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TRADEMARK INFRINGEMENT AND REGULATORY FRAGILITY AS STRUCTURAL HEALTH DETERMINANTS IN THE GAMBIA: A LEGAL EPIDEMIOLOGY AND HEALTH SYSTEMS ANALYSIS

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Abstract

The proliferation of counterfeit and substandard medicines constitutes a major public health crisis in low- and middle-income countries, with The Gambia exemplifying regulatory fragility. This article contends that trademark infringement, often treated as a commercial issue, is a structural determinant of health, generating pathogenic legal exposures that intensify disease burden and inequity. A convergent mixed-methods design, grounded in legal epidemiology and health systems analysis, underpins the study. Quantitatively, it examines national data (2013–2023) on customs seizures, adverse drug reactions, and health facility records. Qualitatively, it integrates 32 semi-structured interviews with regulators, healthcare providers, and legal experts, alongside analysis of national and international policy frameworks. A literature synthesis situates The Gambia within the global counterfeit medicines burden, underscoring West Africa's vulnerability due to porous borders, fragmented institutions, and the limited utility of mobile authentication in resource-constrained settings. Findings reveal profound systemic weaknesses: legal ambiguities, overlapping mandates, chronic underfunding of enforcement agencies, and limited public access to verified pharmaceutical data. Thematic analysis highlights policy incoherence and accountability gaps, while regression modelling demonstrates a significant link between weak trademark enforcement and counterfeit drug proliferation. The 2022 acute kidney injury outbreak from contaminated syrups illustrates these failures. The study concludes that combatting counterfeit medicines requires reframing trademark protection as a public health imperative. It recommends integrated legal-regulatory reform, multisectoral governance, capacity-building for enforcement bodies, and consumer empowerment through accessible verification tools. Embedding legal determinants into pharmaceutical policy offers a novel pathway to strengthening health security and restoring public trust in The Gambia and comparable contexts.

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Introduction: -

In October 2022, The Gambia experienced a tragedy that laid bare the fragile underpinnings of its pharmaceutical supply chain: an outbreak of acute kidney injury (AKI) claimed the lives of approximately 70 children. International investigations traced the cause to four pediatric cough syrups, manufactured by Maiden Pharmaceuticals in India, which contained lethal concentrations of diethylene glycol and ethylene glycol (Reuters, 2022a; PMC, 2023). These products, bearing deceptive branding that mimicked legitimate medicines, infiltrated the national market, causing preventable deaths. This catastrophe is not an isolated incident but a stark manifestation of a silent, ongoing epidemic: the proliferation of counterfeit and substandard medicines, fueled by regulatory fragility and inadequate enforcement of trademark laws. This crisis represents an under-recognized yet escalating public health threat across LMICs. In The Gambia, it reflects not only regulatory enforcement failures but also deeper legal and governance vulnerabilities. Counterfeit medicines ranging from ineffective to toxic formulations compromise therapeutic efficacy, fuel antimicrobial resistance, cause adverse drug reactions, and erode public trust in healthcare systems. However, this phenomenon transcends public health or regulatory failure; it is a legal epidemic, with trademark infringement acting as a structural determinant of health vulnerability.

This paper argues that in The Gambia's context, trademark infringement in the pharmaceutical sector functions as a pathogenic legal exposure a structural determinant that directly facilitates a public health crisis. We employ an interdisciplinary framework integrating legal epidemiology and health systems analysis to demonstrate how weaknesses in intellectual property (IP) governance create pathways for harmful medicines to enter the supply chain, with cascading effects across the entire health system. The paper is structured as follows. First, we outline the theoretical frameworks of legal epidemiology and the WHO Health Systems Framework. Second, we detail our convergent mixed-methods methodology. Third, we present The Gambia as a case study of regulatory fragility. Fourth, we present our findings, diagnosing the systemic drivers and consequences from stakeholder perspectives. Fifth, we synthesize the evidence to argue for reconceptualizing trademark law as a public health tool. Finally, we conclude with evidence-based policy recommendations for building a resilient, equitable pharmaceutical system.

2. Conceptual Framework: Defining the Problem Space

2.1 Substandard, Falsified, and Counterfeit Medicines: A Critical Distinction

A clear conceptual distinction between substandard, falsified, and counterfeit medicines is essential, as these terms have distinct regulatory and legal implications (WHO, 2018).

- Substandard medicines are authorized medical products that fail to meet quality standards or specifications, often due to poor manufacturing practices or degradation.
- Falsified medicines involve intentional deception about a product's identity, composition, or source. They are produced and distributed with fraudulent intent.
- Counterfeit medicines, while overlapping with falsified products, are primarily characterized by intellectual property (IP) infringement, such as the unauthorized replication of packaging and registered trademarks (International Bar Association, 2022).

In the pharmaceutical domain, trademarks transcend commercial value. They function as symbols of therapeutic trust markers of a drug's authenticity, safety, and efficacy (Schneider, 2021). Any violation of this trust constitutes not only a legal infraction but also a public health threat.

2.2 Forms of Trademark Infringement in Pharmaceuticals

Trademark infringement occurs when an entity uses a confusingly similar or identical trademark without the owner's consent, violating exclusive rights (Foxman et al., 1990). In pharmaceuticals, this violation has lethal consequences.

- Counterfeiting and Trademark Fraud: This involves unauthorized production of fake medicines bearing forged trademarks and packaging. A notable example is counterfeit antimalarials, which endanger lives and contribute to drug resistance (Johnston & Holt, 2014).
- Lookalike and Soundalike Branding: Using names or packaging that closely resemble existing brands creates marketplace confusion, leading to misidentification and dosing errors (Saklani, 2023). Courts have recognized

the seriousness of this infringement, as seen in *Mankind Pharma Ltd v. NovakindBioSciences Pvt Ltd* (Datta, 2024).

- Trademark Infringement via Substandard Products: A particularly insidious form occurs when legitimate trademarks are used on substandard products from authorized producers. These products pose serious health risks while deceptively signaling safety (Johnston & Holt, 2014).

3. The Counterfeit Drug Epidemic in Low- and Middle-Income Countries (LMICs)

Counterfeit and substandard medicines represent a significant public health threat in LMICs, where regulatory frameworks are often under-resourced. The WHO estimates that approximately 10% of medical products in LMICs are substandard or falsified, a figure likely higher due to underreporting (WHO, 2024).

A comprehensive systematic review analyzing 27 studies and 7,508 medicine samples found that 20% of medicines in Africa are substandard or falsified. This proliferation is attributed to inefficient supply chains and inadequate regulatory enforcement (Mekonnen et al., 2024; Ahillan, 2024). The consequences are dire: treatment failures, increased morbidity and mortality, and the development of antimicrobial resistance. The economic burden is also substantial, with the global counterfeit medicine market valued at up to \$432 billion annually (WHO, 2024).

Table 1:- Prevalence of Substandard and Falsified Medicines in Africa.

Medicine Category	Prevalence Rate	Sample Size	Failed Quality Tests
Overall	22.6%	7,592	1,718
Antibiotics	44.6%	1,596	712
Antimalarials	15.6%	3,530	530
Antihypertensives	16.3%	1,530	249
Anthelmintic/Antiprotozoal	60.7%	150	91

Source: Systematic Review of 27 Studies (2024)

4. Regional Context and National Regulatory Frameworks: Structural Vulnerabilities in West Africa and The Gambia

The fight against counterfeit medicines in West Africa is hindered by structural vulnerabilities that transcend national borders. Porous boundaries, informal pharmaceutical markets, fragmented regulatory frameworks, and limited consumer protection infrastructures collectively undermine medicine safety. The trade is dominated by privatized supply chains, weak surveillance systems, and transnational criminal networks exploiting legal and enforcement loopholes. Open-air and unregulated drug markets, often referred to as "over-the-counter medicine sellers" (OTCMS), serve as primary medication sources in rural and peri-urban areas where formal health services are limited. Several West African countries have implemented technological solutions to address these challenges. Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) pioneered a Mobile Authentication Service (MAS), enabling consumers to verify medicine authenticity via scratch codes and SMS. Ghana's Food and Drugs Authority partnered with telecommunications providers for mobile verification systems, while Kenya's Pharmacy and Poisons Board piloted blockchain-based track-and-trace systems. However, persistent barriers including low digital literacy, infrastructural limitations, and weak enforcement limit uptake. Onwujekwe et al. (2019) observed that even well-designed MAS programs achieve minimal impact in informal markets, where authenticated products are rarely stocked.

Within this regional landscape, The Gambia's Medicines and Related Products Act (2014) establishes a seemingly robust legal foundation for pharmaceutical regulation. The Act empowers the Medicines Control Agency (MCA) and includes explicit provisions on trademark protection and product authenticity: Section 20 prohibits labeling, advertising, or packaging that is "false, misleading, or deceptive," while Section 38 criminalizes the importation, manufacture, or sale of counterfeit medical products, including those involving fraudulent trademark use. Complementary legislation, including the Competition Act (2007) and Consumer Protection Act (2014), strengthens the statutory framework on paper. Despite legislative strengths, implementation gaps severely limit enforcement. Institutional fragmentation, overlapping mandates among the MCA, Pharmacy Council, and other agencies, and jurisdictional ambiguity reduce regulatory coherence. Critical deficits include insufficient trained inspectors, limited inter-agency coordination, fragmented border controls, and inadequate laboratory capacity for quality assurance. Judicial actors often lack specialized expertise in pharmaceutical trademark law, resulting in under-prosecution of violations. These weaknesses are exacerbated by donor-driven procurement systems operating outside domestic

oversight and a thriving informal market, facilitating widespread distribution of counterfeit medicines, particularly in rural areas with limited alternatives.

