OPEN ACCESS
Indonesian Journal of Health Research and Development **Vol 4 No 1 (2026)** https://doi.org/10.58723/ijhrd.v4i1.593
Check for updates
Research Article

Counterfeit Medicines in Informal Retail: A Governance and Complexity Perspective from South African Spaza Shops

Received: October 12, 2025	Revised: October 27, 2025	Accepted: February 28, 2026	Published: February 28, 2026

Michael Mncedisi Willie[1*] Athandile Hadebe[2]

Abstract

Background: Governance and regulatory enforcement in South Africa reflect complex links between legal frameworks, capacity, and informal markets. While public consultations show transparency, healthcare interventions are often reactive, triggered by crises like food contamination deaths and illegal medicine sales.
Aims: This paper investigated regulatory gaps and enforcement challenges in informal medicine markets, with a focus on spaza shops. The focus was on how structural, operational, and social factors contribute to the circulation of counterfeit and poorly handled medicines, and how governance and community dynamics impact public health.
Methods: A qualitative case-study approach guided this research, focusing on the analysis of secondary data sources and qualitative literature. Purposive selection of documents and reports included government communications, regulatory guidelines, parliamentary hearing transcripts, media coverage, and peer-reviewed studies, ensuring that the sources provided rich insights into governance, regulatory enforcement, and informal pharmaceutical practices.
Result: Systemic gaps exist between regulatory intent and operational reality. Although legal frameworks restrict the dispensing of scheduled medicines to licensed pharmacies and authorised health professionals, widespread non-compliance persists in township spaza shops.
Conclusion: Effective mitigation of counterfeit and illegally sold medicines requires an integrated, multi-dimensional approach that strengthens regulatory oversight, secures supply chains, mobilises community engagement, and leverages technological monitoring. The proposed Integrated Regulatory-Community Framework for Counterfeit Medicines in Spaza Shops (IRCF-CMSS) aligns formal legislation with practical enforcement and social realities, promoting sustained compliance, enhanced public safety, and institutional trust.

Keywords: Counterfeit medicines, Public health, Informal retail, South Africa, Spaza shops

1. INTRODUCTION

Counterfeit and substandard medicines pose a persistent and complex challenge to global public health, affecting both supply and demand dynamics. The global counterfeit pharmaceutical market is valued between US$200 and US$432 billion, impacting high- and low-income countries alike (Ofori-Parku, 2022). Substandard products fail quality standards due to poor manufacturing, while falsified medicines deliberately misrepresent identity, composition, or source, and both are distributed through formal, informal, and online and increased antimicrobial resistance (Feeney et al., 2024; World Health Organization [WHO], 2024). Although regulatory enforcement, inspections, and technological monitoring are essential, supply-side interventions alone are insufficient. Evidence highlights persistent gaps, including rising exposure through online pharmacies and limited attention to healthcare providers' and consumers' knowledge, attitudes, and practices (Pal et al., 2025). Addressing these challenges requires integrated strategies that combine coordinated regulation, public education, and demand-side interventions to mitigate health, economic, and societal risks (Ofori-Parku, 2022; Pal et al., 2025; WHO, 2024).

To strengthen regulatory oversight and ensure effective interventions, it is crucial to clearly differentiate between "counterfeit," "substandard," and "illegally sold" medicines. Substandard and falsified medicines are pharmaceutical products that fail to meet established quality standards or are deliberately misrepresented in terms of their identity, composition, or source, posing significant risks to patient safety and public health (Chabalenge et al., 2025; Feeney et al., 2024). Counterfeit medicines are deliberately falsified with respect to identity, composition, or source; substandard medicines fail to meet quality standards despite legitimate production; and illegally sold medicines may be genuine but are distributed outside authorized

channels (Mourad et al., 2026). Counterfeit pharmaceutical products are medicines that are deliberately and fraudulently mislabelled with respect to their identity, composition, or source, infringing trademarks and posing serious risks to public health and safety (Organisation for Economic Co-operation and Development [OECD], 2020).

Without precise definitions, efforts to enforce regulations and monitor the circulation of medicines risk confusion, inconsistent application of the law, and gaps in protecting communities from unsafe or ineffective products. Establishing clear terminology not only strengthens legal compliance but also supports targeted public health strategies, community awareness campaigns, and data-driven interventions to reduce the presence of harmful medicines.

Consumer attitudes and behaviours play a critical role on the demand side of this issue. Research from the United States (US) indicates that individuals who consider themselves knowledgeable about counterfeit medicines, are older, or view their use as ethical often underestimate the associated risks, which increases their likelihood of purchasing such products (Ofori-Parkus & Park, 2022). In contrast, risk-averse consumers demonstrate lower intentions to engage with counterfeit medicines, highlighting the significant influence of personal risk perception on decision-making. Notably, when factors such as attitudes, risk perception, and social norms are accounted for, the perceived benefits of counterfeit medicines have minimal effect on purchase intentions, suggesting that social and ethical considerations can outweigh anticipated material gains (Ofori-Parkus & Park, 2022).

On the supply side, pharmacy professionals' awareness and attitudes play a critical role in mitigating the circulation of counterfeit medicines. In Harar, Ethiopia, 82.6% of pharmacists reported knowledge of counterfeit medicines; however, their perceptions of safety, efficacy, and economic impact varied, and proactive measures were not consistently applied (Abdunasir et al., 2021). Similarly, Nigerian pharmacists exhibit high awareness of counterfeit risks but face limitations in detection and prevention due to practical constraints and systemic regulatory challenges (Adigwe et al., 2022). These findings demonstrate that knowledge alone is insufficient; operational capacity, resources, and enforcement mechanisms are essential to transform awareness into practical action.

