CARISCA Centre for Applied Research and Innovation in Supply Chain – Africa

COMBATING DRUG COUNTERFEITING FOR BETTER HEALTHCARE: AN ASSESSMENT OF TRACEABILITY IN THE PHARMACEUTICAL SUPPLY CHAIN IN GHANA

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Executive Summary

This study addresses the prevalence of drug counterfeiting within Ghana's pharmaceutical supply chain and evaluates the effectiveness of the existing traceability system. The overarching goal is to propose strategies and technological advancements to improve drug traceability and mitigate the adverse impacts of counterfeiting. Through comprehensive research, the study uncovers a complex network of counterfeit drug activities involving various actors such as illicit manufacturers, supply chain intermediaries, online marketplaces, and cross-border traffickers.

A critical examination of Ghana's current traceability system reveals both strengths and weaknesses. On one hand, the system, primarily based on Post-Market Surveillance, offers increased transparency and plays a vital role in identifying counterfeit products, thus protecting consumers. However, challenges such as limited flexibility, resource constraints, and interoperability issues with other authentication systems hinder its overall effectiveness. The incorporation of technologies like the ProPer Seals system for product verification demonstrates progress in enhancing authentication but falls short in addressing interoperability concerns and vulnerabilities to sophisticated counterfeiting techniques.

Key findings from the study highlight significant increases in the prevalence of counterfeit medicines, with notable shifts in severity ratings for specific drug categories over time. Antibiotics and COVID-related products, in particular, have experienced spikes in severity ratings, signifying emerging challenges in combating counterfeit drugs. The persistence of high-risk counterfeit drugs, such as Levonorgestrel (Postinor 2) and Artemether-Lumefantrine (Coartem), underscores the urgency for comprehensive solutions to tackle counterfeiting.

Moreover, the study identifies sources and routes of drug counterfeiting, revealing varying levels of involvement from illicit manufacturers, online marketplaces, and cross-border traffickers. Weaknesses in distribution channels and the lack of digital regulatory frameworks are recognized as key challenges driving counterfeiting activities.

In response to these findings, the study recommends a holistic approach, combining regulatory enhancements, technological innovations, and collaborative efforts among stakeholders. Strengthening regulatory oversight, integrating advanced technologies such as blockchain and radio frequency identification (RFID), and fostering partnerships between industry players and regulatory bodies are essential steps in fortifying Ghana's pharmaceutical supply chain against counterfeit threats.

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Abbreviations

FDA	Food and Drugs Authority
GS1	Global Standards Identification
IMPACT	World Health Organization's International Medical Products Anti-Counterfeiting Taskforce
INTERPOL	International Criminal Police Organization
QR Code	Quick Response Code
RFID	Radio Frequency Identification
USSD	Unstructured Supplementary Service Data
WHO	World Health Organization

1.0 Introduction

1.1 Background

Proliferation of counterfeit and pirated pharmaceutical and healthcare goods is increasing in many parts of the Low- and Middle-Income Countries (LMICs) where core supply chain infrastructure and control mechanisms are generally weak and less functional. As a result, health consumers continue to be exposed to distribution of counterfeit pharmaceutical and healthcare products that may be life threatening. Such products do not only undermine revenue models but they also threaten genuine health supply chains (Falasca et al., 2022)

Recent studies in Europe and North America estimate the counterfeit drugs economy at US$ 200 billion, with 42% of all cases coming from Africa, where “anti-counterfeiting laws are weak; pharmaceutical regulatory agencies are underfunded and understaffed and legal sanctions are ineffective” (Shipalana et al., 2020, page 3). Conservative estimates from the World Health Organization suggest that counterfeit drugs cost French-speaking African economies alone approximately US$1.5 billion in direct revenue losses, and are responsible for 100,000 deaths annually (WHO, 2017; AfricaNews, 2021). Sales of pharmaceuticals in Ghana was US$462 million in 2020 and is expected to top US$544 million in 2025 at an annual growth rate of 8% (in local currency) (Statista, 2021). Despite such strong growth and an anticipated development of the country as a major pharmaceutical hub in Africa, there is no clear understanding of the prevalence of counterfeiting and the role drug traceability could play in fighting the problem.

According to Ghana’s Food and Drugs Authority (FDA), antimalarials, antibiotics, painkillers, and uterotonics are the most counterfeited pharmaceuticals (Food and Drugs Authority, 2021). To enhance the safety of medicines and the security of pharmaceutical supply chains, several strategies are implemented by regulatory bodies to identify and track medicines. Various industry players collaborate in surveillance, law enforcement, public education, and training to combat the menace with not-quite-certain levels of success. Apparently, what is lacking is a clear description of the nature and impact of the menace across different segments of the health supply chain as well as the type and extent of the approaches to track counterfeit products. Although recent studies suggest that drug traceability contributes significantly to the fight against counterfeiting (e.g., Gayialis et al., 2022; Trautmann et al., 2022; WHO, 2017; Ziavrou, 2022), there appears to be a dearth of studies on drug traceability in the pharmaceutical sector in Ghana. The current landscape of research on health supply chain traceability in the healthcare sector reveals several notable gaps that warrant further exploration. Despite the growing interest in traceability technologies, a significant portion of existing studies lean toward conceptual, model-based, or simulation-focused approaches (Shang et al., 2022). The prevalence of these theoretical frameworks underscores a critical need for more empirical research that actively tests and validates these models in real-life scenarios.

This empirical testing is indispensable for gaining practical insights into the implementation of supply chain traceability, particularly in addressing challenges such as counterfeit medicines, enhancing patient safety, and optimizing the operational performance of firms within the health space.

Moreover, a substantial gap has emerged in the literature concerning the antecedents of adopting blockchain technology and other traceability technologies in the healthcare sector (Yadav and Kumar, 2023). While discussions often focus on the theoretical underpinnings, there is a clear lack of studies that delve into the factors influencing the adoption of various traceability technologies, including but not limited to barcodes and radio frequency identification (RFID). Consequently, there is a pressing need for research that systematically explores these factors, providing nuanced insights to position healthcare firms and stakeholders strategically for effective adoption. This research extends beyond technology choice to encompass a comprehensive understanding of regional dynamics, ensuring that the unique challenges and opportunities within diverse healthcare ecosystems are adequately addressed.

The current study therefore determines the prevalence of drug counterfeiting in Ghana's pharmaceutical supply chain and assesses the potential and limits of drug traceability in combating drug counterfeiting in the country.

1.2 Research Questions

The research questions for the study were meticulously crafted to ensure a comprehensive exploration of the issue. Initially, the focus was on understanding the prevalence and identifying the most counterfeited drugs, as these are crucial for grasping the scope and impact of the problem. Next, questions were formulated to uncover the sources and routes of counterfeit drugs, which is essential for pinpointing vulnerabilities in the supply chain. To address the root causes, questions about the key drivers and factors of counterfeiting were included. The current state of drug traceability was then examined to identify existing practices, benefits, and limitations. Additionally, stakeholder perceptions were considered to gain diverse insights. The study was, therefore, guided by the following research questions:

1. What is the prevalence of drug counterfeiting in Ghana's pharmaceutical supply chains, and what are the most counterfeited drugs?
2. What are the most common sources/routes for counterfeit drugs?
3. What are the key drivers/factors for drug counterfeiting in Ghana's pharmaceutical supply chain?
4. How is drug traceability currently being implemented in Ghana's pharmaceutical supply chains, and what are the benefits and limitations of the current system?
5. What are the perceptions of different stakeholders (e.g., pharmaceutical companies, regulatory agencies, healthcare providers, patients) on the effectiveness of drug traceability in combating drug counterfeiting in Ghana?
6. What are the challenges faced by Ghana's pharmaceutical supply chain in implementing drug traceability, and what strategies can be employed to overcome these challenges?
7. How can technology (e.g., blockchain, mobile authentication, bar code etc.) be utilized to enhance drug traceability and to combat drug counterfeiting in Ghana's pharmaceutical supply chain?

1.3 Aims/Objectives

The study aims to determine the prevalence of drug counterfeiting in Ghana's pharmaceutical supply chain and to assess the potential and limits of drug traceability in combating drug counterfeiting in Ghana. Specifically, it aims to:

1. Assess the prevalence and scope of drug counterfeiting in Ghana's pharmaceutical supply chain and identify the most counterfeited drugs.
2. Evaluate the current system of drug traceability in Ghana's pharmaceutical supply chain, and identify the benefits and limitations of the current system.
3. Identify the key drivers or factors for drug counterfeiting in Ghana's pharmaceutical supply chain.
4. Identify the challenges faced by Ghana's pharmaceutical supply chain in implementing drug traceability, and to develop strategies to overcome these challenges.
5. Explore the perspectives of different stakeholders (e.g., policy makers, pharmaceutical manufacturing companies, importers/exporters, regulatory agencies, healthcare providers, patients) on the effectiveness of drug traceability in combating drug counterfeiting in Ghana.
6. Explore the potential of utilizing technology (e.g., blockchain, mobile authentication, bar code, etc.) to enhance drug traceability and combat drug counterfeiting in Ghana's pharmaceutical supply chain.

1.4 Counterfeit Medicines and Traceability in the Context of the Healthcare Supply Chain

1.4.1 Healthcare supply chain

The healthcare industry is a complex and dynamic sector which relies heavily on an efficient and well-managed supply chain system to ensure the availability of medical products, devices, and services. It encompasses the processes, systems, and resources needed in the procurement, production, storage, and distribution of healthcare goods and services. Healthcare supply chains play a pivotal role in delivering timely and quality care to patients while optimizing costs and minimizing waste (Skowron-Grabowska et al., 2022).

Considering recent global health emergencies, such as the COVID-19 pandemic, the resilience of healthcare supply chains has come into sharp focus. Disruptions caused by the pandemic, including supply shortages, transportation constraints, and increased demand for critical supplies, have highlighted the importance of building robust and agile supply chain systems that can effectively respond to crises (Kamara & Essien, 2022).

With that said, effective supply chain management processes in healthcare are essential for several reasons (Arora & Gigras, 2018; Yousefi & Alibabaei, 2015). First and foremost, they directly impact patient care and outcomes. Well-functioning supply chains ensure that healthcare providers have access to the right products and medications when and where they are needed, allowing them to deliver timely treatments and interventions. For instance, a shortage of critical medications or medical devices can significantly impact patient safety and treatment effectiveness (Kim et al., 2022).

Secondly, an efficient healthcare supply chain is vital for cost containment and financial sustainability. The healthcare industry faces increasing pressures to reduce costs while maintaining the quality of care. Supply chain management offers opportunities for optimizing inventory, streamlining processes, and negotiating favorable pricing and contracts with suppliers. By achieving cost efficiencies in the supply chain, healthcare organizations can allocate resources more effectively and enhance their financial viability (Bastani et al., 2021).

Furthermore, the healthcare supply chain is a highly complex and interconnected network involving various stakeholders. Manufacturers, distributors, healthcare providers, pharmacies, regulators, and logistics and other service providers all play essential roles in ensuring the smooth flow of products and services. Collaboration and coordination among these stakeholders are critical for achieving operational excellence and minimizing disruptions (Jaberidoost et al., 2013).

The healthcare supply chain is evolving rapidly to address numerous challenges and complexities. This transformation is driven by several factors, including the dynamic healthcare landscape, which demands continuous adaptation to new medical technologies and treatments. The increasing demand for specialized products adds layers of complexity to procurement, storage, and distribution processes. Regulatory requirements impose stringent standards that must be met, ensuring patient safety and compliance with laws. Additionally, rigorous quality control measures are essential to combat the significant upsurge in counterfeit medications, which pose a severe threat to patient health and undermine the integrity of the supply chain. To tackle these issues, the healthcare supply chain is integrating advanced technologies, enhancing traceability and security, adopting sustainable practices, fostering collaborative partnerships, and embracing patient-centric approaches (Olutuase et al., 2022; Yadav, 2015).

To address these challenges, the healthcare industry is exploring innovative strategies and technologies. Advanced technologies such as blockchain, Internet of Things (IoT), artificial intelligence (AI), and data analytics hold tremendous potential for enhancing supply chain visibility, traceability, and efficiency. These technologies can enable real-time monitoring of inventory, trace substandard commodities, automate processes, improve demand forecasting, and facilitate seamless information sharing among stakeholders (Chen et al., 2022; Emmanuel et al., 2023).

1.4.2 Access to medicines

Access to medicines is a fundamental component of ensuring quality healthcare and promoting public health globally. Medicine should be available, affordable, and accessible to all individuals, regardless of their socioeconomic status or geographic location. However, achieving universal access to medicines remains a significant challenge, particularly in low- and middle-income countries where healthcare resources are often limited (Ozawa et al., 2019).

From a supply chain perspective, access to medicines is closely linked to the efficient and effective management of pharmaceutical products throughout the entire value chain. The supply chain encompasses the processes, systems, and stakeholders involved in the procurement, manufacturing, storage, transportation, and distribution of medicines. It plays a critical role in bridging the gap between the production of pharmaceuticals and their delivery to patients in need (Årdal et al., 2021; Ghaffar et al., 2021).

The importance of the supply chain in ensuring access to medicines cannot be overstated. A well-functioning supply chain is essential for maintaining adequate stock levels, preventing stockouts, and minimizing the risk of counterfeit or substandard medications entering the market. It involves managing complex logistics, coordinating multiple actors, and addressing regulatory requirements to ensure the safe and timely delivery of medicines to healthcare facilities and patients.

The global nature of pharmaceutical supply chains introduces additional complexities, such as trade barriers, intellectual property rights, and regulatory variations across different countries and regions (Sun et al., 2023). However, in Ghana, numerous challenges impede access to medicines from a supply chain perspective. These challenges may include inadequate infrastructure, weak procurement and distribution systems, inefficient inventory management, lack of supply chain visibility, and high costs associated with transportation and storage (Atiga et al., 2023).

It is worth noting that substandard and falsified medicines have also been shown to have an impact on the health of both patients and the population as a whole. In addition, there are significant economic and social consequences, including the direct costs of additional treatment and indirect social costs of lost confidence in the health system and the government, affecting access to quality and efficacious medicines (Ziavrou et al., 2022).

