

Pharmaceutical Governance Challenges in The Gambia: A Systematic Analysis of Legal and Policy Frameworks

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Abstract

Pharmaceutical governance is fundamental to an effective health system because it influences the availability, affordability, quality, safety, and rational use of medicines. Effective governance requires coherent legislation, capable institutions, adequate financing, transparent procurement, reliable supply chains, and strong accountability. This study examined pharmaceutical governance challenges in The Gambia through systematic analysis of national legal and policy frameworks. A qualitative document analysis design was employed using an instrumental case study approach. Eleven key legal, policy, regulatory, planning, procurement, and financial documents were purposively selected and analysed. The analysis was guided by the World Health Organisation Good Governance for Medicines Framework, the Pharmaceutical Public Value Governance Framework, and the Health System Governance Framework. Thematic and gap analyses were used to identify weaknesses between policy provisions and implementation requirements. The findings revealed systemic governance challenges across regulatory, procurement, financing, supply chain, human resource, information management, and accountability dimensions. Major gaps included weak regulatory independence, limited post-market surveillance, absence of a national medicines quality control laboratory, inadequate pharmaceutical expertise in procurement, weak medicine price transparency, poor storage and inventory systems, limited digitalisation, insufficient pharmaceutical personnel, and weak pharmacovigilance. Also, low government health expenditure, high out-of-pocket expenditure and substantial donor dependence remained serious financial challenges. The National Essential Medicines lists require regular updates to enhance effective stratification of the level of care, procurement linkages and quality assurance processes. Public access to pharmaceutical information was limited by weak whistleblower protection, while inadequate parliamentary and civil society involvement was severely constrained by accountability. In order to strengthen regulatory independence, financial information, pharmaceutical capacity and accountability mechanisms are essential to enhance pharmaceutical governance and medicine security in The Gambia.

Keywords: Accountability, health systems, medicines regulation, pharmacovigilance, pharmaceutical governance and pharmaceutical policy.

Introduction

Pharmaceutical governance constitutes a fundamental pillar of any health system, encompassing the legal, regulatory, institutional, and operational frameworks that determine how medicines are selected, procured, distributed, regulated, and utilised within a country. The effectiveness of pharmaceutical governance has profound implications for population health outcomes, as it directly influences the availability, affordability, quality, and rational use of essential medicines. According to the World Health Organisation (2021), universal health coverage is achieved through access to a safe, effective, and affordable medicines supply. Many countries, particularly in sub-Saharan Africa, continue to face challenges in establishing and maintaining robust pharmaceutical governance systems. It must be noted that pharmaceutical governance is not only about technical considerations of drug supply and regulation, but must also consider the proliferation of substandard and falsified products, medicine stock-outs, irrational prescription practices, antimicrobial resistance, and financial losses through inefficient procurement and corruption (World Health Organisation, 2018). These challenges affect many people in low- and middle-income countries where health funding and regulatory capacities are both limited. The World Health Organisation (2020) reiterated the need for a robust pharmaceutical governance system for good service delivery, reduced health inequalities, that will facilitate the achievement of sustainable development goal for universal health coverage.

To maintain an effective pharmaceutical governance outcome, an integrated approach is required, involving multiple dimensions: regulatory oversight to ensure medicine safety, quality, and efficacy; financing to ensure affordability; human resource capacity; and information systems to support evidence-based decision-making coupled with accountability and transparency to boost the integrity of pharmaceutical sector operations (World Health Organisation, 2019).

The most important components of pharmaceutical governance include registration, licensing, inspection, quality control and pharmacovigilance to ensure the medicines meet the required safety, quality and efficacy standards in order to protect public health. According to the World Health Organisation (2017), one in ten medical products in low- and middle-income countries is substandard or falsified, culminating in significant morbidity, mortality and economic cost. Inadequate legal framework, limited institutional capacity, insufficient human and financial resources, and weak enforcement mechanisms are among the regulatory challenges affecting the pharmaceutical governance system.

Procurement and supply chain governance is another focus that requires attention for sustained quality and cost of the products. Transparency, competition, and technical expertise are essential for medicine selection and evaluation to ensure robust contract management. Appropriate storage conditions, efficient distribution, and effective inventory management are all essential requirements for supply chain systems. It is evident that many countries face serious challenges of fragmented procurement systems, inadequate storage infrastructure, limited logistics capacity, weak inventory management, and insufficient use of information technology (Yadav et al., 2017).

Financing for pharmaceuticals remains a persistent challenge in many health systems, particularly in low- and middle-income countries where government health budgets are often insufficient and out-of-pocket payments for medicines are high. According to the World Health Organisation (2019), countries should allocate at least 15% of their national budgets to health, although many countries fail to meet this target. Inadequate financing leads to medicine stock-outs, financial hardship for patients, and inequitable access to essential treatments. (McIntyre et al., 2017).

Human resource capacity is essential to pharmaceutical governance, as qualified and competent personnel to perform regulatory functions and manage procurement and supply chains are required for quality clinical services to ensure rational medicine use. However, in

many sub-Saharan countries, pharmaceutical personnel are scarce or not adequately trained, with limited opportunity for continuing professional development (World Health Organisation, 2019).

Data-driven decision-making is an essential quality that ensures monitoring, evaluation, and tracking of medicine consumption, stock levels, procurement performance, prescribing patterns and adverse drug reactions in an effectively managed pharmaceutical information system. In this connection, cognisance is given to enhancing interoperability of pharmaceutical information systems with broader health systems and financial management (World Health Organisation, 2021).

Transparency and accountability are required to ensure open scrutiny that will ensure that individuals are held responsible for their actions. Transparency permits that medicine selection, procurement, pricing and regulatory decisions are made to avoid corruption. In this vein, accountability structures will improve audit systems, performance monitoring and complaints mechanisms that are responsive to the needs of the patients and the public (Cohen et al., 2018).

The coronavirus disease 2019 (COVID-19) pandemic marked a pivotal point in pharmaceutical governance, which highlighted vulnerabilities in the global pharmaceutical systems and underscored the need for resilience in the pharmaceutical system for uninterrupted access to essential medicines and medical supplies during public health emergencies (World Health Organisation, 2020). In this background, this study endeavours to make a comprehensive analysis of pharmaceutical governance challenges in The Gambia. The analysis consisted of ten key legal and policy documents that governs pharmaceutical sector operation in The Gambia and include the Constitution of the Second Republic of The Gambia (1997), General Orders (1997), Gambia National Development Plan 2023–2027, National Health Financing Policy 2017–2030, National Health Policy 2021–2030, National Medicines Policy 2022–2025, Medicines and Related Products Act 2014, Pharmacy Council Act 2014, Public Procurement Act 2022, Financial Regulations 2016, and the National Essential Medicines List. Through systematic analysis of these documents, the study identifies systemic challenges across constitutional, legislative, regulatory, administrative, and operational frameworks, and proposes corresponding strategies for strengthening pharmaceutical governance to improve health service delivery in The Gambia.

Literature Review

This section discusses the conceptual, theoretical and empirical reviews.

Conceptual Review

Pharmaceutical governance is a multidimensional concept that has evolved significantly over the past two decades, reflecting growing recognition of the critical role that governance plays in ensuring access to safe, effective, and affordable medicines. The conceptualisation of pharmaceutical governance draws from broader governance theories while incorporating specific dimensions relevant to the pharmaceutical sector.