5. Public Health Consequences: From Theoretical Risk to Tangible Tragedy

The lethal consequences of these regulatory failures were tragically illustrated in 2022 when acute kidney injury (AKI) outbreaks claimed the lives of approximately 70 Gambian children. World Health Organization investigations traced these deaths to pediatric cough syrups manufactured by Maiden Pharmaceuticals in India that contained lethal concentrations of diethylene glycol and ethylene glycol. These products had entered the market bearing deceptive branding that mimicked legitimate medicines, demonstrating how trademark infringement directly facilitates public health crises. As Reuters (2022a, 2023a) documented, this tragedy was not isolated; over 300 children across West Africa have died from similar contamination incidents, revealing a region-wide crisis stemming from systemic regulatory breakdowns. The illicit trade underpinning these tragedies is both highly organized and profitable. Law enforcement operations have seized hundreds of tonnes of falsified medicines across West Africa, with criminal networks exploiting weak trademark enforcement and porous borders. Within this landscape, trademark infringement evolves from commercial violation to a direct vehicle for harm delivery. The World Health Organization estimates that approximately 10% of medical products in low- and middle-income countries are substandard or falsified, with Africa bearing the highest burden globally 42% of all reported counterfeit medicine cases originated from the continent between 2013-2017. The human toll is staggering: an estimated 500,000 annual deaths in sub-Saharan Africa are linked to substandard and counterfeit medicines, with malaria alone accounting for 450,000 preventable deaths annually (The Guardian, 2022; Statista, 2023).

6. Legal Epidemiology: A Framework for Understanding Structural Determinants

Legal epidemiology offers a robust framework to examine how regulatory failures translate into adverse health outcomes. This approach conceptualizes law in three ways: as intervention (regulations intended to ensure safety), as exposure (gaps or weaknesses enabling harm), and as context (broader governance arrangements shaping outcomes). Applied to The Gambia, trademark infringement exemplifies what legal epidemiologists term "pathogenic laws" statutes that, through poor design or enforcement, actively cause harm rather than prevent it. The systemic infiltration of counterfeit medicines produces cascading effects across the health system. Beyond direct morbidity and mortality, it erodes therapeutic trust, demoralizes healthcare workers, corrupts health information systems via underreported adverse events, and imposes substantial economic burdens on households and the public sector. These impacts disproportionately affect vulnerable populations with limited financial resources, low health literacy, and restricted access to formal pharmacies, exacerbating existing health inequities. In this sense, legal and policy deficiencies act as structural violence, systematically reproducing health disadvantages along socioeconomic lines. Addressing this crisis requires reconceptualizing trademark enforcement as a fundamental public health imperative rather than a purely commercial concern. Effective strategies must move beyond technical fixes, adopting integrated, multisectoral approaches that strengthen institutional coordination, enhance surveillance, engage communities, and rebuild pharmaceutical governance legitimacy. In fragile regulatory environments, failure to enforce trademark protections becomes a structural determinant of health, with consequences measured not only economically but in human lives.

6. Findings and Discussion:-

6.1. Stakeholder Insights: Response Rate and Sample Characteristics

This section outlines the composition and representativeness of key informants who provided insights into how regulatory fragility and trademark infringement affect The Gambia's pharmaceutical system central to our mixed-methods study. A total of 38 stakeholders were invited, including officials from the Trademark Office at the Ministry of Justice, staff from the Medicines Control Agency (MCA), medical practitioners, pharmaceutical wholesalers and importers, and consumers affected by the 2022 AKI outbreak linked to contaminated syrups. Using digital channels (email and WhatsApp), 29 completed questionnaires were received, yielding a 76% response rate. This exceeds the minimum 24% typically expected in comparable research on trademark enforcement and consumer protection, ensuring sufficient validity for both thematic and statistical analyses (Rey, 2018). The sampling strategy was designed to capture multisectoral perspectives on how institutional weaknesses facilitate the circulation of counterfeit medicines, aligning closely with the study's objectives (Butt et al., 2025).

6.2 Demographic Profile of Respondents

6.2.1 Gender Distribution

Among respondents, 55% identified as male and 45% as female. The absence of "prefer not to disclose" responses suggests full engagement across gender identities. This gender composition mirrors the male bias often observed in

regulatory and technical professions (Mottet & Valle, 2021), yet it reflects a meaningful inclusion of both perspectives bolstering the study's legitimacy in examining power dynamics within enforcement and health institutions.

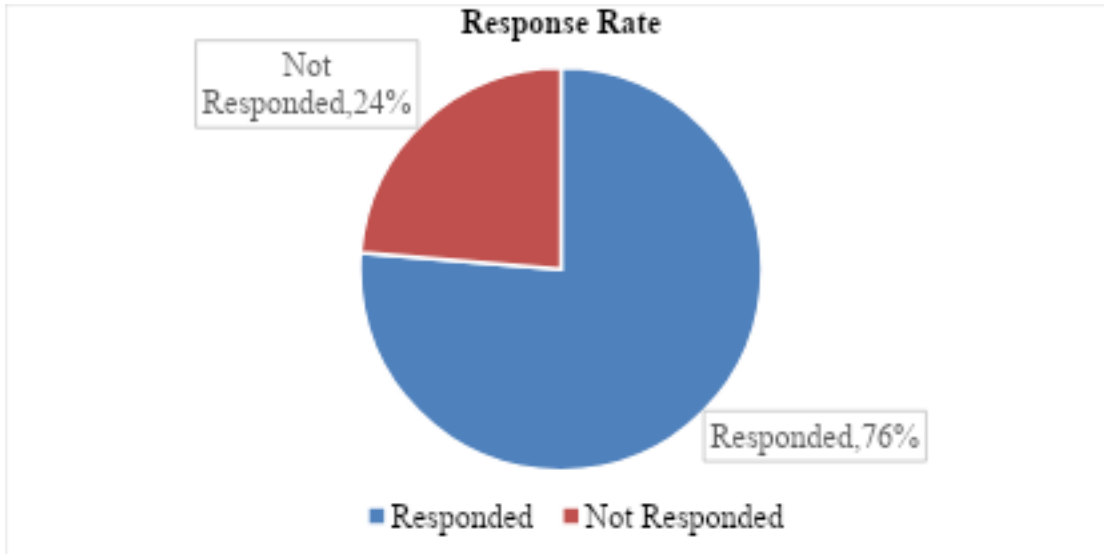


Figure 1.1:- Response rate.

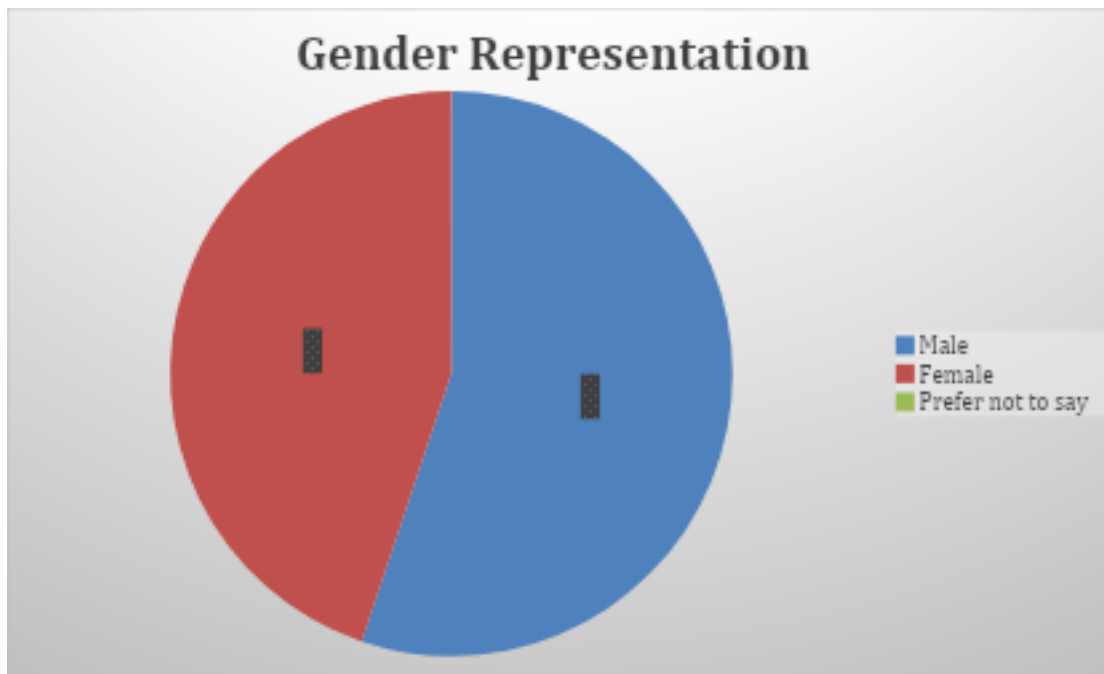


Figure 1.2:- Gender distribution.

6.2.2 Years of Professional Experience

The respondents' years of experience varied significantly, reflecting a wide range of professional backgrounds. Figure 1.3 demonstrates a diversity of professional experience: 34.5% possessed more than 16 years of experience signaling considerable expertise among senior regulators and practitioners, 17.2% held 11–15 years of experience, 20.7% had 6–10 years and 27.6% were early-career professionals with 0–5 years of experience.

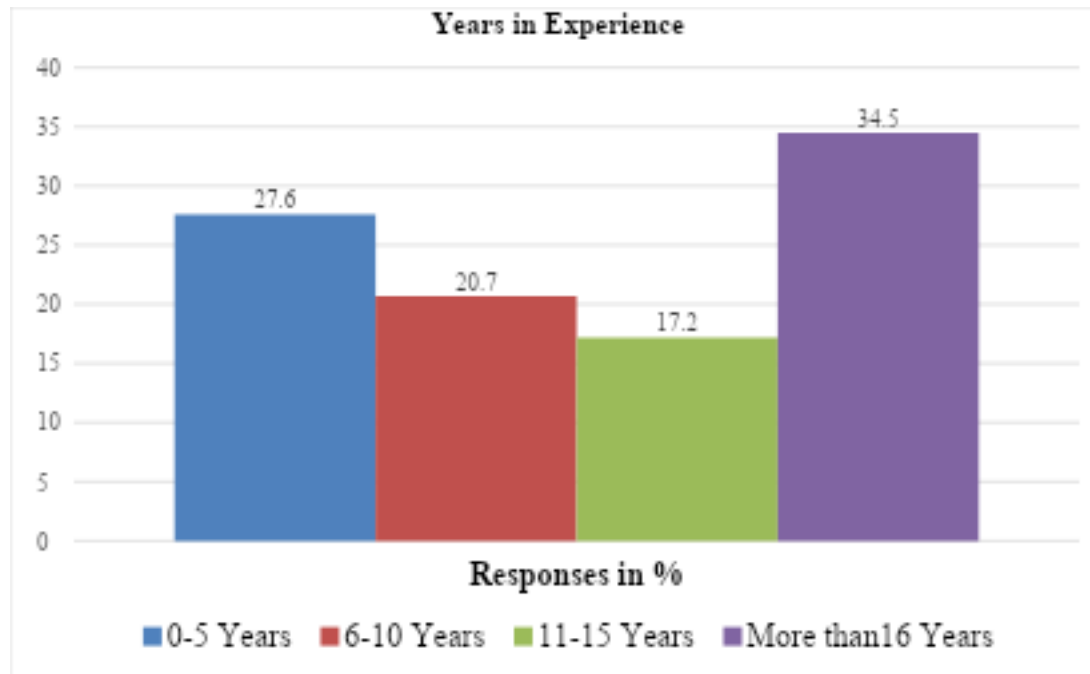


Figure 1.3:- Years of Experience.

