

Policy Brief:

**Enhancing Drug Traceability in
Ghana to Combat Counterfeit
Medicines**

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Executive Overview

Counterfeit medicines have become one of the most pressing threats to consumers in Ghana. They are not only fatal to the health of individuals who use the substandard products, they also compromise the reliability of the supply chain in Ghana. The increase in counterfeit drug incidences in Africa, including Ghana, has escalated to what is estimated to be 42% of the global figure. In the recent past, organizations responsible for the approval of these drugs, for instance, the Food and Drugs Authority in Ghana, have worked toward combating counterfeit drugs; however, they continue to be a major issue in society, which makes medical products a real cause for concern.

Key Findings:

- **Prevalence of Counterfeit Drugs:** Ghana's FDA has noted a 92% failure rate on products tested in 2022. Our study shows that, generally, the most counterfeited substances are antibiotics, antimalarials, and COVID-related products.
- **Challenges in the Supply Chain:** Due to a highly complicated supply chain, poor regulation, open borders and black markets, it becomes easy for counterfeit drugs to penetrate the market. These challenges are compounded by weak technological support and lack of policy convergence with international benchmarks.
- **Traceability as a Solution:** To curb the issue of counterfeit medicines, increasing the ability of a drug to be traced within the supply chain is seen as a key strategy.

Strategic Recommendations:

- **Strengthen Technological Integration:** Support current traceability methods with modern techniques of tracking inventory through the use of blockchain and aerial RFID to fight counterfeit drugs, especially with online businesses.
- **Enhance Regulatory Frameworks:** Synchronize the national policies with the global laws and norms so that everyone in the supply chain is held to the same level of responsibility.
- **Improve Public Awareness:** Provide consumer education on the harms of counterfeit drugs and the need for drug authentication.

- Foster Stakeholder Collaboration: Promote increased collaboration between the government departments, healthcare workers, pharmaceutical companies, drug distributors, retailers and manufacturers to fulfill effective application of traceability solutions and other anti-counterfeiting initiatives.

Conclusion:

By implementing the proposed traceability measures and strengthening regulatory frameworks, Ghana can significantly reduce the threat of counterfeit medicines and enhance the integrity of its healthcare system.

Background

Counterfeit and pirated pharmaceuticals are a growing problem in many African countries, including Ghana. Weak supply chains and inadequate control mechanisms expose consumers to serious health risks from counterfeit drugs. These counterfeit products undermine genuine revenue models and harm the integrity of health supply chains.

Recent studies estimate the global counterfeit drug market at US\$200 billion, with 42% of cases originating in Africa (Nayyar et al., 2019; OECD, 2020). This is due to weak anti-counterfeiting laws, underfunded regulatory agencies, and ineffective legal sanctions. The World Health Organization estimates that counterfeit drugs result in roughly US\$1.5 billion in losses annually and more than 200,000 children's deaths yearly in Africa due to malaria and pneumonia (WHO, 2022).

In Ghana, pharmaceutical sales reached US\$462 million in 2020 and are expected to grow to US\$544 million by 2025, with an annual growth rate of 8% (Fitch Solutions, 2021). Despite this growth, there is limited understanding of how rampant drug counterfeiting is.

Ghana's Food and Drugs Authority (FDA) has said that the most commonly counterfeited drugs are antimalarials, antibiotics, painkillers, and uterotonics (FDA, 2021). Regulatory bodies have made many efforts to make medicine safer and secure the drug supply. These efforts include surveillance, law enforcement, public education and training. However, the success of these measures remains uncertain.

Research indicates that drug traceability can significantly combat counterfeiting. However, few studies focus on drug traceability in Ghana's pharmaceutical sector. Research shows gaps in understanding supply chain traceability in Ghana. It also shows gaps in its practical use in fighting counterfeit medicines, improving patient safety and boosting operations in Ghana's healthcare system.

Moving forward, we observe a significant gap in research on factors influencing the adoption of various traceability technologies in healthcare. While theoretical discussions are common, more research is needed to explore these factors more extensively. Such research should consider the unique challenges and opportunities within a diverse healthcare ecosystem like Ghana's. This will provide nuanced insights and strategically position healthcare firms and stakeholders for effective adoption of traceability strategies.