Pharmaceutical Governance

The concept of pharmaceutical governance, alternatively termed "pharmacogovernance," has been defined as "the manner in which governing structures; policy instruments; and institutional authority (e.g., ability to act, implement and enforce norms, policies and processes) are managed to promote societal interests for patient safety and protection from adverse drug reactions" (Kohler & Moscou, 2016). The concept expresses beyond the traditional believe of regulating to encompass the overall governance that shape pharmaceutical functioning systems of government structure, policy instrument and institutional authority in relation to private sector and public health. Another concept called the Pharmaceutical Public Value Governance

(PPVG) Framework express pharmaceutical governance as a phenomenon of public value creation, generating seven interdependent dimensions. The concept sets out the dimensions as ethical priority setting, evidence-based formulary governance, strategic purchasing, supply-chain resilience, quality assurance, citizens- centred accountability and intergovernmental data coordination (Mackey & Liang, 2014). The frameworks posit that equitable access to essential medicines is gained when pharmaceutical systems transform public resources and regulatory authority into collectively valued outcomes of availability, affordability, quality, trust, and response to social justice. This perspective views medicine access as an important public governance issue of legitimacy, accountability, coordination and public value creation.

Components of Pharmaceutical Governance

The good governance for medicine propounded by the World Health Organisation in 2008 (GGM) generated a five-dimensional framework of accountability, transparency, stakeholder participation, integrity, anti-corruption, and policy development. The two most important principles are transparency and accountability, which can ultimately lead to improved health and pharmaceutical systems outcomes (Pasche et al., 2018). Transparency in pharmaceutical systems involves the public availability of information regarded as a prerequisite for accountability, including standards and commitments, decisions and results, and consequences and responsive actions. Accountability, in turn, requires the provision of information that enables stakeholders to understand the consequences of any deviations from agreed standards and commitments and to be aware of the responsive actions taken by government when these deviations occur (Pasche et al., 2018).

Good governance in the pharmaceutical sector is characterised by being consensus-oriented, accountable, transparent, responsive, equitable and inclusive, effective and efficient, following the rule of law, being participatory, and, in theory, less vulnerable to corruption (Mackey & Liang, 2014). These characteristics provide a normative framework against which pharmaceutical governance systems can be assessed and improved. The emphasis on participation and stakeholder involvement recognises that effective pharmaceutical governance requires the engagement of impartial stakeholders beyond government institutions (Diack et al., 2018).

Pharmaceutical Systems and Governance

A pharmaceutical system consists of all structures and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective medicines (World Health Organisation, 2021). This systems perspective recognises that pharmaceutical governance operates within and across multiple levels of the health system, encompassing policy, laws and governance; regulatory systems; and innovation. Coordination in pharmaceutical systems is a multifaceted task which requires medicine selection, procurement, distribution, regulation and use. Stewardship is a concept that is narrowly defined as governance and refers to a range of functions performed by the government to achieve a national policy objective (World Health Organisation, 2019). This role is essential in the pharmacy sector, where government actions shape market dynamics, regulatory frameworks and access to medicines.

Regulatory Governance and Pharmaceutical Regulation

Regulatory governance in the pharmaceutical sector encompasses the registration, licensing, inspection, quality control, and pharmacovigilance functions that ensure medicines meet established standards of safety, quality, and efficacy (World Health Organisation, 2024). Pharmaceutical regulatory agencies function as complex adaptive systems, requiring affective responsiveness (engagement), cognitive capability (data assimilation and learning), and

spiritual integrity (ethical commitment). Current regulatory models often underutilise these capacities, resulting in rigid, siloed decision-making (World Health Organisation, 2024).

Pharmaceutical regulation has emerged as a subject of philosophical investigation from a number of angles, with scholars examining the epistemic foundations of regulatory decisions and the legitimacy of regulatory arrangements (World Health Organisation, 2025). The regulation of medical products requires a theoretical framework for examining and assessing regulatory arrangements, with some scholars adopting a 'dialogic' approach in which a shared set of normative beliefs and values is formulated as a theoretical tool to identify deficiencies in regulatory arrangements.

Theoretical Review

In this study, good governance theory and the dialogic approach to regulatory legitimacy provide a theoretical framework.

Good Governance Theory

Good governance theory provides a normative framework for assessing and improving pharmaceutical governance. The theory identifies characteristics of a well-governed system: consensus-oriented, accountable, transparent, responsive, equitable and inclusive, effective and efficient, following the rule of law, and participatory (Mackey & Liang, 2014). These characteristics serve as benchmarks against which pharmaceutical governance systems can be evaluated. The application of this theory in the pharmaceutical sector acknowledges that corruption in health can generate a devastating outcome that can be prevented with the effective implementation of this theory (Mackey & Liang, 2014). Corruption in the health sector occurs in various forms. It aggravates inequalities in access to health care services, leading to poor health outcomes arising from the diversion of government health systems spending and the distortion of incentives (Onwujekwe et al., 2025). This theory highlights the importance of country ownership of governance initiatives and the participation of impartial stakeholders (Diack et al., 2018).

Dialogic Approach to Regulatory Legitimacy

A dialogic approach to pharmaceutical regulation provides a theoretical framework for examining and assessing the regulatory arrangements for medical products (World Health Organisation, 2025). This theoretical tool identifies deficiencies in regulatory arrangements and draws on theories of political legitimacy, providing a timely and relevant assessment of the complexities of medical regulatory regimes. The theory further recognises that pharmaceutical regulation differs from the governance of other goods and other economies (World Health Organisation, 2025). The characteristics of information asymmetry between producers and consumers, and the implications of regulatory decisions, make pharmaceutical products unique and require specialised theoretical frameworks for understanding regulatory governance

Empirical Review

Numerous empirical studies exist on pharmaceutical governance, but the following has a direct link to this research.

Antonio et, al. (2025) conducted a qualitative comparative case study in two Rural Health Units in Cavite Province, Philippines, using the Donabedian Structure-Process-Outcome framework. One rural health unit had a licensed pharmacist, while the other did not. Through in-depth interviews with eight rural health unit personnel, supplemented by document validation and on-site medicine records review, the study identified significant differences in pharmaceutical governance performance. The rural health unit with a pharmacist demonstrated higher operational consistency with clearer role delineation, standardised workflows, and strict

storage and documentation protocols. Systematic inventory monitoring and structured procurement planning contributed to improved accountability and reduced stock-out reporting. In contrast, the rural health unit without a pharmacist faced challenges such as role overlap among non-professionals, procurement gaps, and documentation inconsistencies. This study provides empirical evidence that pharmacist integration transforms pharmaceutical governance from reactive task-sharing to regulated, systematic practice.

Similarly, Oseni et al. (2025) conducted a cross-sectional study in Southwestern Nigeria. The study aimed to assess the involvement of community pharmacists in vaccination service delivery in Southwestern Nigeria. The study employed a descriptive cross-sectional study design among 474 community pharmacists in two Southwestern Nigerian states. The Research found a high level of awareness of the National Drug Policy among pharmacists and regulatory officials. Despite this awareness, most participants expressed concerns about the poor organisation of the medicine distribution system. The study identified weak enforcement of pharmaceutical laws, the operation of open drug markets, limited collaboration among stakeholders, and the involvement of non-professionals in medicine distribution as major contributing factors. These findings suggest that awareness of pharmaceutical policies does not necessarily translate into effective implementation. Strong regulatory enforcement, effective coordination among stakeholders, and greater control of medicine distribution activities are therefore required to ensure a safe and well-regulated pharmaceutical supply system.

Furthermore, Tetteh et al. (2019) conducted an exploratory study to examine the governance and regulatory environment surrounding medicines and pharmaceutical practice in Ghana. The researchers used an exploratory assessment based on a structured set of governance indicators. They reviewed relevant legislation, regulatory documents, professional codes and institutional arrangements relating to medicine promotion and pharmaceutical practice. The study found that pharmacists and other pharmacy personnel involved in medicine dispensing were subject to licensing by the Pharmacy Council. The Council also had responsibilities for ensuring the competency of pharmaceutical care providers and inspecting pharmacies and other establishments where medicines were dispensed. The study also identified gaps in the availability and accessibility of some regulatory and professional documents.