Legislative and regulatory frameworks further shape how counterfeit medicines are addressed. In South Africa, although policies exist to combat counterfeiting, enforcement is inconsistent, and data collection remains fragmented, undermining coordinated interventions (Moshoeshoe et al., 2022). Counterfeiting predominantly involves smuggled, non-registered products, including painkillers, herbal remedies, and medical devices, highlighting regulatory vulnerabilities (Moshoeshoe et al., 2022). These systemic weaknesses are compounded in informal retail contexts, such as spaza shops, where scheduled medicines are sold outside licensed pharmacies, exposing communities to expired, counterfeit, or improperly stored products (Gauteng Department of Health [GDoH], 2024; South African Health Products Regulatory Authority [SAHPRA], 2024).

Spaza shops are embedded within South African communities as sources of affordable goods, local employment, and entrepreneurship, yet they operate in a regulatory grey area (Willie, 2025). Governance and enforcement approaches vary across sectors: while constitutional processes such as public consultations on draft Traditional Courts Regulations reflect participatory and forward-looking governance (DoJCD, 2025), interventions in healthcare are often reactive, triggered by crises like food contamination deaths or the illegal sale of medicines (Koko, 2024). Media attention and public perception further influence regulatory action, as social media-driven "fake food" scares demonstrate that formal legislation alone cannot ensure public safety (Hornberger et al., 2023).

This study examined governance, service delivery, and regulatory enforcement in South Africa's informal medicine markets, with a focus on spaza shops. It investigated structural, operational, and socio-cultural factors that contributed to the circulation of counterfeit, expired, and improperly stored medicines, and explored how legal frameworks, community practices, and public health imperatives intersected to shape regulatory effectiveness and public safety.

2. LITERATURE REVIEW

2.1. Governance and Regulatory Frameworks in South Africa

Governance in South Africa reflects a tension between careful, deliberative policy-making and reactive, crisis-driven interventions, revealing how institutional priorities and capacities shape the timing and effectiveness of regulatory action. Deliberative processes, exemplified by the public consultation on the draft Traditional Courts Regulations, reflect principles of transparency, inclusivity, and procedural legitimacy (DoJCD, 2025). Scholars argue that such participatory governance strengthens institutional trust and compliance by engaging diverse stakeholders in decision-making (Quttainah et al., 2025). However, crisis-driven actions in the healthcare sector, including intensified inspections following food contamination fatalities and the illegal distribution of medicines, illustrate reactive governance that prioritises immediate risk mitigation over sustained regulatory planning (Koko, 2024; SAHPRA, 2024). This contrast underscores a persistent challenge: legal frameworks alone are insufficient to ensure public safety; they require complementary operational mechanisms and interagency coordination.

2.2. Health System Operations and Public Service Delivery

The literature on health system performance suggests that operational success depends on structured workflows, clear accountability, and adequate human

resources (Rotea et al., 2023). By contrast, informal retail sectors, especially spaza shops selling scheduled medicines, reveal ongoing gaps in enforcement, quality checks, and monitoring (GDoH, 2024; Hornberger et al., 2023). These challenges are compounded by limited inspections, fragmented oversight, and dependence on informal supply chains, making it difficult for authorities to ensure compliance on the ground. As a result, communities remain exposed to unregulated or counterfeit medicines, underscoring the urgent need for practical, locally grounded regulatory strategies that protect public health.

2.3. Regulatory Gaps in Pharmaceutical Distribution

The illegal sale of scheduled medicines highlights persistent enforcement challenges within South Africa's pharmaceutical sector. Regulatory frameworks, such as the Medicines and Related Substances Act, mandate that only licensed pharmacies and authorised healthcare professionals may dispense controlled medicines (GDoH, 2024; Pharmaceutical Society of South Africa [PSSA], 2020). Despite these provisions, empirical evidence indicates widespread non-compliance in township spaza shops, where expired, counterfeit, or improperly stored medicines circulate (Caxton Local Media, 2023; Tshikalange, 2024). Researchers note that social, economic, and logistical challenges play a key role in these gaps, from insufficient supply-chain monitoring and constrained inspection capacity to communities' reliance on informal retail for everyday medicines (Hornberger et al., 2023; Koko, 2024). This literature suggests that regulatory certainty does not automatically translate into effective enforcement, underscoring the need for integrated strategies that combine legislation, community engagement, and interagency coordination.

2.4. Public Perception, Media Influence, and Crisis Response

Media narratives play a critical role in shaping both public perception and government responsiveness. Events such as social media-driven "fake food" scares illustrate how public concern can catalyse rapid intervention, even when evidence of actual harm is limited (Hornberger et al., 2023). However, research shows that these perception-driven crises often lead to short-term interventions rather than long-lasting improvements in oversight. A similar pattern appears in the airline industry, where reputational crises, especially involving social or governance failures can sharply reduce financial returns, create volatility, and ripple across the sector, with the effects worsening during economic downturns (Akyildirim et al., 2025). Lessons from the COVID-19 pandemic further highlight the human side of crisis management: how local leaders coordinate efforts, manage emotions, and build trust directly shapes team performance and community confidence (Eid et al., 2023). While laws, hospitals, and regulations set the framework for public safety, the actions of leaders and communities in unexpected or informal situations often reveal the strengths and weaknesses of these systems

Existing studies underscore the importance of integrating legal enforcement with proactive monitoring, community engagement, and cross-sectoral coordination (Hornberger et al., 2023; PSSA, 2020; SAHPRA, 2024). Which demonstrate that tackling crises effectively requires more than legal authority; it demands clear communication, engagement with stakeholders, and leaders who can anticipate both practical and reputational challenges to protect communities and institutions alike. However, limited research has examined the simultaneous interactions among these governance, operational, and social factors in township medicine markets, particularly regarding the public health risks posed by informal retail.