1.4.3 The issue of counterfeit medications

The global issue of counterfeit medications poses a significant threat to public health, jeopardizing the well-being of patients worldwide. Counterfeit medications are falsified or substandard pharmaceutical products that are deliberately misrepresented in terms of their identity, composition, or source. They range from medications with incorrect ingredients or dosages to those that contain harmful substances or lack active ingredients altogether. The prevalence of counterfeit medications has reached alarming levels, with estimates suggesting that up to 10% of all medications in low- and middle-income countries are counterfeit, according to the World Health Organization (WHO). This significant presence of counterfeit medicines leads to adverse health consequences, including treatment failures and drug resistance, and is responsible for more than 200,000 children's deaths in Africa yearly due to conditions like malaria and pneumonia alone (Ofori-Parku, 2022; WHO, 2022).

The scale and distribution of counterfeit medications are complex and constantly evolving. Counterfeit medicines can infiltrate both formal and informal supply chains, with the rise of online pharmacies exacerbating the problem. Geographically, the prevalence of counterfeit medications varies, with certain regions experiencing higher rates due to weaker regulatory frameworks, porous borders, or limited enforcement capabilities. Additionally, specific therapeutic areas, such as life-saving medications for chronic diseases or antimalarials, are frequently targeted by counterfeiters (El-Dahiyat et al., 2021; Ozawa et al., 2018).

Research has identified the main factors responsible for the proliferation of counterfeit medications in Ghana. Prominent ones include weak regulatory frameworks, inadequate supply chain controls, corruption, and illicit manufacturing operations, which provide fertile ground for counterfeiters to exploit. Rapid globalization and increased international trade have further complicated the detection and interception of counterfeit medications, requiring coordinated efforts across borders and jurisdictions (Glass, 2014; Onuh et al., 2022).

Addressing the issue of counterfeit medications necessitates a multi-faceted approach involving governments, regulatory agencies, pharmaceutical manufacturers, healthcare providers, and consumers. Legal and regulatory frameworks play a crucial role in deterring counterfeiters, with penalties and enforcement measures being essential deterrents. The development and implementation of robust detection and authentication technologies, such as tamper-evident packaging, serialization, and molecular markers, contribute to supply chain integrity and protect patients from counterfeit medications (Ozawa et al., 2018).

Collaborative initiatives and partnerships have been established at the national and international levels to combat counterfeit medications. Governments, pharmaceutical companies, regulatory agencies, and international organizations work together to share information, conduct investigations, and raise awareness about the risks of counterfeit medications. Patient education and empowerment are also vital components of preventive strategies, ensuring that individuals are informed and vigilant when obtaining and using medications (Ofori-Parku, 2022; Ozawa et al., 2018).

While progress has been made in the fight against counterfeit medications, challenges persist especially in LMICs like Ghana. Strengthening regulatory frameworks, enhancing international cooperation, investing in advanced detection technologies, and promoting public-private partnerships are crucial for a comprehensive response. Continued research, surveillance, and information sharing are essential to adapt to the evolving tactics of counterfeiters and effectively protect public health.

1.4.4 Combating counterfeit medications

Counterfeit medicines pose a grave risk to patients' health and safety, necessitating comprehensive efforts to combat this global problem. The proliferation of counterfeit medicines undermines public trust in healthcare systems, compromises patient outcomes, and fuels criminal activities. Combating counterfeit medicines requires a multi-faceted approach involving regulatory measures, supply chain security, technology-driven solutions, international collaborations, and public awareness. Efforts to combat counterfeit medicines aim to ensure patient safety, protect intellectual property, and uphold the integrity of the pharmaceutical industry (El-Dahiyat et al., 2021; El-Jardali et al., 2015).

1.4.4.1 Strengthening regulatory frameworks

Robust regulatory frameworks are critical in combating counterfeit medicines. Strict legislation, effective enforcement mechanisms, and appropriate penalties for counterfeiters serve as deterrents. Additionally, regulatory authorities must establish stringent quality control measures, including regular inspections of manufacturing facilities, to identify and prevent the entry of counterfeit medicines into the supply chain. Enhanced transparency and traceability, through serialization and unique identifiers, enable the tracking of medicines throughout the supply chain, facilitating the identification of counterfeit products and removing them from circulation.

1.4.4.2 Enhancing supply chain integrity

Ensuring the integrity of the pharmaceutical supply chain is essential to prevent the infiltration of counterfeit medicines. Collaboration among stakeholders, including pharmaceutical manufacturers, distributors, and regulatory authorities, is crucial. Implementing serialization, track-and-trace technologies, and tamper-evident packaging enables the authentication of medicines at various stages of the supply chain. This promotes transparency, reduces the risk of counterfeiting, and allows for the timely identification and removal of counterfeit products. Strengthening supply chain security also involves conducting regular audits, employing risk-based approaches, and implementing robust quality management systems (Fadlallah et al., 2016; Mackey & Liang, 2013).

1.4.4.3 Utilizing technology-driven solutions

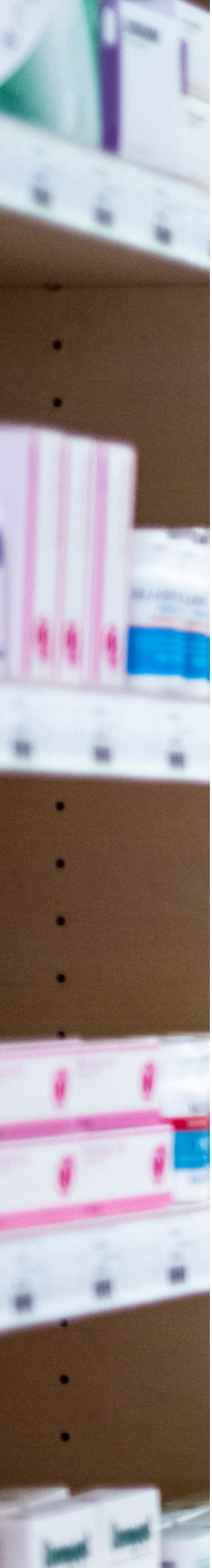
Technological advancements offer promising solutions in the fight against counterfeit medicines. Blockchain technology provides a decentralized and immutable record of transactions, ensuring transparency and traceability throughout the supply chain. Radio frequency identification (RFID) tags enable real-time tracking and authentication of medicines, while mobile authentication apps allow consumers to verify the authenticity of products. Data analytics and artificial intelligence (AI) algorithms can detect patterns of counterfeiting, identify high-risk areas or products, and support proactive measures to prevent counterfeit medicines from entering the market (Hemalatha & Rao, 2015; Islam & Islam, 2022).

1.4.4.4 Strengthening international collaborations

The fight against counterfeit medicines requires international cooperation and collaboration. Governments, regulatory agencies, and international organizations must share information, coordinate enforcement actions, and harmonize regulatory standards. Collaborative initiatives, such as the World Health Organization's International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and INTERPOL's Pharmaceutical Crime Program, facilitate the exchange of intelligence, capacity-building, and joint operations to disrupt counterfeit medicine networks. Additionally, regional, and bilateral agreements can support information sharing and mutual recognition of regulatory processes to enhance supply chain security (Lima & Yonamine, 2023).

1.4.4.5 Public awareness and education

Raising public awareness about counterfeit medicines is crucial in preventing their consumption and reducing demand. Public awareness campaigns, educational programs, and targeted initiatives can inform individuals about the risks of counterfeit medicines, teach them how to identify genuine products, and empower them to report suspicious activities. Collaboration with media outlets, patient advocacy groups, and community organizations helps disseminate and amplify accurate information (El-Dahiyat et al., 2021; Ofori-Parku, 2022).



1.4.5 Traceability as an intervention to combat counterfeit medications

Traceability in the context of pharmaceuticals refers to the ability to trace the entire journey of a medication, from its manufacturing site to the patient. It involves recording and documenting critical information such as the manufacturer, batch number, expiration date, and distribution routes at each stage of the supply chain. By implementing traceability systems, stakeholders can effectively monitor the movement of medications, verify their authenticity, and identify any deviations or counterfeit products (Kumar & Tripathi, 2019).

1.4.5.1 Benefits of traceability

Implementing traceability systems offers several benefits in combating counterfeit medications. Firstly, traceability enhances supply chain visibility, allowing stakeholders to identify and eliminate counterfeit products at various checkpoints. This prevents the entry of counterfeit medications into legitimate distribution channels, safeguarding patients from potential harm. Secondly, traceability improves product recall processes, enabling rapid and targeted recalls in the event of counterfeit medicine detection, reducing the potential risk to patients. Lastly, traceability enhances accountability by establishing clear responsibilities and obligations for all parties involved in the supply chain, ensuring greater transparency, and minimizing opportunities for counterfeiting (Uddin, 2021).

1.4.5.2 Technologies enabling traceability

Various technologies play a crucial role in enabling effective traceability systems. One such technology is serialization, which involves assigning a unique identification number to each individual medication package or unit. This allows for precise tracking and tracing of medications throughout the supply chain. Barcodes, QR codes, or RFID tags are commonly used to capture and store the necessary information. Additionally, emerging technologies such as blockchain offer decentralized and tamper-proof record-keeping, enhancing traceability and providing a higher level of security against counterfeit medicines (Shetty et al., 2022).

1.4.5.3 Regulatory requirements and standards

Many countries and regulatory authorities have recognized the importance of traceability in combating counterfeit medications and have implemented regulations and standards to ensure its implementation. These requirements often include the mandatory use of serialization and unique product identifiers, as well as guidelines on data capture, storage, and sharing. Regulatory compliance not only enhances traceability but also ensures consistency and harmonization across different markets, making it more challenging for counterfeiters to exploit regulatory gaps (Kootstra & Kleinhout-Vliek, 2021).

1.4.5.4 Collaboration among stakeholders

Implementing an effective traceability system requires collaboration among various stakeholders in the pharmaceutical supply chain. This includes pharmaceutical manufacturers, distributors, wholesalers, pharmacies, and regulatory authorities. Each participant plays a vital role in capturing and sharing accurate and timely information, ensuring the seamless flow of data, and maintaining the integrity of the traceability system. Collaborative efforts also extend to sharing best practices, conducting audits, and fostering transparency in supply chain operations (Romero-Torres, 2020).

1.4.6 Challenges and limitations associated with traceability of counterfeit medications

While traceability systems offer significant advantages, they also come with challenges and limitations. Implementation costs, especially for small-scale manufacturers or low-resource settings, can be a barrier. Integration of traceability systems with existing supply chain processes and information systems may also require significant investments and coordination. Additionally, ensuring interoperability and data harmonization across different stakeholders and countries remains a challenge. Data privacy and security concerns need to be addressed to protect sensitive patient information within the traceability system.

1.4.6.1 Fragmented supply chains

One major challenge in tracing counterfeit medicines lies in the complex and fragmented nature of global pharmaceutical supply chains. The pharmaceutical industry involves multiple stakeholders, including manufacturers, distributors, wholesalers, retailers, and healthcare providers. The lack of standardized processes and interoperability among these entities makes it difficult to track the movement of medicines across the entire supply chain effectively (Sim et al., 2022).

1.4.6.2 Limited regulatory harmonization

Counterfeit medicines transcend international borders, necessitating global collaboration to combat their spread. However, there is limited harmonization in regulations and standards related to pharmaceutical traceability among different countries and regions. Varying legal frameworks, labeling requirements, and serialization standards create inconsistencies and hinder seamless traceability efforts (Fadlallah et al., 2016).

1.4.6.3 Lack of universal serialization and informal distribution channels

Serialization involves assigning unique codes to individual medicine packs to enable their identification and tracking throughout the supply chain. While serialization is gaining traction, especially in developed countries, it remains inconsistent globally. Many regions still lack serialization mandates or have delayed implementation, which limits the effectiveness of traceability efforts. Counterfeit medicines often enter the market through informal or unregulated distribution channels, bypassing official supply chains.

These channels may include illicit online pharmacies, street vendors, and unauthorized retailers. Tracing the origin of counterfeit medicines becomes exceedingly challenging in such cases, as these channels operate outside the purview of conventional supply chain monitoring (Omar & Basir, 2020).

1.4.6.4 Technological limitations

The successful traceability of medicines relies on the effective use of technology. However, several technological limitations hinder these efforts. For instance, inadequate infrastructure, particularly in resource-constrained regions, may limit the adoption of advanced traceability systems. Additionally, the lack of standardized data exchange protocols and interoperability among different systems makes it challenging to seamlessly share and integrate information across stakeholders (Islam & Islam, 2022).

1.4.6.5 Counterfeiters' evolving tactics

Counterfeiters continuously adapt their tactics to bypass traceability systems, making it increasingly difficult to stay ahead of their illegal activities. They exploit various vulnerabilities within the supply chain, such as using counterfeit packaging that mimics legitimate products, forging documents to falsify the origins and legitimacy of drugs and tampering with serialization codes to create false traces. These sophisticated methods can result in compromised integrity of traceability data, allowing counterfeit medications to infiltrate the market undetected. Counterfeiters also take advantage of gaps in the latest technologies, hacking into digital systems and employing advanced printing techniques to produce high-quality fake labels and barcodes. Additionally, they often operate in regions with weaker regulatory enforcement, further complicating efforts to control the spread of counterfeit drugs. Addressing these evolving strategies requires constant monitoring, robust security measures, and the use of cutting-edge technologies. Collaborative efforts among pharmaceutical companies, regulatory agencies, and technology providers are essential, as sharing information and best practices can help in developing comprehensive strategies. Strengthening regulatory frameworks and ensuring strict enforcement, along with the imposition of severe penalties for counterfeiting activities, are also critical steps in combating this pervasive issue (Pathak et al., 2023).

1.4.6.6 Limited consumer awareness

Tracing counterfeit medicines also relies on the vigilance of healthcare providers and consumers. However, there is often a lack of awareness among the public regarding the risks and identification of counterfeit medicines. Without adequate knowledge and education, patients may inadvertently purchase counterfeit products, complicating the efforts to trace and eliminate them from the supply chain (Pathak et al., 2023).

2.0 Materials and Methods

2.1 Methods

The study was divided into two phases involving document analysis and interviewing relevant stakeholders.

