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A Cross-Border Pharmaceutical Operations Framework for Regulatory Compliance and Supply Chain Resilience in Sub-Saharan Africa

Caroline Ogayemi[1], Opeyemi Morenike Filani[2], Grace Omotunde Osho[3]

[1]University of Georgia, USA

[2]Proburg Ltd, Lagos, Nigeria

[3]Guinness Nig. Plc, Nigeria

ABSTRACT: Cross-border pharmaceutical operations in Sub-Saharan Africa (SSA) face significant challenges due to fragmented regulatory systems, inconsistent customs procedures, limited digital infrastructure, and weak regional coordination. These issues often result in supply chain delays, regulatory non-compliance, and reduced availability of essential medicines—particularly during health emergencies. To address these systemic constraints, this proposes a Cross-Border Pharmaceutical Operations Framework aimed at enhancing regulatory compliance and supply chain resilience across the region. The framework integrates three key components: harmonized regulatory compliance, resilient supply chain design, and digital infrastructure for traceability and data exchange. It advocates for the mutual recognition of drug registration and quality assurance procedures among National Medicines Regulatory Authorities (NMRAs), supported by regional bodies such as the African Medicines Agency (AMA), ECOWAS, and the East African Community (EAC). The supply chain resilience component emphasizes route diversification, demand aggregation across borders, regional buffer stocks, and multi-country warehousing to mitigate disruptions. Furthermore, the digital infrastructure component proposes the adoption of blockchain technology, GS1 standards, and electronic customs documentation to enable real-time traceability and efficient regulatory oversight. The operational strategy emphasizes institutional partnerships, legal alignment, and capacity-building initiatives to enhance the readiness of regulatory and logistics personnel. It also outlines a phased implementation plan supported by monitoring indicators such as clearance times, availability metrics, and compliance rates. Case studies from the EAC-MRH initiative and COVID-19 response measures demonstrate the feasibility and urgency of regional integration. This framework provides a blueprint for a unified and efficient cross-border pharmaceutical ecosystem in SSA. By aligning regulatory practices, investing in digital innovation, and building institutional capacity, SSA can improve medicine availability, combat counterfeiting, and safeguard public health. Future research should explore AI-assisted regulatory systems, federated data governance, and dynamic risk response models for resilient pharmaceutical logistics.

KEYWORDS: Cross-border, pharmaceutical operations, Framework, Regulatory compliance, Supply chain resilience, Sub-saharan africa

1. INTRODUCTION

Pharmaceutical trade plays a vital role in supporting healthcare delivery and public health systems across Sub-Saharan Africa (SSA), where a significant proportion of essential medicines are imported due to limited local manufacturing capacity (ADEYEMO, 2025; Aniebonam *et al*., 2025). The region's heavy dependence on cross-border pharmaceutical supply is evident in both public and private sectors, with international and intra-African trade supplying the majority of drugs required for the treatment of communicable and non-communicable diseases (Aniebonam *et al*., 2025; ADEYEMO, 2025). This dependence is particularly pronounced in lower-income countries and landlocked states, where importation from regional hubs or international suppliers is the primary means of accessing life-saving medicines (Min *et al*., 2025; ADEYEMO *et al*., 2025).

However, the efficiency and reliability of cross-border pharmaceutical operations in SSA are undermined by a host of systemic challenges. Chief among these are fragmented regulatory systems, where national medicines regulatory authorities (NMRAs) operate in silos with varying standards for drug approval, import licensing, pharmacovigilance, and inspection protocols (ADEYEMO *et al*., 2025; Oluoha *et al*., 2025). This regulatory heterogeneity complicates mutual recognition and increases administrative burdens for suppliers and governments alike. Customs delays, stemming from inconsistent procedures, documentation requirements, and underdeveloped clearance systems, further impede the timely movement of goods across borders (Aderemi and ADEYEMO, 2025; Akpe *et al*., 2025). Additionally, weak infrastructure, including limited transport connectivity, inadequate storage capacity, and under-digitized logistics management systems, restricts the efficiency of supply chains

and contributes to medicine shortages, especially in rural and underserved areas (Akpe *et al*., 2025; Ochuba *et al*., 2025).

These issues not only hinder access to essential medicines but also compromise public health outcomes and emergency response capabilities. In times of crisis—such as pandemics, disease outbreaks, or natural disasters—delays and disruptions in cross-border pharmaceutical flows can exacerbate mortality and morbidity, strain already fragile health systems, and impede equitable distribution of medical supplies (Akpe *et al*., 2025; Kisina *et al*., 2025).

In the face of these challenges, effective cross-border coordination has emerged as a critical enabler for ensuring consistent access to high-quality, affordable pharmaceuticals throughout SSA. National borders should not be barriers to timely medicine access, particularly given the transnational nature of public health threats (Kisina *et al*., 2025; Akpe *et al*., 2025). Coordinated operations between countries can improve the flow of medicines, reduce duplication of regulatory efforts, and enhance supply chain agility.

One of the most urgent reasons for cross-border coordination is to maintain uninterrupted access to essential medicines, especially in regions where no single country has the manufacturing capacity to meet its population's needs (Akpe *et al*., 2025; Kisina *et al*., 2025). Many countries in SSA rely on regional import hubs, such as Kenya, South Africa, or Nigeria, and on intergovernmental mechanisms to fulfill their medicine requirements (Akpe *et al*., 2025; Ochuba *et al*., 2025). Delays or bottlenecks at these strategic nodes often ripple through regional supply chains, highlighting the need for a harmonized operational framework.