3. THEORETICAL FRAMEWORK

This study draws on regulatory governance theory and complexity theory in public health to explore how formal rules, informal markets, and health outcomes interact. Using both theories helps to understand not only what regulations are meant to do, but also how people and systems behave in real-life situations. Complexity theory shows that healthcare systems are constantly changing and adapting. Effective management requires flexible leadership and cooperation among diverse stakeholders to address unexpected problems (A'aqoulah et al., 2025). At the same time, high complexity can make decision-making difficult, as interactions among doctors, patients, and technology may become unpredictable and even lead to errors (A'aqoulah et al., 2025). Evidence from national physical activity policy-making suggests that understanding complexity can help policymakers see how different sectors connect and predict possible outcomes (Rigby et al., 2022). However, applying this understanding in practice is often challenging because stakeholders are not always clearly defined, and the complexity of systems can make translating ideas into action difficult (Rigby et al., 2022). This shows both the potential and the limits of complexity theory for managing health systems. Regulatory governance theory suggests that laws alone are not enough; effective oversight relies on enforcement, institutional capacity, and active engagement of stakeholders (Quttainah et al., 2025).

Instances such as the illegal sale of scheduled medicines in spaza shops reveal the gap between legislative intent and on-the-ground practice (GDoH, 2024; SAHPRA, 2024). Applying regulatory governance alongside complexity theory enables a deeper understanding of how formal rules, operational constraints, and community behaviours interact, but this connection needs to be clearly linked to the analytical procedures and findings to demonstrate how the theories illuminate observed patterns in the data. Complexity theory helps make sense of these situations by showing that problems such as counterfeit or expired medicines are shaped by social pressures, informal markets, and public perceptions, rather than by legal failures (Hornberger at al., 2023; Rotea et al., 2023). Figure 1 below illustrates

how formal laws, enforcement mechanisms, and stakeholder engagement interact with adaptive, complex systems, influencing informal markets and ultimately shaping public health outcomes.

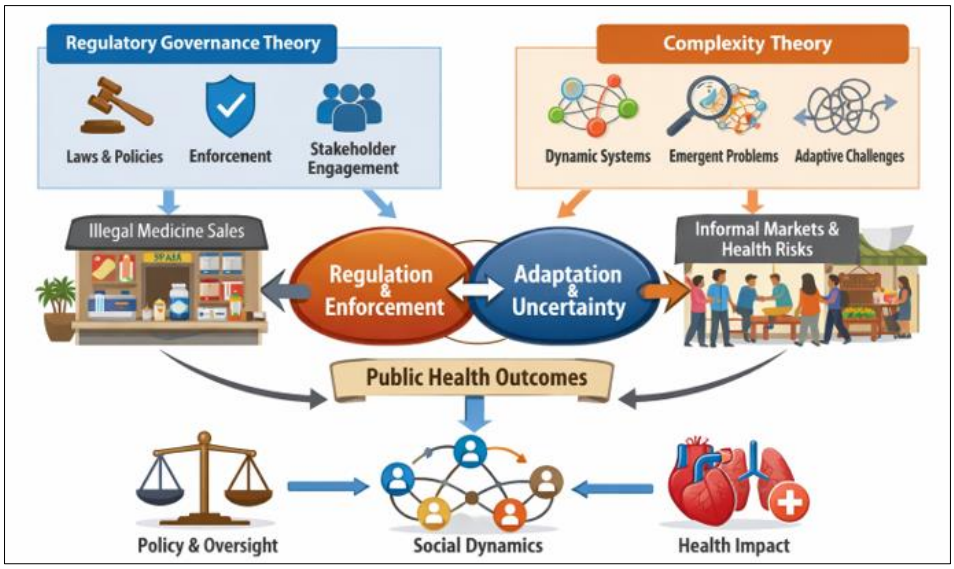

Figure 1. Interaction of Regulatory Governance and Complexity Theory in Public Health.
Source: A'aqoulah et al., 2025 and GDoH, 2024

4. METHODS

This literature review examined existing research and documentation on regulatory enforcement, informal pharmaceutical practices, and their public health implications in South Africa. Employing a systematic and rigorous literature review methodology enhances the reliability and trustworthiness of research by synthesising fragmented and interdisciplinary knowledge in a structured manner (Snyder, 2019). To gain a deeper understanding of stakeholder experiences, the socio-cultural context of informal retail, and the operational dynamics within formal health institutions, the review adopted a qualitative approach based on secondary data. Findings suggest that inconsistent stakeholder engagement in public health research often undermines collaboration, emphasising the need for clearer guidelines and more structured involvement throughout the research process (Laird et al., 2020).

Qualitative secondary analysis enables researchers to maximise the utility of existing qualitative datasets, especially for hard-to-reach populations, while requiring careful methodological planning and transparent reporting to ensure that findings are both valid and appropriately contextualised (Tate & Happ, 2017). Data were collected through a systematic document analysis encompassing government reports, official communications, and media coverage, complemented by secondary qualitative sources such as peer-reviewed studies, parliamentary hearing transcripts, and professional association guidelines (DoJCD, 2025; Hornberger et al., 2023; PSSA, 2020; Parliamentary Monitoring Group, 2008). To ensure transparency and rigour, the study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 framework, which provides updated guidance for systematically identifying, selecting, appraising, and synthesising evidence in reviews (Page et al., 2021). PRISMA 2020 informed the methodological approach to document selection and reporting, guiding the inclusion and screening of government reports, media articles, and peer-reviewed sources, thereby enhancing reproducibility and comprehensiveness, even though laboratory confirmation of counterfeit medicines was not conducted. The flow of document identification, screening, inclusion, and exclusion is illustrated in Figure 2 below.