2.1.1 Phase one

2.1.1.1 Evaluation of archival records

Document analysis was conducted on public records of health and regulatory governmental institutions – Ministry of Health, Food and Drugs Authority, Ghana Standards Authority, and Pharmacy Council. These included press releases and annual reports released between 2019 and 2022 that contain reported incidents of counterfeit medicines and seizure of such goods. The evaluation aimed to assess the prevalence of drug counterfeiting in Ghana's pharmaceutical supply chain to identify the most counterfeited drugs, assess the factors that drive drug counterfeiting, and evaluate traceability approaches employed by these agencies.

2.1.1.2 Inclusion criteria

The search engines Google and Google Scholar were employed in the search as well as the official websites of these institutions. The keywords used for the search were: fake, counterfeit, substandard, imitation or falsified combined with drugs, medicines, pharmaceuticals, Ghana regulation, pharmaceutical policy, regulation of medicines, public health or synonyms. Only reports in English were considered. Additional records not online were sought directly from the institutions.

2.1.1.3 Exclusion criteria

Data on other types of counterfeited products other than pharmaceuticals, records on counterfeit pharmaceutical products from other countries other than in Ghana and annual report records before the reporting period of 2019 were not considered. Reports not in English were excluded.

2.1.2 Phase two

This phase involved interviewing key stakeholders from the Pharmacy Council, Food and Drugs Authority, Ghana Standards Authority, Pharmaceutical Traceability Group (Ministry of Health), and the Customs Excise and Preventive Service. Stakeholders from selected pharmaceutical companies involved in importation and distribution of medicines, public and private hospitals, and retail pharmacies were also interviewed. The interviews aimed to identify any potential gaps in regulation related to enforcement and post-market surveillance, institutional capacity for traceability, stakeholder collaboration, and information sharing. Additionally, the perceptions of different stakeholders on the effectiveness of drug traceability in combating drug counterfeiting in Ghana were assessed through the interviews.

2.1.2.1 Sample selection and recruitment

Purposive and snowball sampling was used to select study respondents. Respondents were chosen purposefully and through referrals from existing participants (snowball sampling). Selection criteria focused on their firsthand experience and deep knowledge of the subject (detailed method in Appendix).

2.1.2.2 Data collection

Prior to data collection, the study participants were asked to sign informed consent forms. Data collection involved two main methods: surveys and interviews. Surveys were administered to all respondents selected through purposive sampling, with a total of 79 participants completing the survey questionnaire. An instrument developed as the data collection tool was employed (Appendix A). Additionally, interviews were conducted with all selected stakeholders to gain deeper insights into the subject matter. A total of 79 interviews were conducted with key informants representing regulatory authorities, pharmaceutical industry professionals, healthcare practitioners, and consumers. These interviews were semi-structured in nature, allowing for open-ended discussions on topics such as the prevalence of counterfeit medicines, challenges in the pharmaceutical supply chain, and recommendations for enhancing traceability systems. Follow-up telephone and/or email interviews were conducted with respondents, where clarity was needed. Principles of anonymity and trustworthiness were applied during the interview process. Interviews were also digitally recorded and transcribed.

2.1.2.3 Ethical consideration

The study adhered rigorously to ethical guidelines to safeguard the integrity, rights, and welfare of all participants involved. Ethical clearance was obtained from the Kwame Nkrumah University of Science and Technology's Humanities and Social Sciences Research Ethics Committee prior to the commencement of any fieldwork activities. In accordance with ethical standards, informed consent was diligently obtained from all participants. Prior to any data collection, participants were provided with detailed information regarding the purpose, objectives, and potential outcomes of the study. Emphasis was placed on maintaining the confidentiality and anonymity of participants throughout all stages of the research process.

3.0 Study Findings

3.1 Demographic Analysis of Stakeholder Groups

Key stakeholders, including Raw Material Suppliers, Manufacturers, Distributors, Wholesalers, Importers, Retail Outlets (Community Pharmacies and Hospital Pharmacies), Regulators, Medical Stores, and Consumers (End Users), were interviewed to explore critical aspects of drug traceability throughout the supply chain (refer to Table 3.1). Raw material suppliers provided insights on sourcing and traceability while manufacturers discussed production-related traceability issues. Distributors, wholesalers, and importers shared their challenges and strategies for ensuring traceability within the supply chain. Retail outlets, representing the extensive network of over 5000 registered retail pharmacies in Ghana, were highlighted in interviews as playing a crucial role in maintaining traceability. Additionally, the study incorporated the end-user perspective to assess awareness of counterfeit medications and countermeasures against counterfeiting within the pharmaceutical supply chain. Involvement of regulatory authorities provided further insights into their roles, challenges, and potential areas for improvement. The focus on retail pharmacies and end-user perspectives offers valuable insights for combating counterfeit drugs in Ghana's pharmaceutical sector, underscoring the significant prevalence of retail outlets in the country.

Table 3.1 Summary of stakeholders interviewed

Stakeholder Groups	Interviews Conducted
Raw Material Suppliers	2
Manufacturers	9
Distributors/Wholesalers/ Importers	8
Retail Outlets (Community Pharmacies)	14
Retail Outlets (Hospital)	10
Regulators	4
Medical Stores	2
Consumers	30

3.1.1 Gender distribution

Analysis of gender distribution of the interviewed population reveals 60% of the participants identified as male, which is reflective of the gender composition of the labor force in Ghana's pharmaceutical supply chain as shown in Figure 3.1.

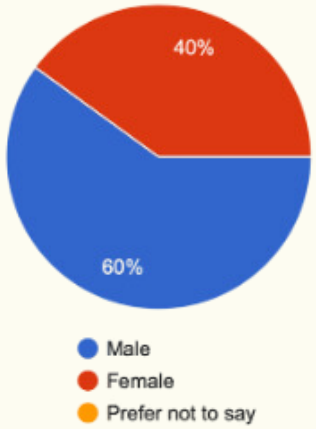


Figure 3.1 Gender distribution of interviewed stakeholders

3.2 Prevalence and Scope of Drug Counterfeiting in Ghana's Pharmaceutical Supply Chain

3.2.1 Prevalence of counterfeit medicines

Data sourced from the Food and Drugs Authority (FDA, Ghana), which verifies the quality of medicines, served as the foundation for analysis. Prevalence was defined as the ratio of Substandard Medicines (failed quality evaluation) to the Total Samples or Products assessed. Data accessed span 2019, 2021, and 2022, with a notable absence in 2020 owing to the pandemic's impact. In 2019, 96 drug samples underwent testing, and 11 of them failed quality evaluation, indicating a prevalence of roughly 11.46% for substandard medicines. Jumping ahead to 2022, there was a significant 330% increase in testing capacity. Among 95,093 products assessed, a staggering 92% were flagged as substandard or falsified, resulting in approximately 87,507 products failing to meet quality standards (refer to Figure 3.2).

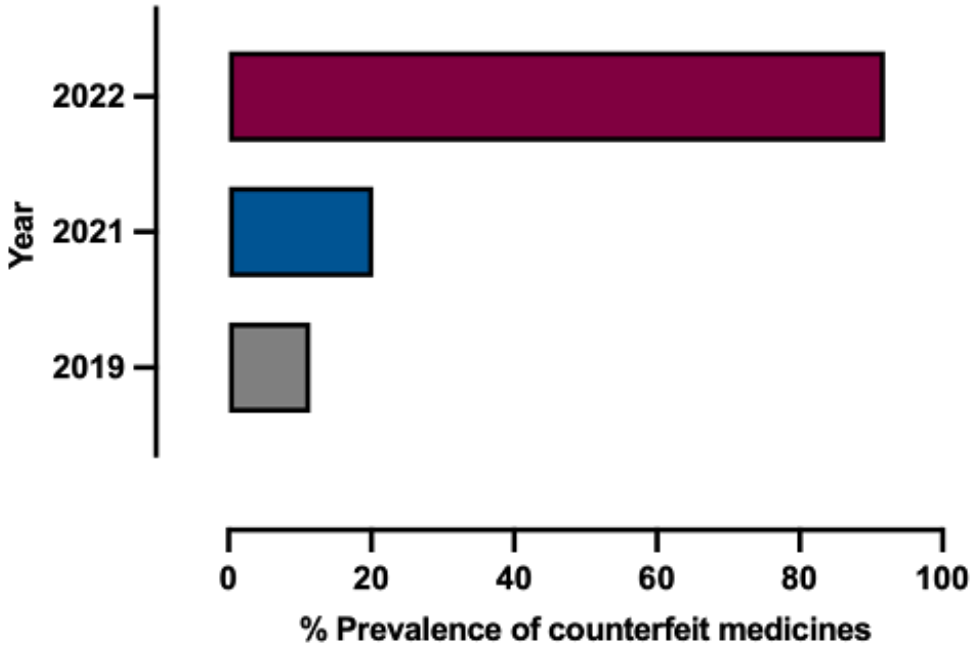


Figure 3.2 Annual calculated prevalence of counterfeit medicines from 2019-2022. Data obtained from the Food and Drugs Authority, Ghana

3.2.2 Common counterfeit drugs and severity ratings (Regulatory data)

A Severity Index was designed to assess recorded incidents of drug counterfeiting by incorporating two primary factors. Frequency denotes the number of reported incidents each year involving specific substandard drugs (weighted at 0.4), while Criticality reflects the potential health risks associated with counterfeiting particular drugs or drug classes (weighted at 0.6). The incorporation of the two factors increases the robustness of this metric. Details of common counterfeit drugs with their severity ratings derived are presented in Table 3.2, chronologically specified for relevant years. Key findings include a notable increase in severity rating for antibiotics, shifting from moderate in 2019 to high in 2022, particularly for Amoxicillin and Clavulanic Acid (Augmentin) due to their widespread use. Antimalarials (Artemether-Lumefantrine) showed a relative decrease in severity rating over the years, registering as moderate severity in 2019. COVID-related products, especially unregistered homeopathic medicines for COVID-19 management, exhibited a significant in severity rating in 2020. This was driven by global demand, with consequential effects on individual health and pandemic control. Unregistered herbal medicines displayed a moderate severity rating in 2021. Specific drug brands like Postinor 2, Procold, and Aboniki Ointment consistently exhibited high severity ratings. Dewormers such as Zentel and Vermox brands showed a high severity rating. Moreover, Sildenafil (Viagra) and Vildagliptin+Metformin (Galvus Met) demonstrated a high severity rating in 2022. Oral contraceptives, specifically Postinor 2, antidiabetics, dewormers, sex-enhancing medicines, and antimalarials consistently encounter high-frequency incidents. This may be attributed to substantial demand and critical health implications in reproductive health, diabetes management, and infection control.

Table 3.2 Common counterfeit drugs and severity ratings (Regulatory data)

Drug Type	Severity Rating by Year
Antibiotics	2019: Moderate 2022: High
• Amoxicillin and Clavulanic Acid (Augmentin)	High
• Ciprofloxacin	Moderate
Antimalarials (Artemether-Lumefantrine)	2019: Moderate
COVID-related Products (Unregistered homeopathic medicines)	2020: High
Unregistered Herbal Medicines	2021: Moderate
Specific Brands (Postinor 2, Procold, Aboniki Ointment)	2022: High
Dewormers (Zentel and Vermox)	2022: High
Sildenafil (Viagra)	2022: High
Antidiabetics: Vildagliptin+Metformin (Galvus Met)	2022: High

3.2.3 Common counterfeit drugs and severity ratings (Other stakeholders)

Table 3.3 presents an overview of common counterfeit drugs and their severity ratings as reported by other supply chain stakeholders without national regulatory functions. Levonorgestrel (Postinor 2), Artemether-Lumefantrine (Coartem), and Vildagliptin+Metformin (Galvus Met) were consistently rated as high-risk counterfeit drugs.

Antimalarials, Amoxicillin and Clavulanic Acid (Augmentin), Bromazepam (Lexotanil), Lorazepam, Paracetamol, and Albendazole (Zentel) were assessed to be of moderate severity ratings, signifying a notable but less acute level of risk.

Table 3.3 Common counterfeit drugs and severity ratings (Other stakeholders*)

Drug	Severity Rating
Levonorgestrel (Postinor 2)	High
Arte me ther-Lumefantrine (Coartem)	High
Vild agliptin+Metformin (Galvus Met)	High
Antimalarials	Moderate
Amoxicillin and Clavulanic Acid (Augmentin)	Moderate
Bromazepam (Lexotanil)	Moderate
Lorazepam	Moderate
Paracetamol	Moderate
Albendazole (Zentel)	Moderate
Misoprostol (Cytotec)	Moderate
Funbact A	Moderate
Cough mixtures	Moderate
Amlodipine	Moderate
Levetiracetam (Keppra)	Low
Rivaroxaban (Xarelto)	Low
Rosuvastatin (Crestor)	Low
Feroglobin caps	Low
Amlodipine/Valsartan (Exforge)	Low
Powder for antibiotics	Low
Sildenafil (Viagra)	Low

**Other Stakeholders include Manufacturers, Distributors, Wholesalers, Importers, Retail Outlets (Community Pharmacies), Retail Outlets (Hospital Pharmacies), Medical Stores.*

3.2.4 Commonest counterfeit drugs

The generated word cloud visually summarizes the prevalence of counterfeit drugs based on the collective data from regulators and other stakeholders in the supply chain. It pinpoints crucial areas for anti-counterfeiting endeavors, providing an insightful visual depiction of drugs warranting intensified regulatory scrutiny. The size and prominence of each drug name within the cloud corresponds to its frequency of occurrence across datasets. Notably, the word cloud conspicuously highlights Postinor, Coartem, and Galvus Met as commonly counterfeited medicines as seen in Figure 3.3.

Figure 3.3 Word cloud of most common counterfeit drugs

3.2.5 Sources and routes for counterfeit medicines

Analysis of counterfeit drug sources and routes reveals a complicated landscape with varying degrees of involvement from different entities. Illicit manufacturers, engaged in locally produced counterfeit herbal medicines, showed a moderate level of activity, often adulterating products with allopathic medicines. Ghana has a rich tradition of herbal medicine, and the presence of an informal herbal medicine market might contribute to the production of counterfeit drugs, especially when traditional and allopathic practices overlap (refer to Table 3.4).

Supply chain intermediaries demonstrated a moderate involvement. Supply chain intermediaries play a role in both unintentionally enabling counterfeiting and in actively contributing to it. Here are ways they may contribute:

3.2.5.1 Unintentional enablement

Lack of Traceability: In complex supply chains, the lack of proper tracking mechanisms allows counterfeit products to blend in without easy identification.