Study

The Center for Applied Research and Innovation in Supply Chain-Africa (CARISCA) at the Kwame Nkrumah University of Science and Technology (KNUST) studied the prevalence of counterfeit medicines in Ghana's Pharmaceutical Supply Chain. We also assessed the use of traceability in combating the menace. Our study employed document analysis and stakeholder interviews. We examined public records from health and regulatory institutions in Ghana from 2019-2022. These records were examined to assess counterfeit drug rates, find commonly counterfeited drugs, analyze causes of drug counterfeiting, and evaluate traceability methods. Key stakeholders from regulatory bodies, pharmaceutical companies, hospitals, and community pharmacies were interviewed. We identified 79 participants with relevant expertise. Surveys and semi-structured interviews were applied to explore the gaps in drug regulation, traceability capacity of the health system, stakeholder collaboration, and perceptions of traceability effectiveness.



The issue of counterfeit drugs in Ghana

Recent data from Ghana's Food and Drugs Authority (FDA) show a concerning rise in counterfeit medicines. In 2019, 11 out of 96 drug samples tested were substandard, reflecting an 11.46% prevalence. By 2022, the FDA had significantly increased its testing capacity, assessing 95,093 products. Shockingly, 92% of these, about 87,507 products, failed to meet quality standards.

To better understand the issue, we developed a Severity Index that assesses the frequency and impact of counterfeit drugs on health and safety. For instance, the severity rating for antibiotics like Amoxicillin and Clavulanic Acid (Augmentin) rose from moderate in 2019 to high in 2022. Conversely, the severity of counterfeit antimalarials decreased over the same period, being considered of moderate severity (Table 1). COVID-related products scored high in severity due to the pandemic, similar to unregistered herbal medicines. The combination antidiabetic drug Vildagliptin with Metformin (Galvus Met) was identified as a high-risk counterfeit drug. Likewise, Sildenafil (Viagra) received high severity ratings. Other medicines, including antimalarials, had moderate severity.

¹ Severity Index (SI)=F×I×P

Where: F: Frequency of occurrence (High = 3, Medium = 2, Low = 1); I: Impact on health/safety (Severe = 3, Moderate = 2, Mild = 1); P: Probability of detection/occurrence (High = 3, Medium = 2, Low = 1)

Table 1: Common Counterfeit Drugs and their Overall Severity Ratings

Drug Type	Regulatory Severity Rating	Stakeholder Severity Rating
Antibiotics		
• Amoxicillin and Clavulanic Acid (Augmentin)	High	Moderate
• Ciprofloxacin	Moderate	Moderate
Antimalarials		
Artemether-Lumefantrine	Moderate	Moderate
COVID-related Products (Unregistered Homeopathic Medicines)	High	High
Unregistered Herbal Medicines	Moderate	Moderate
Levonorgestrel (Postinor 2)	High	High
Specific Brands		
Procold	High	High
Aboniki Ointment	High	High
Dewormers	High	Low
Zentel	High	Low
Vermox	High	Low
Sildenafil (Viagra)	High	Low
Antidiabetics: Vildagliptin+Metformin (Galvus Met)	High	High

Similarly, data from other supply chain stakeholders, including drug distributors and pharmacists, revealed that Levonorgestrel (Postinor 2) and Artemether-Lumefantrine (Coartem) were frequently counterfeited and received a high and moderate severity rating, respectively. A word cloud (Figure 1) generated from collective data highlighted Postinor, Coartem, and Galvus Met as the most commonly counterfeited drugs, underscoring the need for targeted regulatory actions.



Figure 1: Word cloud of most common counterfeit drugs

The difficulty of these challenges is further illustrated by the various channels through which counterfeit medicines infiltrate the market. The sources and routes of counterfeit medicines are varied. Illicit manufacturers, intermediaries in the supply chain, online marketplaces, and cross-border trafficking all contribute to the problem. Supply chain intermediaries, sometimes unwittingly, facilitate the spread of counterfeit drugs. Issues such as inadequate verification of products, weak documentation, and poor communication among supply chain actors collectively enable counterfeit products to infiltrate and blend within the highly complex supply chain. In contrast, some intermediaries such as importers, wholesalers, and retailers, knowingly facilitate the sale of fake products, divert genuine products to unauthorized markets, and engage in improper handling and storage practices, thus compromising the quality of legitimate medicines.

