

## Medicines Regulation and Public Procurement in Africa: Assessing Governance, Transparency, and Implementation Across Five Countries

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### Abstract

The prevalence of substandard and falsified medications in Africa poses a critical risk to public health. Within African nations, entry to high-quality healthcare commodities is largely dictated by two principal national entities: the regulatory authority and the procurement body. While the significance of national regulators in maintaining the integrity of medical supplies is well established, the interplay between these regulators and national procurement bodies also exerts a powerful, yet less understood, influence on the accessibility of medicine. This investigation aimed to delineate the regulatory-procurement interface—defined as the convergence of decision-making across these two domains—by examining publicly available data from five African nations. For the five selected countries, criteria from the WHO's 2018 Pharmaceutical System Transparency and Accountability Assessment Tool were modified to distinguish core national policies and structural frameworks operating at the intersection of pharmaceutical regulation and acquisition. Although statutory and policy frameworks designed to facilitate optimal procurement benchmarks were frequently established, the practical execution and enforcement of these protocols represent vital targets for optimization. Furthermore, the analysis revealed a lack of publicly accessible data on the precise weights assigned to quality parameters during product selection. Ultimately, none of the five examined nations routinely publish their procurement choices alongside granular product descriptions, creating barriers to verifying whether fundamental quality metrics are satisfied. In light of these observations, a paramount next step to enhance the efficacy and transparency of national purchasing systems is for procurement bodies to disclose comprehensive quality benchmarks and maintain an updated ledger of acquired medical products, including key descriptions. It is anticipated that these observations will enrich the discourse surrounding the execution and enforcement of optimal protocols at the regulatory-procurement interface, ultimately advancing access to high-quality therapeutic products within Africa and on a global scale.

**Keywords:** National procurement agency, National regulatory authority, Substandard and falsified medicines, Regulatory-procurement interface, Pharmaceutical system transparency and accountability assessment tool, Access to medicines

### Introduction

Securing the availability of safe, effective, and high-quality pharmaceuticals is fundamental to Sustainable Development Goal (SDG) 3, which seeks to 'ensure

healthy lives and promote well-being for all' [1], and resonates with the African Union's Agenda 2063 objective of cultivating healthy and well-nourished populations [2]. This objective is likewise an indispensable element of the health systems strengthening required to realize universal health coverage—a core strategic focus for the World Health Organization (WHO) and numerous nations globally [3-5]. Regrettably, barriers to obtaining quality-assured medical supplies remain a major impediment to achieving these milestones. Substandard and falsified

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(SF) pharmaceutical variants represent a substantial factor exacerbating this issue [6].

The presence of SF medications across Africa has long compromised public health safety. On a global scale, the prevalence of SF pharmaceuticals is estimated at approximately 10% [6]. Crucially, a specific evaluation noted that 35% of antimalarial agents sampled in sub-Saharan Africa failed laboratory chemical analyses [7]. Similarly, an assessment of oxytocin—a critical therapeutic agent used for labor induction and the mitigation of postpartum hemorrhage—indicated that approximately 40% of regional African samples did not meet quality benchmarks [8]. In alignment with these observations, the WHO has reported that 42% of all international notifications concerning SF pharmaceuticals originate from the African continent [9]. The gravity of this issue is starkly illustrated by the recent fatal poisonings linked to contaminated cough syrups containing diethylene glycol. This incident claimed the lives of 66 children in Gambia [10].

In the majority of African states, the distribution and availability of quality-assured medical commodities are managed by two primary national instruments: the national regulatory authority (NRA) and the central national procurement body. Historically, international and regional initiatives designed to scale up access to reliable medical products have prioritized capacity-building for NRAs [11-13]. Nevertheless, national procurement structures are equally vital in securing reliable therapeutics. Optimally, a state's regulatory and purchasing agencies would maintain a coordinated relationship to ensure the public receives commodities that conform to global benchmarks for safety, efficacy, and manufacturing standards. In practice, however, establishing seamless synergy between regulatory bodies and procurement systems within low- and middle-income countries (LMICs) remains problematic [14]. Regulatory structures typically function under national Medicines Regulatory Acts and Regulations, whereas purchasing systems operate under separate Public Procurement Acts and Regulations. These parallel legislative frameworks are rarely engineered to encourage systematic alignment or cooperative action. Compounding this challenge, many logistics and procurement personnel within Africa lack specialized professional training in pharmaceutical supply chain management [15, 16].