Inadequate Verification: Failure to thoroughly vet suppliers or products allows counterfeit goods to enter the supply chain.

Weak Documentation: Incomplete or inaccurate documentation makes it easier for counterfeiters to introduce fake products unnoticed.

Poor Communication: Ineffective communication between intermediaries increases the vulnerability of the supply chain to infiltration.

3.2.5.2 Active contribution

Intentional Complicity: Some intermediaries knowingly facilitate counterfeit goods by providing false documentation or knowingly purchasing fake products.

Diversion Practices: Intermediaries might divert authentic products meant for one market to another, replacing them with counterfeits; substituting genuine drugs with counterfeit ones during distribution.

Gray Market Activities: Selling products through unauthorized channels, thereby increasing the risk of counterfeits entering legitimate supply chains.

Substandard Handling: Improper handling or storage practices might compromise the authenticity and quality of genuine products.

Online marketplaces exhibited a high level of involvement in the illicit trade of counterfeit drugs, emphasizing the significant challenge posed by unregulated digital platforms. Buyers, unaware of the lack of oversight, often unintentionally purchase counterfeit medications. Cross-border trafficking, particularly in border regions, demonstrated a high frequency of counterfeit drugs entering Ghana, illustrating the cross-border dimension of the issue. Online marketplaces and cross-border trafficking appear to be the most important channels through which counterfeit medications enter the Ghanaian market. Firstly, Ghana's porous borders and proximity to neighboring countries create challenges in effectively monitoring and controlling the inflow of pharmaceuticals, facilitating the illegal cross-border trade in counterfeit medications. Additionally, the country's extensive coastline provides avenues for maritime routes that further complicate regulatory oversight. The Ghana-Togo border was cited as the primary route of cross-border trafficking, where counterfeit medicines were often brought into the country from Nigeria. These medicines may be concealed in car parts. Moreover, the rapidly increasing use of online marketplaces in Ghana, fueled by increased internet penetration and smartphone accessibility, offers an ideal platform for illicit pharmaceutical trade. The anonymity afforded by online platforms enables traffickers to operate discreetly, making it difficult for authorities to trace and intercept such activities. The combination of lax border controls, geographical factors, and the rise of digital platforms amplifies the challenges in curbing the trafficking of counterfeit medications, emphasizing the need for comprehensive regulatory measures and international collaboration.

Table 3.4 Sources and routes for counterfeit medicines

Source/Routes	Frequency/Involvement	Description
Illicit Manufacturers	Moderate	Several instances were found where counterfeit herbal medicines/drugs were locally produced adulterated with allopathic medicines.
Supply Chain Intermediaries	Moderate	Instances of involvement by intermediaries within the supply chain observed. This includes cases where genuine drugs are swapped with counterfeit ones during distribution
Online Marketplaces	High	Significant presence of counterfeit drugs being sold on unregulated online platforms. Buyers are often unaware of authenticity due to lack of oversight. Common route for illicit Viagra/libido enhancers, antidiabetics, weight loss drugs.
Cross-border Trafficking	High	Counterfeit drugs identified entering Ghana via cross-border trade routes. Instances of large-scale trafficking observed in border regions. Common route for illicit antimalarials, innovator drugs e.g. antihypertensives.

3.3 Key Drivers of Drug Counterfeiting in Ghana's Pharmaceutical Supply Chain

The presence of counterfeit drugs in the Ghanaian medicine supply chain is influenced by several key drivers and factors. Weak regulatory oversight stands out as a significant contributor, with a high impact level. This is characterized by limited inspections and inadequate oversight, creating gaps in monitoring that allow counterfeit drugs to enter the market easily.

Additionally, the lack of enforcement plays a notable role, with a moderate impact level. Despite existing regulations such as the Public Health Act 2012, Act 851, inconsistent enforcement provides opportunities for counterfeiters to thrive within the system.

The complexity of the supply chain further exacerbates the issue, marked by a high impact level. Complex supply chains with multiple intermediaries create difficulties in tracking and verifying the authenticity of drugs, allowing counterfeit products to infiltrate the market.

Moreover, the high demand for cheap medications significantly impacts the prevalence of counterfeit drugs, with a high impact level. The strong consumer demand for affordable medications leads individuals toward cheaper counterfeit alternatives, fostering a market for illicit pharmaceuticals.

Technological challenges also contribute significantly, characterized by a high impact level. Outdated or non-existent technological infrastructure hinders effective traceability and authentication methods, making it challenging to implement robust systems to ensure the security of the supply chain (refer to Table 3.5).

3.4 Elements of Traceability

Our study identified the three keystone activities of traceability as follows:

Serialization: This is the establishment of a unique identity for a drug product as it moves through the supply chain. For instance, assigning barcodes to products exemplifies serialization.

Track and Trace: This encompasses two aspects.

Tracking: This term often refers to the forward movement of a product. It answers questions like where a product is currently located within the supply chain and whether there is ongoing capturing of information as it moves through the supply chain.

Tracing: This takes a historical view, focusing on where the product has been and who has owned it.

Verification: After establishing a unique identity and the ability to track and trace a product, verification ensures the accuracy and authenticity of the information about the commodities obtained.

Table 3.5 Key drivers of counterfeit drugs

Key Drivers/Factors	Impact Level	Description of Impact
Weak Regulatory Oversight	High	Limited inspections and inadequate oversight lead to gaps in monitoring, allowing counterfeit drugs to enter the country easily.
Lack of Enforcement	Moderate	Regulations exist but are inconsistently enforced, providing opportunities for counterfeiters to thrive.
Supply Chain Complexity	High	Complex supply chains with multiple intermediaries create difficulties in tracking and verifying drug authenticity.
High Demand for Cheap Meds	High	Strong demand for affordable medications leads consumers toward cheaper counterfeit alternatives.
Technological Challenges	High	Outdated and/or lack of essential technological infrastructure hinders effective traceability and authentication methods.

These three key elements—serialization, track and trace, and verification—also depend on other factors. Product identification feeds into serialization, data capture supports track and trace, and data sharing facilitates verification. Additionally, a robust traceability system requires a proper regulatory framework, technological infrastructure, and a recall management system as seen in Figure 3.4.

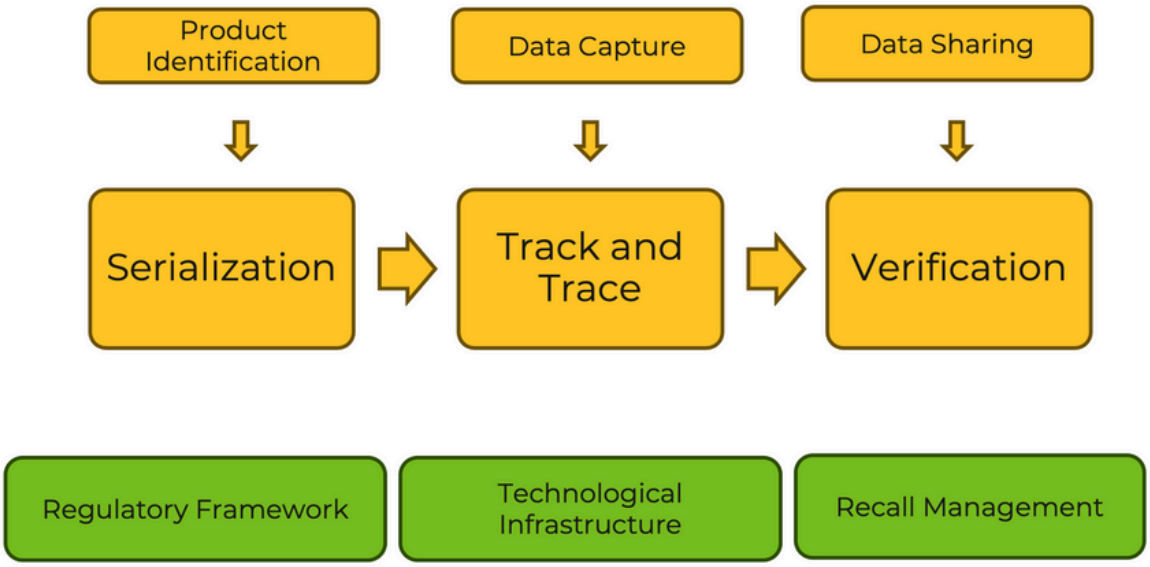


Figure 3.4 Elements of traceability

3.4.1 Assessment of pharmaceutical supply chain traceability practices

From our stakeholder interviews and site visits, we identified several critical insights into the current state of pharmaceutical supply chain practices.

Product Identification: We found that 95% of pharmaceutical products in the facilities had proper mechanisms for identification. These mechanisms include the use of barcodes, batch numbers, and lot numbers, which are essential for tracking and tracing the products throughout the supply chain. However, approximately 5% of the products lacked any form of identification, not even batch or lot numbers. This lack of identification poses significant risks, including difficulties in tracking the product's origin, verifying its authenticity, and managing recalls effectively.

Data Capture: Only 3% of supply chain actors utilized digital data capture methods, such as scanning barcodes for inventory or retail purposes. The limited adoption of digital data capture technologies hinders the ability to maintain accurate and real-time records of product movement, leading to inefficiencies and increased risk of errors in the supply chain. The use of manual methods, which are prone to human error, still prevails in most of the facilities.

Data Sharing: A mere 1% of stakeholders engaged in data sharing through platforms with sister companies or other partners they typically work with. The absence of widespread data sharing practices limits the transparency and collaboration within the supply chain. Without robust data sharing mechanisms, it becomes challenging to track the flow of products across different entities, identify potential issues promptly, and coordinate responses effectively.

Verification: Only 0.5% of stakeholders used any system to verify product authenticity. This extremely low adoption rate of verification systems highlights a significant vulnerability in the supply chain. Verification systems are crucial for ensuring that products are genuine and have not been tampered with or counterfeited. The lack of verification measures increases the risk of counterfeit drugs entering the supply chain, posing serious threats to patient safety and undermining trust in pharmaceutical products.

In summary, while there are mechanisms in place for product identification in most facilities, the adoption of digital data capture, data sharing, and verification systems remains exceedingly low. These gaps indicate a need for substantial improvements in the implementation of advanced technologies and collaborative practices to enhance the overall traceability and security of the pharmaceutical supply chain (refer to Figure 3.5).

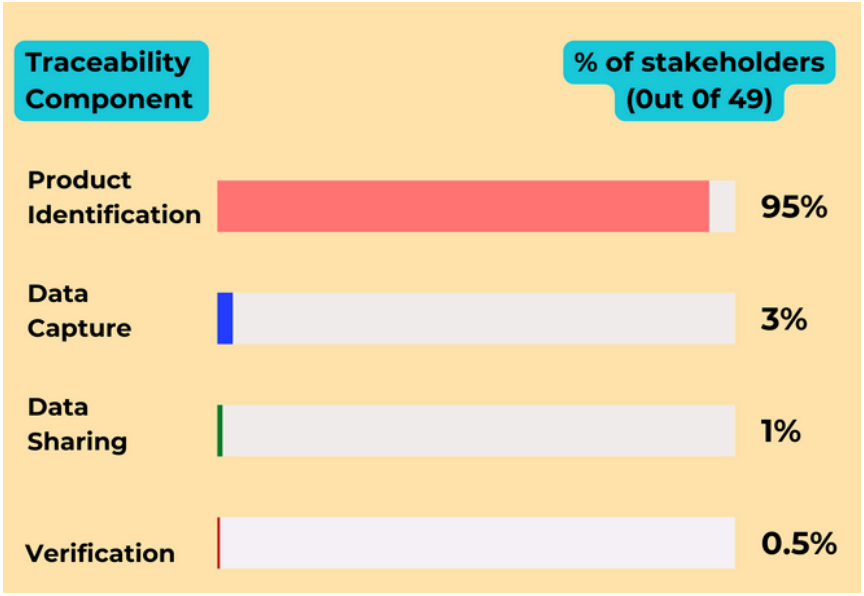


Figure 3.5 Assessment of pharmaceutical supply chain traceability practices of stakeholders

3.5 The Current System of Drug Traceability in Ghana's Pharmaceutical Supply Chain

The existing system relies on post-market surveillance data and is structured around various aspects of traceability. The benefits and limitations of the current system were analyzed in terms of the existing regulatory framework, technological infrastructure, product authentication and drug recall management. In terms of the regulatory framework, this provides improved oversight on patient safety, ensuring that adverse events are promptly identified and addressed to protect public health. Additionally, real-world monitoring of drug effectiveness enables regulators to assess how medications perform outside of controlled clinical trials, providing valuable insights into their actual impact on patient outcomes. Another key function is the identification of counterfeit products on the market, which helps safeguard consumers from potentially harmful or ineffective treatments. However, challenges such as limited flexibility for adaptation, inadequate data quality, and limited resources for monitoring can hinder the effectiveness

of post-market surveillance efforts. Furthermore, the regulatory burden placed on industry stakeholders to comply with reporting requirements and surveillance activities can also pose challenges to the efficient operation of the regulatory framework.

Technologically, the current system incorporates the ProPer Seals system to enhance product verification. ProPer Seal is a website where you can input information such as FDA registration numbers, batch numbers, product seals, etc. of commodities and verify their FDA registration status. ProPer Seals was introduced to support the supply chain objectives of the Africa Continental Free Trade Area initiative. This integration contributes to improved product authentication. However, the system faces challenges related to interoperability issues with other authentication systems, introducing potential barriers to seamless communication and data sharing across different components of the traceability infrastructure. Regarding compliance and adoption, the use of the ProPer Seals system for product authentication aligns with traceability objectives, ensuring accurate verification of critical product information. Despite this, there are concerns about potential vulnerabilities to sophisticated counterfeiting such as precise packaging and labeling replication and parallel trade, emphasizing the need for ongoing updates and improvements to stay ahead of evolving counterfeiting techniques.

In terms of recall management, the post-market surveillance system demonstrates relatively efficient recall processes, enabling the identification and removal of substandard products from the market. However, a notable limitation exists in the form of inadequate communication channels for rapid recalls. Timely and effective communication is crucial during recall situations, and any delays in communication channels can impact the overall efficiency of the recall process.