One grave concern is about the channels through which counterfeit drugs enter the country. These channels include online sales and smuggling across borders. Significant amounts of counterfeit medicines enter Ghana from Nigeria through the Ghana-Togo border. These porous borders and the high volume of informal trade in these areas allow for these fake medicines to slip through undetected. Traffickers exploit the inadequate regulatory oversight and enforcement along these borders. Therefore, it is crucial for Ghana to strengthen its border control measures and collaborate internationally to effectively combat this serious issue.

Additionally, the complexity of Ghana's supply chain, high demand for inexpensive drugs, and technological challenges further worsen the issue. These factors create an environment where counterfeit drugs can easily infiltrate the supply chain, highlighting the urgent need for stronger regulatory measures to combat this threat.

Traceability in Ghana

To address the extensive threat of counterfeit medicines in Ghana's supply chain, enhancing traceability emerges as a critical solution. Enhancing traceability systems offers Ghana the ability to track and verify the authenticity of pharmaceutical products across every point of the supply chain, from manufacturing to distribution and final sale and even use. This significantly reduces the likelihood of counterfeit drugs entering the market. Strengthening traceability not only improves regulatory compliance but also protects public health and builds trust among consumers.

Analysis of current traceability mechanisms in Ghana

Ghana's current traceability mechanisms aim to secure its pharmaceutical supply chain and combat counterfeit medicines. The traceability mechanisms include regulatory and technological approaches. The FDA oversees the regulatory framework. This framework includes post-market surveillance and recalls. The framework ensures that products on the market are sold according to local laws. Key initiatives, like the ProPer Seals System, allow stakeholders to verify product authenticity. This is done by entering FDA or batch numbers, product seals, etc., into a verification platform. These measures are designed to protect public health and ensure the integrity of medical products from manufacturers to consumers.

Ghana's drug traceability policy: The Ghana National Pharmaceutical Traceability Strategy

To further enhance traceability in Ghana's pharmaceutical supply chain, the Ministry of Health (MOH) and the FDA have developed a comprehensive strategy to ensure the availability of high-quality, safe, and effective medical products throughout the country. This strategy highlights the government's dedication to protecting public health through rigorous oversight and control measures. The strategy incorporates advanced mechanisms such as unique identifiers, data capture and verification systems, centered on adopting GS1 standards. These standards offer a global framework for product identification and data sharing. This standardization ensures smooth communication and interoperability among various stakeholders within the pharmaceutical supply chain, both within Ghana and internationally. The GS1 system has various features such as the

Global Trade Item Numbers (GTINs), which uniquely identify products, while the Serial Shipping Container Codes (SSCCs) track logistics units. Global Location Numbers (GLNs) pinpoint parties and locations, enhancing supply chain transparency. Global Data Synchronization Networks (GDSNs) ensure all stakeholders access accurate, current product data, minimizing counterfeit risks. These tools work in concert, maintaining authenticity throughout the distribution process. These mechanisms are essential for tracking medical products from the manufacturer to the consumer, significantly enhancing the ability to detect and remove counterfeit medicines from the supply chain.

How does Ghana compare to global best practices?

Regions like the United States (US), European Union (EU), and India have established comprehensive traceability systems by leveraging advanced technologies and stringent regulatory frameworks (Table 2). These systems have proven effective in ensuring the authenticity and safety of medical products, providing valuable models for other nations to follow. Ghana's goal of ensuring the availability of quality, safe, and effective medical products aligns with the objectives of global leaders in pharmaceutical traceability (Table 3).