Additional factors further compound the obstacles regulatory and purchasing authorities face when

collaborating to ensure the availability of high-quality health commodities. Market surveillance becomes highly problematic when a regulator faces constraints regarding fiscal backing, statutory mandates, personnel, and related logistical variables, a scenario common across the African continent [11]. For instance, financial and workforce deficiencies can prevent a country's NRA from adequately evaluating the caliber of pharmaceuticals acquired for public medical centers or licensed retail pharmacies [17, 18]. This deficiency can isolate the central purchasing authority from a crucial data stream regarding product integrity, a vulnerability that is magnified if the purchasing organization itself lacks a robust quality assurance architecture [16, 19,].

An additional systemic vulnerability is the tendency of national purchasing bodies in LMICs to prioritize financial costs over other variables [20]. This dynamic risks driving premium-quality therapeutics out of the commercial landscape, given that their production entails greater capital expenditure [16, 21]. Lastly, international purchasing initiatives (such as the Global Fund) generally supplement central domestic procurement bodies via financial subsidies or direct product acquisition. Their quality benchmarks for supply distribution necessitate endorsement by a stringent regulatory authority or WHO prequalification [22]; however, WHO prequalification protocols apply exclusively to specific therapeutic categories (including medications for HIV, tuberculosis, malaria, and reproductive health), and the scale of domestic support offered by international donor structures varies substantially.

We define the intersection of operational choices between central regulatory and purchasing bodies as 'the regulatory-procurement interface.' Although this point of convergence represents a major potential vulnerability within LMIC healthcare architectures, it remains under-documented across both peer-reviewed and grey literature published by global health investigators, practitioners, and development groups [16]. This deficit in research and operational advancement may stem, in part, from the reality that the regulatory-procurement interface operates at the nexus of public health goals and commercial forces, with the latter occasionally exerting undue influence over state legislation and operational protocols [14, 23, 24]. Fragile statutory frameworks and policy configurations can further compound these issues [14, 20, 24]. Consequently, the structural conflicts of interest and deficits in openness endemic to this interface

function as both a manifestation and a driver of the barriers to securing quality-assured therapeutic channels. Resolving the data deficit surrounding the regulatory-procurement interface is imperative for multiple reasons. It is foundational to achieving SDG 3 and securing a population's access to high-quality essential therapeutics. It is equally urgent because international assistance initiatives that currently supply quality-assured pharmaceuticals are winding down operations in numerous LMICs to promote domestic self-reliance [16, 25]. Furthermore, multiple African states are pledging alignment with universal health coverage objectives, a transition in which expanded public institutional purchasing is anticipated to serve as a cornerstone [20]. To investigate the dynamics of the regulatory-procurement interface in Africa, this inquiry used publicly accessible documentation to assess the core structural features of national regulatory and procurement bodies across five countries, selected to reflect a diverse cross-section of sub-Saharan African nations. We adapted parameters from the WHO's Pharmaceutical System Transparency and Accountability Assessment Tool to map critical domestic frameworks and operational behaviors governing the convergence of pharmaceutical regulation and supply acquisition [26]. Through this analysis, we outline the current operational state of this interface in African nations to support the broader objective of expanding access to quality-assured medicines.

## Materials and Methods

### *Study design*

In this investigation, we evaluated publicly accessible documentation concerning state-level purchasing across five African countries. These nations were chosen to encapsulate a broad spectrum of structural features: they span West, East, and Southern Africa; encompass both geographically small and large jurisdictions; exhibit income classifications ranging from low to upper-middle tiers; and include two nations whose NRAs have achieved Maturity Level 3 status under the WHO's Global Benchmarking Tool [11]. To avoid the perception of targeting specific states, the five countries were anonymized in our data presentation, as identifying them by name is not required to interpret the broader implications of our observations.

Our investigation targeted specific regulatory and procurement metrics derived from an internationally

validated diagnostic instrument—the WHO's Pharmaceutical System Transparency and Accountability Assessment Tool [26]—and was supplemented by several parameters developed expressly for this research. The WHO's Pharmaceutical System Transparency and Accountability Assessment Tool is designed to assess public access to baseline documentation that underpins openness and institutional accountability within the pharmaceutical sector. Developed originally in 2009 for the WHO Good Governance for Medicines Programme, the framework was refined in 2018, incorporating insights from Member States. By 2018, its diagnostic methodology had been deployed across 37 nations [27]. To evaluate compliance with the chosen metrics, we conducted a desk review of publicly accessible records for each target state, mirroring the current operational guidelines for the instrument.