3.5.1. Stakeholder perceptions of the effectiveness of the current drug traceability systems

Stakeholders in the Ghanaian pharmaceutical landscape hold varied perspectives on the effectiveness of traceability systems, each providing valuable insights into different aspects of the current framework. Pharmaceutical companies express concerns about the system's reliability, rating it as low. While acknowledging a moderate impact on patient safety and usability, they emphasize the need for enhanced stakeholder collaborations and improved technical infrastructure as crucial areas for improvement, as seen in Table 3.6.

In contrast, regulatory agencies view the system more favorably, attributing this view to its high reliability and a significant impact on patient safety. However, they mention that it is only moderately user-friendly, suggesting that improvements in stakeholder collaborations could further enhance the system's effectiveness.

Table 3.6 Current drug traceability system analysis

Traceability System Aspect	Benefits	Limitations
Regulatory Framework	Improved oversight on patient safety; real-world monitoring of drug effectiveness; identification of counterfeit products on the market.	Limited flexibility for adaptation; inadequate data quality; limited resources for monitoring; regulatory burden.
Technological Infrastructure	Use of the ProPer Seals system helps verify an FDA number, batch number, or a product seal.	Interoperability issues between systems. Compliance and adoption.
Product Authentication	Use of the ProPer Seals system helps verify an FDA number, batch number, or product seal.	Potential vulnerabilities to sophisticated counterfeiting.
Drug Recall Management	Relatively efficient recall processes.	Inadequate communication channels for rapid recalls.

Healthcare providers, like pharmaceutical companies, express reservations about the system's reliability, rating it as low. They recognize a moderate impact on patient safety and usability. A common theme emerges, with stakeholders in this group also emphasizing the necessity for improved collaborations among stakeholders and technical infrastructure enhancements.

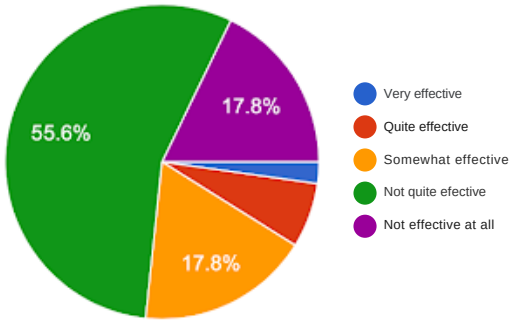
Patients, as end-users, perceive the system's reliability as low, reflecting concerns about its effectiveness. They highlight a low impact on patient safety and moderate usability. Patients recommend improvements focused on enhancing the technical infrastructure, indicating a desire for a more robust and reliable traceability system (refer to Table 3.7).

Collectively, stakeholders across pharmaceutical companies, regulatory agencies, healthcare providers, and patients emphasize the importance of collaboration among stakeholders and improvements in technical infrastructure to enhance the overall effectiveness of the traceability system. The diverse perspectives provide a comprehensive understanding of the existing challenges and potential pathways for optimizing traceability in the Ghanaian pharmaceutical landscape as seen in Figure 3.6.

Table 3.7 Stakeholders' perspectives on traceability's effectiveness

Perception Aspect	Pharmaceutical Companies	Regulatory Agencies	Healthcare Providers	Consumers
System Reliability	Low	High	Low	Low
Impact on Patient Safety	Moderate	High	Moderate	Low
Usability	Moderate	Moderate	Moderate	Moderate
Suggestions for Improvement	•Improved stakeholder collaborations •Improved technical infrastructure	•Improved stakeholder collaborations	•Improved Stakeholder collaborations •Improved technical infrastructure	•Improved technical infrastructure

Figure 3.6 Stakeholder perceptions of the effectiveness of the current drug traceability systems



3.6 Challenges Faced by Ghana's Pharmaceutical Supply Chain in Implementing Drug Traceability

Perceived challenges faced by the pharmaceutical supply chain in implementing drug traceability were rated by stakeholders. The ratings provide valuable insights into the perceived severity of challenges faced by Ghana's pharmaceutical supply chain as reported by various stakeholders. Across the board, challenges such as regulatory compliance, supply chain fragmentation, and resource constraints consistently received high severity ratings from all stakeholder groups as seen in Table 3.8. This indicates a shared recognition among stakeholders of the significant impact these challenges have on the efficiency, safety, and integrity of the pharmaceutical supply chain in Ghana. Additionally, the ratings highlight areas where stakeholders may have differing perceptions of severity. For example, while pharmaceutical companies and regulatory agencies rated technological constraints as high, healthcare providers rated this area as moderate. This discrepancy suggests a potential need for enhanced communication and collaboration among stakeholders to align perceptions and prioritize efforts in addressing critical challenges.

By acknowledging and understanding these challenges, stakeholders can work collaboratively to implement targeted interventions and strategies aimed at mitigating risks, enhancing compliance, and ultimately improving the quality and accessibility of pharmaceutical products for the benefit of the Ghanaian population.

Table 3.8 Stakeholder views on challenges faced by Ghana's pharmaceutical supply chain in implementing drug traceability

Challenges	Pharmaceutical Companies	Regulatory Agencies	Healthcare Providers	Overall Rating
Infrastructure Limitations	Moderate	Moderate	High	Moderate
Technological Constraints	High	High	Moderate	High
Data Standardization	Moderate	Moderate	Moderate	Moderate
Regulatory Compliance	High	High	High	High
Supply Chain Fragmentation	High	High	Moderate	High
Resource Constraints	High	High	High	High
Public Awareness and Education	Moderate	Moderate	Moderate	Moderate

3.6.1 Regulation (Enforcement and inspections)

The line chart, depicting the annual regulatory inspections in Ghana over the past four years, unmistakably illustrates this upward trajectory. In 2022, Ghana witnessed a noteworthy surge in regulatory activities, conducting 1330 regulatory inspections—an increase of 0.45% from the preceding year. The number of facilities inspected also increased, to 15, 215 (refer to Figure 3.7).

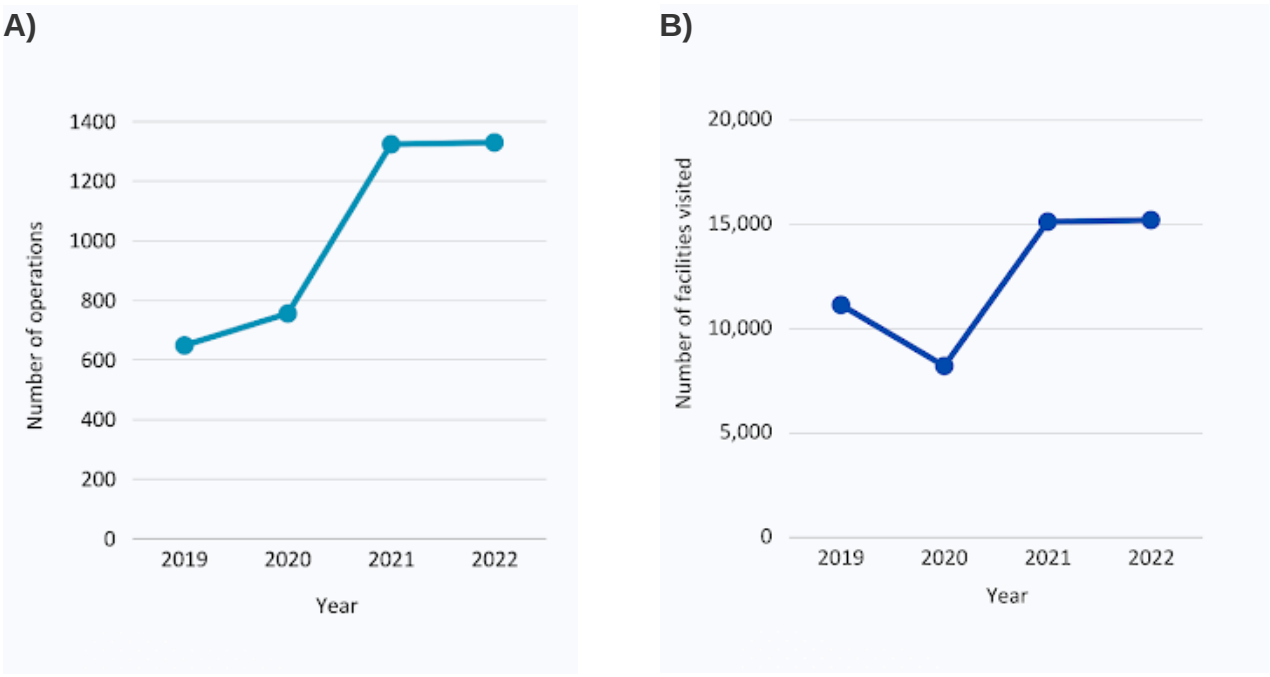


Figure 3.7 A) Regulatory inspections in Ghana 2019-2022 B) Number of facilities inspected in Ghana 2019-2022

3.7 The Potential of Utilizing Technology to Enhance Drug Traceability in Ghana's Pharmaceutical Supply Chain.

3.7.1 Potential for technological integration in Ghana

In our assessment of the potential for technological integration in Ghana, we undertook a thorough examination across various dimensions to gauge the current landscape. Primarily, two major assessments were conducted: the Connectivity Index and the Technological Integration Capacity Assessment. This assessment utilizes a scale ranging from 1 to 10 to evaluate various factors contributing to the country's capacity to adopt advanced technologies. Each factor is weighted differently.

3.7.1.1 Ghana’s connectivity index

Delving into the Connectivity Index, a metric paramount for evaluating the nation's digital infrastructure, we observed a commendable upward trajectory. Notably, the internet penetration rate, representing the percentage of the population with internet access, demonstrated a steady progression from 1.92 in 2019 to 2.72 in 2022. Concurrently, mobile network coverage, indispensable for communication in both urban and rural areas, exhibited relative uniformity over the assessed period. Furthermore, broadband speeds, a pivotal determinant of data transmission efficiency, underscored an ongoing commitment to enhancing digital infrastructure. Likewise, the pace of digital inclusion, gauged by the availability and usage of digital services among diverse demographic groups, has shown a gradual ascent. Conversely, E-government initiatives, indicative of the government's aspirations to harness technology for public services, have increased in

recent years, signaling the commitment to its renowned Digitalization agenda. Noteworthy factors such as smartphone penetration and the proliferation of public Wi-Fi hotspots also contribute to the multi-faceted landscape of technological integration in Ghana (refer to Table 3.9).

Table 3.9 Connectivity indices for Ghana 2019- 2022

Simple Connectivity Index for Ghana (Scale: 1-10)	2019	2020	2021	2022
Internet Penetration Rate (40% weight)	1.92	2.00	2.12	2.72
Mobile Network Coverage (20% weight)	2.60	2.52	2.46	2.40
Broadband Speeds (15% weight)	0.24	0.41	0.69	0.83
Digital Inclusion (10% weight)	0.19	0.20	0.24	0.27
E-Government Initiatives (5% weight)	0.05	0.10	0.15	0.20
Smartphone Penetration (5% weight)	0.09	0.13	0.17	0.19
Public Wi-Fi Availability (5% weight)	0.01	0.03	0.04	0.05
Weighted Average (Technological Connectivity Index)	5.10	5.38	5.87	6.66

3.7.1.2 Ghana's technological integration capacity

When considering integration capability, which serves as a metric for assessing a country's readiness to adopt advanced technologies, our analysis reveals consistent growth over the evaluated years as seen in Table 3.10. Government initiatives assess the effectiveness of policies and initiatives aimed at promoting technology adoption and innovation within the country. Over the years, scores indicate a gradual increase, suggesting improving efforts in this aspect. Industry adoption evaluates the extent to which industries in Ghana are embracing advanced technologies in their operations. Scores show a slight decline, indicating potential challenges or slower adoption rates within industries. Digital infrastructure examines components such as high-speed internet, data centers, and cloud services. Scores demonstrate a consistent upward trend, reflecting ongoing improvements in digital infrastructure. Education and workforce development indicate efforts at enhancing the skills and capabilities of the Ghanaian workforce in the context of technological advancements. While scores are relatively low, there is a gradual increase over the years, indicating progress in this area.

The start-up ecosystem evaluates the vibrancy and growth of start-ups in Ghana, crucial for driving innovation. Scores remain relatively stable over the years. Digital literacy rates measure the population's ability to effectively engage with digital technologies. Scores show a consistent increase, indicating improvements in digital literacy. Overall, the increasing trend in the weighted average of these factors yields the Technological

Integration Capacity Score for each year, representing Ghana's overall capacity to integrate advanced technologies into its socio-economic fabric. This upward trend suggests positive developments in Ghana's technological landscape over the assessed period.

Table 3.10 Technological integration capacity assessment of Ghana 2019- 2022

Technological Integration Capacity Assessment (Scale:1 -10)	2019	2020	2021	2022
Government Initiatives (25% weight)	0.70	1.40	2.10	2.80
Industry Adoption (20% weight)	0.30	0.28	0.27	0.26
Digital Infrastructure (15% weight)	0.26	0.38	0.50	0.57
Education and Workforce Development (15% weight)	0.0015	0.0075	0.01	0.02
Start-up Ecosystem (10% weight)	0.012	0.015	0.02	0.01
Digital Literacy Rates (10% weight)	0.24	0.30	0.33	0.43
Weighted Average (Technological Integration Capacity Score)	1.52	2.38	3.24	4.09

3.7.1.3 Technological infrastructure

The evaluation of Ghana's technological infrastructure for the implementation of advanced traceability technologies in the pharmaceutical supply chain reveals a mixed landscape. The strengths and areas of improvement identified in the assessment, draw attention to the significance of upgrading infrastructure to support the seamless integration of technology.

Network connectivity: Ghana's moderate network coverage with its occasional disruptions highlights the need for improvements to ensure a stable and reliable network infrastructure. The recommendation to invest in expanding coverage aligns with global best practices, as a robust network is fundamental for the effective functioning of traceability technologies (refer to Table 3.11).

Table 3.11 Current technological infrastructure in Ghana

Infrastructure Component	Current Status	Recommended Actions for Upgrades
Network Connectivity	Moderate coverage, occasional disruptions.	Invest in expanding coverage and improving reliability.
Data Storage and Processing	Limited capacity, some systems outdated.	Implement scalable and updated data storage solutions.
Cybersecurity Measures	Basic protocols in place, room for improvement.	Strengthen protocols, conduct regular cybersecurity audits.
Mobile Network Penetration	Moderately high penetration, moderately reliable mobile networks.	Leverage mobile networks for enhanced traceability apps.
Regulatory Compliance Systems	Basic systems, manual record-keeping are prevalent.	Introduce digital compliance systems, reduce manual processes.

