement, complicates the regulatory defence challenges and will not succeed without comprehensive inter-agency collaboration and centralized databases to support effective, real-time data sharing (Directorate of Revenue Intelligence, 2023).

The comparative review of the regulatory environments in the US, EU, and China can inform India's tactical response to prevent pharmaceutical crime (WHO, 2021). In comparison to all three countries, the US is ahead of the curve with the Ryan Haight Online Pharmacy Consumer Protection Act to address online pharmacy issues (U.S. Congress, 2008). There is the EU's Falsified Medicines Directive (FMD), which is useful for highlighting the necessity for serialized tracking systems for the distribution of pharmaceuticals that have sufficient tamper-proof package systems in place (European Parliament, 2011). Harmonization and centralization of regulatory schemes are important control measures where cross-border pharmaceutical crime is concerned (EMA, 2022).

China's preoccupation with the manufacture and distribution of counterfeit drugs helps provide a counterpoint to the argument (National Medical Products Administration [NMPA], 2022). Despite employing complex track-and-trace systems, China's straggling supply network and poorly regulated rural markets are major areas of weakness (INTERPOL, 2022). The principal focus must always be on initiating a serious engagement with imposing enforcement mechanisms with a focus on cooperation both within China and beyond (NMPA, 2022). Cooperation with global regulatory organizations and collaborative partnerships to improve enforcement continuously to respond to the interdisciplinary health threat of counterfeit pharmaceuticals in and outside of China (WHO, 2021).

4. Deterrence Mechanisms: Beyond Legal Frameworks

The ability for legitimate regulatory authorities to enforce laws designed to combat pharmaceutical crimes does not rest simply on legislative principles (UNODC, 2021). The use of illegal drugs and medicines involves dynamic forces attempting to disrupt the illicit networks responsible for facilitating the trafficking of counterfeit or substandard medicines (INTERPOL, 2022). As such, the networks that exploit gaps in medicine regulatory systems (are not local networks, but rather well-organized networks that operate in a highly organized action multi-situated systems across more than one jurisdiction), to create activities that continually push forward over which law enforcement agencies must sort through a legal and logistical gap in this organized overlap (UNODC, 2021). The organized sophistication and complexity processes of these organized crime phenomena require a large-scale response from law enforcement agencies, national or not, and sometimes even coordinated international enforcement efforts are not even a sufficient means for intervention (INTERPOL, 2022; Lemmens & Gibson, 2014).

Pharmaceutical crimes are being effectively tackled by agencies enforcing at a national level (WHO, 2021). In India, the Central Bureau of Investigation (CBI) specializes in the detection and disruption of counterfeit pharmaceuticals (Government of India, 2023), the United States has the Drug Enforcement Agency (DEA) (U.S. Department of Justice, 2023), and in the UK there is the National Crime Agency (NCA) (Home Office, 2023). These agencies have the responsibility not only to identify groups involved in the distribution of counterfeit drugs, but also to find out who the key players are and to conduct covert actions to infiltrate and dismantle those criminal groups (INTERPOL, 2022).

Unfortunately, their ability to carry out their enforcement orders is undermined by the transnational nature of the pharmaceutical black market (UNODC, 2021). Often, the drugs have been manufactured in one jurisdiction, trafficked through one or more transit countries, and then sold in a third jurisdiction to an unsuspecting consumer (WHO, 2021). The transnational environment necessitates international collaboration; no single country has the reach and capability to combat these crimes within its jurisdiction and even neighbouring countries (INTERPOL, 2022).

The activities of organizations like Interpol and Europol are valuable in bridging national enforcement efforts (INTERPOL, 2022; Europol, 2023). These organizations assist not just through the sharing of intelligence or facilitating collaborative actions to arrest offenders in their jurisdictions or to bring matters to court, but also through aligning legal systems and the way national enforcement authorities enforce the law, so that criminal networks cannot evade law enforcement by exploiting differences between national jurisdictions (Europol, 2023). This collaboration is essential in developing a practical means to counter the multi-layered forms of pharmaceutical crime (UNODC, 2021).