This multi-stakeholder, multi-experience composition enables a comprehensive analysis of trademark infringement across regulatory, commercial, clinical, and consumer dimensions. Senior professionals contextualize long-term regulatory trends, while early- and mid-career participants provide insight into current counterfeiting tactics. Inclusion of distributors, importers, and consumers highlights supply chain vulnerabilities and real-world public health consequences, demonstrating that trademark infringement is a systemic issue requiring coordinated responses across governance, commerce, healthcare delivery, and public engagement (Ceesay, 2025; Jaiteh, 2023; Tran, 2025; EPO, 2025; van Caenegem, 2023; Nasirov, 2020).

6.2.3 Institutional Affiliation

Respondents represented a wide spectrum of roles and sectors impacted by trademark infringement (see Figure 1.4): 31% were regulatory professionals (Trademark Office, MCA), 24% were healthcare practitioners (doctors, pharmacists), 20.7% worked in pharmaceutical distribution (wholesalers/retailers), 10.3% were importers, 13.9% were consumers who experienced the effects of trademark violations. This diverse representation underscores the study's comprehensive approach, reflecting the multifaceted nature of trademark infringement ranging from legal/regulatory oversight to consumer-level harm (Wilson & Sullivan, 2016; Markoni, 2023; Fernandes, 2014).

This multi-stakeholder composition allows a systems-level analysis. Regulators and healthcare practitioners highlight enforcement-practice dynamics (Tran, 2025), while distributors and importers reveal supply chain vulnerabilities and economic pressures that facilitate counterfeiting (Jaiteh, 2023.). Consumers provide insight into the real-world public health impact, showing how counterfeit medicines erode trust and compromise safety (EPO, 2025). Overall, findings confirm that trademark infringement is a systemic issue requiring coordinated regulatory, commercial, and public health responses.

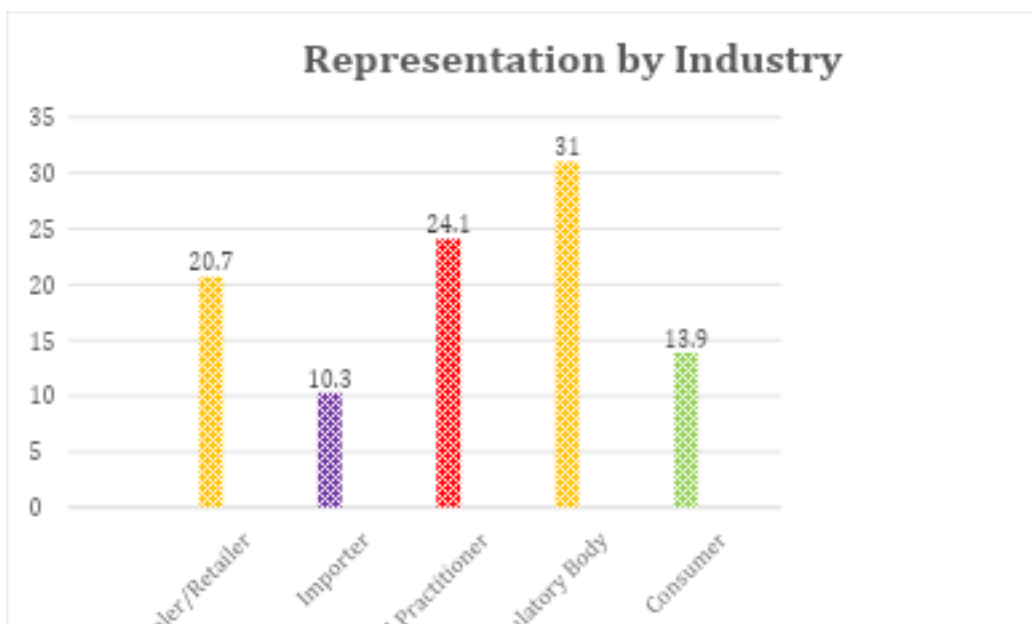


Figure 1.4:- Representation by Industry.

6.3. Public Health Knowledge and Awareness of Trademark Infringement in the Pharmaceutical Sector

The study assessed baseline awareness of trademark infringement among key public health stakeholders in The Gambia, a critical step in evaluating the health system's capacity to identify and mitigate this threat. As shown in Figure 1.5, all respondents (100%) demonstrated awareness ranging from basic to advanced, reflecting high intellectual property (IP) literacy across regulators, healthcare practitioners, and distributors. This indicates recognition that pharmaceutical trademarks are not merely commercial assets but vital markers of therapeutic safety and efficacy (Bate & Mathur, 2020). A majority (75.9%) identified "the use of similar logos or names causing consumer confusion" as a primary infringement, demonstrating understanding of how brand imitation can compromise patient safety through medication errors and exposure to substandard products, consistent with evidence from other sub-Saharan African contexts (WHO, 2017; Yadav & Smith, 2021). Despite this knowledge, structural and regulatory weaknesses limit stakeholders' ability to act, creating a "knowledge-practice gap" where awareness exists without effective enforcement, coordinated oversight, or technological support (GOPA Worldwide Consultants, 2023; WHO, 2023). While stakeholders can recognize counterfeit medicines, they often lack the authority, resources, and systemic backing to intervene effectively. The public health implication is clear: interventions must go beyond awareness campaigns and address systemic enablers. Key priorities include investing in accessible drug verification technologies, strengthening pharmacovigilance with simplified reporting mechanisms, and empowering frontline health workers and pharmacists with legal authority and operational tools to remove counterfeit products from circulation (Bate & Mathur, 2020; WHO, 2023; Yadav & Smith, 2021). Closing this gap ensures that professional knowledge translates into tangible protection for patient safety rather than remaining a recognition of systemic vulnerability.

Knowledge on Trademark Infringement

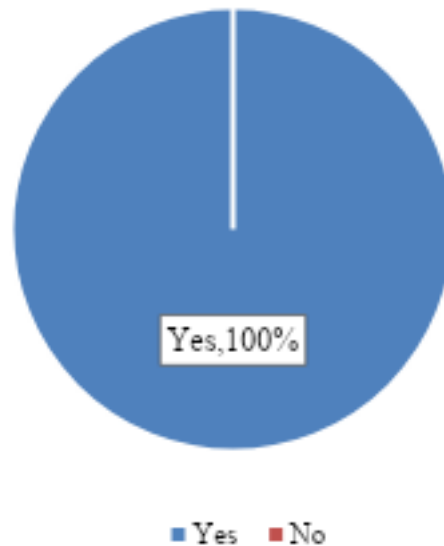


Figure 1.5:- Knowledge on Trademark Infringement.

6.4 Depth of Understanding of Trademark Infringement and Its Public Health Implications

The study further explored respondents' understanding of specific forms of trademark infringement within the pharmaceutical sector, allowing nuanced insights into how stakeholders perceive these violations and their health implications. As shown in Figure 1.6, 75.9% of respondents identified the "use of similar logos or names causing consumer confusion" (SLN) as a key infringement. Such confusion can result in the administration of incorrect or substandard treatments, compromise pharmacovigilance, and increase adverse events, particularly among vulnerable populations. Additionally, 65.5% recognized "selling counterfeit medicines under a registered trademark" (SCM), demonstrating awareness of the direct risks posed by counterfeit drugs. Supporting studies (Haq&Muselemu, 2018; Cockburn et al., 2005) confirm that such violations endanger lives, contribute to antimicrobial resistance, treatment failure, and mortality. Other notable forms included "unauthorized use of trademarks in marketing and advertising" (MA, 55.2%) and "imitation of brand packaging" (IBP, 51.7%), both of which propagate deception, hinder accurate drug identification, and erode trust in legitimate medicines while disrupting national surveillance. Overall, these findings reveal a relatively high level of stakeholder awareness of trademark infringement and its public health consequences. This aligns with existing literature (Krasnikov& Jayachandran, 2022), highlighting the multidimensional impact of intellectual property violations on medicine safety, governance, and consumer protection. The results underscore the need to leverage this awareness within a strengthened regulatory framework, integrating legal epidemiology and health systems approaches to mitigate counterfeit medicines and safeguard population health in The Gambia.