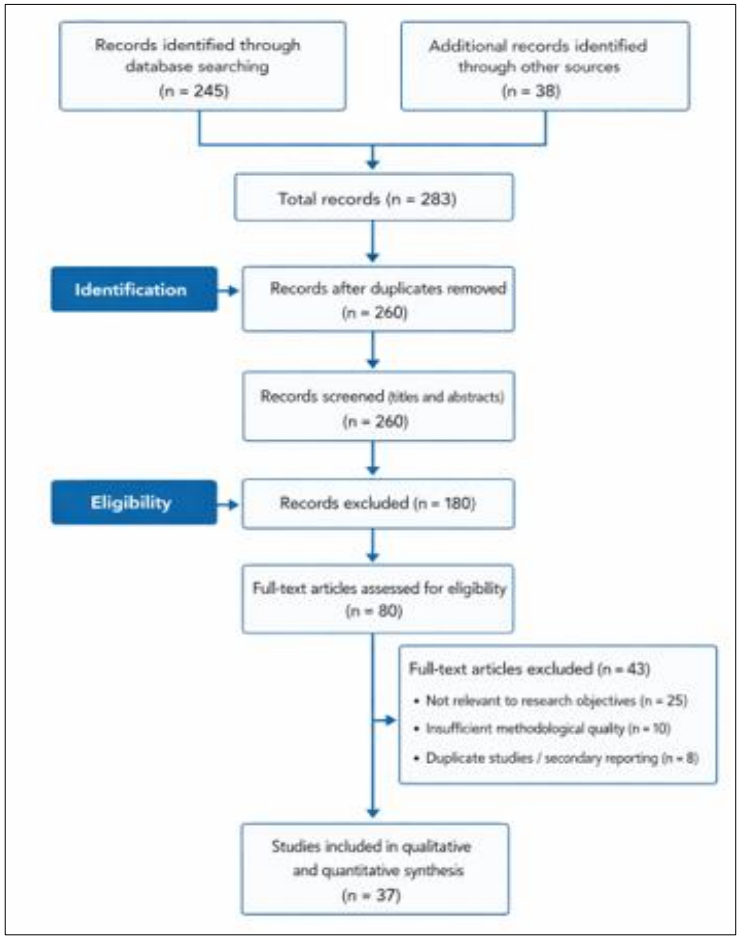

Figure 2. PRISMA Flow Diagram of Document Selection.

Thirty-three sources were selected based on clear criteria, as depicted in Figure 2: relevance to regulatory enforcement, operational practices, and community impact; publication dates between 2008 and 2025; and inclusion of multiple institutional and regional contexts. While several sources cited instances of counterfeit or substandard medicines, it is important to note that these cases were not confirmed through laboratory testing. This lack of laboratory verification is a limitation of the study, as it limits the ability to determine the prevalence and composition of falsified products. Nonetheless, the documents provide valuable insights into reported patterns, regulatory responses, and community-level impacts, forming a robust basis for qualitative analysis of enforcement gaps and systemic challenges.

Thematic analysis was conducted using an iterative coding process that combined deductive codes drawn from regulatory governance and complexity theory with inductive codes emerging from the data. Thematic analysis provides a structured and flexible framework for identifying and interpreting patterns in qualitative data, and its rigorous, reflexive application enhances the trustworthiness and depth of research findings (Swami et al., 2021). Triangulation across the 20 diverse sources enhanced validity, while constant comparison enabled identification of systemic gaps and alignments between formal governance structures and community-level practices.

5. SUPPLY CHAINS, COUNTERFEIT MEDICINES, AND PUBLIC HEALTH RISKS IN INFORMAL RETAIL

The informal pharmaceutical market in South Africa's townships exposes a critical vulnerability in the nation's healthcare system: the unregulated supply of medicines to spaza shops. Investigations indicate that a substantial proportion of these outlets, particularly in urban hubs such as Durban and Gauteng, operate without licences and often procure medicines from unverified wholesalers or informal manufacturers (Caxton Local Media, 2023; Hornberger et al., 2023). These supply chains are largely opaque, lacking formal quality control, traceability, and adherence to storage standards, thereby increasing the likelihood that counterfeit, expired, or improperly stored products enter communities (GDoH, 2024; PSSA, 2020).

Counterfeit medicines found in these settings range from common analgesics, such as Panado, to high-demand paediatric formulations, and occasionally to life-saving drugs such as salbutamol inhalers (Hornberger et al., 2023; TimesLIVE, 2024). The fraudulent products often mimic legitimate packaging but contain incorrect ingredients, incorrect dosages, or no active

pharmaceutical ingredient. Additional risks arise when medicines are exposed to high ambient temperatures, humidity, or light, which can degrade chemical stability and render drugs toxic or therapeutically ineffective (GDoH, 2024; PSSA, 2020).

The circulation of such medicines carries severe implications for public health. Beyond the immediate risk of toxicity or treatment failure, counterfeit medicines undermine trust in the healthcare system and exacerbate vulnerabilities in populations already experiencing limited access to licensed pharmacies. Social dynamics, including xenophobia and misinformation on social media, further complicate the regulatory response, as accusations of "fake" medicines may trigger both community panic and misdirected enforcement actions (Hornberger et al., 2023).

Addressing these supply-side challenges is critical, as the persistent circulation of counterfeit and substandard medicines in South African spaza shops constitutes a major public health concern. High-demand medications, including antimalarials, antibiotics, painkillers, and antiretrovirals, are particularly vulnerable to falsification, placing communities at risk of treatment failure, toxicity, and preventable morbidity and mortality (Katerere, 2025). Strengthening regulatory oversight of wholesalers and distributors, enforcing licensing compliance in spaza shops, implementing systematic quality monitoring, and fostering public awareness are therefore interdependent strategies that collectively mitigate these risks. Without coordinated interventions, informal retail channels will continue to serve as conduits for unsafe products, undermining public health and community trust in formal healthcare systems, underscoring the urgent need for integrated, multi-level approaches to secure the medicine supply and protect vulnerable populations.