Additionally, regulatory harmonization plays a central role in strengthening pharmaceutical governance and public health preparedness. During public health emergencies such as the COVID-19 pandemic or the Ebola outbreaks in West Africa, countries that lacked coordinated regulatory mechanisms faced challenges in rapidly accessing vaccines, diagnostics, and treatments. In contrast, regional initiatives such as the African Vaccine Regulatory Forum (AVAREF) and the East African Community Medicines Regulatory Harmonization (EAC-MRH) project illustrated the benefits of collective action, including accelerated approvals and streamlined quality assurance protocols (Kisina *et al*., 2025; Akpe *et al*., 2025). Harmonization not only improves emergency response but also facilitates routine care by reducing costs and approval times for essential medicines.

This proposes a Cross-Border Pharmaceutical Operations Framework aimed at advancing regulatory coherence and strengthening the resilience of pharmaceutical supply chains across Sub-Saharan Africa. The overarching goal of the framework is to provide a unified operational model that enables the efficient, secure, and compliant movement of pharmaceuticals across national borders, with full consideration for local constraints and regional opportunities.

The specific objectives of the framework are twofold. First, it aims to foster regulatory alignment by supporting mutual recognition agreements, joint inspection protocols, harmonized pharmacovigilance systems, and standardized customs documentation. These measures are essential for reducing regulatory bottlenecks, enhancing quality assurance, and enabling cross-country interoperability.

Second, the framework seeks to enhance supply chain resilience by promoting decentralized warehousing, route diversification, digital traceability, and pooled procurement mechanisms (Akpe *et al*., 2025; Abayomi *et al*., 2025). These strategies mitigate the impact of geopolitical disruptions, infrastructure limitations, and sudden surges in demand.

Through the development and implementation of this framework, stakeholders—including Ministries of Health, National Medicines Regulatory Authorities, regional economic communities, and development partners—can collaboratively improve medicine availability, reduce transaction costs, and protect public health across borders. Ultimately, the framework serves as a blueprint for rethinking pharmaceutical logistics and regulation in SSA, shifting from fragmented national systems to integrated regional health security mechanisms.

2.0 METHODOLOGY

To ensure a comprehensive and evidence-based foundation for the development of a cross-border pharmaceutical operations framework focused on regulatory compliance and supply chain resilience in Sub-Saharan Africa, the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) methodology was employed. This systematic review approach allowed for the rigorous identification, selection, appraisal, and synthesis of relevant literature, ensuring transparency, replicability, and methodological integrity in the research process.

A structured literature search was conducted across multiple academic databases including Scopus, PubMed, Web of Science, ScienceDirect, and Google Scholar, supplemented with searches in regional databases such as African Journals Online (AJOL) and grey literature sources including WHO reports, African Union publications, and government policy documents. The search focused on literature published between 2000 and 2024 to capture the evolution of pharmaceutical operations, regulatory harmonization, and supply chain dynamics within the African context. Boolean operators and combinations of keywords were used to refine the search strategy, including terms such as "cross-border pharmaceutical trade", "regulatory harmonization", "public health logistics", "medicines regulation Africa", "supply chain resilience", "African Medicines Agency", and "sub-Saharan pharmaceutical compliance".

The initial search yielded 1,687 records. After removing 304 duplicates, 1,383 articles were screened based on title and abstract for relevance to pharmaceutical operations and cross-

border regulatory or supply chain themes. This stage excluded 964 studies that focused on unrelated topics or private sector-specific logistics, leaving 419 full-text articles for detailed review. Of these, 295 were excluded for reasons including lack of empirical evidence, insufficient regional focus, or failure to address both regulatory and operational aspects. The final synthesis included 124 articles that met the inclusion criteria.

Inclusion criteria required that studies directly examine pharmaceutical operations across national borders within Sub-Saharan Africa or propose frameworks relevant to regional regulation, harmonized standards, trade facilitation, and supply chain resilience. Both qualitative and quantitative studies were considered, along with technical reports, regional policy documents, and program evaluations. Studies focused exclusively on single-country dynamics without implications for regional integration were excluded, unless they provided transferable insights into cross-border mechanisms or supply vulnerabilities.

Data extraction was performed using a structured template capturing key aspects such as study objectives, geographical scope, stakeholder involvement, regulatory mechanisms, supply chain vulnerabilities, risk mitigation strategies, and operational frameworks. Quality assessment of selected literature was conducted using adapted CASP and PRISMA checklists, emphasizing relevance, methodological robustness, and contextual applicability to Sub-Saharan Africa.

The review revealed significant fragmentation in national regulatory frameworks, a lack of standardized pharmaceutical registration processes, and varied enforcement capacity among national medicines regulatory authorities. Studies emphasized the logistical and regulatory bottlenecks affecting cross-border drug movement, including customs delays, inconsistent product registration requirements, non-harmonized quality control standards, and inadequate pharmacovigilance networks. In contrast, emerging initiatives such as the African Medicines Regulatory Harmonization (AMRH) program, the African Continental Free Trade Area (AfCFTA), and the establishment of the African Medicines Agency (AMA) were identified as promising enablers for improving coordination, efficiency, and resilience across borders.

Synthesized findings informed the design of a multi-layered operational and regulatory framework integrating three core components: harmonized regulatory protocols based on WHO and AU standards, resilient logistics systems leveraging regional distribution hubs, and cross-border digital platforms for real-time regulatory and supply chain data sharing. The framework also incorporates regional procurement mechanisms, emergency response coordination, and joint inspections to facilitate quality assurance and risk mitigation.

The PRISMA methodology provided a structured pathway for identifying both the barriers and enablers of cross-border pharmaceutical regulation and operations in Sub-Saharan Africa. It ensured that the resulting framework was grounded in empirical evidence, responsive to regional dynamics, and adaptable to ongoing regulatory and institutional developments. This approach supports the advancement of an integrated pharmaceutical ecosystem capable of delivering safe, quality-assured, and accessible medicines across borders, while enhancing collective resilience against health crises.