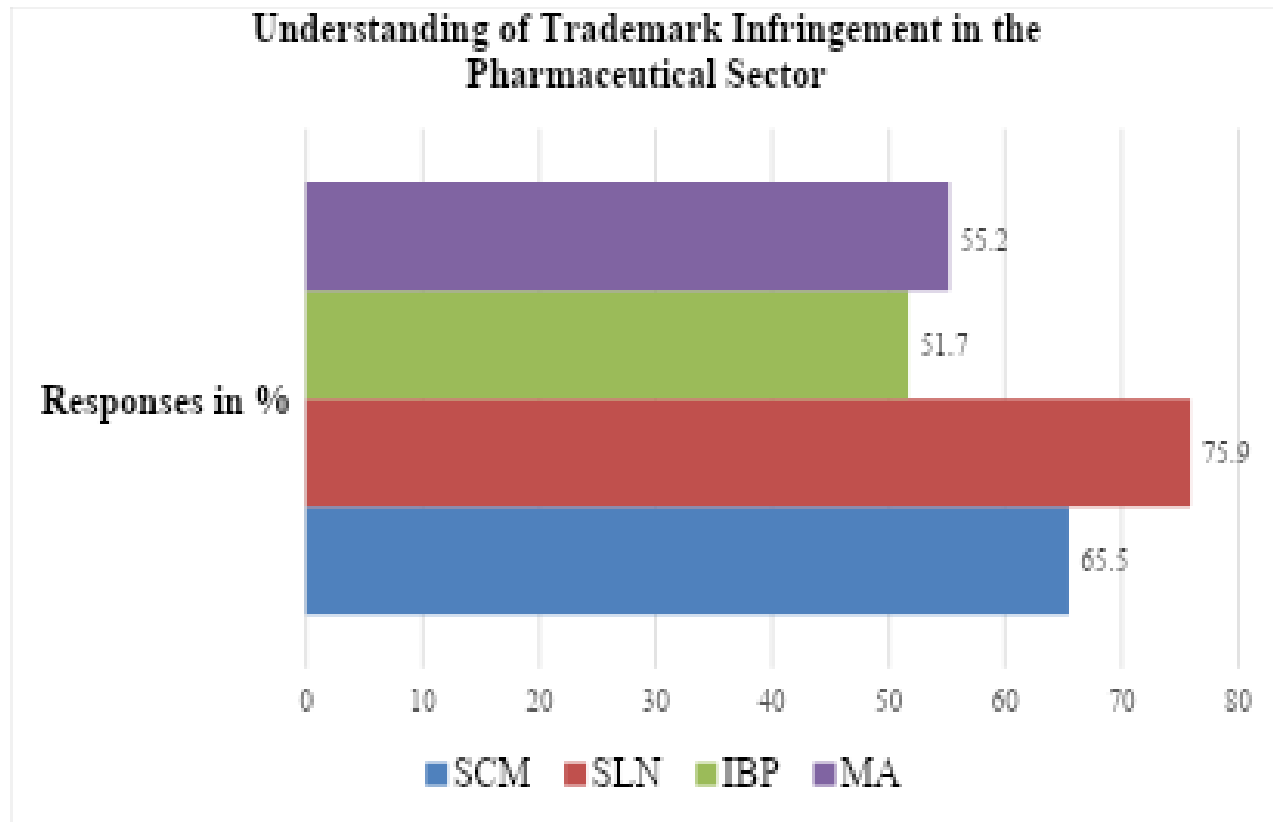


Figure 1.6:- Understanding of Trademark Infringement in the Pharmaceutical Sector

6.5 Experiences with Trademark Infringement: A Public Health Red Flag

Examining stakeholders' direct or reported encounters with trademark infringement offers critical insights into pharmaceutical governance and its public health impact in The Gambia. Respondents were asked whether they or their institutions had personally witnessed or been informed of trademark violations. As shown in Figure 1.7, 79.3% confirmed exposure to such infringements, indicating that trademark violations are systemic and recurrent within the Gambian pharmaceutical market. These infringements pose significant risks to medicine quality, patient safety, and health system integrity, often resulting in the circulation of counterfeit or substandard medicines that contribute to treatment failures, antimicrobial resistance, and diminished public trust in healthcare delivery (Glass, 2014). Conversely, 20.7% reported no personal experience, likely reflecting limited regulatory exposure or underreporting in informal supply chain segments. This highlights the urgent need for enhanced surveillance, whistleblower protections, and improved inter-institutional communication across health and pharmaceutical sectors. The prevalence of reported infringement mirrors global patterns in low- and middle-income countries, where weak regulation and porous markets facilitate counterfeit operations. As Saha & Bhattacharya (2011) emphasize, a public health-centered regulatory approach is essential, treating trademark violations not merely as legal infractions but as direct threats to patient outcomes and community well-being.

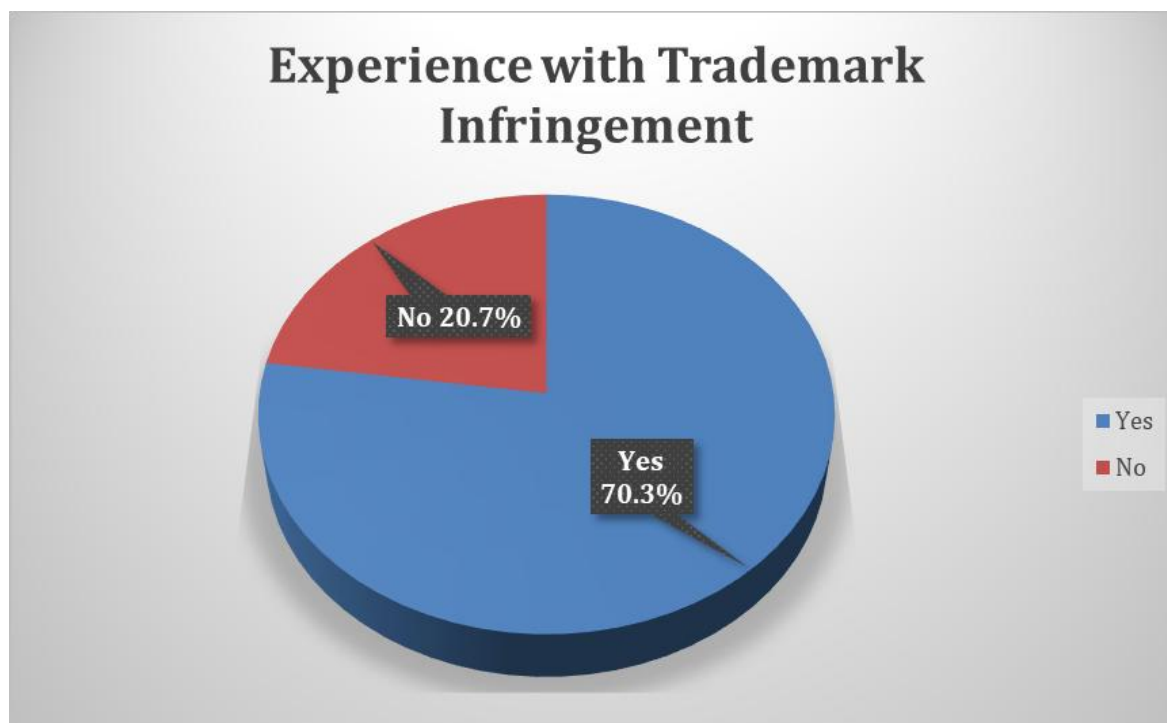


Figure 1.7:- Experience with Trademark Infringement.

6.6 Data Deficiency and Systemic Blind Spots

Despite widespread stakeholder encounters with trademark infringement, profound data deficiencies hinder effective public health responses in The Gambia. Limited surveillance and the absence of a robust data infrastructure on counterfeit medicines prevent early detection of medicine-related harm and delay interventions (Ceesay, 2025). The lack of national databases for medicine registration, adverse event reporting, and regulatory inspections further undermines evidence-based decision-making (Adams & Adams, n.d.; Jaiteh, 2023.). Without routine data collection and reporting mechanisms, situational analyses remain largely reactive, compromising both national planning and institutional responsiveness. Consequently, counterfeit operations persist undetected in segments of the pharmaceutical supply chain (The Soapbox Collaborative, 2019). The co-existence of high reported exposure to trademark violations and poor data availability creates a dangerous paradox: although stakeholders recognize the threat experientially, the absence of formal documentation renders its systemic nature invisible to policy and regulatory frameworks (Ceesay, 2025; Adams & Adams, n.d.). Interventions, therefore, tend to be piecemeal, inconsistently applied, and slow to adapt to evolving market dynamics, perpetuating vulnerabilities in medicine quality and patient safety.

6.6 Data Deficiency and Systemic Blind Spots

Respondents were asked to estimate the extent of trademark infringement within The Gambia's pharmaceutical sector, a key indicator of systemic vulnerability in medicine quality assurance processes. As shown in Figure 1.8, 58.6% of participants described trademark infringement as "somewhat widespread," while 27.6% considered it "very widespread." Collectively, over 86% of stakeholders perceive the problem as pervasive, underscoring growing concerns that existing quality control mechanisms are insufficient to prevent the circulation of counterfeit and misbranded products. These perceptions echo Brennan (2015), who highlighted the paradox of trademarked pharmaceuticals in fragmented regulatory contexts: while brand identity is legally protected, it can be exploited by counterfeiters to deceive consumers, undermining both therapeutic efficacy and public trust. This dynamic places additional strain on health systems already constrained by limited resources. A smaller proportion of respondents 10.3% viewed trademark infringement as a minor issue, and only 3.4% believed it was nearly non-existent. While reflecting some heterogeneity in experiences or exposure, the overwhelming majority consensus points to an urgent need for a public health response embedded within regulatory reform and strengthened pharmaceutical market oversight.