Consumers also play a critical role in early detection of counterfeit products through visual inspection of packaging, expiry dates, batch numbers, and the physical integrity of medicines, with targeted awareness campaigns essential for fostering community vigilance (Callanan, 2021). However, these measures are not always feasible, particularly for unwell patients who have limited health literacy or reside in rural areas with high dependence on informal markets and few alternative sources of care. In such contexts, the ability to assess medicines critically is constrained, underscoring the need for complementary interventions, including regulatory enforcement, community education, and strengthened supply chains, to protect public health effectively. Table 1 further outlines methods for Consumers to Detect Counterfeit Medicines in Spaza Shops.

Table 1. Key Methods for Consumers to Detect Counterfeit Medicines

Detection Method	Description
Check the Source	Verify the legitimacy of the source from which the medicine was purchased.
Examine Packaging	Inspects the outer box, labels, packaging colour scheme, and inserts for errors or tampering.
Check Expiry Dates & Batch Numbers	Ensure medicines are within their valid usage period and traceable.
Assess Physical Appearance	Inspect pills, capsules, or liquids for uniformity and quality.
Observe Seals and Packaging Integrity	Confirm that the product packaging is intact and untampered with.
Compare with Previous Purchases	Verify consistency with previously bought authentic versions.
Smell and Texture (for liquids & powders)	Detect unusual odours or textures.
Verify Online or App Resources	Use official platforms or databases to confirm authenticity.
Seek Professional Advice	Where possible, consult trained personnel when uncertain.

6. CONCEPTUAL FRAMEWORK FOR ADDRESSING COUNTERFEIT AND ILLEGALLY SOLD MEDICINES IN INFORMAL RETAIL

Building on the literature on regulatory enforcement, public health risk, and informal supply chains, this study proposes a multi-dimensional framework to address the persistent challenges posed by counterfeit and unlicensed medicines in South African spaza shops. The framework integrates governance, supply chain management, community engagement, and technological monitoring to create a coordinated and sustainable intervention strategy.

6.1 Strengthening Regulatory Oversight

At the core of the framework is the enhancement of formal regulatory structures. Licensed oversight bodies, including the South African Health Products Regulatory Authority (SAHPRA) and provincial health departments, must implement continuous monitoring of wholesalers and retail outlets to ensure compliance with licensing and storage standards (GDoH, 2024; PSSA, 2020). The framework encourages the introduction of regular audits, certification programs, and sanctions for non-compliance to promote accountability and help close the enforcement gaps observed in spaza shops (Caxton Local Media, 2023). At the same time, many claims about systemic weaknesses and widespread non-compliance would benefit from stronger evidence or a clearer explanation of the data on which they are based, to ensure the recommendations are grounded.

6.2 Securing Supply Chains

The framework emphasises transparency and traceability in medicine supply chains. Wholesalers and

distributors supplying spaza shops should be required to adhere to standardised quality assurance protocols, maintain verifiable records of origin, and implement temperature-controlled logistics for temperature-sensitive medicines (Hornberger et al., 2023).

6.3 Community Engagement and Public Awareness

A critical component involves mobilising communities to participate actively in regulatory compliance. Public awareness campaigns should educate consumers on how to identify licensed pharmacies, recognise counterfeit products, and report illegal sales (TimesLIVE, 2024). Integrating residents into enforcement and monitoring mechanisms helps address socio-cultural dynamics, including misinformation and xenophobia, which influence public perception and responses to health risks (Hornberger et al., 2023).

6.4 Technological Monitoring and Data Integration

Figure 3 below illustrates the importance of leveraging technology, such as digital reporting platforms, inventory tracking systems, and mobile verification applications, to enable real-time monitoring and rapid enforcement interventions. Integration of data from regulatory bodies, law enforcement, and community reports allows predictive analytics to identify high-risk areas and respond proactively rather than reactively (SAHPRA, 2024). Integrated Regulatory-Community Framework for Counterfeit Medicines in Spaza Shops (IRCF-CMSS) provides a structured, coordinated approach to addressing the circulation of counterfeit and illegally sold medicines in South African spaza shops. Figure 3 illustrates how key inputs, including regulatory oversight, supply chain verification, and technological monitoring, are linked to strategic objectives such as enforcement compliance, public awareness, and risk reduction. These objectives are designed to produce measurable outcomes, including decreased distribution of counterfeit medicines, strengthened community vigilance, and improved public health protection. The framework emphasises the interconnected roles of authorities, local communities, and technological systems, highlighting the need for sustained collaboration and proactive interventions to address complex public health challenges in informal pharmaceutical markets.

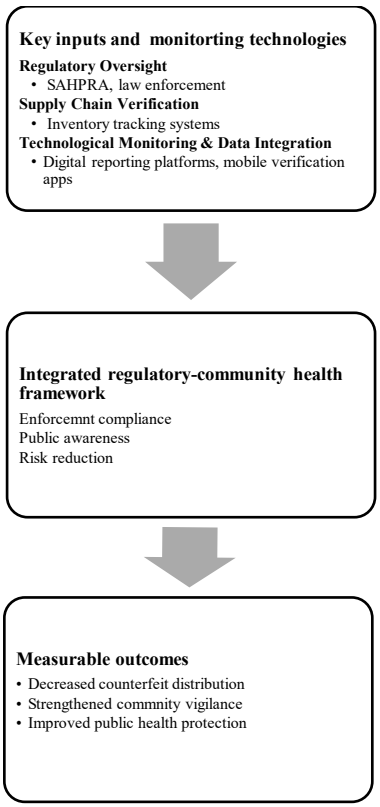

Figure 3. Conceptual framework - integrated regulatory-community framework for addressing counterfeit and illegally sold medicines in spaza shops

7. DISCUSSION

This study examined the structural, operational, and socio-cultural factors contributing to the circulation of counterfeit and substandard medicines in South African spaza shops, and explored how governance, regulatory enforcement, and community practices intersect to influence public health outcomes. The findings reveal that informal retail spaces operate within a complex ecosystem in which regulatory intent, supply chain vulnerabilities, and community dependence converge to shape the local risk environment.