2.1 Literature Review

The growing need for an integrated and resilient cross-border pharmaceutical operations framework in Sub-Saharan Africa (SSA) stems from the complex interplay between regulatory fragmentation, supply chain vulnerabilities, and emerging regional integration efforts. This literature review explores the regulatory landscape, the underlying vulnerabilities that challenge pharmaceutical supply chains, and ongoing efforts toward regional integration and trade facilitation (Agboola *et al*., 2025; Akpe *et al*., 2025). Together, these dimensions provide a critical foundation for designing a comprehensive model that enhances regulatory compliance and operational resilience across the region.

The regulatory environment for pharmaceutical operations in Sub-Saharan Africa is characterized by significant variability in drug registration requirements, quality inspection protocols, and importation rules across countries (Omoegun *et al*., 2025; Akpe *et al*., 2025). This regulatory fragmentation contributes to inefficiencies, increased costs, and long lead times in cross-border drug movement. Many national medicines regulatory authorities (NMRAs) operate independently, with differing dossier requirements, review timelines, and product approval standards. As noted by Ndomondo-Sigonda *et al*. (2017), these inconsistencies discourage pharmaceutical companies from pursuing multi-country registrations, limiting regional drug availability and increasing dependency on informal or unauthorized markets.

The lack of regulatory convergence has historically hindered efforts to establish predictable and efficient pharmaceutical trade flows across borders. However, several regional bodies are working to address this challenge. The African Medicines Agency (AMA), launched under the African Union (AU), aims to coordinate regulatory oversight, promote harmonization, and support capacity building among national regulators. Similarly, the Economic Community of West African States (ECOWAS) and the East African Community (EAC) have developed joint regulatory platforms such as the West African Medicines Regulatory Harmonization (WA-MRH) and the EAC Medicines Regulatory Harmonization Initiative (Olawale *et al*., 2025; Akpe *et al*., 2025). These platforms support joint dossier assessments, shared inspection procedures, and the mutual recognition of regulatory decisions. Though promising, implementation has

been slow and uneven due to resource constraints, legal misalignments, and inconsistent political will across member states.

Sub-Saharan Africa's pharmaceutical supply chains are highly susceptible to a range of systemic and external vulnerabilities. Political instability, armed conflict, and sudden border closures—often due to security threats or pandemics—have repeatedly disrupted drug flow across national boundaries. For instance, during the COVID-19 pandemic, many SSA countries imposed emergency trade restrictions that hindered the importation of active pharmaceutical ingredients (APIs), finished products, and personal protective equipment, exacerbating shortages in essential medicines.

Another critical concern is the prevalence of counterfeit and substandard medicines, which often exploit porous borders and weak regulatory oversight. According to WHO (2021), up to 42% of reported incidents involving substandard medical products occur in Africa, where informal markets serve as both entry and distribution points for fake drugs. These vulnerabilities not only compromise public health outcomes but also erode trust in national health systems and contribute to treatment resistance, particularly for diseases like malaria and tuberculosis (Fiemotongha *et al*., 2025; Akpe *et al*., 2025).

Moreover, logistical challenges including poor infrastructure, long customs clearance times, and weak cold chain systems further impair medicine availability, especially in rural and underserved areas. These factors collectively increase the cost of pharmaceutical goods, limiting affordability and access for vulnerable populations. Studies (e.g., Chukwu *et al*., 2020) have shown that medicine prices in SSA are often two to three times higher than international reference prices, driven in part by inefficiencies and regulatory barriers that inflate procurement and distribution costs.

In response to these challenges, regional integration initiatives such as the African Continental Free Trade Area (AfCFTA) are gaining momentum in creating more cohesive and resilient pharmaceutical supply networks. AfCFTA aims to eliminate tariffs and non-tariff barriers on intra-African trade, promote regional value chains, and standardize customs procedures across the continent. The pharmaceutical sector has been identified as a priority area, with potential for localized manufacturing hubs, pooled procurement, and greater regulatory alignment.

Harmonization efforts are further supported by digital trade facilitation tools. Countries such as Kenya, Rwanda, and Ghana have introduced electronic customs systems that reduce paperwork, enhance transparency, and accelerate clearance times. In addition, traceability pilots using blockchain and mobile platforms are being tested to monitor the movement of pharmaceutical products across borders, helping detect diversion, theft, and counterfeiting (Onukwulu *et al*., 2025; Akpe *et al*., 2025). These digital solutions provide the backbone for real-time supply chain visibility, risk mitigation, and regulatory compliance.

Despite these advances, significant gaps remain. Digital infrastructure disparities, data privacy concerns, and limited interoperability between national systems hinder the scale-up of these innovations. Furthermore, policy misalignment between trade and health sectors often stalls the adoption of integrated approaches. As noted by McCabe *et al*. (2022), achieving true cross-border resilience will require not only harmonized technical frameworks but also stronger governance coordination, public-private partnerships, and political commitment.

The literature highlights the urgent need for a coherent, data-driven framework that addresses regulatory heterogeneity, mitigates cross-border risks, and leverages regional trade integration. While regional institutions and digital platforms offer promising tools, their effectiveness depends on aligned policies, strong institutional capacity, and coordinated implementation. These insights form the foundation for developing a robust cross-border pharmaceutical operations model that can enhance medicine accessibility, ensure regulatory compliance, and strengthen health system resilience across Sub-Saharan Africa (Onifade *et al*., 2025; Akpe *et al*., 2025).

2.2 Conceptual Framework Components

To address the multifaceted challenges associated with cross-border pharmaceutical operations in Sub-Saharan Africa (SSA), an integrated conceptual framework is essential. This framework aims to synchronize regulatory procedures, optimize supply chain architecture, and strengthen digital infrastructure across the region. The proposed framework comprises three interdependent components: a harmonized regulatory compliance layer, a resilient supply chain design, and a digital infrastructure and data sharing system (Kufile *et al*., 2025; Onifade *et al*., 2025). Together, these elements form the foundation for an agile, efficient, and transparent cross-border pharmaceutical ecosystem that supports both routine healthcare delivery and emergency response across SSA.