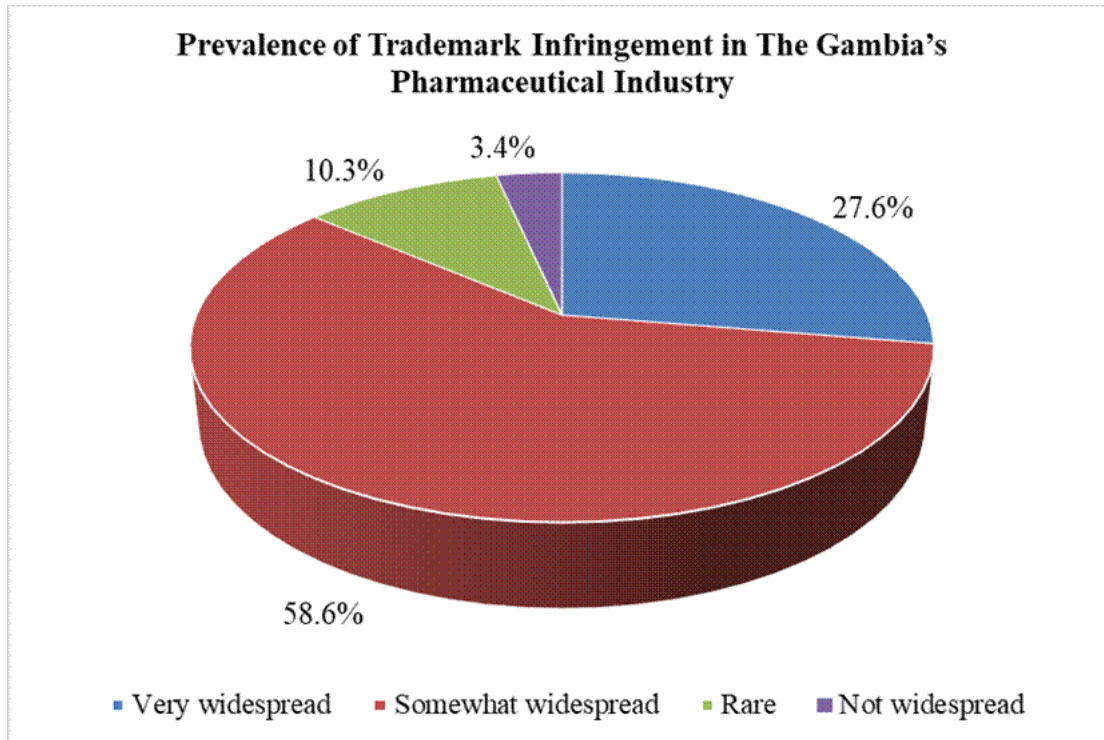


Figure 1.8 - Prevalence of Trademark Infringement in The Gambia's Pharmaceutical Industry.

6.8 Frequency of Trademark Infringement: Measuring the Pulse of a Hidden Epidemic

To further explore the magnitude of this regulatory health challenge, respondents were asked how often they observed or encountered trademark infringement in practice. The frequency of these violations provides insight into the rate at which potentially harmful pharmaceutical products may be infiltrating the health system and reaching patients. As seen in Figure 1.9, 3.4% of respondents reported encountering trademark infringement very frequently multiple times per month. Another 31% described it as a frequent monthly occurrence. These findings suggest that for a substantial segment of industry actors, trademark infringement is not episodic but rather an enduring and normalized feature of the market landscape. Additionally, 27.6% noted that such occurrences are occasional, indicating intermittent exposure to the problem. Meanwhile, 20.7% rarely observed such issues, and 17.2% claimed they had never encountered trademark infringement. While these lower-frequency reports may indicate better practices in specific settings, they may also reflect gaps in detection, reporting, or awareness especially in informal distribution channels. This distribution of experiences is consistent with global evidence on counterfeit medicine circulation, particularly in countries with limited pharmaceutical oversight (Ekeigwe, 2019). From a public health standpoint, even sporadic instances of trademark infringement can have cascading effects delaying diagnosis, compromising therapeutic outcomes, and increasing health system costs due to mismanagement of drug resistance or failed treatments.

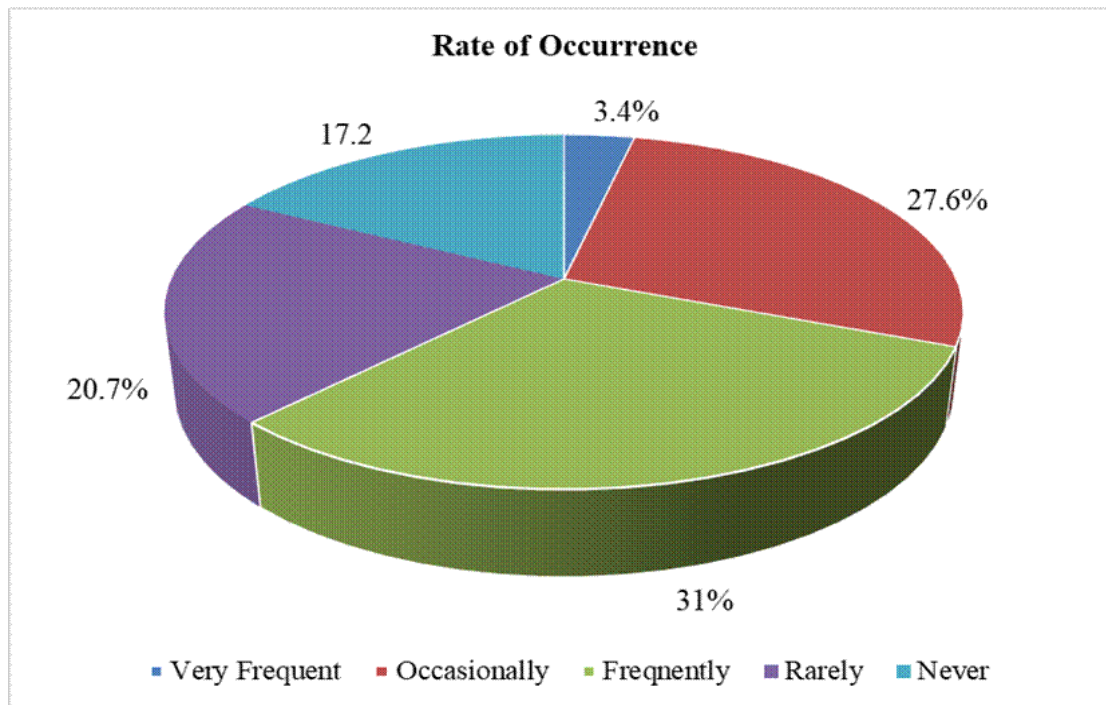


Figure 1.9:- Rate of Occurrence.

6.9 Awareness of Trademark Infringement Among Pharmacies: Implications for Public Health Surveillance

Evaluation of pharmacy awareness levels reveals critical vulnerabilities in The Gambia's pharmaceutical supply chain, as shown in Figure 2.0, with 48.3% of respondents characterizing trademark law awareness as low, 34.5% as moderate, and only 13.8% as high, while 3.4% were uncertain. This deficit in frontline protection exists within a global context where the World Health Organization estimates 1 in 10 medical products in low- and middle-income countries are substandard or falsified (WHO, 2017). The limited understanding of trademark protections among nearly half of Gambian pharmacies undermines the essential public health function of trademarks as tools for patient safety and product identification (Schneider, 2021). Consequently, this awareness gap creates substantial risks, as demonstrated by the tragic deaths of 66 Gambian children linked to contaminated cough syrups that entered the supply chain (Reuters, 2022). The variability in awareness levels further reflects systemic disparities in training and regulatory outreach, compromising uniform pharmaceutical safety standards and potentially contributing to antimicrobial resistance through ineffective treatments (WHO, 2017). Addressing these vulnerabilities requires a coordinated approach combining mandatory education on counterfeit identification, implementation of verification technologies, and strengthened legal frameworks to secure the supply chain against infiltrated medicines.

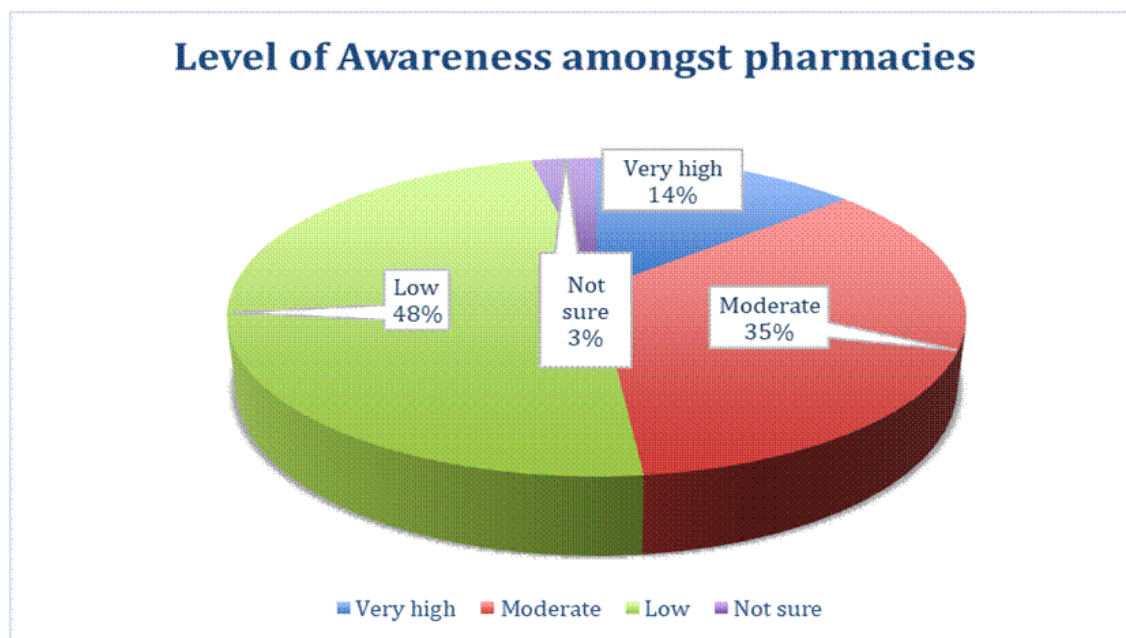


Figure 2.0:- Level of Awareness amongst pharmacies.