GS1 standards, which involve barcoding and product serialization for uniquely identifying medicines, is crucial for enabling the FDA to monitor, detect, and prevent counterfeit medicines from entering the market. In addition to these standards, integrating blockchain technology would further enhance traceability by providing an unalterable, transparent record of all transactions regarding medicines. This is especially crucial for addressing the challenges posed by informal markets and cross-border smuggling. It is crucial that we encourage the adaptation of multiple systems to enhance traceability. Strengthening regulatory frameworks, akin to those in the US and EU, with rigorous verification processes and harmonized international standards would further bolster efforts.

Additionally, effective collaboration among government agencies, pharmaceutical companies, and healthcare providers is crucial. Lessons from India, Nigeria, and Kenya emphasize the importance of consumer engagement, public awareness, and stakeholder buy-in for successful implementation, which Ghana can emulate by fostering stronger partnerships and enhancing public education efforts (Table 2).

Table 2: Comparison of traceability among selected countries

Country/Region	Traceability System	Key Technologies	Regulatory Framework	Successes	Challenges
United States	Drug Supply Chain Security Act (DSCSA)	GS1 standards, electronic track and trace systems, blockchain RFID, barcoding, serialization, interoperable data exchange protocols	Comprehensive system for prescription drugs	Significant reduction in counterfeit drugs	High implementation costs and complex regulatory requirements
European Union	Falsified Medicines Directive (FMD)	Unique identifiers (2D barcodes with product codes, serial numbers, batch numbers and expiration dates), anti-tampering devices (ATDs), European Medicines Verification System (EMVS), and National Medicines Verification System (NMVS)	Centralized system for medicine verification	Effective stakeholder collaboration	Ensuring uniform implementation and raising consumer awareness

India	Drug Authentication and Verification Application (DAVA)	QR codes, SMS-based verification	Digital platform for tracking and authenticating drugs	High consumer engagement	Technological barriers and scalability issues
Nigeria	Mobile Authentication Service (MAS)	SMS-based verification	Implementation by National Agency For Food And Drug Administration And Control (NAFDAC)	Increased adoption and reduction in counterfeit drugs	Initial low consumer awareness and technological limitations
Kenya	Serialization and Traceability System	Unique identifiers	System required by Pharmacy and Poisons Board (PPB)	Improved supply chain security	Resistance from stakeholders due to costs
Ghana	National Pharmaceutical Traceability Strategy	Unique identifiers, GS1 standards	Overseeing by FDA	Alignment with international standards	Need for advanced technologies and stronger regulatory framework



Table 3: Summary of Ghana's comparative position to global traceability practices

Aspect	Ghana's Approach	Comparative Position
Objective Alignment	Ensures availability of quality, safe and effective medical products	Aligns with global objectives
Implementation and Standards	Uses unique identifiers and GS1 standards	Similar to global best practices
Technological Integration	Potential for adopting blockchain, Artificial Intelligence (AI), and Internet of Things (IoT)	Could benefit from integrating advanced technologies
Regulatory Frameworks	Overseen by FDA with room for strengthening	Could be enhanced by adopting rigorous verification processes
Stakeholder Collaboration	Focuses on partnerships and public education	Can learn from international examples for better engagement

Traceability and combating counterfeit drugs in Ghana

Despite Ghana's pharmaceutical traceability policy's strengths, several challenges impede its full implementation. These challenges include interoperability issues arising from disparate systems used by different stakeholders, hindering cohesive data sharing. Additionally, limited regulatory harmonization with international standards and resource constraints, including financial and technological limitations, pose significant obstacles to achieving the policy's objectives.

Furthermore, counterfeiters have developed sophisticated techniques that make detection and prevention more challenging. These include high-quality replicas, advanced printing technology, chemical composition manipulation, and reusing legitimate packaging.