Data storage and processing: The limited capacity and presence of outdated systems underscore potential challenges in handling the data load associated with advanced traceability technologies. The suggestion to implement scalable and updated data storage solutions is crucial for accommodating the increased data volume generated by traceability systems.

Cybersecurity measures: While basic cybersecurity protocols are in place, the call for strengthening these measures and conducting regular audits reflects the recognition of the critical role cybersecurity plays in safeguarding sensitive pharmaceutical data. Enhancing security protocols aligns with global efforts to mitigate the risks associated with cyber threats in the pharmaceutical sector.

Mobile network penetration: The moderately high mobile network penetration in Ghana is a notable strength that can be leveraged for the implementation of enhanced traceability applications. Mobile networks play a pivotal role in supporting real-time data exchange and mobile authentication systems, contributing to the overall efficiency of traceability measures.

Regulatory compliance systems: The presence of basic regulatory compliance systems with prevalent manual record-keeping indicates an opportunity for digital transformation. The recommendation to introduce digital compliance systems aligns with the broader trend of digitizing regulatory processes to enhance efficiency, accuracy, and transparency.

3.7.2 Cost-benefit analysis of GS1, blockchain, and RFID technologies

Three distinct technologies—GS1, Blockchain, and RFID—were evaluated in terms of their financial implications and the advantages they offer. These three technologies were selected due to their relative lack of use in the country. Cost analysis estimates were conducted based on the cost for a pharmaceutical company to employ the technology for their common line items. The adoption of GS1 standards aligns with global initiatives promoting standardized identification and data exchange in the pharmaceutical supply chain, offering benefits such as improved data accuracy and increased efficiency. Blockchain technology demonstrates its potential to revolutionize traceability and security, ensuring tamper-proof records and addressing concerns related to counterfeit drugs. RFID technology plays an important role in real-time tracking, efficient inventory management, and enhanced security, anticipating reductions in stockouts and overstocks.

Financially, GS1, with initial setup costs of $300,000 and annual ongoing costs of $50,000, presents a compelling case for adoption, promising a 20% reduction in data errors and a 15% enhancement in overall supply chain efficiency. Blockchain, with initial setup costs of $500,000 and annual ongoing costs of $80,000, offers robust solutions, ensuring tamper-proof records and reducing the risk of fraud. RFID technology, with initial setup costs of $400,000 and annual ongoing costs of $60,000, emerges as a powerful tool for real-time tracking and inventory management, anticipating a 25% reduction in stockouts and overstocks.

While the individual technologies offer unique advantages, successful integration into the existing pharmaceutical supply chain may pose challenges. Interoperability, data standardization, and collaboration among stakeholders are crucial factors for successful implementation. Robust change management strategies and stakeholder engagement efforts will be vital in overcoming resistance to technology adoption (refer to Table 3.12).

Table 3.12 Cost-benefit analysis of selected technologies

Technology			
	GS1	Blockchain	RFID
Costs (US Dollars)			
Initial Setup	300,000	500,000	400,000
Annual Ongoing	50,000	80,000	60,000
	Benefits		
	Improved Data Accuracy: 20% reduction in data errors.Enhanced Interoperability: Streamlined communication with global partners.Compliance with Standards: Mitigation of regulatory compliance risks.Increased Efficiency: 15% improvement in supply chain efficiency.	Tamper-Proof Records: Ensures data integrity and security.Enhanced Transparency: Real-time visibility across the supply chain.Reduced Fraud: Reduction of counterfeit products.Improved Traceability: Quick identification of product origins.	Real-Time Tracking: Improved visibility in product movements.Efficient Inventory Management: 25% reduction in stockouts and overstocks.Quick Product Retrieval: Accelerated recalls and returns.Enhanced Security: Prevention of unauthorized access.

3.7.3 Stakeholder involvement in implementation of drug traceability technology

The assessment of key stakeholders and their involvement in the implementation of technology solutions for drug traceability in Ghana provides valuable insights into the collaborative dynamics within the pharmaceutical supply chain as seen in Table 3.13. Understanding the roles and levels of engagement of government agencies, pharmaceutical manufacturers, distributors, and healthcare providers is crucial for the successful integration of traceability technologies.

Government agencies: The high level of involvement of government agencies, as indicated by their active funding support and collaboration in policy development, aligns with the recognized role of regulatory bodies in shaping and enforcing standards within the pharmaceutical industry. Government initiatives and financial backing are instrumental in driving the adoption of advanced technologies, ensuring compliance, and creating a regulatory framework conducive to technological advancements.

Pharmaceutical manufacturers: The high level of involvement of pharmaceutical manufacturers is consistent with their position as key players in the production and distribution of pharmaceuticals. The focus on implementing traceability technologies and adhering to regulatory guidelines reflects the industry's recognition of the importance of technology in ensuring product quality, authenticity, and compliance.

Distributors: The high involvement of distributors in adopting technology for supply chain efficiency is in line with global trends emphasizing the role of distributors in ensuring the integrity of the pharmaceutical supply chain. Their cooperation in information sharing is particularly noteworthy, as seamless data flow is critical for effective traceability, inventory management, and response to potential issues.

Healthcare providers: The medium level of involvement of healthcare providers, particularly in the integration of mobile authentication systems and participation in awareness campaigns, reflects their dual role as end-users of pharmaceuticals and contributors to public awareness. Mobile authentication systems contribute to the verification of product authenticity, while participation in awareness campaigns fosters a culture of transparency and safety among the public.

Collaborative dynamics: The varying levels of involvement across stakeholders underscore the interconnected nature of the pharmaceutical supply chain. Effective traceability requires collaboration among diverse entities, each contributing to different facets of the implementation process. Government support provides the necessary regulatory framework, manufacturers ensure product compliance, distributors streamline supply chains, and healthcare providers contribute to public awareness and authentication efforts.

Table 3.13 Key stakeholder involvement in the implementation of drug traceability technology

Stakeholder	Level of involvement	Support initiatives
Government Agencies	High	Funding for technology implementation, collaboration in policy development.
Pharmaceutical Manufacturers	High	Implementation of traceability technologies, adherence to regulatory guidelines.
Distributors	High	Adoption of technology for supply chain efficiency, cooperation in information sharing
Healthcare Providers	Medium	Integration of mobile authentication systems, participation in awareness campaigns.

3.7.4. Perceptions and feedback from stakeholders

The examination of stakeholder perceptions and feedback regarding the implementation of technology solutions for drug traceability in Ghana offers valuable insights into the dynamics of stakeholder engagement. The varying levels of involvement and distinct perceptions among government agencies, pharmaceutical manufacturers, distributors, and healthcare providers underscore the nuanced landscape of technology adoption within the pharmaceutical supply chain.

Government agencies: The high level of involvement demonstrated by government agencies aligns with their pivotal role in shaping regulatory frameworks and enforcing standards within the pharmaceutical industry. The positive perception expressed by government agencies reflects an acknowledgment of technology's crucial role in ensuring drug safety and fostering a secure and regulated pharmaceutical supply chain.

Pharmaceutical manufacturers: The cautiously optimistic stance of pharmaceutical manufacturers is a common sentiment observed in technology adoption within industries. While recognizing the long-term benefits of technology implementation, concerns about initial costs are not uncommon. This reflects a pragmatic approach, considering both the potential advantages and challenges associated with integrating traceability technologies into pharmaceutical manufacturing processes.

Distributors: The very positive perception among distributors signifies a keen embrace of technology for streamlining supply chain operations. This aligns with the global trend of distributors playing a central role in ensuring the integrity and efficiency of pharmaceutical supply chains through technological advancements.

Healthcare providers: The mixed perceptions among healthcare providers highlight the complexity of technology adoption in this sector. While there is evident interest in embracing technology, voiced caution about potential implementation challenges emphasizes the need for careful consideration of the unique operational aspects and challenges faced by healthcare providers (refer to Table 3.14).

Table 3.14 Stakeholder perceptions on technology adoption

Stakeholder	Perception	Key Feedback
Government Agencies	Positive	Acknowledgment of the role of technology in ensuring drug safety.
Pharmaceutical Manufacturers	Cautiously Optimistic	Concerns about initial costs but recognizing long-term benefits.
Distributors	Very Positive	Embracing technology for streamlining supply chain operations.
Healthcare Providers	Mixed	Interest in technology adoption but cautious about implementation challenges.

3.7.5 Stakeholder preferences for traceability technologies

Stakeholder preferences for traceability technologies provide valuable insights into the diverse perspectives within the pharmaceutical supply chain in Ghana.

QR codes: Stakeholders, particularly regulatory bodies, pharmaceutical manufacturers, and consumers, recognize the potential of QR codes for quick verification. The ease of scanning and widespread consumer familiarity make QR codes suitable for rapid adoption, aligning with the global trend of leveraging QR technology for traceability and authenticity verification.

Barcodes: Distributors and consumers exhibit a preference for barcodes, emphasizing their simplicity and familiarity. The cost-effectiveness, simplicity, and global standardization of barcodes contribute to their popularity among stakeholders, with established practices in various industries (refer to Table 3.15).

Blockchain: Regulatory bodies and pharmaceutical manufacturers recognize the potential of blockchain for transparency and supply chain visibility. The acknowledgment of blockchain's tamper-proof features aligns with its reputation for enhancing data integrity and security in supply chain applications.

Mobile authentication (USSD): Healthcare providers and consumers see potential in mobile authentication (USSD) for patient engagement and direct verification. The acknowledgment of its value in healthcare-related interactions aligns with the increasing use of mobile technologies in healthcare for patient-centric applications.

Table 3.15 Stakeholder preferences for traceability technologies

Stakeholder Group	QRCodes (%)	Bar Codes (%)	Block chain (%)	Mobile Authentication (USSD) (%)	RFID (%)	Global Standards (%)
Regulatory	15	20	40	10	10	10
Pharmaceutical Manufacturers	20	30	35	5	5	5
Distributors	10	40	30	10	5	2
Healthcare Providers	5	30	25	15	10	5
Consumers	8	35	20	25	5	2

RFID: Distributors and healthcare providers appreciate RFID for its efficiency in large-scale inventory management and accurate tracking. RFID's real-time tracking capabilities align with its proven efficiency in inventory and supply chain management (refer to Figure 3.8).

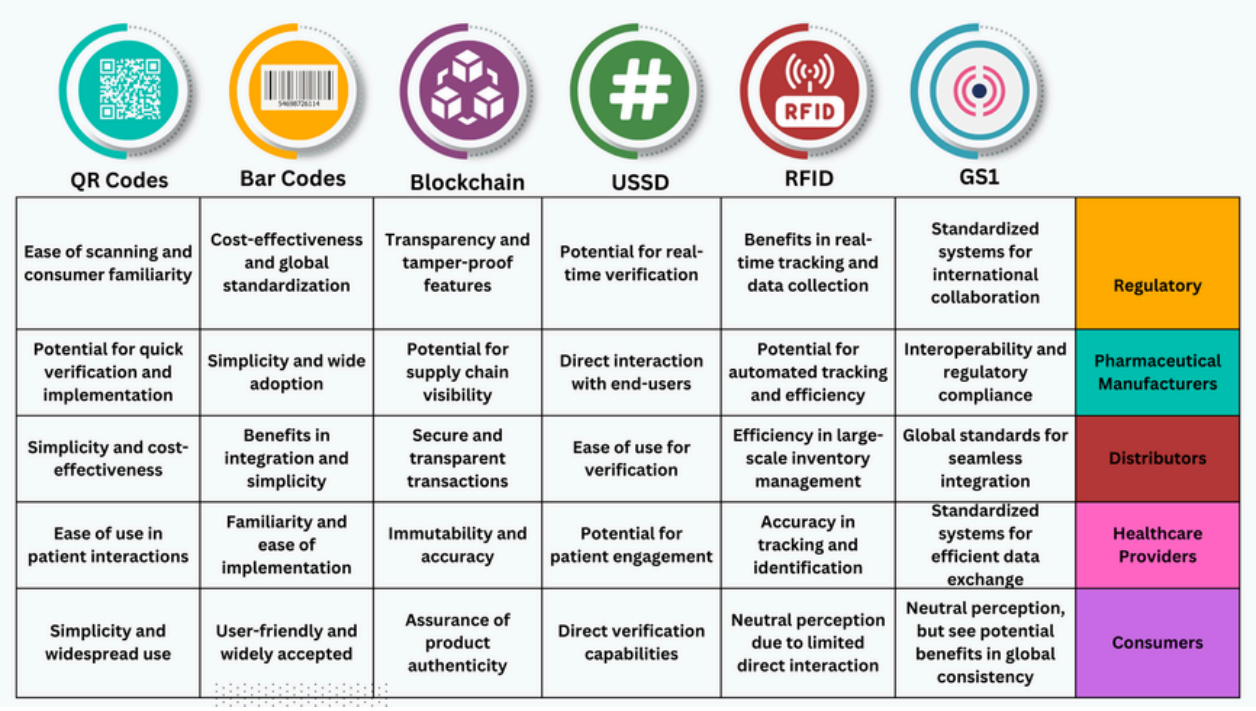


Figure 3.8 The qualitative feedback on stakeholder preferences, concerns, and the overall acceptability of new traceability methods in Ghana's pharmaceutical supply chain

3.8 Comparative Analysis of Drug Counterfeiting Across Ghana and Africa

The landscape of drug counterfeiting in Ghana presents similarities and differences when compared to other countries in Africa. Similarities can be observed in the widespread prevalence of counterfeit medicines across the continent, driven by factors such as porous borders, weak regulatory frameworks, and high demand for affordable healthcare. Like Ghana, many African countries struggle with the infiltration of counterfeit drugs into their pharmaceutical supply chains, posing significant challenges to public health and safety (Adigwe, 2023; Ogbodum et al., 2023).