Frempong et al. (2021) conducted a study of OTC medicine seller facilities in Ghana's Upper East Region, focusing on their compliance with regulatory requirements. The research examined the extent to which facilities complied with requirements governing pharmaceutical practice. The study provides evidence of the practical challenges involved in achieving compliance among regulated pharmaceutical outlets. It demonstrates the importance of inspection, licensing and regulatory monitoring in maintaining standards among medicine sellers. The statutory functions of the Ghana Pharmacy Council include registration, licensing, inspection, professional standards and disciplinary action. The Council also has formal disciplinary structures for professional misconduct.

Oseni (2021) conducted a study aimed at evaluating pharmacy practice laws and regulations in Nigeria from the perspective of pharmaceutical inspectors and identifying challenges affecting their implementation. The study used a cross-sectional survey design. A semi-structured questionnaire containing 19 questions was administered to pharmaceutical inspectors of the Pharmacists Council of Nigeria. The questions examined the adequacy of pharmacy laws and regulations, challenges in implementation and possible amendments. The data were analysed using descriptive statistics. The study found substantial concerns among the inspectors about the adequacy of the existing regulatory framework.

Ndwandwe (2026) employed a broader qualitative design to examine pharmaceutical governance from the perspectives of health care professionals, pharmacy managers and district health officials in South Africa. The study highlighted persistent challenges such as a weak pharmaceutical supply chain system, fragmented communication channels across levels of the

health system, insufficient budget transparency in pharmaceutical allocation, limited functionality of pharmacy and therapeutics committees, and inadequate accountability mechanisms for pharmaceutical staff. The findings elucidated the interconnectedness of governance failures, where weaknesses in one area overlap to affect multiple dimensions of pharmaceutical system performance.

Similarly, Edward et al. (2026) conducted a systematic review of peer-reviewed articles in sub-Saharan countries between 2016 and 2026 to establish the relationship between health system governance and pharmaceutical supply chain governance. The study consisted of thirty-two studies from fourteen countries and indicated some fragmented procurement systems, which ultimately led to increased medicine prices, supply instability, administrative duplication, weakened market-shaping capacity, and heightened vulnerability to external shocks. The findings indicated that countries with stronger governance frameworks with clear procurement policies, transparent decision-making processes, and effective oversight mechanisms demonstrated a more reliable medicine availability with cheaper procurement cost. The findings further identified a regional pooled procurement initiative as a promising intervention for cost reduction and improved supply predictability. The success of these initiatives depends largely on coordination and a strong political will.

Furthermore, Kohler et al. (2016) performed an extensive conceptual and empirical analysis of pharmaceutical governance. He generated a framework that defines pharmaceutical governance as the manner in which governing structures, policy instruments, and institutional authority are managed to promote societal interest for patient safety and protection from adverse drug reactions. This empirical work across many countries demonstrated that governance capacity, defined as the ability to act, implement, and enforce norms, policies, and processes, is an indicator of pharmaceutical system performance. The research highlighted that countries with stronger governance capacity demonstrated better regulatory outcomes, more effective procurement systems and improved medicine availability. The research concluded that multiple pathways enhance governance capacity, such as regulatory enforcement, accountability mechanisms, and stakeholder engagement. He intimated that pharmaceutical governance strengthening requires a holistic approach rather than a narrow technical intervention.

Mengesha et al. (2025) performed a qualitative study in southern Ethiopia that problematised the assumption that strengthening domestic laws and enforcement measures is sufficient to reduce illegal pharmaceutical supply. The researchers conducted in-depth interviews with thirty-five pharmacists, wholesalers, pharmacy owners, regulators, law enforcement personnel and health professionals. The interviews were subsequently complemented by participant observation and the review of policy and legal documents. The findings indicated that corruption is associated with weak regulatory systems, complex supply chains with multiple intermediaries, and socioeconomic pressures that create incentives for informal pharmaceutical distribution. The research ultimately concluded that legal reforms alone were insufficient to address corruption and reiterated that pharmaceutical corruption was often driven by economic necessity rather than criminal intent. It is suggested that pharmaceutical corruption requires legal reforms combined with practical strategies that account for local market realities.

Onwujekwe et al. (2025) examined the relationship between pharmaceutical sector corruption and health outcomes in six sub-Saharan countries. A mixed-methods approach was used to collect data from households and health facility assessments, with key informant interviews. The findings indicated that corruption in the pharmaceutical sector exacerbates inequities in health care services. The findings reaffirm that corruption diverts government health system spending away from priority health interventions. Corruption also distorts incentives for health care providers.

WHO (2023) examined the parliamentary oversight mechanism across fifteen countries in the pharmaceutical sector. The study found that parliamentary health committees have an important role in pharmaceutical governance in generating pharmaceutical policies, budgets and performance. The study also found that countries with stronger parliamentary oversight provided better pharmaceutical governance outcomes, improved budget allocation for medicines, reduced corruption and better accountability.

Methodology

Research Design

This study employs a document analysis research design and is implemented through a case study approach. This enables an in-depth, contextualised examination of pharmaceutical governance within the Gambian context.

Document Selection and Sampling

Inclusion Criteria

Documents were purposively selected based on their relevance to pharmaceutical governance and their contribution to understanding the legal, policy, institutional, financial, procurement, regulatory and operational arrangements within the pharmaceutical sector in The Gambia. The selection process focused on documents officially adopted or issued by the government of The Gambia and relevant government institutions. Priority was given to documents that were currently in force or reflected the country's current policy direction. Documents were also selected based on their coverage of important aspects of pharmaceutical governance, medicine regulation, procurement, financing, distribution, quality assurance, professional practice, accountability and access to essential medicines. Only documents that were publicly available or accessible through official government and institutional sources were considered for review.

Selected Documents

Using the above criteria, eleven key legal, policy, regulatory, planning, and financial documents were purposively selected for analysis. The documents were selected to provide broad coverage of the pharmaceutical governance system in The Gambia.

Ethical Considerations

As this study involves only the analysis of publicly available legal and policy documents and does not involve human participants, the ethical considerations primarily relate to document handling, interpretation, and use, as well as the researcher's responsibilities in conducting and reporting the research with integrity and respect. The ethical framework is grounded in recognised principles of research integrity: honesty, transparency, accountability and respect for intellectual property (Resnik, 2020; British Educational Research Association, 2018). All documents analysed in this study are officially published and publicly available documents. Documents were interpreted with care and respect for the institutional and political context in which they were created. Interpretations are based on systematic analysis and are supported by evidence from the documents. Documents were not used in ways that misrepresent their content or intent.

Results

This comprehensive analysis synthesises findings from ten key legal and policy documents governing The Gambia's pharmaceutical sector. The analysis identifies systematic challenges across constitutional, regulatory, administrative, and operational frameworks and the proposed corresponding strategies for reform.