The widespread presence of counterfeit medicines in spaza shops highlights the persistent gap between formal legal frameworks and everyday practice. While the Medicines and Related Substances Act clearly restricts the dispensing of scheduled medicines, enforcement is constrained by limited inspection capacity, fragmented oversight across provincial and national authorities, and reliance on informal supply chains (GDoH, 2024; PSSA, 2020). These challenges indicate that compliance cannot be assumed solely on the basis of legislation; effective regulation requires coordinated monitoring, practical accountability mechanisms, and enforcement strategies that are sensitive to local realities. Several claims regarding systemic gaps and widespread non-compliance, however, would benefit from stronger empirical support or clearer documentation of data sources to ensure evidence-based recommendations.

Consumers also play a critical yet constrained role in mitigating risk. Vigilant practices, such as inspecting packaging, checking expiry dates and batch numbers,

and assessing the physical integrity of medicines, can help detect counterfeit products early (Callanan, 2021). However, structural and social factors, including limited health literacy, illness, and geographic isolation, limit individuals' ability to consistently implement such safeguards. High dependence on informal markets in rural and peri-urban areas further heightens vulnerability, indicating that consumer-based interventions alone are insufficient. These dynamics align with complexity theory, which suggests that public health outcomes in informal systems emerge from the interactions of interdependent actors, institutions, and socio-cultural factors (Hornberger et al., 2023; Rotea et al., 2023).

Media narratives and public perception further influence regulatory responses. Social media amplification of suspected counterfeit products can trigger reactive interventions, yet episodic attention does not ensure sustained compliance or systemic improvements. Integrating community awareness, participatory monitoring, and risk communication with formal enforcement mechanisms can enhance both the legitimacy and effectiveness of interventions (Hornberger et al., 2023).

The proposed framework addresses these interdependencies by aligning regulatory oversight, supply chain transparency, consumer engagement, and technological monitoring. Findings suggest that without such a coordinated, multi-dimensional approach, interventions remain fragmented, regulatory objectives are undermined, and public health risks persist. The framework underscores a key insight from the study: safeguarding community health requires simultaneous attention to legal enforcement, operational capacity, and the socio-cultural realities of informal medicine markets. Its feasibility, however, depends on practical considerations such as resource availability, institutional capacity, and effective collaboration among stakeholders. Moreover, while the framework draws on international studies and examples, its applicability to South African informal markets must be considered cautiously, as differences in regulatory infrastructure, cultural practices, and market structures may affect transferability.

7.1 Research contribution

This study contributes to the literature on pharmaceutical governance by bringing regulatory governance theory and complexity theory together to examine South Africa's informal medicine markets in a more integrated way. The analysis moves beyond framing counterfeit and illegally sold medicines in spaza shops purely as issues of criminality or rule-breaking and instead situates them within the interaction of formal legislation, enforcement constraints, adaptive informal supply chains, and community reliance on local retail. The synthesis of policy documents, media reports, and scholarly research provides a grounded account of how regulatory intent often diverges from everyday practice in township settings. The proposed IRCF-CMSS extends this contribution by translating theoretical insight into a practical governance model that acknowledges complexity while offering structured pathways for coordinated intervention.

7.2 Implication

The findings suggest that improving medicine safety in informal retail environments requires more than tightening legal provisions; it requires stronger alignment between policy design, enforcement capacity, supply chain monitoring, and community engagement. Sustainable progress depends on moving away from reactive, crisis-driven enforcement toward continuous oversight, improved interagency coordination, and greater transparency across distribution networks, while recognising the socio-economic realities that make spaza shops central to everyday access. Consumer awareness initiatives and accessible technological verification tools can further strengthen shared responsibility and early detection. Future research would benefit from field-based and laboratory-confirmed studies to generate more precise evidence on prevalence and risk. Taken together, these implications point toward a collaborative, system-oriented response that treats counterfeit medicines in informal markets as a governance and public health challenge shaped by interconnected institutional and social dynamics.

7.3 Limitations

While this study provides critical insights into the circulation of counterfeit and substandard medicines in South African spaza shops, the following limitations are acknowledged.

i. The research relies exclusively on secondary data sources, including government communications, media reports, and peer-reviewed literature. Although this approach enabled a comprehensive examination of regulatory frameworks, enforcement practices, and community dynamics, it precludes the collection of firsthand accounts from consumers, shop owners, or regulatory personnel, thereby limiting the depth of contextual understanding.

ii. The study`s limitation is the reliance on qualitative case-study analysis and document review prevents precise quantitative estimation of counterfeit medicine prevalence or the frequency of enforcement actions. As a result, while the findings illuminate systemic trends, regulatory gaps, and operational challenges, they cannot provide population-level measures of exposure or risk.

iii. Secondary the cited examples of counterfeit or substandard medicines were drawn from media reports or official communications and were not confirmed through laboratory testing. This restricts the ability to definitively verify the composition or authenticity of the products, highlighting a constraint in interpreting the reported cases as conclusive evidence of counterfeit circulation.

iv. The reliance on publicly available sources introduces potential bias. Media reports may overemphasise dramatic incidents of counterfeit

medicines, and government communications may present an idealised view of regulatory capacity. These factors could skew perceptions of both the prevalence of unsafe products and the effectiveness of enforcement interventions.

v. Contextual factors such as variations in spaza shop operations across urban and rural settings, differences in community health literacy, and local economic conditions were not directly observed, which limits the generalisability of the findings across all informal retail contexts.