7.0 Typology of Trademark Infringements in the Pharmaceutical Sector: Health Risks and Systemic Vulnerabilities

To further illuminate the scope and nature of trademark violations within The Gambia's Respondents were asked to identify the most common types of trademark infringement, highlighting the intersections between intellectual property violations and public health consequences. As shown in Figure 2.1, the sale of substandard pharmaceutical products (SSP) was the most frequently identified issue, noted by 58.5% of respondents. This form of infringement compromises drug quality, leading to therapeutic failure, drug resistance, or toxicity, and underscores how weak enforcement of trademark protections allows poor-quality products to penetrate the healthcare supply chain. Unauthorized use of a registered logo or name (URLN) was reported by 44.8% of participants. Such violations mislead consumers regarding product authenticity and origin, undermining informed decision-making and exposing patients to unsafe or ineffective medications perceived as legitimate. Sale of counterfeit pharmaceutical products (SCP) was cited by 27.6% of respondents. These visually indistinguishable products may contain incorrect or harmful ingredients or none at all representing a direct public health emergency that contributes to preventable morbidity and mortality, particularly among populations with limited diagnostic access. Misleading packaging or labels (MPL) were identified by 20.7% of participants. Deceptive labeling obscures critical information such as dosage, expiry, or composition, increasing risks of overdose, underdose, or allergic reactions. Although trademark dilution (TD) was noted by 17.2% of respondents, it was considered less pressing. Legally, dilution diminishes brand value, but from a public health perspective, its significance lies in eroding consumer trust and weakening long-term quality assurance efforts. Overall, this typology demonstrates that trademark infringement in the pharmaceutical industry extends beyond legal or commercial concerns, constituting a tangible public health hazard. The frequent occurrence of these violations underscores the urgent need for regulatory reforms that integrate intellectual property enforcement into national medicine quality assurance frameworks.

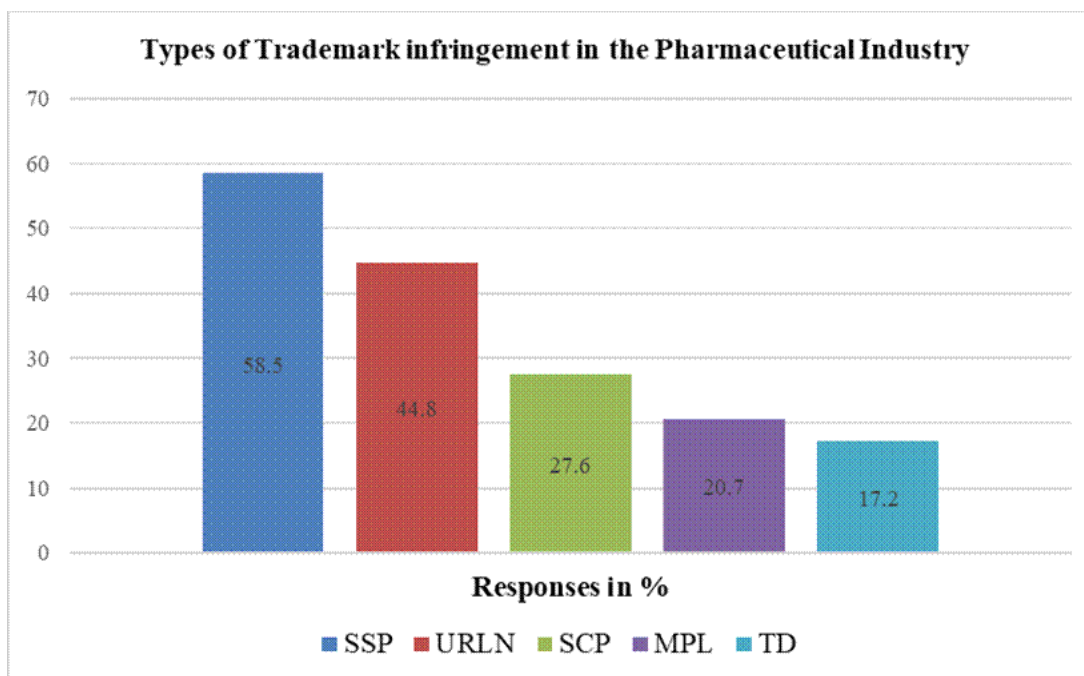


Figure 2.1:- Types of Trademark infringement in the Pharmaceutical Industry.

7.1.1 Deficits in Public and Professional Awareness of Intellectual Property and Consumer Safety

A substantial 65.7% of respondents identified low awareness of intellectual property (IP) rights particularly trademarks as a key factor driving pharmaceutical trademark violations. This knowledge gap exists at both the supply and demand ends of the healthcare system, directly affecting medicine quality, patient safety, and treatment outcomes. Among pharmaceutical providers, many fail to register or adequately protect their brand identities due to limited understanding of the legal and commercial implications. Unregistered or weakly protected trademarks render products vulnerable to counterfeiting and imitation, facilitating the circulation of substandard and falsified medicines (SFMs). This compromises therapeutic efficacy, increasing the risk of drug resistance, delayed treatment, and toxicity, while simultaneously undermining legitimate business operations. Equally concerning is the knowledge deficit among consumers. Many members of the public cannot reliably distinguish authentic products from counterfeit ones. Deceptive packaging, pirated brand names, and manipulated logos create the illusion of legitimacy, leading users to trust ineffective or harmful products inadvertently. This unintentional consumer participation sustains demand for illicit pharmaceuticals and exacerbates community-level health risks, particularly in underserved or poorly regulated areas. The International Federation of Pharmaceutical Manufacturers & Associations (2022) and related research consistently emphasize that such gaps in awareness create fertile conditions for counterfeit pharmaceutical markets, a pattern clearly reflected in the Gambian context.

7.1.2 Weak Regulatory Enforcement and Corruption: Erosion of Public Health Protections

A further 53.2% of respondents identified inadequate enforcement of IP laws and systemic corruption as primary drivers of trademark infringement. From a public health perspective, this institutional fragility is not merely a legal lapse; it constitutes a breakdown in governance, surveillance, and medicine quality assurance. Regulatory bodies in The Gambia frequently lack the human, technical, and logistical resources required to monitor the pharmaceutical market effectively. Understaffed agencies, outdated inspection protocols, and poor inter-agency coordination allow counterfeit products to bypass checkpoints, entering the distribution chain undetected. Consequently, fake medicines circulate alongside legitimate ones, creating confusion for both pharmacists and patients. Corruption exacerbates this crisis. Evidence and prior research (e.g., Onwujekwe et al., 2020) indicate that customs officials and regulatory inspectors are often bribed to overlook IP violations. Such practices weaken fragile regulatory mechanisms, enabling trademark-infringing goods sometimes with life-threatening consequences to reach consumers with minimal resistance. These structural weaknesses reflect global patterns: the WHO (2017) estimated that roughly 10% of medicines in low- and middle-income countries are counterfeit, largely due to weak IP enforcement and entrenched corruption. In The Gambia, the absence of technological verification tools, such as drug authentication systems, further undermines supply chain oversight. The public health implications are severe. Counterfeit and infringing

products compromise the efficacy of legitimate interventions, contribute to antimicrobial resistance, cause treatment failures and preventable deaths, and erode trust in healthcare institutions. Weak enforcement also hampers surveillance systems, preventing accurate tracking of the origin, composition, and safety of distributed medicines.

7.1.3 Fragmented Legal Frameworks and Their Public Health Consequences

Nearly 49% of respondents identified the inadequacy of The Gambia's intellectual property (IP) legislation as a key enabler of trademark infringement in the pharmaceutical sector. From a public health perspective, the absence of clear, enforceable legal mechanisms directly undermines the integrity of the national drug supply and compromises consumer safety. Although broad IP laws exist, they lack pharmaceutical-specific provisions addressing counterfeit drug identification, trademark enforcement in medicine branding, and penalties for IP violations involving health products. This legislative gap limits institutional capacity to respond effectively to drug counterfeiting, leaving counterfeiters operating with minimal risk and allowing substandard medicines to circulate unchecked. Consequently, public trust and health system resilience are eroded. These findings align with Andanda (2016), who highlighted that weak legislative specificity across sub-Saharan Africa perpetuates the circulation of falsified pharmaceuticals, emphasizing the intersection of IP protection and public health. For The Gambia, the evidence underscores the urgent need for a sector-sensitive, updated legal framework to safeguard medicine quality and protect population health.

7.1.4 Weak Quality Control Systems and Drug Surveillance: A Breach in the Health Protection Barrier

An alarming 53% of respondents identified deficiencies in drug testing and distribution controls as major public health failures facilitating the circulation of counterfeit and trademark-infringing medicines. These systemic gaps allow substandard or falsified drugs to bypass regulatory checkpoints and enter the market under deceptive branding, often imitating trusted pharmaceutical trademarks. Inadequate post-market surveillance, limited laboratory infrastructure, and fragmented drug registration processes mean many pharmaceuticals reach consumers without verification of efficacy, authenticity, or safety. Consequently, individuals are exposed to toxic, ineffective, or mislabelled medications, increasing risks of allergic reactions, treatment resistance, and mortality. Feeney et al. (2024) link counterfeit drugs to heightened morbidity and mortality in low-regulation environments, while the World Health Organization (2017) highlights that falsified medicines frequently mimic well-known brands, misleading patients and undermining public confidence. In The Gambia, weak enforcement of IP laws exacerbates these risks, allowing dangerous, misbranded products to coexist with legitimate medicines on pharmacy shelves. Additionally, studies by Glass et al. (2014) and Ogunleye (2021) point to corruption and regulatory dysfunction as systemic contributors to poor drug quality assurance. Bribes to overlook safety violations, inadequate enforcement capacity, and the absence of real-time product traceability enable counterfeit medicines to proliferate. These conditions create a high-risk pharmaceutical ecosystem where health outcomes are determined as much by regulatory gaps as by disease burden.

7.1.5 Economic Pressures and Unethical Market Practices: A Public Health Threat

According to 41% of respondents, intense market competition and financial pressures have driven some actors in The Gambia's pharmaceutical sector to engage in practices that compromise public health. The pursuit of lower production costs and higher profit margins has led to the intentional manufacture and distribution of counterfeit or substandard drugs bearing unauthorized trademarks. This commercially driven behavior undermines consumer trust, damages the credibility of legitimate pharmaceutical brands, and exposes the public to harmful products. Consumers seeking low-cost alternatives may unknowingly purchase fake medicines, assuming they are clinically tested and safe. This phenomenon is not unique to The Gambia. The African Centre for Combating Illicit Trade in Pharmaceuticals (A-CAPP) reports that counterfeiting causes over \$500 million in annual losses in East Africa, with Tanzania alone losing up to \$617 million per year. Beyond financial losses, the true cost is human, as counterfeit drugs compromise therapeutic integrity and fuel public health crises. The OECD (2020) notes that such counterfeit medicines often contain toxic or inert ingredients, making them ineffective or dangerous. From a legal epidemiology perspective, these economically motivated violations represent structural assaults on health equity and pharmaceutical safety, illustrating how commercial incentives intersect with public health vulnerabilities.