One commonality across Africa is the presence of illicit manufacturers, supply chain intermediaries, and online marketplaces facilitating the distribution of counterfeit drugs (Adigwe, 2023; Ogbodum et al., 2023). These actors operate within a complex network that spans national and international borders, making it difficult for regulatory authorities to effectively combat counterfeit activities. Additionally, the lack of stringent regulatory enforcement and limited resources further exacerbate the problem, allowing counterfeiters to exploit loopholes in the system.

However, there are also notable differences in the extent and nature of drug counterfeiting between Ghana and other African countries. Variations in regulatory oversight, healthcare infrastructure, and socio-economic factors can influence the prevalence and severity of counterfeit drug incidents. For instance, weaker regulatory frameworks and healthcare systems may cause more significant challenges in combating counterfeit medicines compared to those with more robust governance structures and healthcare infrastructure.

Moreover, the types of counterfeit drugs prevalent in Ghana may differ from those found in other African countries, depending on factors such as disease burden, treatment preferences, and market demand. Variations in consumer behavior, healthcare practices, and cultural norms can also impact the types of drugs targeted by counterfeiters (Karungamye, 2023).

In terms of efforts to address drug counterfeiting, there may be differences in the strategies employed by various African countries. While some countries may prioritize regulatory reforms and technological advancements in drug traceability, others may focus on international collaborations and capacity-building initiatives to strengthen their anti-counterfeiting efforts (Schneider and Ho Tu Nam, 2021; Tijani and Tomiwa, 2022).

Overall, while the challenges posed by drug counterfeiting are widespread across Africa, the specific contexts and dynamics vary from country to country. Understanding these similarities and differences is essential for developing tailored interventions and collaborative approaches to combat counterfeit medicines effectively across the continent.

4.0 The Way Forward

4.1 Recommendations

These recommendations entail strengthening regulatory bodies, such as the Food and Drugs Authority (FDA), to better monitor and regulate the pharmaceutical market. Key actions include:

- Increased Testing Capacities and Quality Assurance and Monitoring: Investing in cutting-edge laboratory facilities and equipment to expand the capacity for testing pharmaceutical products for quality and authenticity. Policymakers should prioritize initiatives to improve quality assurance mechanisms across the supply chain. This includes enforcing stringent quality standards, and ensuring compliance with Good Manufacturing Practices (GMP) to safeguard the integrity of medicines.

- Regular Surveillance: Implementing proactive monitoring programs to detect and address instances of counterfeit medicines in the market.

- Enforcement of Stringent Penalties: Establishing and enforcing strict penalties for individuals and entities involved in the production, distribution, or sale of counterfeit drugs to deter illicit activities.

- Investment in Data Quality Assurance: Ensuring data quality is crucial for the accuracy and reliability of drug traceability systems. This recommendation involves establishing mechanisms for maintaining the integrity, completeness, and accuracy of collected data. Investing in data quality assurance measures, such as validation, verification, and auditing, will help identify and rectify errors in real time.

- Targeted Interventions: Specific drugs of concern, such as antibiotics and COVID-related products, require targeted interventions to address the root causes of counterfeiting. Policymakers should prioritize regulatory scrutiny, supply chain monitoring, and enforcement actions for high-risk medications.

- Continuous Monitoring and Evaluation: Robust monitoring and evaluation mechanisms are essential for assessing the effectiveness of interventions over time. Regular data collection, analysis, and reporting are necessary for tracking progress and refining strategies to address evolving challenges.

- Regulatory Reforms for Flexibility and Adaptation: The regulatory framework governing drug traceability should be agile and adaptable to changing market dynamics. Comprehensive reviews and reforms should enhance flexibility, streamline processes, and empower regulatory agencies to enforce compliance effectively.

- Enhanced Regulatory Enforcement and Inspections: Strengthened enforcement mechanisms and increased regulatory oversight are necessary to address compliance challenges. The government should allocate resources for regular inspections and adopt digital compliance systems to streamline regulatory processes and improve transparency in the pharmaceutical supply chain. It should enforce stringent regulations that mandate intermediaries in the supply chain to maintain accurate records and provide transparency into their operations. This regulatory oversight helps identify and address potential vulnerabilities in the system.

- Implementation of Digital Tracking Systems: Adopting advanced technologies like blockchain to establish immutable records of drug transactions and movements across the supply chain. This ensures transparency and accountability at every stage of the distribution process.

- Collaboration with E-commerce Platforms and Border Security Agencies: Given the significant role of online marketplaces and cross-border trafficking in the counterfeit drug trade, collaboration between regulatory authorities and relevant stakeholders is imperative. Actions may include partnering with online marketplaces to implement robust verification processes for pharmaceutical sellers and to monitor online transactions for any suspicious activities. This collaboration ensures that only legitimate sellers operate on these platforms, reducing the risk of counterfeit drug sales.

- Enhancement of Border Security: Strengthening border surveillance and intelligence-sharing mechanisms with neighboring countries to detect and intercept counterfeit drugs entering the country through cross-border routes. This proactive approach helps prevent the infiltration of counterfeit drugs into the domestic market, safeguarding public health.

- Improved Technical Infrastructure: The enhancement of technical infrastructure supporting the drug traceability system is crucial to overcome existing limitations and embrace emerging technologies. This recommendation advocates investing in cutting-edge tracking, authentication, and data management systems that seamlessly integrate with current platforms. By upgrading infrastructure, system reliability, interoperability, and data quality will improve, facilitating more efficient tracking and verification of pharmaceutical products across the supply chain. Moreover, stakeholders should undergo training programs to ensure proficiency in utilizing new technologies effectively.

- International Collaboration and Information Sharing: Acknowledging the global nature of counterfeit drug trafficking, fostering international collaboration and information sharing is imperative to effectively combat the illicit trade. This recommendation advocates strengthening partnerships with international organizations, regulatory bodies, law enforcement agencies, and relevant stakeholders. By facilitating the exchange of intelligence, sharing best practices, harmonizing standards, and coordinating enforcement actions, Ghana can bolster its capacity to detect, deter, and disrupt counterfeit drug activities transcending borders. Collaborating with neighboring countries and international allies enables the pooling of expertise, resources, and capabilities to combat counterfeit drugs effectively on a global scale.

- Facilitation of Public-Private Partnerships: Recognizing the resource constraints faced by stakeholders, promoting collaboration between the public and private sectors emerges as a pivotal strategy for fostering technological innovation and sustainable development in the pharmaceutical sector. The government should institute incentives and mechanisms to stimulate private sector investment in traceability infrastructure and technological solutions. Public-private partnerships offer a conduit for harnessing the expertise and resources of both sectors, thereby surmounting implementation hurdles and accelerating progress toward achieving comprehensive drug traceability in Ghana. Such collaborations pave the way for mutually beneficial endeavors that advance the nation's pharmaceutical industry while safeguarding public health.

- Pilot Programs and Proof of Concept Initiatives: To demonstrate the feasibility and effectiveness of traceability technologies in the Ghanaian pharmaceutical supply chain, the government should initiate pilot programs and proof of concept initiatives in collaboration with industry partners. These programs can serve as testbeds for evaluating different technologies, identifying implementation challenges, and refining strategies for broader deployment.

- Incentivize Collaboration and Interoperability: To address challenges related to interoperability and data standardization, the government should incentivize collaboration among stakeholders, including regulatory agencies, pharmaceutical manufacturers, distributors, and healthcare providers. Collaboration incentives could include tax breaks, grants for collaborative projects, or recognition programs for organizations that demonstrate effective collaboration in implementing traceability technologies.

- Capacity Building and Training: Investing in training programs and capacity-building initiatives for stakeholders across the pharmaceutical supply chain to enhance their knowledge and skills in identifying counterfeit medicines and implementing traceability measures.

- Public Awareness and Education: These campaigns can raise awareness about common signs of counterfeit drugs, such as unusual packaging, spelling errors, and suspiciously low prices. By empowering consumers to make informed choices, these initiatives can help reduce demand for counterfeit medicines and disrupt illicit trade networks.

- Supply Chain Integrity and Transparency: Fostering a culture of integrity and accountability by promoting ethical sourcing, responsible manufacturing practices, and transparent reporting of supply chain transactions.

- Ethical Leadership and Governance: Upholding principles of integrity, accountability, and transparency in decision-making processes and organizational practices at all levels of the pharmaceutical sector. This step will inspire trust and confidence in the pharmaceutical sector.

5.0 Summary of Key Findings

5.1 Key Findings

Prevalence of counterfeit medicines

- In 2019, 11.46% of drug samples failed quality evaluation, while, in 2022, 92% of sampled drugs were flagged as substandard or falsified.
- Antibiotics like Amoxicillin and Clavulanic Acid (Augmentin) saw a notable increase in severity rating, while antimalarials showed fluctuating ratings.
- COVID-related products experienced a spike in severity rating in 2020.
- Specific drug brands like Postinor 2, Procold, and Aboniki Ointment consistently exhibited high severity ratings.
- Levonorgestrel (Postinor 2), Artemether-Lumefantrine (Coartem), and Vildagliptin + Metformin (Galvus Met) were consistently rated as high-risk counterfeit drugs by other stakeholders.

Sources and routes of drug counterfeiting

- Illicit manufacturers engage moderately, often blending traditional and allopathic practices.
- Supply chain intermediaries show moderate involvement, substituting genuine drugs during distribution.
- Online marketplaces exhibit high involvement, posing a significant challenge for regulators.
- Cross-border trafficking, especially in border regions, reflects a high frequency of counterfeit drugs entering Ghana, especially via the Ghana-Togo border.

Current traceability system evaluation

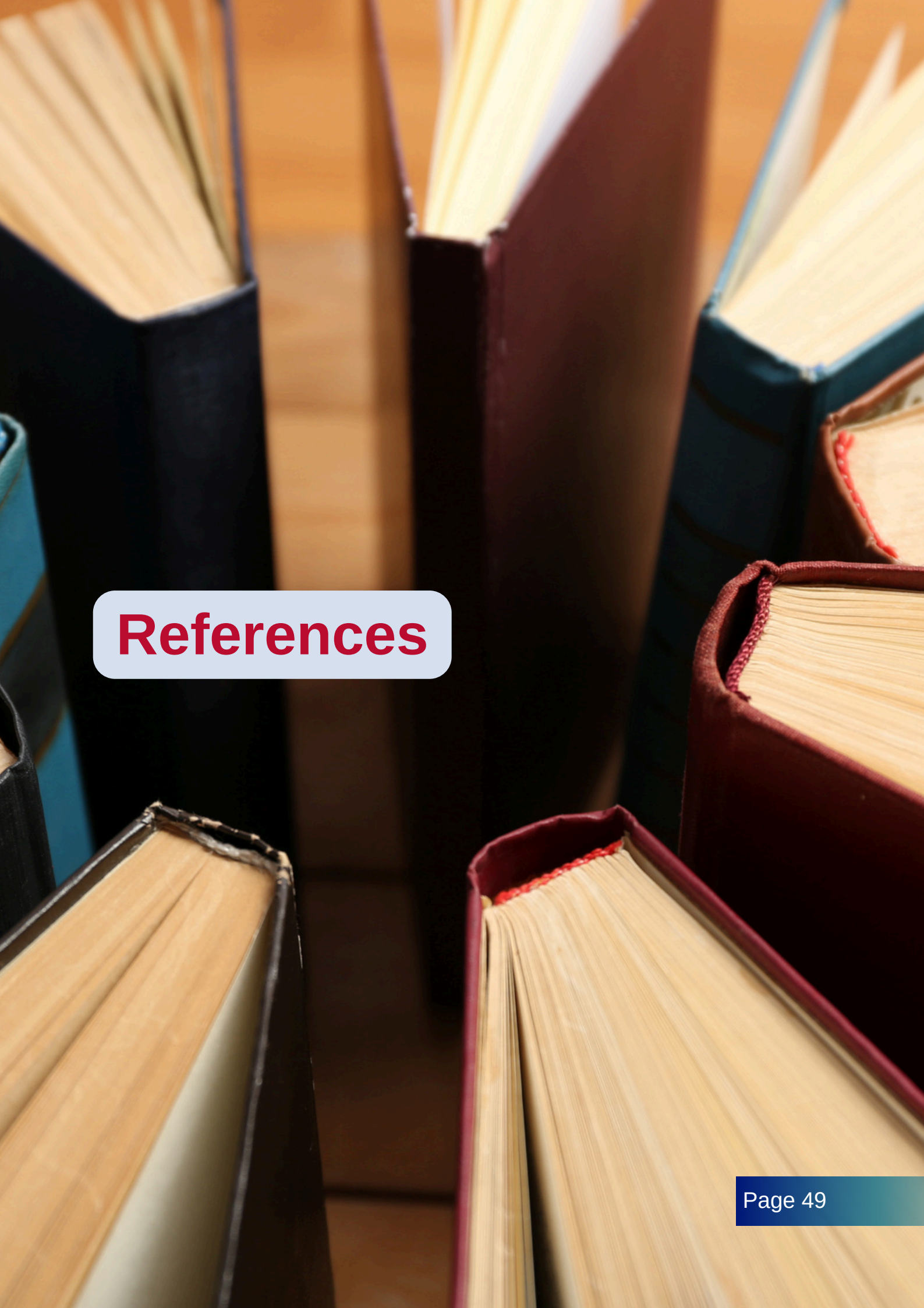
- Ghana's traceability system is based on post-market surveillance.
- Post-market surveillance has positive and negative aspects, including increased transparency.
    - Enables real-world monitoring of drug effectiveness, offering insights into patient outcomes.
    - Identifies counterfeit products, safeguarding consumers, but faces challenges like limited flexibility and resource constraints.
    - Incorporates the ProPer Seals system for product verification, enhancing authentication.
    - Faces interoperability issues with other systems, hindering seamless communication and data sharing.
    - Aligns with traceability objectives but vulnerable to sophisticated counterfeiting techniques, necessitating ongoing updates.

Challenges and drivers of counterfeiting

- Challenges faced include weaknesses in distribution channels and potential integration issues.
- Drivers of counterfeiting involve porous borders, lack of digital regulatory frameworks, and gaps in consumer education.

Technology solutions for drug traceability

- Evaluation of GS1, Blockchain, and RFID technologies reveals potential benefits in improving data accuracy, transparency, and security.
- Cost-benefit analyses indicate long-term value despite initial setup costs.
- Integration challenges and the need for robust change management strategies are recognized.