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4.1 Role of Advanced Technologies

In the pharmaceutical black market, technology has a dual role: it serves to facilitate criminals operating in this unregulated market while also serving as a major resource for regulators and law enforcement officials (UNODC, 2020). Digital environments, specifically, darknet markets, have facilitated the drug black markets, allowing sellers and buyers to remain anonymous, use secure, untraceable payment methods, and consumers to still have evade the detection of law enforcement (INTERPOL, 2019). Sophisticated darknet markets such as those of Hydra and AlphaBay obscure communications and use multilayered independent networks, making them possible to intercept or trace (Mangan, 2022; UNODC, 2020). Uncontrolled social media and online trading websites promote counterfeit, ease of drug supply(piracy) products to favoured buyers, but also give a method, without commercial risk, to the public at large (FDA, 2021).

Conversely, devices, digital technologies, and software applications deliver forms of remediation to counter this (EMA, 2020). Blockchain technology represents an example of technology's unique contribution. The proposed legal decision-making models use blockchain-based technologies to develop immutable supply chain records for all people with vested interests in medicines so stakeholders can verify they are consuming legitimate medicines at every point in the production and distribution of a medicine (CDSCO, 2021). Anytime authorities can capture large amounts of data, with data analytics, AI, and machine learning, vis major, and make investigations from suspicious consumption transactions that are usually offline (INTERPOL, 2019). RFID tags, QR codes, blockchain technologies, and advanced online systems or people can improve real-time tracing and continuous monitoring of pharmaceutical products (EMA, 2020).

4.1.1 AI and Blockchain in Combatting Pharmaceutical Crime

The potential of blockchain technology and artificial intelligence (AI) as viable alternatives to combating pharmaceutical crime is commendable (World Health Organization [WHO], 2021). Nevertheless, the practical application of real-world implementation presents numerous challenges in different contexts, worth analyzing further. Whereas blockchain is a technology that can uniquely provide transparency regarding the supply chain, there are major barriers to systematic application (European Medicines Agency [EMA], 2022). Not only are operational costs, infrastructure for developing decentralized ledgers, and scalability issues notable challenges, but these approval and widespread adoption challenges remain significant and are not only burdensome for all pharmaceutical companies,

but particularly for smaller ones (U.S. Food and Drug Administration [FDA], 2023). The infrastructure built allows for technology-driven supplemental healthcare, which means that low-income areas or those with limited digital mechanisms may find challenges that would prevent blockchain from being universally applied (International Criminal Police Organization [INTERPOL], 2022).

AI systems can analyze millions of records and can also help to identify patterns and inconsistencies that are complex in nature (FDA, 2023). New applications allow for a common view of the supply chain, and this includes public law enforcement identification of pharma flow (from origin to distribution) with great precision, enabling investigators to disrupt counterfeit drugs through collaborative enforcement (WHO, 2021). Blockchain technology has been introduced as a potentially groundbreaking strategy to verify drug authenticity (EMA, 2022). Blockchain's decentralized, immutable ledger technology incorporates validation, immutability, and transparency, building documented evidence of manufacturing, distribution, and sale (FDA, 2023). Such transparency provides no opportunity for supply chain participants to misrepresent products (INTERPOL, 2022). Notably, all parties in the pharmaceutical supply chain will bear some accountability by contributing to the creation of an immutable record of each stage of manufacture, to which the authorities, regulators, and consumers will have access (EMA, 2022).

This immutable record appears to deter strongly any attempt to mix illegitimate drugs into the authenticated drugs distributed in the supply chain (WHO, 2021). Furthermore, the operational audibility of blockchain pathways will enhance the transparency of regulatory obligations, regulatory compliance, and consumer confidence (FDA, 2023). Ultimately, this technology may support a self-regulating pharmaceutical supply chain that is resilient against manipulation (EMA, 2022; Lemmens & Gibson, 2014).

The potential for blockchain and AI to deter pharmaceutical crime presents a high elevation of opportunity; however, the feasible application of these innovations contains formidable technical, economic, and operational engagement challenges (FDA, 2023). The very ambitious move to support the legal and regulatory frameworks and overall operational legal mechanism - common frameworks; a greater level of inter-agency and international collaboration, and the sound allocation of overall resources (including infrastructure) for implementation into innovation (UNODC, 2021) will take commitment across both emerging and developed markets. The contrast between different jurisdictions presents a rich source of knowledge and experience for organizations (EMA, 2022). Nevertheless, the chances of successful translation will depend to a large degree on the socio-economic and infrastructural contexts (WHO, 2021).