7.1.6 Border Vulnerabilities and Transnational Pharmaceutical Smuggling

The final factor, identified by 46% of respondents, is weak border control and the prevalence of drug smuggling, which fuels the entry of trademark-infringing pharmaceuticals into The Gambia. Porous borders, limited customs infrastructure, and poor inter-agency coordination allow illicit medicines to enter undetected, often via informal or black-market routes. Once in circulation, counterfeit products mix with legitimate drugs, complicating

pharmacovigilance, confusing consumers and health providers, and undermining safe prescribing. This blurred distinction erodes public trust and diminishes the effectiveness of health system interventions. The WHO (2017) highlights that such border vulnerabilities facilitate the transnational movement of falsified medicines, turning national issues into regional crises. Smugglers often exploit weak enforcement and collusion with corrupt officials, flooding markets with dangerous products that infringe trademarks. These dynamics compromise the integrity of the national medicine supply chain and leave health systems exposed to both local and imported pharmaceutical fraud.

7.1.7 Regulatory and Administrative Inefficiencies as Public Health Risks

Although The Gambia has established regulatory bodies such as the Medicines Control Agency (MCA) to oversee pharmaceutical safety, 51.6% of respondents reported that rigid regulatory structures and limited intellectual property (IP) literacy among regulators significantly weaken the system's ability to protect public health. These gaps allow counterfeit and trademark-infringing medicines to enter the supply chain, threatening treatment efficacy and patient safety. While the MCA's regulations are necessary, they are often outpaced by the rapidly evolving pharmaceutical trade, where counterfeiters continually adapt branding strategies to mimic legitimate products. The agency's limited flexibility and narrow mandate compromise its responsiveness, and a lack of IP-focused training prevents staff from effectively detecting and addressing trademark violations, particularly when such infringements have broader health consequences. From a public health perspective, the failure to integrate IP enforcement into national pharmaceutical regulation undermines consumer protection, pharmacovigilance, and medicine quality assurance. Strengthening regulatory capacity and harmonizing enforcement strategies are essential to prevent trademark infringement from remaining a structural driver of health risks.

7.1.8 Substandard Drug Production and Misleading Labelling: Eroding Health Safety and Consumer Trust

The production of substandard pharmaceuticals, often driven by unethical manufacturing and profit motives, was identified by 56% of respondents as a major contributor to both trademark infringement and public health hazards. Manufacturers, particularly in the generics sector, produce drugs that closely mimic established brands but fail to meet basic safety, efficacy, or quality standards. These products are frequently distributed with misleading packaging and labeling designed to resemble trusted brands. Such deception violates trademark protections and misleads consumers, many of whom unknowingly purchase unsafe medications believing them to be authentic. The false assurance provided by counterfeit labeling undermines treatment adherence, promotes therapeutic failure, and endangers vulnerable populations with limited access to verified medicines. In resource-limited settings like The Gambia, low public awareness and weak regulatory enforcement exacerbate this risk. The cumulative effect is a health system inundated with substandard treatments, contributing to antimicrobial resistance, chronic illness, and preventable mortality.

7.1.9 Public Health Implications of Trademark Infringement Drivers

Trademark infringement in The Gambia's pharmaceutical market extends beyond legal concerns; it constitutes a systemic public health crisis, compromising the safety, efficacy, and reliability of medical treatments. Respondents identified key factors contributing to this epidemic, providing insight into where policy and public health interventions are most urgently needed. As shown in Figure 4.12, the most significant contributors were: Lack of public awareness of trademark infringement (56.7%), limited understanding of trademark laws (56.7%), weak intellectual property infrastructure (50.0%) and inadequate enforcement of existing IP laws (40.0%). These findings reveal layered vulnerabilities in both regulatory and societal dimensions of medicine governance. Consumer and regulatory illiteracy allows counterfeiters to flourish, while enforcement fatigue and weak infrastructure ensure minimal risk for violators. Consequently, poor-quality medicines reach patients, undermining treatment efficacy and eroding trust in the formal health system. Economic pressures (8%) and high competition (10%) were ranked among the least significant factors. While these may influence broader unethical practices, the data suggest that knowledge gaps, regulatory weaknesses, and enforcement failures are the primary levers for improving public health outcomes. From a legal epidemiology perspective, these results illustrate how structural weaknesses in IP governance translate into population-level health risks. Aligning trademark enforcement with national health objectives is critical to ensuring medicines are safe, effective, and trusted by the communities they serve.

Significance of the factors is in contributing to trademark infringement.

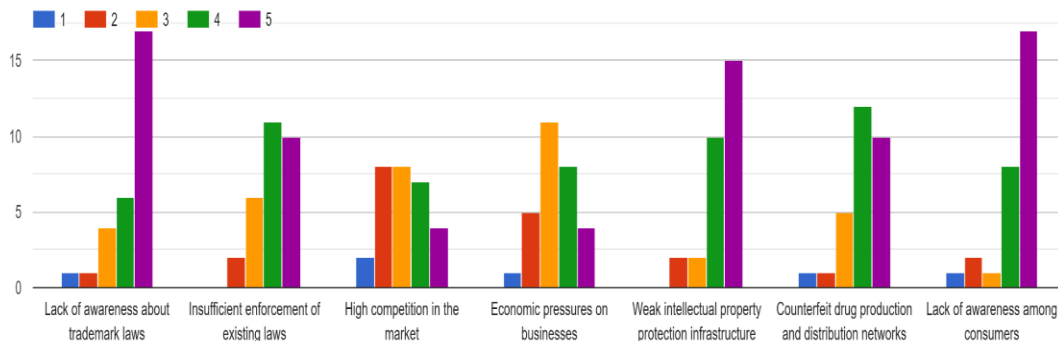


Figure 2.2:- Significance of the factors in contributing to trademark infringement.

7.2.0 Public Health Effects of Trademark Infringement in The Gambia’s Pharmaceutical Sector

Investigating the public health consequences of trademark infringement in the pharmaceutical industry, the analysis includes impacts on both consumers and trademark owners, with a focus on how these violations compromise access to safe, effective, and trustworthy medicines.

7.2.1 Impact on Pharmaceutical Businesses and Health Systems Stability

As shown in Figure 2.3, 69% of respondents reported that trademark infringement significantly disrupts the pharmaceutical industry, causing revenue loss, reputational damage, and legal vulnerabilities for legitimate manufacturers. While these appear as commercial concerns, their ripple effects extend to the health system, including reduced innovation, withdrawal of reputable suppliers, and diminished public trust in formal healthcare. This instability in the pharmaceutical supply chain creates opportunities for counterfeiters. When trusted brands are undermined, both the availability and affordability of quality-assured medicines are threatened, ultimately compromising treatment adherence and health outcomes. A smaller proportion of respondents perceived the impact as moderate (13.8%) or minimal (13.8%), with only 3.4% reporting no impact. Even minor tolerance of trademark violations within medicine supply chains can have severe public health consequences, given the life-critical nature of these products.

Impact of trademark infringement on your business or the pharmaceutical industry

29 responses

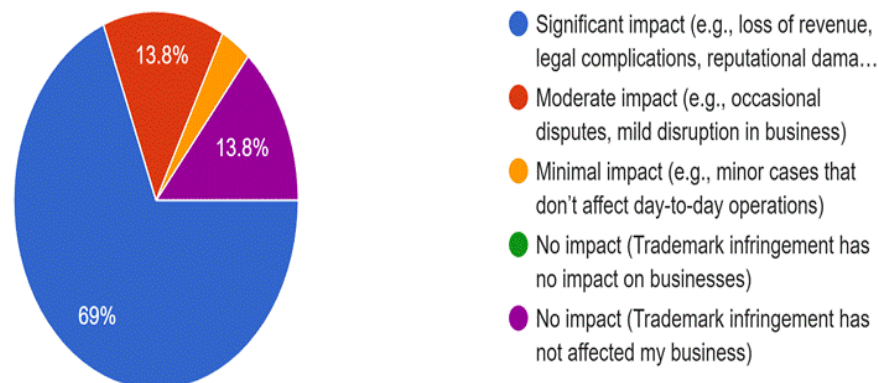


Figure 2.3:- Impact of trademark Infringement in the Pharmaceutical industry on Businesses.

7.2.2 Effects on Consumers and Trademark Owners: A Public Health Threat

As illustrated in Figure 2.4, 96.6% of respondents reported a severe erosion of consumer trust due to trademark infringement in the pharmaceutical sector. When counterfeit or substandard medicines masquerade as trusted brands, they contribute to misdiagnosis, treatment failure, and increased morbidity and mortality, representing a breakdown in the social contract between health systems and communities. Additionally, 75.9% of respondents highlighted reputational damage to both pharmaceutical companies and national regulatory authorities, further undermining confidence in healthcare delivery. 65.5% cited direct adverse health effects and life-threatening complications from counterfeit medicines. Financial losses were recognized by 58.6%, and 31% acknowledged the burden of legal and regulatory penalties, particularly affecting legitimate pharmaceutical actors. Taken together, these findings reveal a dangerous convergence of legal, regulatory, and health system failures. Weak enforcement, limited awareness, and fragmented accountability mechanisms allow counterfeit medicines to persist, posing systemic threats to public health and trust.