In addition to the previously mentioned challenges, the proliferation of online marketplaces for medicines introduces unique complexities to traceability and anti-counterfeiting efforts. These platforms facilitate the global distribution of counterfeit medicines, complicating the process of tracking and enforcement across different jurisdictions. The anonymity provided by online platforms makes it difficult to identify and hold counterfeiters accountable. Moreover, inconsistent regulatory frameworks across countries further hinder coordinated efforts to combat counterfeit medicines effectively. Additionally, there is a widespread lack of consumer awareness about the risks associated with purchasing medicines online and the critical importance of verifying their authenticity. Online marketplaces further compound the problem of sophisticated counterfeiting. These platforms allow counterfeiters to easily create professional-looking storefronts that mimic legitimate businesses, making it difficult for consumers to distinguish between genuine and fake products. Furthermore, the sheer volume of transactions and listings on these marketplaces can overwhelm regulatory authorities, making it challenging to monitor and enforce regulations effectively. Additionally, the ability to use online payment systems and digital marketing tools allows counterfeiters to operate with greater sophistication, targeting specific demographics and regions with tailored fake products, thereby amplifying their reach and impact. These factors collectively pose significant obstacles to ensuring the safety and integrity of the pharmaceutical supply chain.

The Way Forward

Ghana faces several critical challenges in improving its pharmaceutical traceability systems, each requiring specific solutions. Interoperability issues arise because current traceability systems do not seamlessly integrate with global standards or other local systems, leading to gaps in data sharing and verification. Addressing this requires emphasizing technological solutions that ensure seamless integration and data sharing. Additionally, resource constraints, such as limited funding and technological infrastructure, hinder comprehensive implementation. Increasing technological investments are crucial steps toward building robust traceability systems.

Furthermore, enhancing traceability in online marketplaces is essential. Technologies such as blockchain and Radio-Frequency Identification (RFID) can play a vital role in combating counterfeit drugs. RFID uses electromagnetic fields to automatically identify and track tags attached to objects, providing real-time tracking information. This technology significantly enhances the ability to monitor and verify the authenticity of pharmaceutical products throughout the supply chain.

The anonymity provided by online platforms can be mitigated by enhancing regulatory frameworks, ensuring that all stakeholders in the supply chain are accountable. **Regulatory harmonization** is another significant challenge, where discrepancies between national and international standards complicate enforcement. Harmonizing national regulations with international standards, especially within the subregion, is necessary to ensure consistent compliance and accountability.

Low consumer awareness about the risks of purchasing medicines online and the importance of verifying their authenticity can be addressed through comprehensive public education campaigns. By tackling these challenges with targeted solutions, Ghana can significantly improve the safety and integrity of its pharmaceutical supply chain

To combat sophisticated counterfeiting, advanced traceability approaches are being implemented, especially in online marketplaces. Table 4 summarizes suggested traceability approaches to the counterfeiting techniques.

Table 4: Proposed traceability approaches to sophisticated counterfeiting techniques

Counterfeiting Technique	Traceability Approach
High-Quality Replicas	Unique Identifiers (GTIN, SSCC)
Advanced Printing Technology	Anti-tampering Devices, QR Codes
Chemical Composition Manipulation	Blockchain Verification
Reusing Legitimate Packaging	RFID Tracking

We urge policymakers, including the Ministry of Health, the Food and Drugs Authority, pharmaceutical companies, healthcare providers, NGOs, and private investors, to carefully consider the comprehensive solutions proposed to enhance drug traceability and combat counterfeit medicines. Implementing these measures will significantly strengthen the safety and integrity of Ghana's pharmaceutical supply chain, ensuring that only safe and effective medical products are available to the public. By addressing these critical challenges, policymakers can protect public health and harness the full potential of Ghana's healthcare system, thereby contributing to the country's socio-economic development.

References

Nayyar, G.M., Breman, J.G., Mackey, T.K., Clark, J.P., Hajjou, M., Littrell, M. and Herrington, J.E. (2019). Falsified and substandard drugs: stopping the pandemic. *The American journal of tropical medicine and hygiene*, 100(5), 1058.

OECD(2019). *Illicit Trade: Trends in Trade in Counterfeit and Pirated Goods*.

Fitch Solutions (2021). *Projected pharmaceutical sales in Ghana from 2019 to 2025 (in million U.S. dollars)*. Retrieved from <https://store.fitchsolutions.com/pharmaceuticals-healthcare/ghana-pharmaceuticals-report/> (Accessed on 01 September, 2024).

World Health Organization (2022). *The WHO Member State Mechanism on Substandard and Falsified Medical Products Update*. Member State Mechanism Secretariat, World Health Organization.

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