Table 1: Constitutional Framework (The Constitution of the Second Republic of The Gambia, January 1997)

Challenge	Strategy/Recommendation
Challenge 1: No Constitutional Right to Health or Essential Medicines; directive principles (Section 216) are non-justiciable (Section 211, p. 89), limiting ability to challenge stock-outs or discriminatory access	Recommendation: Amend Constitution to include justiciable right to health and essential medicines; pursue constitutional litigation under Sections 18 (right to life) and 21 (protection from inhuman treatment) as interim measures
Challenge 2: No Dedicated Constitutional Framework for Pharmaceutical Regulation; no constitutional requirement for medicines regulatory agency, pharmacy council, or national drug quality control laboratory	Recommendation: Establish constitutional or statutory mandate for Medicines Control Agency and Pharmacy Council with guaranteed independence; consider constitutional amendment to create pharmaceutical regulatory body
Challenge 3: Weak Constitutional Protection for Whistleblowers; Section 222(6) requires action on contraventions but provides no explicit protection for reporters of corruption in the pharmaceutical sector	Recommendation: Enact whistleblower protection legislation with constitutional status; include protections in Public Procurement Act and Public Service Regulations
Challenge 4: No Constitutional Requirement for Public Procurement Transparency; no requirement for publication of procurement contracts; asset declarations made to Ombudsman rather than publicly accessible	Recommendation: Amend the Constitution to mandate public disclosure of procurement contracts; establish a public register of asset declarations
Challenge 5: No Constitutional Right to Information on Medicines and Health Services; press freedom guaranteed (Section 207) but individual right to access government information absent	Recommendation: Enact Right to Information Act; require proactive publication of medicine stock levels, procurement prices, and inspection reports
Challenge 6: No Constitutional Provision for Parliamentary Oversight of Pharmaceutical Sector; National Assembly has Finance and Public Accounts Committee (Section 109, p. 46) but no dedicated health committee required	Recommendation: Establish mandatory Parliamentary Health Committee; require annual pharmaceutical sector performance reports to Parliament
Challenge 7: Special Criminal Court's Jurisdiction Limited; composition (Section 135, p. 54) and procedures not fully specified; National Assembly to make further provision (Section 136, p. 55)	Recommendation: Enact implementing legislation specifying procedures for pharmaceutical corruption cases; ensure court has jurisdiction over counterfeit medicines and regulatory offences

Challenge 8: Limited Remedy for Patients Denied Essential Medicines; no explicit constitutional remedy; right to life (Section 18) and protection from inhuman treatment (Section 21) indirect and untested (no reported case law on medicine access)	Recommendation: Support strategic litigation on right to medicines; develop guidelines for High Court enforcement of fundamental rights (Section 37, p. 19) in health contexts; document case law
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Table 2: Public Service Framework (General Orders, 1997)

Challenge	Strategy/Recommendation
Challenge 1: Absence of Pharmaceutical-Specific Governance Framework; no dedicated provisions for medicine procurement, supply chain, storage standards, or expiry date management	Recommendation: Develop pharmaceutical-specific Public Service Regulations. Include provisions for drug management, cold chain maintenance, and expiry date tracking.
Challenge 2: Weak Stock Accountability and Audit Trails; no mandated frequency for routine stock verification, no surprise audits, no digital tracking; vehicle log sheets mandated (p. 40) but medicine disbursement logs not	Recommendation: Mandate monthly physical stock verification of all medicines; require surprise audits; implement digital inventory management system integrated with CHANEL.
Challenge 3: Conflict of Interest Risks in Pharmaceutical Procurement; officers must disclose shareholdings (p. 17); medical officers cannot own pharmacies (p. 36) but no explicit prohibition for pharmacy officers, storekeepers	Recommendation: Extend conflict of interest provisions to all pharmaceutical staff; prohibit ownership of drug supply companies; regulate receipt of gifts from pharmaceutical representatives
Challenge 4: Limited Transparency and Procedural Fairness; officers cannot access confidential records relating to themselves (p. 47); Medical Board findings confidential (p. 35)	Recommendation: Establish right of officers to access their own records; limit confidentiality exceptions; create independent appeal mechanism for disciplinary decisions
Challenge 5: No Outcome Measurement for Pharmaceutical Services; no metrics for medicine availability, patient satisfaction, dispensing accuracy, or clinical outcomes	Recommendation: Develop pharmaceutical service performance indicators; conduct patient satisfaction surveys; establish dispensing accuracy monitoring systems
Challenge 6: Inadequate Protection for Whistleblowers; officers required to report fraud (p. 63) but no explicit protection against retaliation	Recommendation: Amend General Orders to include whistleblower protection provisions; establish anonymous reporting channels
Challenge 7: Insurance Coverage Gaps for Medicines; medical insurance covers 60% with dental/optical capped at D6,000/year (p. 31); no cap for medicines but no guarantee of full coverage	Recommendation: Expand insurance coverage to include essential medicines; establish clear medicine coverage policy; reduce out-of-pocket barriers

Challenge 8: Delegation Without Pharmaceutical Expertise; no requirement for pharmacist inclusion in disciplinary or appointments committees for pharmaceutical staff (pp. 8, 81)	Recommendation: Require pharmacist representation on all committees dealing with pharmaceutical staff; establish pharmaceutical professional advisory committees
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Table 3: National Development Framework (Gambia National Development Plan 2023-2027)

Challenge	Strategy/Recommendation
Challenge 1: Weak Quality Assurance and Pharmacovigilance; "lack of quality testing of medical products; weak patient safety monitoring" (p. 122); no accredited laboratory for medicine quality control	Recommendation: Establish a national medicines quality control laboratory under the Medicines Control Agency; implement a pharmacovigilance system with WHO support; strengthen regulatory inspection capacity
Challenge 2: Inadequate Storage and Supply Chain Infrastructure; "inadequate storage conditions for health products" and "interruption of supply system" (p. 122); Central Medical Stores under-resourced and centralised	Recommendation: Decentralise storage to regional hubs; improve infrastructure at Central Medical Stores; implement risk management plan for supply chain
Challenge 3: Outdated Pharmaceutical Legislation; Medicines and Related Products Act 2014 needs review (p. 124); may not address substandard medicines, e-commerce, or international regulatory cooperation	Recommendation: Review and update Medicines and Related Products Act; address emerging issues including e-commerce, substandard medicines, and international regulatory cooperation
Challenge 4: Shortage of Pharmaceutical Workforce; "inadequate human resource capacity" (p. 122); lack of pharmacy school	Recommendation: Establish national pharmacy school; develop five-year human resource development plan for pharmaceutical sector; create continuing professional development programs
Challenge 5: Low Budget Allocation and High Out-of-Pocket Expenditure; health budget "well below 15% Abuja Declaration target"; "out-of-pocket expenditure on health by population is high" (p. 125)	Recommendation: Increase health budget to meet Abuja Declaration target; establish National Health Insurance Scheme; implement cost recovery and domestic resource mobilisation
Challenge 6: No Pharmaceutical Performance Indicators in M&E Framework; results framework (pp. 238-253) contains no indicators for medicine availability, procurement lead times, or storage conditions	Recommendation: Include pharmaceutical performance indicators in national M&E framework; establish routine data collection and reporting on medicine availability and supply chain performance
Challenge 7: Unregulated Traditional Medicine; "unregulated traditional medicine practices" (p. 122) leading to harmful interactions and delays in seeking effective care	Recommendation: Develop traditional medicine policy; integrate traditional medicine into the health system; regulate traditional medicine practitioners and products

Challenge 8: Weak Coordination Between Health and Procurement Institutions; "weak health governance and partnership framework" (p. 13); fragmented implementation (p. 49) involving Ministry of Health, GPPA, Central Medical Stores, Ministry of Finance	Recommendation: Establish a multi-sectoral coordination mechanism for pharmaceutical procurement; clarify roles and responsibilities; develop a partnership framework
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Table 4: Health Financing Framework (Gambia National Health Financing Policy 2017-2030)

Challenge	Strategy/Recommendation
Challenge 1: Low Government Budget Allocation to Health; below Abuja Declaration target of 15% (p. 13); 10.56% in 2016 (p. 20); underfunding starves the pharmaceutical system	Recommendation: Increase government budget allocation to health to meet Abuja target; allocate specific funds for medicines procurement
Challenge 2: High Out-of-Pocket Expenditure on Medicines; increased from 9% in 2004 to 21.21% in 2013 (p. 13); most for medicines; leading to financial hardship and inequitable access	Recommendation: Reduce out-of-pocket expenditure through National Health Insurance; expand Drug Revolving Fund coverage; exempt vulnerable populations from user fees
Challenge 3: No Social Health Insurance and Weak Risk Pooling; no NHIS (p. 19); fragmented risk pooling; no cross-subsidisation between healthy/sick and rich/poor	Recommendation: Establish National Health Insurance Scheme; create unified risk pool; implement mandatory health insurance
Challenge 4: Underutilization of Drug Revolving Fund; not functioning effectively (p. 20); limiting availability of essential medicines	Recommendation: Reform Drug Revolving Fund management; improve governance and accountability; link to insurance schemes
Challenge 5: Lack of Transparency and Accountability in Pharmaceutical Procurement; policy emphasises transparency (p. 24) but does not detail mechanisms	Recommendation: Implement electronic procurement systems; publish medicine prices and procurement reports; establish procurement oversight committees
Challenge 6: Weak Human Resources for Health Financing and Pharmaceutical Management; "health financing personnel represent one of the most understaffed cadres" (p. 30)	Recommendation: Strengthen health financing workforce; train pharmaceutical managers in financial management; create career development pathways
Challenge 7: Donor Dependency and Fragmented Funding; external funding accounts for 46% of total health expenditure (p. 13); unpredictability and orphan programmes	Recommendation: Reduce donor dependency through domestic resource mobilisation; coordinate donor funding; align external funding with national priorities