Despite these limitations, the study contributes valuable theoretical and practical insights by synthesising governance, operational, and socio-cultural perspectives. It establishes a foundation for future empirical research, including field-based studies that can capture consumer experiences, supply chain dynamics, and real-time regulatory compliance.

7.4 Suggestion

Addressing the persistent circulation of counterfeit and substandard medicines in South African spaza shops requires an integrated and multi-level strategy that aligns regulatory oversight, supply chain integrity, and community engagement.

I. Regulatory authorities should prioritise strengthening enforcement mechanisms. This includes regular audits of spaza shops and wholesalers, clear licensing requirements, and the implementation of punitive measures for non-compliance, thereby reducing operational gaps and incentivising adherence to legal standards.

II. Supply chain transparency must be enhanced. Wholesalers and distributors should be mandated to maintain verifiable records of the provenance of medicines, implement quality assurance protocols, and ensure safe storage and transport conditions for temperature-sensitive products. These measures will limit the entry of counterfeit medicines into informal retail channels.

III. Public awareness and consumer education should be elevated as complementary safeguards. Awareness campaigns can equip communities with practical knowledge to identify potentially unsafe medicines and encourage reporting of suspicious products to authorities. Interventions should be tailored to account for rural contexts, low health literacy, and high dependency on informal markets, recognising that not all consumers possess the capacity to verify medicines independently.

IV. Leveraging technology is critical. Digital reporting platforms, mobile verification tools, and integrated databases linking regulators, law enforcement, and community reports can facilitate real-time monitoring and predictive enforcement interventions. Such technological integration enhances responsiveness, reduces the lag between detection and action, and allows regulators to target high-risk areas effectively.

V. A coordinated multi-stakeholder approach is recommended. Collaboration among regulatory authorities, provincial health departments, community organisations, and consumer advocacy groups is essential to sustain compliance, build trust, and ensure that interventions are contextually appropriate and socially accepted. This approach aligns with IRCF-CMSS, providing a roadmap for systemic, sustainable, and community-centred mitigation of public health risks associated with informal medicine markets.

8. CONCLUSION

This study shows that the circulation of counterfeit, expired, and improperly stored medicines in South African spaza shops reflects a complex interplay between regulatory gaps, informal market practices, and public health vulnerabilities. Despite existing legal frameworks, enforcement challenges, opaque supply chains, and limited consumer capacity, especially in rural or underserved communities, unsafe products persist. Findings underscore that mitigating these risks requires integrated interventions combining strengthened regulatory oversight, supply chain transparency, community engagement, and technological monitoring. The proposed framework offers a multidimensional approach to enhance compliance, foster public trust, and protect vulnerable populations, demonstrating that addressing counterfeit medicines in informal markets is a governance and socio-technical challenge.

ACKNOWLEDGEMENT

The authors wish to acknowledge the support of colleagues and institutional peers, including Athandile Hadebe, who contributed to this manuscript through constructive discussions, guidance, and feedback during its development.

AUTHOR CONTRIBUTION STATEMENT

Michael Mncedisi Willie led the conceptualisation, research, analysis, and writing of the manuscript. Athandile Hadebe contributed to critical review, methodological input, and refinement of the analysis and discussion.

AUTHOR INFORMATION

Corresponding Author

Michael Mncedisi Willie, Policy Research and Monitoring, Council for Medical Schemes, Pretoria, South Africa.
ORCiD: https://orcid.org/0000-0003-4322-7857
Email: m.willie@medicalschemes.co.za

Author

Athandile Hadebe, University of South Africa, Department of Psychology, Pretoria, South Africa.
ORCiD: https://orcid.org/0000-0002-0947-171X
Email: slindile.hadebe87@gmail.com

REFERENCES

A'aqoulah A, El-Metwally AA, Al Khateeb B, Alammari D, Alshahrani A, Aldubikhi A, Alsulami A, Fatani F, Innab N. Challenges and opportunities of complexity theory in health care systems. J Taibah Univ Med Sci. 2025;20(4):429–434. https://doi.org/10.1016/j.jtumed.2025.06.006

Abdunasir E, Sosengo T, Amare F. Assessment of awareness and attitude towards counterfeit medicines among pharmacy professionals working in community drug retail outlets in Harar town, Ethiopia. OJPSR. 2021;11(1). https://doi.org/10.36811/ojpsr.2020.110010

Adigwe OP, Onavbavba G, Wilson DO. Challenges associated with addressing counterfeit medicines in Nigeria: An exploration of pharmacists' knowledge, practices, and perceptions. Integr Pharm Res Pract. 2022;11:177–186. https://doi.org/10.2147/IPRP.S387354

Akyildirim E, Corbet S, Nicolau JL, Oxley L. Understanding reputational disaster during economic crises: Evaluating aviation sector response differentials. Tour Manag. 2025;106:105028. https://doi.org/10.1016/j.tourman.2024.105028

Callanan A. How to check and identify fake medicines. Pfizer Global Security. 2021. https://www.pfizer.com

Caxton Local Media. Local shop owner caught with unlicensed products [Internet]. Soweto Urban: The Citizen; 2026 Feb 28 [cited 2026 Feb 28]. Available from: https://www.citizen.co.za/news/local-news/

Chabalenge B, Sahota T, Ermolina I, Tanna S. Substandard and falsified medicines in Africa: healthcare systems challenges, supply chain issues, regulatory challenges and strategies to increase access to quality medicines. Front Pharmacol. 2025;16:1708784. https://doi:10.3389/fphar.2025.1708784

Department of Justice and Constitutional Development. Public has until 13 February to comment on draft Traditional Courts Regulations. 2025 Dec 26.