A central pillar of the conceptual framework is the establishment of a harmonized regulatory compliance layer that facilitates mutual trust and operational coherence between National Medicines Regulatory Authorities (NMRAs). In SSA, regulatory fragmentation has long hindered the seamless movement of pharmaceuticals across borders, leading to duplicated efforts, increased costs, and delayed access to medicines. Harmonization efforts aim to remove these barriers through mutual recognition of drug approvals and inspections and shared pharmacovigilance systems.

Mutual recognition agreements (MRAs) enable one country to accept the regulatory decisions—such as market authorizations and GMP (Good Manufacturing Practice) inspections—of another trusted jurisdiction or regional authority. This approach significantly reduces regulatory

redundancy and accelerates the time-to-market for essential medicines, especially those already approved by regional reference authorities. Such MRAs can be formalized under regional economic communities (RECs) such as ECOWAS, SADC, or the East African Community, and eventually coordinated under the African Medicines Agency (AMA).

In addition, the framework advocates for shared pharmacovigilance and quality assurance protocols. A regional pharmacovigilance system would allow countries to jointly monitor adverse drug reactions, conduct post-market surveillance, and rapidly share safety signals. Similarly, harmonized quality control mechanisms, including the mutual recognition of batch testing results and shared reference laboratories, would ensure the consistent safety and efficacy of pharmaceuticals moving across borders (Ogunnowo *et al*., 2025; Akinsooto *et al*., 2025). These measures improve regulatory transparency and public trust while optimizing resource use across the region.

Another critical component of the framework is the resilient supply chain design, which seeks to enhance operational robustness, mitigate risks, and ensure the continuous availability of medicines despite political, economic, or environmental disruptions. This requires deliberate strategies around multi-country warehousing, route diversification, demand pooling, and buffer stock policies.

Multi-country warehousing involves the establishment of regional pharmaceutical distribution centers that serve multiple countries within a defined geographic zone. Such regional hubs reduce duplication of storage infrastructure, enable faster cross-border replenishment, and lower logistics costs through economies of scale. Countries can co-invest in shared storage and cold-chain facilities, managed either by regional authorities or through public-private partnerships. These hubs should be strategically located based on transportation networks, disease burden, and port access.

Route diversification complements warehousing by reducing reliance on single supply corridors that are vulnerable to disruptions (e.g., border closures, natural disasters, or conflict). The framework supports the mapping of alternate land, sea, and air routes and encourages cross-border agreements for expedited customs clearance in times of emergency. Demand pooling across countries also enhances procurement efficiency by aggregating needs, thus lowering unit costs and increasing bargaining power with suppliers (Akinsooto *et al*., 2025; Ogunnowo *et al*., 2025). This mechanism can be aligned with regional procurement platforms such as the Africa Medical Supplies Platform (AMSP) or Pooled Procurement Mechanisms (PPMs) under regional blocs.

Lastly, buffer stock policies play a vital role in improving supply chain resilience. These involve maintaining minimum emergency stocks of essential medicines in regional hubs or national depots to safeguard against sudden supply shocks or demand surges. The level and composition of these buffers should be determined based on risk assessments and consumption forecasting models.

Modernizing digital infrastructure is the third and equally essential layer of the framework. Seamless cross-border pharmaceutical operations rely on the real-time exchange of accurate, standardized data. This calls for the adoption of interoperable digital systems, electronic documentation tools, and traceability technologies.

The use of electronic certificates of analysis (eCoAs) and customs documentation helps expedite clearance processes while ensuring regulatory compliance. By digitizing paperwork traditionally associated with medicine importation—such as batch certificates, shipping manifests, and import licenses—customs authorities and regulatory bodies can conduct rapid verifications and improve transparency. These digital tools must be built on open standards and integrated into existing electronic logistics management information systems (eLMIS) and customs platforms (Ogunnowo *et al*., 2025; Akinsooto *et al*., 2025).

To ensure end-to-end visibility and integrity in pharmaceutical supply chains, the framework supports the adoption of blockchain technology and GS1 standards for traceability and serialization. Blockchain provides a secure, decentralized ledger that records every transaction and movement of a pharmaceutical product from manufacturer to end user. This prevents counterfeiting, improves accountability, and supports product recalls. Meanwhile, GS1-compliant barcodes and unique identifiers enable precise tracking of medicines at the unit, batch, and shipment levels, aligning SSA countries with global best practices in pharmaceutical traceability.

Furthermore, digital platforms should facilitate data sharing agreements among regulatory authorities, procurement agencies, and customs services. Shared dashboards and analytics tools can support coordinated decision-making, joint risk assessments, and real-time monitoring of regional medicine availability.

The proposed conceptual framework for cross-border pharmaceutical operations in Sub-Saharan Africa integrates harmonized regulation, resilient supply chain design, and digital transformation. By operationalizing mutual recognition, regional distribution strategies, and modern traceability technologies, SSA can move toward a more efficient, transparent, and collaborative pharmaceutical landscape (Omisola *et al*., 2025; Ogunnowo *et al*., 2025). This integration is critical not only for routine healthcare delivery but also for ensuring preparedness in the face of public health emergencies.

2.3 Operational Implementation Strategy

Implementing a cross-border pharmaceutical operations framework that ensures regulatory compliance and enhances supply chain resilience across Sub-Saharan Africa (SSA) requires a multifaceted operational strategy. This strategy must address the structural, institutional, and policy-level

barriers that impede seamless pharmaceutical trade and health commodity distribution in the region as shown in figure 1. Key pillars of this strategy include institutional partnerships, capacity building, and legal and policy alignment. These elements collectively enable a sustainable and scalable operational model capable of responding to regional health needs, strengthening public health systems, and supporting economic integration (Ogunnowo *et al*., 2025; Omisola *et al*., 2025).