Challenge 8: No Dedicated Fund for Primary Health Care Medicines; policy identifies need for dedicated fund to support primary health care, including medicines	Recommendation: Establish primary health care medicines fund; allocate specific budget for PHC medicines; improve supply chain for PHC facilities
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Table 5: Procurement Framework (The Gambia Public Procurement Act, 2022)

Challenge	Strategy/Recommendation
Challenge 1: No Pharmaceutical-Specific Procurement Expertise; no requirement for pharmacists/clinicians on procurement committees; Section 74 allows "any other person familiar with the substance" but not mandatory (p. 84)	Recommendation: Require pharmacist/clinician representation on health sector procurement committees; establish pharmaceutical procurement expertise requirements
Challenge 2: Weak Integration with Medicines Regulatory Oversight; no requirement that procured medicines be registered or pre-qualified; no GMP or WHO pre-qualification demonstration required; Section 32(4) does not specifically include regulatory approval	Recommendation: Require WHO pre-qualification or stringent regulatory authority approval for procured medicines; mandate GMP compliance; establish pre-qualification requirements
Challenge 3: Limited Transparency on Medicine Prices and Contract Details; Section 66(21) requires publication of contract price but not unit prices, volumes, or delivery schedules; Section 36 allows withholding information for commercial interests (p. 44)	Recommendation: Require publication of unit prices, volumes, and delivery schedules; limit commercial interest exceptions; establish public register of pharmaceutical procurement contracts
Challenge 4: No Specific Provisions for Disposal of Expired or Unusable Medicines; Part IX (Sections 86-91) general disposal provisions; Section 86(3) mentions expiry but procedures not detailed (p. 94)	Recommendation: Develop specific procedures for disposal of expired/damaged medicines; require environmentally sound destruction (incineration); prohibit sale or transfer of expired medicines
Challenge 5: No Requirement for Supply Chain Performance Monitoring; Section 97 holds heads personally responsible but no KPIs for stock-out rates, order fulfilment times, or expiry rates	Recommendation: Establish KPIs for supply chain performance; require regular reporting on stock-out rates, order fulfilment, and expiry rates; link performance to accountability
Challenge 6: Weak Protection for Whistleblowers in Procurement; prohibits corrupt practices (Section 24) and conflicts (Section 23) but no explicit protection for reporters of corruption	Recommendation: Include whistleblower protection in the Procurement Act; establish anonymous reporting mechanisms; protect whistleblowers from retaliation
Challenge 7: Domestic Preference May Limit Competition for Specialised Medicines; Section 33 allows domestic preference for local economic operators and marginalised groups (p. 41); could delay access for specialized/patented medicines	Recommendation: Limit domestic preference to non-specialised products; ensure access to specialised medicines through international procurement; balance local development with health needs

Challenge 8: Exemptions for Defence and Security May Be Misapplied; Section 21(2)(a) exempts defence/security procurement but specifically excludes general stores, uniforms, stationery, computers, standard vehicles (p. 26); could be stretched to medical supplies	Recommendation: Strictly limit defence exemption to genuine military requirements; ensure medical supplies for military health facilities follow normal procurement procedures
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Table 6: National Health Policy Framework (National Health Policy 2021-2030)

Challenge	Strategy/Recommendation
Challenge 1: Weak Health System Capacity; identified as a major barrier affecting pharmaceutical governance and healthcare delivery (Ministry of Health, 2021, pp. 78-80)	Recommendation: Strengthen health system capacity through institutional development; invest in pharmaceutical management infrastructure
Challenge 2: Inadequate Financing and Donor Dependency; insufficient domestic financing for medicines (Ministry of Health, 2021, pp. 78-80)	Recommendation: Increase domestic financing for medicines; reduce donor dependency; implement sustainable financing mechanisms
Challenge 3: Weak Coordination and Limited Regulatory Guidance; fragmented implementation and limited pharmaceutical regulatory guidance (Ministry of Health, 2021, pp. 78-80)	Recommendation: Strengthen regulatory guidance; improve coordination between health and procurement institutions; develop regulatory frameworks
Challenge 4: Human Resource Constraints and Information System Limitations; affecting pharmaceutical governance and healthcare delivery (Ministry of Health, 2021, pp. 78-80)	Recommendation: Develop human resource capacity; improve information systems; train pharmaceutical staff in management and governance
Challenge 5: Weak Regulatory Systems; strengthening medicine registration, pharmacovigilance, quality surveillance, regulatory inspections, and enforcement against counterfeit medicines required (Ministry of Health, 2021, pp. 80-82)	Recommendation: Strengthen medicine registration systems; improve pharmacovigilance; increase quality surveillance; enhance inspections; strengthen enforcement
Challenge 6: Limited Procurement Transparency; need for electronic procurement, regular audits, publication of reports, supplier evaluation (Ministry of Health, 2021, pp. 82-83)	Recommendation: Implement electronic procurement systems; conduct regular procurement audits; publish procurement reports; strengthen supplier evaluation
Challenge 7: Weak Supply Chain and Information Systems; need to expand LMIS coverage, improve forecasting, reduce stock-outs, strengthen warehousing, improve cold chain (Ministry of Health, 2021, pp. 83-86)	Recommendation: Expand LMIS coverage; improve stock forecasting; reduce stock-outs; strengthen warehousing; improve cold chain; integrate LMIS, HMIS, and IFMIS

Challenge 8: Limited M&E and Digital Health Systems; need to strengthen M&E systems and integrate digital health systems (Ministry of Health, 2021, pp. 83-86)	Recommendation: Strengthen M&E systems; integrate digital health systems; improve data collection and reporting; implement performance monitoring
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Table 7: Essential Medicines Framework (The Gambia National Essential Medicines List - Date Unknown)

Challenge	Strategy/Recommendation
Challenge 1: No Date or Revision Schedule; document does not indicate issue date or revision schedule; may include obsolete medicines (e.g., chloroquine listed on p. 13; artemisinin combinations now standard)	Recommendation: Establish regular revision schedule (every 2-3 years); ensure timely updates; remove obsolete medicines; add new essential medicines
Challenge 2: No Stratification by Level of Care; no differentiation between medicines for primary, secondary, or tertiary levels; leads to inappropriate stocking	Recommendation: Stratify EML by level of care; specify which medicines should be available at health posts, health centres, hospitals, and tertiary facilities
Challenge 3: No Standard Treatment Guidelines or Dosing Information; list includes strengths (e.g., "amoxicillin 250mg/500mg capsules") but no dosing schedules or indications; risk of misuse	Recommendation: Link EML to Standard Treatment Guidelines; include basic dosing information; develop clinical guidelines for each medicine.
Challenge 4: No Link to Procurement and Supply Chain Management; EML not linked to quantification, procurement planning, or stock monitoring systems; approved medicines may not be available	Recommendation: Link EML to quantification and procurement systems; use EML as basis for forecasting; integrate EML with CHANEL and supply chain systems
Challenge 5: No Transparency on Selection Criteria; document does not explain how medicines were chosen; reduces trust and accountability	Recommendation: Publish selection criteria for EML; establish transparent review process; include stakeholders in medicine selection
Challenge 6: No Inclusion of Quality Assurance Requirements; states medicines are "approved" but does not require WHO pre-qualification or SRA registration; room for substandard products	Recommendation: Require WHO pre-qualification or SRA approval for EML medicines; establish quality assurance criteria; include quality standards in procurement
Challenge 7: Potential Duplication or Outdated Entries; chloroquine 150mg base listed on p. 13 (not recommended for malaria treatment due to resistance; may be for other conditions); multiple forms of metronidazole listed; could be streamlined	Recommendation: Review and streamline EML; remove redundant entries; update based on current clinical evidence; include rationale for each medicine