Eid J, Hansen AL, Andreassen N, Espevik R, Brattebø G, Johnsen BH. Developing local crisis leadership – A research and training agenda. Front Psychol. 2023;14:1041387. https://doi.org/10.3389/fpsyg.2023.1041387

Feeney AJ, Goad JA, Flaherty GT. Global perspective of the risks of falsified and counterfeit medicines: A critical review of the literature. Travel Med Infect Dis. 2024;61:102758. https://doi.org/10.1016/j.tmaid.2024.102758

Gauteng Department of Health. Gauteng Health warns shops against the sale of scheduled medication without a licence. 2024 Nov 7. www.gov.za

Hornberger J, Hodges S, Chitukutuku E. Fake-talk and the spaza shop: A fake food furore and the spectre of public health emergencies in South Africa. Matatu J Afr Media Stud. 2023;10(3):71–136. https://doi.org/10.17157/mat.10.3.7136

Katerere DR. Fake medicines are a dangerous threat in Africa: 3 ways to spot them. The Conversation. 2025. https://theconversation.com

Koko M. GP Health looks to SAHPRA to establish task team tackling illegal sale of medicine at spaza shops. 2024 Nov 9. https://www.ewn.co.za

Laird Y, Manner J, Baldwin L, Hunter R, McAteer J, Rodgers S, Williamson C, Jepson R. Stakeholders' experiences of the public health research process: time to change the system? Health Res Policy Syst. 2020;18:83. https://doi.org/10.1186/s12961-020-00599-5

Moshoeshoe RJ, Enslin GM, Katerere DR. An exploratory assessment of the legislative framework for combating counterfeit medicines in South Africa. J Pharm Policy Pract. 2022;15(1). https://doi.org/10.1186/s40545-021-00387-8

Mourad N, Haddad C, Sacre H, Al Tawil S, Zeenny RM, Younes S, et al. Knowledge, practices, and recognition ability of counterfeit medicines among Lebanese community pharmacists during concurrent national crises. Sci Rep. 2026;16:109. https://doi:10.1038/s41598-025-00000-x

Ofori-Parkus S, Park SE. I (don't) want to consume counterfeit medicines: Exploratory study on the antecedents of consumer attitudes toward counterfeit medicines. BMC Public Health. 2022;22:13529. https://doi.org/10.1186/s12889-022-13529-7

Ofori-Parku SS. Fighting the global counterfeit medicines challenge: A consumer-facing communication strategy in the US is an imperative. J Glob Health. 2022;12:03018. https://doi.org/10.7189/jogh.12.03018

Organisation for Economic Co-operation and Development (OECD). Trade in Counterfeit Pharmaceutical Products. Paris: OECD Publishing; 2020. https://www.oecd.org

Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, Shamseer L, Tetzlaff JM, Akl EA, Brennan SE, Chou R, Glanville J, Grimshaw JM, Hróbjartsson A, Lalu MM, Li T, Loder EW, Mayo-Wilson E,

McDonald S, … Moher D. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. BMJ. 2021;372:n71. https://doi.org/10.1136/bmj.n71

Pal E, Merchant L, Koffi AK, Mehta R, Rusatira JC, Kubiak L. Assessing knowledge, attitudes, and practices and demand-side interventions for combating substandard and falsified medicines: A scoping review. J Pharm Policy Pract. 2025;18(1):2550369. https://doi.org/10.1080/20523211.2025.2550369

Parliamentary Monitoring Group. Medicines and Related Substances Amendment Bill: Public hearings. 2008 Aug 5. https://pmg.org.za/committee-meeting/861/

Pharmaceutical Society of South Africa. Limits on dispensing and sales of prescription and over the counter medicines [PDF]. 2020 Mar 24. https://www.pssa.org.za

Quttainah MA, Pathak A, Soni T. Configurations of corporate governance mechanisms and sustainable development: a review [Internet]. Indian J Corp Gov. 2025 Apr 21;18(1). Available from: https://doi.org/10.1177/09746862251327829

Rigby BP, Dodd-Reynolds CJ, Oliver EJ. The understanding, application and influence of complexity in national physical activity policy-making. Health Res Policy Syst. 2022;20:59. https://doi.org/10.1186/s12961-022-00857-9

Rotea CC, Ploscaru AN, Bocean CG, Vărzaru AA, Mangra MG, Mangra GI. The link between HRM practices and performance in healthcare: the mediating role of the organizational change process [Internet]. Healthcare (Basel). 2023 Apr 26;11(9):1236. Available from: https://doi.org/10.3390/healthcare11091236

Snyder H. Literature review as a research methodology: An overview and guidelines. J Bus Res. 2019;104:333–339. https://doi:10.1016/j.jbusres.2019.07.039

South African Health Products Regulatory Authority (SAHPRA). SA's health emergency: Efforts to tackle unhealthy medication sales [Television broadcast]. eNCA, DStv Channel 403; 2024 Nov 14.

Swami Gurunand Jnanathapaswi. Thematic analysis & coding: An overview of the qualitative paradigm. In: An introduction to social science research. APH Publishing Corporation; 2021. https://doi.org/10.6084/m9.figshare.17159249

Tate JA, Happ MB. Qualitative secondary analysis: A case exemplar. J Pediatr Health Care. 2017;32(3):308–312. https://doi:10.1016/j.pedhc.2017.09.007

Tshikalange S. Scheduled medication sold illegally at shops: Selling scheduled medication without a licence places lives at risk. TimesLIVE. 2024 Nov 8. https://www.timeslive.co.za/news/south-africa/

Willie MM. A review of the diversity and characteristics of Spaza shops in South Africa. Golden Ratio of Data in Summary. 2025;5(2):44–46. https://doi.org/10.52970/grdis.v5i2.467

World Health Organization (WHO). Substandard and falsified medical products. 2024 Dec 3. https://www.who.int