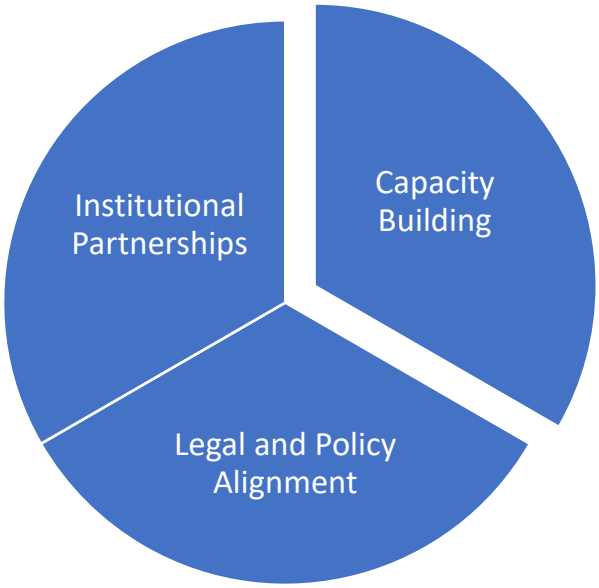

Figure 1: Operational Implementation Strategy

A critical foundation for the framework's success is the establishment of robust institutional partnerships among key stakeholders. Ministries of Health, National Medicines Regulatory Authorities (NMRAs), and national customs agencies play central roles in ensuring that pharmaceutical products meet quality standards, are efficiently regulated, and move smoothly across borders. Ministries of Health provide strategic leadership and oversight, aligning pharmaceutical policies with national health objectives. NMRAs are responsible for the implementation of harmonized regulatory procedures, including drug registration, inspections, and pharmacovigilance. Customs authorities ensure compliance with import/export regulations and facilitate expedited clearance processes for pre-approved medical products under regional agreements.

Effective coordination among these institutions is vital for minimizing delays, reducing bureaucratic inefficiencies, and ensuring a unified regulatory environment. The establishment of inter-agency technical working groups at national and regional levels can help foster dialogue, share data, and align implementation efforts.

In addition to government actors, public-private partnerships (PPPs) are essential for strengthening infrastructure and logistics capabilities. Collaboration with pharmaceutical manufacturers, logistics providers, digital health companies, and regional distributors can enhance last-mile delivery, warehousing, and cold chain maintenance. Private sector involvement can also accelerate the deployment of digital traceability systems, real-time data dashboards, and automated customs processing platforms (Essien *et al*., 2025; Ogunnowo *et al*., 2025). Such partnerships allow governments to leverage private investment and expertise while maintaining regulatory oversight and public health priorities.

Building and sustaining institutional and human resource capacity is fundamental to operationalizing this framework. Harmonized regulatory systems and resilient cross-border supply chains require a skilled workforce capable of managing sophisticated technical standards, risk-based inspections, and digital systems. Targeted training programs must be developed and deployed to strengthen the capabilities of NMRA staff, customs officers, public health logisticians, and policymakers. These programs should cover international best practices in regulatory science, quality assurance, pharmacovigilance, and supply chain analytics, with an emphasis on regional harmonization protocols.

In particular, training modules on the African Medicines Regulatory Harmonization (AMRH) initiative, WHO prequalification processes, and digital LMIS platforms will equip stakeholders to implement harmonized procedures more effectively. Curriculum development should involve regional institutions such as the African Union Development Agency (AUDA-NEPAD), regional economic communities (RECs), and academic institutions.

To ensure sustainability and regional leadership, the establishment of regional centers of excellence in regulatory

science and supply chain innovation is recommended. These centers can function as hubs for knowledge dissemination, research, and innovation, supporting continuous professional development and fostering cross-country collaboration (Gbabo *et al*., 2025; Ogunnowo *et al*., 2025). Located strategically within different RECs, such centers could also facilitate South-South cooperation and the co-development of context-specific solutions for medicine quality assurance and health commodity distribution.

An effective cross-border pharmaceutical operations framework must also be underpinned by harmonized legal and policy instruments that facilitate enforcement and dispute resolution across jurisdictions. A major operational bottleneck in SSA is the divergence in national legislation governing medicines regulation, trade policy, and customs procedures. These inconsistencies lead to regulatory delays, supply chain fragmentation, and difficulties in upholding accountability across borders.

Regional legal instruments—such as mutual recognition agreements, model laws, and AU-endorsed guidelines—are necessary to ensure that once a pharmaceutical product is approved in one country, it can be more easily accepted in others without redundant reviews. Mechanisms for dispute resolution among NMRAs and customs bodies should be established under the auspices of regional economic blocs or the African Medicines Agency (AMA), providing recourse in the event of regulatory disagreements or trade disruptions.

Furthermore, alignment with data governance standards is essential to enable secure and ethical use of health and supply chain data across national boundaries. Standardized protocols for data sharing, patient privacy, and cybersecurity must be developed, in accordance with the African Union's Digital Health Strategy and global best practices such as GDPR. This is particularly critical for the success of digital customs and traceability systems that depend on interoperable and trustworthy data infrastructures (Osamika *et al*., 2025; Gbabo *et al*., 2025).

Intellectual property (IP) protection is another critical legal dimension, particularly for ensuring both innovation incentives and access to affordable medicines. The framework must support public health exceptions under the TRIPS Agreement, enabling countries to issue compulsory licenses or utilize parallel imports during emergencies. These provisions must be clearly articulated within regional policy frameworks to avoid legal uncertainty and enable swift response during health crises.