Challenge 8: No Specific Category for Traceability and Pharmacovigilance; EML does not assign unique identifiers or reference national drug code; hinders tracking and adverse event reporting	Recommendation: Assign unique identifiers to EML medicines; link to pharmacovigilance system; implement national drug coding system
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Table 8: Financial Management Framework (Financial Regulations, 2016)

Challenge	Strategy/Recommendation
Challenge 1: No Specific Provisions for Pharmaceutical Stores and Inventory Management; Regulation 38 addresses government stores generally but not medicines, cold chain, expiry dates, batch tracking, or controlled substances; Regulation 2 (p. 5) is generic; Regulation 38(7) (p. 71) is only for unallocated stores; no mandatory periodic stock verification of medicines	Recommendation: Develop pharmaceutical-specific inventory regulations; mandate regular stock verification of all medicines; establish cold chain management requirements; implement batch tracking and expiry date management systems
Challenge 2: Cash Flow Delays Leading to Medicine Stock-Outs; Regulation 12(13) restricts cash allocations to availability of funds (p. 27); Regulation 13(1) prohibits expenditure without sufficient provision (p. 29); Regulation 26(30) requires payments by crossed cheque (p. 43) taking days to clear; Regulation 31(2) requires two signatures on cheques (p. 55)	Recommendation: Establish direct budgetary allocation for medicines; streamline payment processes for pharmaceutical suppliers; implement electronic payment systems; create pre-approved emergency procurement procedures
Challenge 3: Weak Linkage Between Budget Execution and Medicine Demand Forecasting; Regulation 4 requires strategic plans and cost activities (p. 14) but no integration of disease burden, consumption patterns, or epidemiological forecasts	Recommendation: Integrate disease burden and consumption data into budget formulation; link budget requests to epidemiological forecasts; align budgets with medicine demand
Challenge 4: Inadequate Accountability for Medicine Losses; Regulation 39 provides loss reporting and surcharge but does not address pharmaceutical losses (expiry, theft, spoilage, cold chain failure); no requirement for pharmacist inclusion in Losses Advisory Committee; Regulation 39(6) (p. 76) allows police investigation for theft, but many losses are due to negligence	Recommendation: Require pharmacist inclusion in Losses Advisory Committee; establish specific procedures for pharmaceutical losses; strengthen accountability for negligence; conduct regular loss investigations

Challenge 5: Limited Transparency in Pharmaceutical Expenditure; Regulations do not require public disclosure of medicine expenditure, unit prices, or supplier performance; Regulation 36 allows access to records on request (p. 67), but no proactive publication; Regulation 34(36) requires internal reporting not public	Recommendation: Require proactive publication of pharmaceutical expenditure; publish unit prices and supplier performance; establish public transparency mechanisms
Challenge 6: No Specific Rules for Donor-Funded Medicine Procurement; Regulation 30 addresses project accounts and external aid (pp. 53-55); requires Accountant General and Auditor General consultation (Regulation 30(7), p. 53) but no specific provisions for donor-funded medicines that may bypass normal controls	Recommendation: Establish specific rules for donor-funded medicines; ensure donor-funded medicines follow the same quality and accountability standards; strengthen controls for in-kind donations
Challenge 7: Insufficient Training and Qualification of Financial Staff in Health Facilities; Regulation 7(1)(a) requires appropriate accounting systems (p. 19); Regulation 33(8) requires frequent checks; no mandate for training on pharmaceutical financial management	Recommendation: Mandate pharmaceutical financial management training for health facility staff; develop training modules on handling impress, verifying cold chain invoices, and processing insurance claims
Challenge 8: No Integration with Health Information Systems; Financial Regulations do not mention integration with LMIS, HMIS, or IFMIS	Recommendation: Integrate financial management with health information systems; link financial tracking to medicine consumption data; implement electronic systems integration

Table 9: National Medicines Policy Framework (The National Medicines Policy 2022-2025)

Challenge	Strategy/Recommendation
Challenge 1: Legal and Regulatory Gaps; "Most of these Acts are old and have limited execution" (p. 16); overlaps in functions between MCA and Pharmacy Council (p. 16); "There is no AMR policy" (p. 16)	Recommendation: Review and revise current legislation (p. 16); digitise regulatory functions (p. 16); develop and implement national AMR policy; develop national guideline on Good Governance (p. 17)
Challenge 2: Human Resource Shortages; ratio of pharmaceutical staff critically low (p. 17); "The training of pharmacists is done abroad" (p. 17)	Recommendation: Develop and implement a five-year human resource development plan for the pharmaceutical sector (p. 17); develop a digital platform for continuing training (p. 17); establish local pharmacy training

Challenge 3: Inadequate Financing; government health expenditure decreased from 38.60% in 2016 to 30.6% in 2017 (p. 18); "Government contribution to procurement of medicines less than WHO threshold of US\$2.00 per capita" (p. 18)

Recommendation: Set up financing mechanisms for sustainable financing of health products, including cost recovery, domestic resource mobilisation, and National Health Insurance Scheme (p. 18)

Challenge 4: Weak Supply Chain and Logistics; "Inadequate storage capacity, inefficient security and non-existence of a risk management plan" (p. 24); "CHANEL is not interoperable" (p. 24); "Lack of utility vehicles at CMS to support pickup from ports" (p. 25)

Recommendation: Implement a national roadmap for digitalisation of stock management (p. 25); improve warehousing capacity for CMS (p. 24); improve the national distribution system with effective monitoring (p. 25)

Challenge 5: Poor Quality Control; "QC services are outsourced due to lack of a national medicines quality control testing laboratory" (p. 19)

Recommendation: Set up a functioning Quality Control Laboratory in cooperation with African Vision and other partners (p. 19)

Challenge 6: Insufficient Pharmacovigilance; "Monitoring and reporting on safety of medicines still a challenge" (p. 20); "No Poisons Centre" (p. 20); "Limited technical and financial resources" (p. 20)

Recommendation: Migrate to or adopt an e-pharmacovigilance system (p. 21); improve the pharmacovigilance risk management system (p. 21); establish a Poisons Centre

Challenge 7: Lack of Monitoring and Evaluation Capacity; "Since there is limited capacity at M&E Unit, there is need to outsource M&E activities to independent minds" (p. 33)

Recommendation: Improve M&E capacity to collaborate with stakeholders and undertake external assessment (p. 33); establish mechanism for external assessment (p. 33); create national multidisciplinary and multisectoral group for monitoring and evaluation (p. 39)

Challenge 8: Absence of Policies for Traditional Medicine; "Traditional medicines are not included on Essential Medicines List" (p. 28); "TM is not integrated in national health system, and no policy exists" (p. 28)

Recommendation: Improve traditional medicine regulatory system (p. 29); support development of traditional medicines policy (p. 29); integrate traditional medicine into health system

Challenge 9: Limited Innovation and Environmental Sustainability; need to use new technologies and promote digital transformation (pp. 30-32)

Recommendation: Use new technologies to optimise the pharmaceutical system (p. 30); promote digital transformation and environmental sustainability (p. 32)