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5. Conclusion

The transnational black market for pharmaceuticals causes serious worldwide health, economic, and security issues (World Health Organization [WHO], 2021). This analysis illustrates the need for a coordinated partnership and a multi-pronged response based on transnational criminology to tackle the very real threats that illicit pharmaceuticals are creating (United Nations Office on Drugs and Crime [UNODC], 2022). It is important to establish that the three key global areas: India, the United States, the European Union, and China, have either developing or established legislative and enforcement regimes (U.S. Food and Drug Administration [FDA], 2023; European Medicines Agency [EMA], 2022; Central Drugs Standard Control Organization [CDSCO], 2022) but despite the legal capacity to take action across the globe on illicit drugs, there are still enforcement issues and jurisdiction challenges from having a truly global response (INTERPOL, 2023).

Effective enforcement against pharmaceutical crime requires a comprehensive approach that integrates national enforcement capacities, international collaboration, technology innovation, and sustained mutual efforts (UNODC, 2021). As a form of transnational crime that is very advanced and sophisticated, pharmaceutical crime necessitates developing new solutions that can only happen through collaboration situated beyond the boundaries of traditional criminal justice partnerships, and sustained for a long-term agenda (INTERPOL, 2022). Law enforcement agencies around the world must increasingly embrace new technologies such as AI and blockchain, not simply for improved investigative capacity and safeguarding the integrity of supply chains, but to create future-proof models of pharmaceutical distribution that ensure transparency and resiliency (WHO, 2021).

AI initiatives, including predictive policing models that build on large datasets to recognize patterns of criminal behavior, are expensive to train, tailor, and implement within an organization (United Nations Office on Drugs and Crime {UNODC}, 2021). Conspicuously building AI algorithms that are equipped to deal with the complexities of an international pharmaceutical supply chain will require expert knowledge and funding that many stakeholders may not have (WHO, 2021). While multicentric and trustworthy data is vital for AI systems to succeed, jurisdictional barriers to purchasing history data dramatically restrict available implementation opportunities (EMA, 2022). Yet, the potential of using AI for counteracting the scale of pharmaceutical crimes will never happen without establishing international standards around getting all stakeholders to agree to share data and mechanisms to protect privacy and security (INTERPOL, 2022).

To meet these goals, this paper calls for a number of important actions. First, the global harmonization of basic processes and practices through organizations like the WHO and INTERPOL to create effective mechanisms for compliance and to ensure the legitimate flow of pharmaceuticals across borders (WHO, 2021; INTERPOL, 2023). Second, targeted investment in blockchain technology to allow more effective tracking of goods in the supply chain (EMA, 2022), and investment in AI systems to allow the detection of counterfeit transactions in real-time and establish a consistent monitoring protocol (FDA, 2023). Third, a formalized partnership between pharmaceutical companies and regulators is required for the monitoring of supply chain activity and implementing joint anti-counterfeit activities (UNODC, 2022).

A full understanding of the socio-economic issues that can lead to illicit demand for pharmaceuticals needs to be systematically evaluated and remediated (WHO, 2021). Further exposing prospective solutions through developing and utilizing new technologies, such as machine learning or the Internet of Things for sampling, should be a value added to the current state of data in detecting the growth of illicit pharmaceuticals (FDA, 2023). Additionally, a comparative evaluation of common regional approaches to detect illicit pharmaceuticals, such as the Falsified Medicines Directive, should identify best practices and model approaches for improved policy (EMA, 2022; European Parliament, 2011).

Only with comprehensive, technology-based, and internationally developed strategies will an approach be proven effective to protect the rights of individuals and vulnerable groups to not being harmed in the crime of pharmaceuticals while deployed by sophisticated networks. This requires sustained, collaborative responsibility and ingenuity among all stakeholder groups going forward, with a passion for health.

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The Author(s) declare that this work is original and has never been published in any form or any other media, nor is it under consideration for publication in any journal, and all sources cited in this work refer to the basic standards of scientific citation.

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