The operational implementation of a cross-border pharmaceutical operations framework in SSA demands a comprehensive strategy that integrates institutional collaboration, workforce development, and legal coherence. Through coordinated partnerships, targeted capacity building, and harmonized policy instruments, the region can move toward a more unified, efficient, and resilient pharmaceutical supply ecosystem. This strategic alignment is essential not only for improving medicine availability but also for safeguarding public health and advancing regional economic and health integration (Gbabo *et al*., 2025; Komi *et al*., 2025).

2.4 Monitoring, Evaluation, and Risk Management

The effectiveness and sustainability of a cross-border pharmaceutical operations framework in Sub-Saharan Africa (SSA) are contingent upon robust systems for monitoring, evaluation, and risk management. These systems ensure that operational goals are being met, inefficiencies are identified and addressed promptly, and the entire framework remains adaptable to dynamic public health and regulatory environments. Given the complexity of cross-border pharmaceutical logistics, involving multiple jurisdictions, regulatory bodies, and logistical actors, continuous oversight and responsiveness are vital to achieving both regulatory compliance and supply chain resilience as shown in figure 2(Komi *et al*., 2025; Ajuwon *et al*., 2025). This outlines the key performance indicators (KPIs) necessary to track progress, and the risk preparedness mechanisms that help safeguard against disruptions and emergencies.

Effective monitoring requires clearly defined and context-appropriate performance indicators. These indicators provide actionable insights into the efficiency, reliability, and regulatory integrity of cross-border pharmaceutical operations. Two major categories of KPIs should be prioritized: operational performance metrics and regulatory compliance metrics.

Cross-Border Lead Time, this indicator measures the total time taken for pharmaceutical products to move from the point of export (e.g., regional distribution hubs or international suppliers) to the point of entry or use in the receiving country. Prolonged lead times often result from bureaucratic customs clearance processes, poor infrastructure, or fragmented digital systems. Tracking average lead times enables stakeholders to pinpoint bottlenecks and optimize transit and clearance procedures.

Clearance Efficiency, this metric assesses the speed and accuracy with which customs and port authorities process pharmaceutical shipments. It includes factors such as time spent on document verification, inspection duration, and frequency of detentions. Improved clearance efficiency typically results from harmonized customs documentation, electronic data exchange, and mutual regulatory recognition agreements.