Challenge 10: No Implementation Plan; policy notes need for a budgeted five-year implementation plan (pp. 38-39)

Recommendation: Ministry of Health pledges to develop a budgeted five-year implementation plan, mobilise internal and external resources, and create a communication and advocacy plan (pp. 38-39); National Pharmaceutical Services designated as lead implementing agency (p. 38)

Table 10: Medicines Regulatory Framework (The Medicines and Related Products Act, 2014)

Challenge	Strategy/Recommendation
Challenge 1: Limited Public Transparency in Decision-Making; publication of registration decisions in the Gazette is required (p. 22, §30(2)), but there is no public access to Board meeting minutes, inspection reports, or quality control laboratory reports (p. 32, §54)	Recommendation: Require proactive publication of Board meeting minutes and inspection reports; publish quarterly quality control laboratory reports; create public online repository for regulatory decisions
Challenge 2: Absence of Expedited Emergency Procurement Mechanisms; "exigency" defined (p. 6) but no fast-track registration, import, or distribution procedures for emergencies	Recommendation: Develop emergency procurement procedures; establish fast-track registration for emergency medicines; create emergency import and distribution mechanisms
Challenge 3: Weak Post-Market Safety Monitoring; relies on local representatives reporting adverse events (p. 29, §48); no direct patient reporting; no mandatory timelines; passive surveillance may miss significant safety signals	Recommendation: Implement direct patient adverse event reporting; establish mandatory timelines for reporting; strengthen pharmacovigilance system; create e-pharmacovigilance platform
Challenge 4: Potential for Under-Resourced Inspection and Enforcement; broad powers granted (p. 31, §51; p. 33-34, §57) but no minimum staffing levels or guaranteed funding; enforcement may be sporadic and ineffective	Recommendation: Set minimum staffing levels for inspectorate; guarantee funding for inspection activities; establish inspection performance standards; develop risk-based inspection planning
Challenge 5: No Independent Appeal Mechanism for Agency Decisions; applicants may make representations through the Executive Director within sixty days (p. 22, §29); the Executive Director is an Agency employee; no independent administrative appeals tribunal	Recommendation: Establish independent administrative appeals tribunal for Agency decisions; ensure impartial review process; create independent appeal mechanism
Challenge 6: Incomplete Coverage of Health Practitioners; "health practitioner" defined broadly (p. 6) but categories authorised to prescribe/supply medicines not detailed; ambiguity could lead to inconsistent practice	Recommendation: Clearly define categories of health practitioners authorised to prescribe and supply medicines; specify prescribing and supply rights; develop practice guidelines
Challenge 7: Limited Patient-Centered Provisions; Agency required to provide unbiased information and attend to complaints (p. 11, §4(k)(q)) but no mechanism for regular patient satisfaction surveys or incorporating patient feedback into regulatory decisions	Recommendation: Conduct regular patient satisfaction surveys; incorporate patient feedback into regulatory decisions; establish patient advisory committees; create patient complaint mechanism

Challenge 8: No Integration with Procurement Systems; Act does not link to procurement requirements for registered medicines	Recommendation: Link registration requirements to procurement; require registration for all procured medicines; integrate medicines registration with procurement systems
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Table 11: Pharmacy Regulation Framework (Pharmacy Council Act, 2014)

Challenge	Strategy/Recommendation
Challenge 1: Lack of Specified Meeting Frequency and Quorum for Council; unlike the MCA Act mandating meetings every two months with a quorum of seven, the Pharmacy Council Act does not specify meeting frequency or quorum (pp. 7-8, §4-5); could lead to irregular governance oversight and delayed decision-making.	Recommendation: Amend Act to specify minimum meeting frequency and quorum; establish regular meeting schedule; ensure consistent governance oversight
Challenge 2: Ministerial Appointment of Chairperson May Compromise Independence; Chairperson appointed by Minister rather than elected by profession (p. 7, §4(a)); potential for executive influence	Recommendation: Consider independent appointment mechanism; ensure professional representation; maintain regulatory independence
Challenge 3: Limited Appeal Mechanism for Disciplinary Decisions; dissatisfied persons may appeal only to the Minister of Health (p. 14, §20); no further appeal to an independent administrative tribunal or courts; may violate natural justice principles	Recommendation: Establish an appeal mechanism to an independent administrative tribunal; ensure the right to judicial review; maintain natural justice principles
Challenge 4: No Explicit Emergency or Remote Access Provisions; provides for drug store outlets in deprived communities (p. 15-16, §22) but no emergency supply chains or tele-pharmacy services; exigency provisions from MCA Act absent	Recommendation: Develop emergency supply chain provisions; establish tele-pharmacy guidelines; create regulatory framework for remote access
Challenge 5: Incomplete Integration with Medicines Control Agency; refers to "Agency" (MCA) for determining medicine ranges (p. 18, §29(2)(b)) and approving drug store outlet medicine lists (p. 18, §29(2)(d)) but no formal coordination mechanism; regulatory gaps or duplication possible	Recommendation: Establish formal coordination mechanism between Pharmacy Council and MCA; clarify roles and responsibilities; develop joint regulatory procedures
Challenge 6: No Continuing Professional Development (CPD) Enforcement Mechanism; Council mandated to establish CPD standards (p. 9, §6(1)) but no requirement for mandatory CPD for license renewal or penalties for non-compliance	Recommendation: Mandate CPD for license renewal; establish CPD compliance monitoring; develop penalties for non-compliance; create CPD tracking system
Challenge 7: Patient Feedback and Satisfaction Not Explicitly Addressed; Council must attend to consumer complaints (p. 8, §6(h)) but no requirement for systematic patient satisfaction measurement or use of data to improve pharmacy practice	

Discussion

The assessment of pharmaceutical governance in The Gambia demonstrates that the effectiveness of health service delivery is closely linked to the strength of medicine regulation, financing, procurement systems, supply chain management, professional capacity, and accountability mechanisms. The review of the Constitution of the Second Republic of The Gambia, 1997, General Orders, National Development Plan 2023–2027, National Health Financing Policy 2017–2030, National Health Policy 2021–2030, National Medicines Policy 2022–2025, Medicines and Related Products Act 2014, Pharmacy Council Act 2014, Public Procurement Act 2022, Financial Regulations 2016, and Essential Medicines List reveals several systemic challenges that influence medicine availability, quality, affordability, and patient safety.

One of the fundamental challenges identified is the absence of an explicit constitutional right to health and access to essential medicines. Although the Constitution provides protection of life and establishes principles related to public welfare, it does not recognise access to medicines as an enforceable entitlement. This creates limitations in holding institutions accountable for medicine shortages, inadequate pharmaceutical services, and inequitable access to treatment. The lack of a constitutional foundation for pharmaceutical governance means that medicine access depends largely on government policies, institutional performance, and available resources. Strengthening this area requires the development of stronger legal provisions that define government responsibility for essential medicines and establish clear accountability mechanisms for pharmaceutical service delivery.

The Medicines and Related Products Act 2014 provides mechanisms for medicines registration and inspection, but the most important challenges remain the issues of quality assurance, post-market surveillance, transparency and enforcement capacity. The testing and detection of substandard or falsified products is limited by the lack of a national medicines' quality control laboratory in The Gambia. The health system's ability to monitor and reduce medicine safety issues and adverse reactions is limited due to inefficient pharmacovigilance systems. Maintaining robust and strengthened regulatory governance requires investment in quality control infrastructure, enhanced and facilitated regulatory inspections, pharmacovigilance reporting systems and improved capacity of regulatory institutions, particularly in staff training and education. It must be acknowledged that the regulatory staff of either the Pharmacy Council or the Medicines Control Agency are even short of the minimum standard required by the personnel management of the civil service of The Gambia. Procurement governance is another major challenge affecting pharmaceutical performance. In The Gambia, the general procurement procedures of the Public Procurement Act 2022 do not provide sufficient pharmaceutical-specific requirements. It must be noted that medicine procurement involves technical considerations of therapeutic effectiveness, quality standards, storage requirements and regulatory compliance. The Procurement Act 2022 did not specify any representation of pharmaceutical personnel in the procurement committees, which increases the risk that procurement decisions are focused mainly on administrative and financial considerations rather than medicine quality and clinical appropriateness. In order to strengthen procurement governance, there must be a mandatory pharmaceutical representation and/or other relevant health professionals in the procurement process that will improve supplier evaluation systems, strengthen quality requirements for suppliers, and increased transparency in medicine procurement information.