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Appendix

Method for purposive and snowball sampling:

Purposive sampling was employed to ensure that participants selected for the study possessed specific characteristics relevant to the research objectives. This involved identifying and selecting participants based on their expertise, knowledge, and experience related to drug counterfeiting and pharmaceutical supply chains in Ghana. Purposive sampling allowed researchers to target individuals who could provide valuable insights and perspectives on the prevalence of counterfeit medicines and the effectiveness of the traceability system.

To implement purposive sampling, the researchers identified key stakeholders such as regulatory authorities, pharmaceutical industry professionals, and healthcare practitioners with expertise in the subject matter. These individuals were selected based on their roles, responsibilities, and involvement in activities related to drug regulation, supply chain management, and public health in Ghana.

Once the initial participants were identified, snowball sampling was used to expand the sample size and reach additional relevant participants. Initial participants were asked to refer or nominate other individuals who meet the criteria for participation in the study.

As the snowballing process continued, additional participants were contacted based on referrals from previously interviewed individuals, gradually expanding the sample size and diversifying the perspectives represented in the study. This iterative process allowed the researchers to access a broader range of insights and experiences related to drug counterfeiting in Ghana's pharmaceutical supply chain, enhancing the comprehensiveness and depth of the research findings.

Questionnaire 1:
Combating drug counterfeiting for better healthcare: An assessment of traceability in the pharmaceutical supply chain in Ghana.

Introduction:
Thank you for participating in this survey. The purpose of this survey is to assess the traceability of counterfeit medicines and medical supplies in Ghana's pharmaceutical supply chain. Your responses will help us understand the current state of traceability and identify potential areas for improvement. Please answer the following questions to the best of your knowledge and provide any additional comments or suggestions you may have. Your participation is voluntary, and confidential.

Section 1: General Information
1. Gender:

2. Age:

3. Please provide your organization's primary role within the pharmaceutical supply chain:
a) Manufacturer
b) Distributor/Wholesaler
c) Medical Stores/Warehouse
d) Retailer/Pharmacy
e) Regulatory Authority
f) Healthcare Professional
g) End user/Patient
h) Police/Law enforcement agency
i) Other (please specify):

4. What is your primary function in the organization?
5. How long have you been working in the pharmaceutical industry in Ghana?
a) Under 3 years
b) 3-10 years
c) Over 10 years

Section 2: Knowledge of counterfeit medicines and medical supplies

6. How familiar are you with the concept of counterfeit medicines and medical supplies?
a) Very familiar
b) Quite familiar
c) Somewhat familiar
d) Not quite familiar
e) Not familiar at all

7. In your opinion, the most common characteristics of counterfeit medicines and medical supplies in Ghana are _____. (Please, select the top four)
a) Differences in packaging (e.g., labelling, fonts, colors)
b) Variation in taste, smell, or texture of the medication
c) Incorrect or missing expiration dates
d) Lack of manufacturer information or contact details
e) Unusual side effects or lack of efficacy
f) Inconsistent or illegible batch/lot numbers
g) Other (please specify)

8. Have you received any training or education on identifying counterfeit medicines and medical supplies?
a) Yes
b) No

9. If yes, please provide details about the training or education you have received:
10. How confident are you in your ability to identify counterfeit medicines and medical supplies?
a) Very confident
b) Quite confident
c) Somewhat confident
d) Not quite confident
e) Not confident at all

11. Have you encountered or been informed about incidents of drug counterfeiting within Ghana's pharmaceutical supply chains?
a) Yes
b) No

12. If yes, please specify the drugs (specific names or classes) that were found to be counterfeit:

13. In your opinion or experience, what are the most common routes for counterfeit drugs and supplies entering pharmaceutical supply chains in Ghana?

14. What do you believe are the key factors contributing to drug counterfeiting in the pharmaceutical supply chain in Ghana? (Select all that apply)
a) Weak regulatory enforcement
b) Lack of proper documentation and record-keeping
c) Inadequate quality control measures
d) High demand for certain drugs
e) Supply chain complexity
f) Lack of transparency
g) Others (Please specify):

Section 3: Awareness and Implementation of Traceability Systems

15. Do you know of ways in which medicines and medical supplies are traced back to their manufacturers, distributors, or stores in Ghana?
a) Yes
b) No

16. If yes, please provide details of the mechanisms for tracing medicines and medical supplies that you are familiar with:
a) Serial number tracking
b) Barcoding
c) QR codes
d) RFID (Radio Frequency Identification)
e) Blockchain applications
f) USSD authentication on mobile phones
g) Paper-based documentation
h) Other (please specify)

17. Has your organization implemented any traceability system(s) for medicines in the last five years?
a) Yes
b) No

18. If yes, please describe the traceability system(s) implemented by your organization:

19. What are the perceived benefits of the current drug traceability system in Ghana's pharmaceutical supply chain? (Open-ended response)

20. How effective do you believe the current drug traceability system is in combating drug counterfeiting in Ghana's pharmaceutical supply chain?
a) Very effective
b) Quite effective
c) Somewhat effective
d) Not quite effective
e) Not effective at all

Section 4: Challenges and Barriers to Effective Traceability

21. In your opinion, what are the major challenges or barriers to implementing effective traceability systems in Ghana's pharmaceutical supply chain? (Select all that apply)
a) Lack of regulatory enforcement
b) Insufficient technical infrastructure
c) High implementation costs
d) Lack of stakeholder collaboration
e) Limited awareness and education on traceability
f) Other (please specify)

22. Have you encountered any specific challenges or difficulties related to traceability in your day-to-day operations?

23. If yes, please provide details:

Section 5: Detection and Reporting of Counterfeit Medicines and Medical Supplies

24. Have you come across any instances of counterfeit medicines and medical supplies in the supply chain?
a) Yes
b) No

25. If yes, how were these counterfeit medicines and medical supplies detected? (Select all that apply)
a) Visual or physical inspection
b) Packaging anomalies
c) Suspicious supplier behavior
d) Testing in a laboratory
e) Reports from customers or patients
f) Reports from healthcare professionals
g) Reports from civil society actors
i) Serial number tracking
j) Barcoding
k) QR codes
i) RFID (Radio Frequency Identification)
m) Blockchain applications
n) USSD authentication on mobile phones
o) Other (please specify)

26. How are cases of counterfeit medicines and medical supplies usually reported within the pharmaceutical supply chain in Ghana? (Tick only one column per method)

Reporting method:	Most times	Sometimes	Hardly
a) Reporting to regulatory authorities			
b) Reporting to law enforcement agencies			
c) Internal reporting within the organization			
d) Other (please specify):			

Section 6: Improving Traceability Systems

27. How familiar are you with each of the following technologies in tracking drugs back to their true sources? (Tick only one column per technology)

Technology	How familiar I am with the technology				
	Not familiar at all	Not much familiar	Somewhat familiar	Quite familiar	Very familiar
QR code					
Bar codes					
Blockchains					
Mobile authentication (USSD)					
RFID (Radio Frequency ID)					
Blockchain barcodes					
GS1					
Others (Please, specify):					

28. In your line of work, how often have you used any of the following technologies in tracing drugs back to their true sources? (Tick only one column per technology)

Technology	How familiar I am with the technology				
	Never used	Not often used	Somewhat often used	Quite often used	Very often used
QR code					
Bar codes					
Blockchains					
Mobile authentication (USSD)					
RFID (Radio Frequency ID)					
Blockchain barcodes					
Global standards 1					
Others (Please, specify):					

29. For those you are familiar with (or have used in your line of duty), how do you think these technologies can be most effectively used to enhance drug traceability in Ghana's pharmaceutical supply chains? (Open-ended response):

30. What measures do you believe would improve the traceability of medicines and medical supplies in Ghana's pharmaceutical supply chain? (Select all that apply)

a) Stricter regulatory enforcement
b) Improved technical infrastructure
c) Increased collaboration among stakeholders
d) Mandatory implementation of traceability systems
e) Enhanced awareness and education programs
f) Advanced authentication technologies
g) Other (please specify)

31. Do you have any additional comments or suggestions for improving the traceability of medicines and medical supplies in Ghana's pharmaceutical supply chain?

31. Do you have any additional comments or suggestions for improving the traceability of medicines and medical supplies in Ghana's pharmaceutical supply chain?

Section 7: Market Surveillance and SC Traceability

32. Which organizations or entities are responsible for conducting inspections within the pharmaceutical supply chain? (Select all that apply)
a) Regulatory authorities
b) Law enforcement agencies
c) Pharmaceutical industry associations
d) Third-party auditors
e) Other (please specify)

33. In your opinion, how effective are the current inspection procedures in detecting counterfeit medications?
a) Very effective
b) Quite effective
c) Somewhat effective
d) Not quite effective
e) Not effective at all

34. How frequently are inspections conducted within the pharmaceutical supply chain in Ghana?
a) Regularly (at least once a year)
b) Occasionally (every few years)
c) Rarely (infrequently or not at all)

Section 8: Awareness Creation and SC Traceability

39. How aware are the general public and healthcare professionals in Ghana about the risks and prevalence of counterfeit medicines and medical supplies?
a) Very much aware
b) Quite aware
c) Somewhat aware
d) Not quite aware
e) Not aware at all

40. Are there any awareness campaigns or educational programs currently in place to educate the public and healthcare professionals about counterfeit medicines and medical supplies?
a) Yes
b) No

41. If yes, please provide details about the existing awareness campaigns or educational programs:
a) For general public:
b) For healthcare professionals:

42. In your opinion, how effective are the current awareness campaigns and educational programs in addressing the issue of counterfeit medicines and medical supplies?
a) Very effective
b) Quite effective
c) Somewhat effective
d) Not quite effective
e) Not effective at all

43. Are there any specific challenges or barriers to raising awareness about counterfeit medicines and medical supplies among the general public and healthcare professionals?
a) Yes
b) No

44. If yes, please provide details:
a) For general public:
b) For healthcare professionals:

45. What additional measures or strategies do you believe would improve awareness and communication about counterfeit medicines and medical supplies in Ghana? (Please, select all that apply)
a) Increased media coverage and public service announcements
b) Collaboration with healthcare professional associations and organizations
c) Distribution of informational materials and brochures
d) Training programs for healthcare professionals
e) Social media campaigns and online resources
f) Other (please specify):

46. Do you have any additional comments or suggestions on supply chain traceability and its contributions to the fight against counterfeit medicines and medical supplies in Ghana?

Thank you for taking the time to complete this survey. Your input is valuable and will contribute to a better understanding of the traceability challenges in Ghana's pharmaceutical supply chain.

Questionnaire 2: Archival Records/Data Questionnaire on Counterfeit Drugs and Incidences

Section 1: Introduction

1. Name of Regulatory Body:
2. Your Position/Role in the Regulatory Body:
3. Contact Information (Email/Phone Number):

Section 2: Data Collection Period

4. What is the time frame for the data requested? (Please specify start and end dates):

Section 3: General Information

5. How does your institution define and classify counterfeit drugs?

6. Can you provide a brief overview of the reporting and recording process for counterfeit drug incidences in Ghana?

Section 4: Incidences of Counterfeit Drugs

7. How many incidents of counterfeit drugs have been recorded within Ghana's pharmaceutical supply chain during the specified data collection period?

8. For each recorded incident, please provide the following details:
a) Incident Number/Reference:
b) Date of Incident:
c) Name of Counterfeit Drug:
d) Dosage Form and Strength:
e) Batch/Lot Number (if available):
f) Reported Location(s) of Incident:

Section 5: Identification and Verification of Counterfeit Drugs

9. How were the counterfeit drugs identified and verified in each recorded incident? (e.g., through visual inspection, laboratory analysis)

10. Were any specific technologies or tools utilized to aid in the identification of counterfeit drugs?
a) Yes
b) No
If yes, please specify the technology or tool used:

Section 6: Sources/Routes of Counterfeit Drugs

11. Based on historical data, what are the most common sources or routes through which counterfeit drugs have entered Ghana's pharmaceutical supply chain?

Section 7: Actions Taken Against Counterfeit Drugs

12. In each recorded incident, what actions were taken by the regulatory body in response to the identification of counterfeit drugs? (e.g., product recall, legal actions)

Section 8: Collaboration and Information Sharing

13. Does your regulatory body collaborate with other agencies (e.g., law enforcement, customs, other regulatory bodies) to address counterfeit drugs?

a) Yes

b) No

If yes, please briefly describe the nature of collaboration and information-sharing activities:

Section 9: Challenges in Addressing Counterfeit Drugs

14. Based on historical data, what were the major challenges faced by your regulatory body in addressing counterfeit drugs within Ghana's pharmaceutical supply chain?

Section 10: Additional Comments

15. Please provide any additional comments or insights related to historical data on counterfeit drugs and incidences recorded within Ghana's pharmaceutical supply chains.

Thank you for your cooperation and willingness to provide the requested information. Your input is valuable and will contribute to a better understanding of the traceability challenges in Ghana's pharmaceutical supply chain.

Sample calculations:

Connectivity index for Ghana
Internet Penetration Rate (40% weight): 8/10
Mobile Network Coverage (20% weight): 7/10
Broadband Speeds (15% weight): 6/10
Digital Inclusion (10% weight): 7/10
E-Government Initiatives (5% weight): 8/10
Smartphone Penetration (5% weight): 9/10
Public Wi-Fi Availability (5% weight): 7/10

Technological Connectivity Index
= (0.4×8)+(0.2×7)+(0.15×6)+(0.1×7)+(0.05×8)+(0.05×9)+(0.05×7)
Technological Connectivity Index=3.2+1.4+0.9+0.7+0.4+0.45+0.35
Technological Connectivity Index
=7.55

Quick Technological Integration Capacity Assessment:
Government Initiatives (25% weight): 7/10
Industry Adoption (20% weight): 6/10
Digital Infrastructure (15% weight): 8/10
Education and Workforce Development (15% weight): 7/10
Start-up Ecosystem (10% weight): 6/10
Digital Literacy Rates (10% weight): 7/10
International Collaboration (5% weight): 8/10

Technological Integration Capacity Score

Technological Integration Capacity Score=(0.25×7)+(0.2×6)+(0.15×8)+(0.15×7)+(0.1×6)+(0.1×7)+(0.05×8)

Technological Integration Capacity Score=1.75+1.2+1.2+1.05+0.6+0.7+0.4
Technological Integration Capacity Score=6.9

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