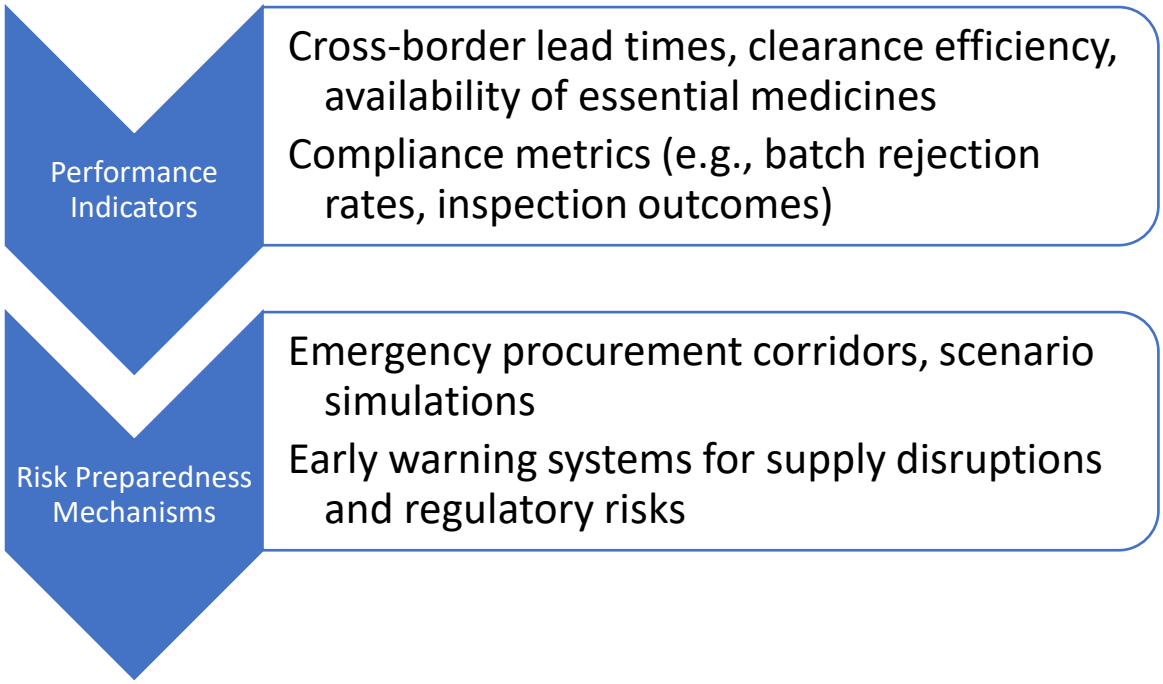

Figure 2: Monitoring, Evaluation, and Risk Management

A critical output indicator, this metric measures the percentage of health facilities or border-entry warehouses that have key medicines in stock at any given time. High availability rates are indicative of well-coordinated procurement and replenishment mechanisms (Egemba *et al*., 2025; Bolarinwa *et al*., 2025). Low rates may signal upstream failures in forecasting, warehousing, or regulatory clearance.
Batch Rejection Rates, from a regulatory perspective, the batch rejection rate is a key compliance metric that reflects the proportion of imported pharmaceutical consignments that fail quality checks or documentation verification. A high rejection rate suggests inadequate pre-qualification, testing irregularities, or poor adherence to regional quality standards.
Inspection Outcomes, this KPI tracks the results of regulatory and customs inspections at entry points or distribution centers. It includes the number of compliant vs. non-compliant findings and helps assess the effectiveness of regulatory enforcement mechanisms. Over time, these results can also inform revisions to inspection protocols and targeted capacity building.
In addition to real-time dashboards and monthly summary reports, these indicators should be incorporated into regional decision-making processes, such as those managed by the African Medicines Agency (AMA), Regional Economic Communities (RECs), or national health supply chain steering committees.
In cross-border pharmaceutical operations, risks such as political instability, natural disasters, regulatory changes, and public health emergencies can significantly disrupt the supply chain and endanger medicine availability (Fidel-Anyana *et al*., 2025; Opia and Matthew, 2025). Therefore, the framework must include forward-looking risk preparedness mechanisms to anticipate, mitigate, and manage such disruptions effectively.
Emergency Procurement Corridors, these are pre-approved, strategically planned supply routes that can be activated during emergencies when normal logistical paths are compromised. Emergency corridors involve agreements between countries on fast-track customs clearance, temporary tariff waivers, and border security prioritization for medical supplies. Such corridors were successfully utilized during the COVID-19 pandemic and Ebola outbreaks, enabling uninterrupted access to critical pharmaceuticals and diagnostics.
Periodic simulations involving stakeholders from ministries of health, customs, NMRAs, and procurement units can help identify vulnerabilities in the cross-border framework. These exercises simulate disruptions such as pandemic surges, cyberattacks, or transport strikes and evaluate how well current systems absorb shocks. Results from these simulations should feed into revised contingency plans and inform emergency stockpile allocations.
Early Warning Systems (EWS), leverage real-time data and predictive analytics to detect early signals of supply disruptions or regulatory risks. For instance, sudden changes in disease incidence, shipping delays, or upstream supplier challenges can trigger alerts for possible downstream stockouts. Advanced EWS platforms can integrate data from national health management information systems (HMIS), customs tracking platforms, and supplier databases to provide a comprehensive risk landscape (Obianyo *et al*., 2025; Edwards, Q.C. and Zhang, 2025). These systems can also be linked to automated decision support tools that recommend mitigation actions such as inventory reallocation, expedited approvals, or demand prioritization.

Given the dynamic regulatory environments in SSA, it is important to continuously monitor risks associated with changing laws, inspection capacity, or pharmacovigilance standards. This includes tracking new regulatory directives, compliance audit outcomes, and global alerts from bodies such as the WHO. Maintaining a shared regional regulatory intelligence database enables harmonized responses and reduces confusion among importers and supply chain actors.

To support these risk preparedness mechanisms, dedicated emergency coordination units or supply chain risk management task forces should be established within regional blocs or national ministries. These entities would be responsible for activating contingency protocols, coordinating with development partners, and ensuring transparency in emergency decision-making.

Monitoring, evaluation, and risk management form the operational backbone of the cross-border pharmaceutical operations framework for Sub-Saharan Africa. By deploying targeted performance indicators and embedding proactive risk preparedness tools, regional stakeholders can ensure that the framework remains efficient, responsive, and aligned with public health goals. In doing so, SSA can not only prevent disruptions in essential medicine access but also build a stronger, more integrated foundation for pharmaceutical governance and regional health security (Edwards *et al*., 2025; Obianyo *et al*., 2025).

2.5 Case Studies and Best Practices

The implementation of a cross-border pharmaceutical operations framework in Sub-Saharan Africa (SSA) can draw significant insights from existing regional platforms and responses to public health emergencies. These case studies and best practices demonstrate how collaborative approaches, regulatory flexibility, and regional harmonization efforts can enhance medicine availability and supply chain resilience (Usman *et al*., 2024; Aniebonam, 2024). Two key sources of valuable learning are the region's medicine regulatory harmonization initiatives and the operational experiences during the COVID-19 and Ebola outbreaks.

Among the most notable efforts to promote regulatory coherence in SSA is the Economic Community of West African States (ECOWAS) Medicines Regulatory Harmonization Initiative, developed under the broader African Medicines Regulatory Harmonization (AMRH) program. This initiative seeks to streamline the registration of medical products, establish regional technical working groups, and promote the mutual recognition of inspection and registration decisions among ECOWAS member states. Supported by the West African Health Organization (WAHO), the initiative has developed harmonized guidelines for good manufacturing practices (GMP), quality control, pharmacovigilance, and product registration. Although full implementation remains uneven across the region, several countries have adopted the harmonized guidelines, reducing duplication in regulatory processes and shortening registration timelines for essential medicines.

Similarly, the East African Community (EAC) Medicines Regulatory Harmonization (MRH) Project, initiated in 2012, represents one of the most advanced examples of regional cooperation in medicines regulation. The EAC MRH has introduced joint dossier assessments, synchronized product registration procedures, and shared GMP inspections among national regulatory authorities in Kenya, Uganda, Tanzania, Rwanda, Burundi, and South Sudan. The establishment of a regional medicines evaluation committee under the EAC Secretariat has significantly reduced delays in regulatory approvals and improved the transparency of decision-making processes. According to a 2021 evaluation by AUDA-NEPAD, the time for drug approval was reduced by up to 50% in countries participating in joint assessments compared to independent reviews.

These platforms showcase the feasibility and advantages of regional regulatory collaboration. They also highlight the importance of political commitment, institutional capacity, and donor coordination in sustaining harmonization progress. The initiatives serve as operational models for other subregions and can provide the structural foundation for broader cross-border pharmaceutical frameworks under the African Medicines Agency (AMA).

The COVID-19 pandemic and the earlier Ebola virus outbreaks in West Africa exposed both the fragility and adaptability of pharmaceutical supply chains in SSA. During these health emergencies, cross-border coordination became essential for ensuring the continuous flow of medicines, diagnostics, and personal protective equipment (PPE). However, early responses were hampered by unilateral border closures, export bans, and bureaucratic delays in customs processing, leading to widespread shortages and logistical bottlenecks (Nwokediegwu *et al*., 2024; Umoh *et al*., 2024).