Effects of trademark infringement in the Pharmaceutical Industry on consumers and trademark owners
29 responses

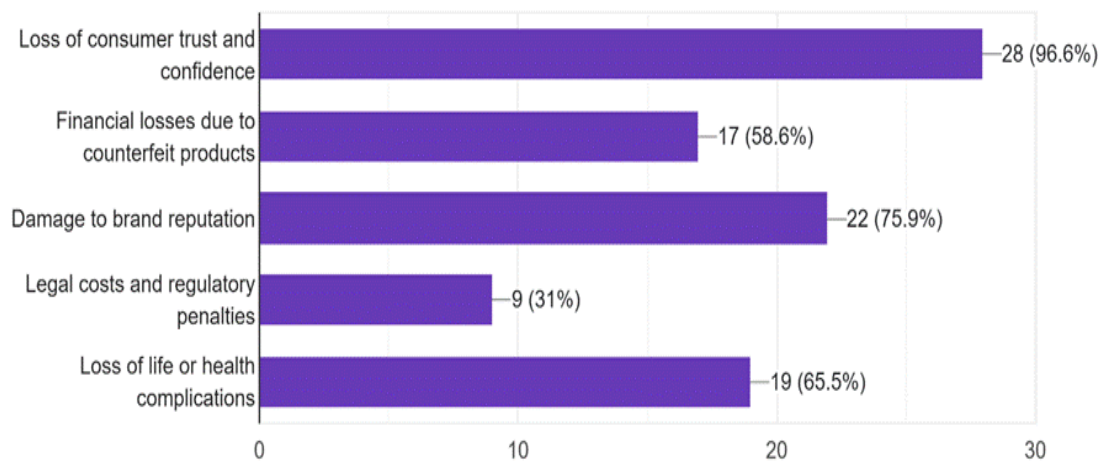


Figure 2.4:- Effects of trademark infringement in the Pharmaceutical Industry on consumers and trademark owners.

7.3 Enhancing the Protection and Enforcement of Trademark Rights for Public Health

While exploring strategies for strengthening trademark protection and enforcement in The Gambia's pharmaceutical sector in order to mitigate public health risks associated with counterfeit medicines the following findings were evident:

7.3.1 Adequacy of the Current Legal Framework for Safeguarding Health through Trademark Protection

Respondents were asked whether The Gambia's current legal and institutional infrastructure adequately protects pharmaceutical trademarks. As shown in Figure 2.5, 75.9% considered the framework insufficient, emphasizing the urgent need for legal reform and stronger enforcement to address the public health risks posed by counterfeit medicines. Only 13.8% viewed the existing system as adequate, while 10.3% were unsure, highlighting widespread uncertainty and limited awareness of IP laws among professionals and the public. This ambiguity undermines accountability and weakens the law's protective role, allowing counterfeit and substandard products to circulate. Overall, the findings underscore the need for enhanced IP enforcement, targeted training for regulatory personnel, public education initiatives, and integration of trademark protection into broader health system resilience strategies.

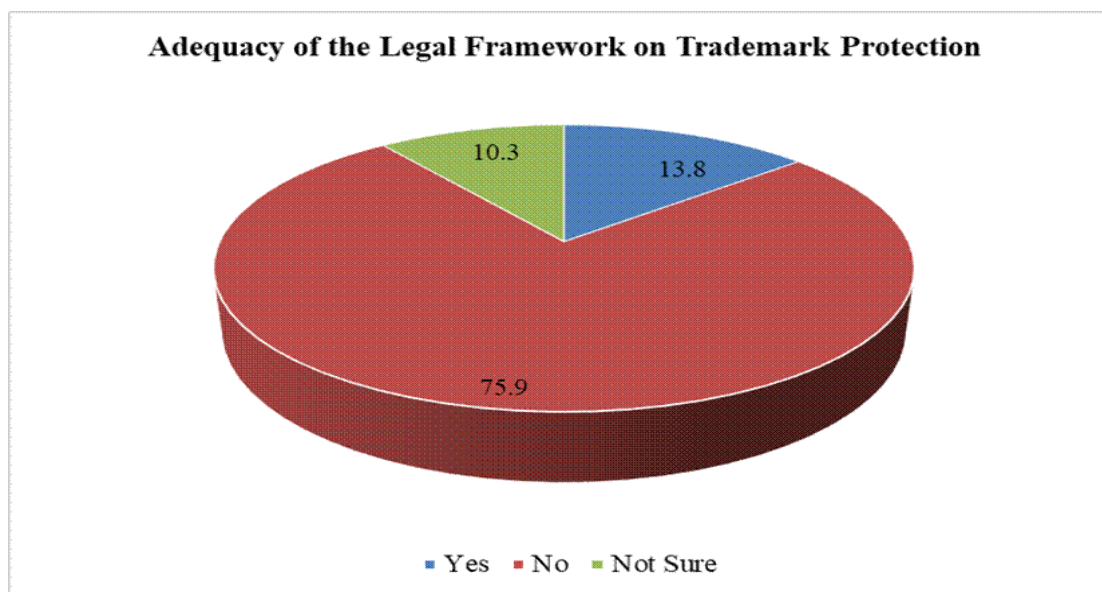


Figure 2.5:- Adequacy of the Legal Framework on Trademark Protection.

7.4 Strengthening Trademark Protection as a Public Health Imperative: Proposed Interventions

Addressing trademark infringement in The Gambia's pharmaceutical sector is not only a legal or economic concern it is a critical public health issue. Respondents highlighted several interrelated strategies to enhance trademark protection, focusing on legal and policy reform, institutional strengthening, public education, and improved pharmaceutical manufacturing standards (Mukhtar et al., 2018). These measures are vital to ensure access to safe, effective, and reliable medicines while preventing the circulation of substandard or counterfeit products.

7.4.1 Reinforcing Institutional Capacity and Public Health Governance

The capacity of regulatory and trademark enforcement institutions directly affects the health system's ability to guarantee medicine safety. Respondents stressed the need to strengthen key institutions, particularly the Medicines Control Agency (MCA), the Ministry of Health, and the Registrar General's Office, to administer and enforce pharmaceutical trademark laws effectively. Although The Gambia's Industrial Property (Amended) Act 2015 adheres to the "first-to-file" principle in trademark registration (ARIPO, n.d.), enforcement challenges have created gaps in protection. These weaknesses allow counterfeit medicines to infiltrate the supply chain, often going undetected until they result in treatment failure or adverse health outcomes. Strengthening technical capacity, inter-agency coordination, and regulatory oversight across IP and public health authorities is essential to mitigate these systemic risks. Enhanced collaboration between the health and justice sectors is particularly critical to improve responsiveness, facilitate joint operations in surveillance and enforcement, and support product authentication initiatives. Such integration ensures that trademark protection functions not merely as a legal mechanism but as a cornerstone of public health security.

7.4.2 Enhancing Public Awareness and Health Literacy on Pharmaceutical Safety

Respondents emphasized the urgent need to educate consumers, pharmacists, healthcare providers, and businesses about the critical role of trademarks in identifying authentic, quality-assured medicines. Limited awareness among end-users contributes to the consumption of falsified or misbranded drugs, with serious consequences for disease control, antimicrobial resistance, and patient safety. Public health communication campaigns should: highlight the health risks posed by counterfeit and unverified medicines, teach consumers to verify legitimate pharmaceuticals using trademarks and promote accessible reporting channels for suspected counterfeit products. These awareness-raising initiatives go beyond legal compliance, functioning as essential community health protection strategies that empower stakeholders to participate actively in safeguarding medicine quality.

7.4.3 Advancing Pharmaceutical Manufacturing Standards for Safer Supply Chains

Respondents also identified weaknesses in local pharmaceutical production as a major risk factor, driving reliance on foreign-manufactured drugs, some of which enter through unregulated or fraudulent channels. Promoting Good Manufacturing Practices (GMP) and investing in domestic quality testing laboratories were highlighted as critical

priorities to strengthen drug safety. Given The Gambia's limited pharmaceutical infrastructure, dependence on external testing results can be risky when standards abroad are inconsistent or inadequately enforced. Strengthening local production and laboratory capacity would improve quality control, enhance detection of counterfeit and trademark-infringing products, and reduce public health vulnerabilities (PMC, 2017).

7.4.4 Policy and Legal Reform: A Pillar for Public Health Protection

The study highlights the urgent need for comprehensive policy and legislative reform to address the evolving threat of trademark infringement and its public health consequences. Key reforms should:

- Clarify, simplify, and strengthen IP laws specific to pharmaceuticals;
- Explicitly recognize the health risks posed by trademark violations;
- Establish dedicated enforcement units and fast-track judicial procedures for IP-related public health offenses;
- Ensure active involvement of public health stakeholders in policymaking, integrating IP protections into national health strategies rather than treating them solely as commercial matters.

The study's 76% stakeholder response rate exceeds standard benchmarks (Zdep, 1986), providing a robust dataset that captures both contemporary practice and institutional memory (Zaichkowsky, 2020; Laguna-Goya & de Andres-Trelles, 2014). Seventy-six percent of respondents defined infringement in line with international standards, underscoring that consumer confusion directly undermines pharmaceutical traceability and elevates the risk of counterfeit drug consumption (Bone, 2012). High prevalence and systemic penetration were reported, with 79.3% of stakeholders experiencing infringement and 86.2% perceiving it as widespread. Weak legal frameworks, acknowledged by 49% of respondents, enable this crisis, reflecting trends across Africa, including South Africa (Modjadji et al., 2021; WHO, 2017; Andanda, 2016). Structural drivers poor IP awareness, inadequate enforcement, corruption (53%), and economic pressures compound public health risks, including preventable morbidity and mortality from falsified medicines (Wilson & Fenoff, 2011; Feeney et al., 2024; Wada et al., 2022).

Stakeholders identified severe consequences: loss of consumer trust (96.6%), reputational damage (75.9%), and direct health risks (65.5%), consistent with documented therapeutic failures, adverse events, and fatalities from counterfeit medicines (Lewis, 2009; Ramjiawan et al., 2012; Reuters, 2022; WHO, 2017). The findings align with WHO estimates that ~10% of medicines in LMICs are counterfeit, confirming the validity of stakeholder perceptions. Future studies should integrate randomized drug testing to corroborate these insights. Addressing the crisis demands a multi-sectoral, public health-centered approach: legislative reform to create coherent, enforceable laws; strengthened enforcement to curb corruption; comprehensive education to close awareness gaps; and technological innovations such as the mPedigree authentication platform (Isah, 2012). Alignment with global standards like the MEDICRIME Convention and the African Medicines Agency provides additional pathways for building regulatory resilience (Council of Europe, 2011; African Medicines Agency, 2025). Through these comprehensive reforms, The Gambia can restore consumer confidence, reduce preventable health harms, and create a safer, more equitable pharmaceutical environment, safeguarding public health nationally and regionally.

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