In The Gambia, weak supply chain management further affects medicine availability and health service delivery. According to the National Development Plan 2023-2027 and the National Health Policy 2025, inadequate storage capacity, supply interruptions, weak logistics systems and limited inventory management capacity are significant barriers. Existing public service and financial regulations provide general guidance on government stores, but do not adequately address pharmaceutical-specific requirements such as batch tracking, expiry

monitoring, cold chain management, and medicines loss prevention. In order to improve the pharmaceutical supply chain system, an electronic logistics management information system is required to ensure regular stock monitoring, improved warehouse infrastructure for effective distribution systems and routine pharmaceutical audits.

The most important challenge hindering access to medicine is financial constraints, as highlighted by the National Health Financing Policy 2017-2030, which indicated low government financing for health, high out-of-pocket expenditure, weak risk pooling mechanisms, and dependence on external funding. These are major barriers that require attention for effective patient care as well as maximum sustainability of the medicine supply system. Without a sustainable medicine financing system, the health system will continue to struggle to ensure the availability of essential medicines. In this respect, domestic strategies are required to address this challenge for an improved social protection arrangement, ultimately leading to a dedicated financing mechanism for essential medicines, particularly at the primary health care level.

Moreover, human resource limitations also affect pharmaceutical governance. According to the National Medicines Policy 2025, the shortage of pharmaceutical personnel with limited local training opportunities coupled with inadequate technical capacity remains a major barrier to effective medicine management. These limitations affect regulatory activities, procurement, dispensing practices, pharmacovigilance and supply chain operations. Strengthening human resource capacity requires empowering staff with the requisite pharmacy education and competence in pharmaceutical management and regulatory functions.

Although existing frameworks provide mechanisms for reporting corruption and managing public resources, transparency, accountability and public participation remain important areas requiring improvement. There is limited or no, protection for individuals who report pharmaceutical-related misconduct, and weak access to information on medicine procurement, stock availability, supplier performance and regulatory decisions reduces public oversight and institutional accountability. Transparency may require stronger whistleblower protection mechanisms, routine publication of pharmaceutical information, improved audit systems, and effective complaint mechanisms for patients and health workers.

The essential medicines list guides approved medicines; limitations exist regarding revision schedules, linkages with procurement systems, treatment guidelines, medicine selection criteria, and traceability mechanisms. Challenges exist with regard to rational medicine selection and supply planning. Without regular updating and integration with the supply chain system, the essential medicines list may not fully support current health care needs. In essence, the pharmaceutical governance challenges in The Gambia are interconnected and require coordinated and comprehensive responses that improve medicine regulation, procurement systems, financing mechanisms, workforce capacity, information systems and institutional coordination.

Conclusion

This study set out to identify key challenges and propose strategies for strengthening pharmaceutical governance to improve health service delivery in The Gambia. The study revealed systematic challenges across constitutional, legislative, regulatory, administrative and operational frameworks that collectively influence the effectiveness of pharmaceutical governance and health services in The Gambia. The challenges in the pharmaceutical governance is rooted out from the constitutional foundation to operational implementations across the entire pharmaceutical system. At its core, the constitution does not establish a justiciable right to health or access to essential medicines.

The regulatory framework for pharmaceuticals, established primarily through the Medicines and Related Products Act 2014 and the Pharmacy Council Act 2014, demonstrates several gaps, which include limited public transparency in decision-making, no independent

appeal mechanism for agency decisions, incomplete coverage of health practitioners' prescribing and supply rights and no integration with the procurement system. The absence of a national medicines quality control laboratory further limits local capacity to test medicines and detect substandard or falsified products.

The Public Procurement Act, 2022 did not specify any mandatory requirement for pharmacist or clinician representation on the procurement committee. No requirement for supply chain performance monitoring and weak protection for whistleblowers in procurement. Both the National Development Plan and the National Medicines Policy 2022-2025 both identified inadequate storage conditions, supply interruptions amongst others. The non-interoperability of the logistics electronic network limits its effectiveness for supply chain management.

The National Health Financing Policy 2017-2030 highlighted persistent financial challenges with low government budget allocation to health, which is below the Abuja Declaration target of 15%. A recurring theme across the documents is the gap between policy intentions and implementation realities. The National Medicines Policy 2022–2025, for example, articulates comprehensive strategies for pharmaceutical governance but acknowledges implementation challenges. Similarly, the National Health Financing Policy sets ambitious targets but lacks detailed implementation provisions. This policy-implementation gap suggests that strengthening pharmaceutical governance requires not only good policies but also the institutional capacity, resources, and accountability mechanisms to implement them effectively.

Recommendations

Based on the findings of the documentary analysis, ten priority recommendations are proposed to strengthen pharmaceutical governance and improve medicine availability, quality, affordability, and patient safety in The Gambia.

1. Strengthen the legal and regulatory framework: The Government should review and update pharmaceutical legislation to address current governance gaps. The legal framework should strengthen the independence, authority, accountability, and enforcement capacity of the Medicines Control Agency and Pharmacy Council.
2. Improve medicine quality assurance and pharmacovigilance: The Medicines Control Agency should strengthen medicine registration, inspection, post-market surveillance, and adverse drug reaction reporting. A national medicines quality control laboratory should be established and adequately equipped.
3. Strengthen pharmaceutical procurement and transparency: Pharmaceutical procurement should involve qualified pharmacists and other relevant technical professionals.
4. Strengthen medicine supply chain and inventory management: The Ministry of Health should improve storage, distribution, stock management, and inventory control systems.
5. Increase sustainable financing for medicines: The government should increase domestic financing for health and establish predictable funding for essential medicines.
6. Strengthen pharmaceutical human resources: The pharmaceutical workforce should be expanded through improved recruitment, retention, training, and professional development.
7. Improve the Essential Medicines List and rational medicine use: The Essential Medicines List should be reviewed regularly and updated according to current disease patterns, treatment guidelines, and evidence.
8. Strengthen digital pharmaceutical information systems: The Ministry of Health should strengthen digital systems for medicine procurement, stock management, distribution, and reporting. Strengthen institutional coordination, transparency, and accountability

9. Clear roles should be established among the Ministry of Health, Medicines Control Agency, Pharmacy Council, Central Medical Stores, Gambia Public Procurement Authority, Ministry of Finance, and other relevant institutions.
10. Establish a comprehensive implementation and monitoring framework: The National Medicines Policy should be supported by a costed implementation plan with clear responsibilities, timelines, resources, and measurable indicators.

Authors' Contributions

Essa Camara, as the first author, conceptualised the study, developed the methodology, conducted the document review and data analysis, interpreted the findings, and prepared the initial manuscript. Michael Olabode Tomori, as co-author, contributed to the study design, reviewed and interpreted the findings, provided critical intellectual input, and critically revised the manuscript. Both authors reviewed and approved the final version of the manuscript and agreed to be accountable for the integrity and accuracy of the work.

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Conflict of Interest

The authors declare that they have no financial, professional, personal, or institutional conflicts of interest that could have influenced the design, analysis, interpretation, or reporting of this study. The study was based on the review and analysis of publicly available legal, policy, regulatory, planning, procurement, and financial documents, and no commercial interests influenced the findings or conclusions.

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