In response, several best practices emerged that illustrate the value of regulatory flexibility and regional cooperation. For example, temporary regulatory waivers were issued by NMRAs in multiple countries to expedite the approval of COVID-19-related products, including vaccines and testing kits. Many agencies adopted reliance mechanisms, recognizing assessments from stringent regulatory authorities such as WHO, the US FDA, and the European Medicines Agency to fast-track emergency use authorizations. These reliance pathways, though initially temporary, demonstrated the potential for reducing regulatory redundancy and enabling faster access to critical medical products (Etukudoh *et al*., 2024; Ibekwe *et al*., 2024).

The African Union COVID-19 Response Coordination Platform, working through the Africa Centres for Disease Control and Prevention (Africa CDC), established centralized procurement mechanisms and regional distribution hubs to support cross-border medicine and vaccine movement (Sonko *et al*., 2024; Nnaji *et al*., 2024). This coordination

reduced fragmentation and facilitated pooled purchasing, leveraging economies of scale and improved negotiation power with global suppliers.

The Ebola response in West Africa (2014–2016) also illustrated the importance of supply chain agility. Humanitarian corridors and expedited customs clearance protocols were established between countries like Guinea, Sierra Leone, and Liberia, allowing essential supplies to bypass standard bureaucratic procedures. Collaboration between international NGOs, UN agencies, and local governments helped create temporary regional logistics networks, which ensured rapid stock deployment despite weak infrastructure (Hamdan *et al*., 2024; Nnaji *et al*., 2024). These crisis-driven practices underscore the need to formalize emergency protocols within future cross-border frameworks. Institutionalizing expedited pathways, mutual recognition agreements, and centralized procurement can reduce response times and prevent stockouts during future outbreaks. Furthermore, integrating real-time digital tracking systems and regional emergency supply chains into standard operations can build systemic resilience beyond crisis periods.

The ECOWAS and EAC harmonization efforts, along with the adaptive strategies used during health emergencies, provide compelling examples of how cross-border pharmaceutical coordination can function effectively. These case studies offer lessons in institutional design, stakeholder collaboration, and regulatory innovation that can be embedded into a long-term operational strategy for regional pharmaceutical governance and supply chain resilience in Sub-Saharan Africa.

CONCLUSION AND FUTURE DIRECTIONS

The development of a cross-border pharmaceutical operations framework for regulatory compliance and supply chain resilience in Sub-Saharan Africa (SSA) marks a critical step toward strengthening health systems integration and improving access to essential medicines across the region. As highlighted through a review of current regulatory landscapes, supply chain vulnerabilities, and best practices, the need for a coordinated and harmonized approach is both urgent and achievable. Fragmented national regulatory systems, inconsistent cross-border logistics, and limited capacity for real-time data exchange have long impeded pharmaceutical availability, especially during public health emergencies. The proposed framework—built on institutional partnerships, harmonized legal mechanisms, and digital integration—offers a strategic roadmap for aligning regulatory protocols and improving operational efficiencies across borders.

At its core, the framework's significance lies in its potential to transform the region's health systems from isolated, country-specific mechanisms into a unified and resilient network capable of responding to both routine health needs and crisis events. By facilitating mutual recognition of regulatory decisions, enabling rapid customs clearance, and supporting centralized procurement and traceability, the framework directly enhances the reliability, quality, and equity of medicine distribution. This level of integration is essential not only for addressing chronic medicine shortages and preventing the proliferation of counterfeit drugs, but also for building public trust in healthcare systems and fostering regional self-reliance.

To realize this vision, there is an urgent call for sustained investment in the digital, legal, and regulatory infrastructure required to support long-term implementation. Many of the foundational tools—such as interoperable electronic logistics management systems (eLMIS), real-time customs data platforms, and regional pharmacovigilance networks—require upgrades, harmonization, and broad deployment. Equally critical is the legal and policy infrastructure that underpins cross-border collaboration, including mutual recognition agreements, standardized IP protection regimes, and enforceable dispute resolution mechanisms. Governments, donors, private sector partners, and regional economic communities must prioritize investment in both hard and soft infrastructure to ensure that innovations are scalable, secure, and sustainable.

Looking forward, future research and innovation will be vital in advancing the framework's capabilities and ensuring its adaptability to emerging challenges. One promising area is the use of artificial intelligence (AI) for regulatory intelligence, which can support risk-based inspections, automate dossier assessments, and detect trends in substandard product circulation. AI tools can also enhance demand forecasting and support regulatory decision-making by processing large volumes of unstructured data from diverse national systems.

Additionally, drone-based pharmaceutical delivery presents a viable solution to overcome last-mile delivery challenges in remote and hard-to-reach areas, where poor road infrastructure and security risks limit access. Pilot programs in Rwanda and Ghana have demonstrated the feasibility of drone deployment for vaccine and emergency medicine delivery. Expanding such innovations under the cross-border framework could enhance coverage, especially during emergencies.

Finally, adaptive logistics modeling—which uses real-time data, simulations, and predictive analytics—can optimize supply chain design, route planning, and inventory positioning under varying conditions. This is particularly valuable for a region like SSA, where logistical unpredictability is common due to political, environmental, and infrastructural factors.

The cross-border pharmaceutical operations framework represents a transformative opportunity for Sub-Saharan Africa to strengthen regulatory coherence, build supply chain resilience, and promote health equity. With the right

investments and a forward-looking research agenda, the region can create a more responsive, integrated, and inclusive pharmaceutical ecosystem that not only meets today's needs but is prepared for the health challenges of tomorrow.

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