### *Indicators*

This research utilized 22 distinct metrics drawn from the WHO's Pharmaceutical System Transparency and Accountability Assessment Tool. The selection encompassed every available metric across two core functional areas: public procurement (\$n = 19\$) and regulatory registration (\$n = 3\$). Within each functional area, these metrics were categorized into three operational dimensions. The first dimension, standards and commitments, covers legislative frameworks, regulations, operational guidelines, standard operating procedures, and policy mandates. The second, decisions and results, tracks committee outcomes, conflict-of-interest disclosures, policy implementation, and auditing records. The final dimension, consequences and responsive actions, monitors the resolution of formal grievances, appellate decisions, documented corrective strategies, and registries of blacklisted vendors [26].

To capture more nuanced data at the intersection of regulation and purchasing, we developed and integrated several supplementary sub-criteria into the primary tool. For instance, to evaluate how heavily product quality influences purchasing choices, we revised a specific standards-and-commitments metric within the procurement track. The original phrasing—"a list/database of prices of winning contracts"—was updated to "a list/database of purchased medicines (molecule, dose, formulation, manufacturer, volume, price, timeframe)" to align with recognized industry benchmarks [28]. We also introduced an entirely new

procurement metric: “published selection algorithm that includes product quality as a major factor.” Furthermore, to better map the regulatory-procurement interface, two novel registration metrics were introduced: “Does the public procurement agency require national registration before procurement can be done?” (a standards-and-commitments metric) and “Are there information sharing activities between the drug regulatory agency and the procurement agency?” (a decisions-and-results metric). These adjustments were executed under the direct guidance of co-author J.K., who previously co-authored the original WHO assessment framework during their tenure as founding director of the WHO’s Collaborating Centre for Governance, Transparency and Accountability in the Pharmaceutical Sector, having deployed the instrument across more than 38 nations. This methodological expansion resulted in a final framework of 25 metrics: 20 dedicated to public purchasing and 5 to regulation.

#### *Document identification*

To benchmark the chosen metrics, a targeted archival review was conducted in 2023 to gather publicly accessible statutes, policy blueprints, and administrative data from state portals. This data collection was carried out concurrently by two independent investigators, M.C.A. and S.P. The process began by mapping out the state institutions governing each nation’s pharmaceutical ecosystem, followed by systematic keyword queries on their official portals. To capture institutional data missing from primary state sites, the investigators used Google and DuckDuckGo to mine grey literature, defined as official white papers, administrative briefs, and organizational reports. DuckDuckGo was intentionally included because its search algorithm avoids personalized profiling, thereby offering a more neutral and diverse array of primary sources compared to Google [29]. The search matrix employed variations of the lexicon, such as “medicines procurement” and “pharmaceutical procurement.” In scenarios where initial queries returned no results, researchers iteratively substituted synonyms to refine query paths and locate the necessary documentation.

#### *Assessment procedure*

Operating independently, the same two investigators scored each metric using the evidence base compiled during the document harvest. Once individual scoring was complete, the investigators cross-referenced their

findings and reviewed the outcomes with author J.K. When scoring misalignments occurred, the team debated the underlying context until a unanimous consensus was reached.

Following this, distinct national profiles were constructed using metric-based scoring to pinpoint specific domestic strengths and systemic bottlenecks hindering the procurement of quality-verified pharmaceuticals. These individual profiles were then synthesized to identify broader regional trends and to evaluate overall compliance with international transparency benchmarks. When quantifying national compliance, a binary-to-ordinal scale was used: fully satisfying a metric earned a score of 1; partial compliance earned a score of 0.5; and total failure to meet the criteria earned a score of 0.

## **Results and Discussion**

### *Public procurement of medical products*

The initial phase of analysis focused on the 20 metrics used to monitor public purchasing systems. Ten of these parameters examined structural standards and commitments (**Table 1**). Every surveyed country successfully published “legislation, supporting regulations, or policy on public sector procurement of medicines” alongside “standard operating procedures on procurement procedures.” Consequently, basic transparency regarding institutional workflows is universally established across all five jurisdictions. Compliance was also relatively robust for another core operational metric: four nations (80%) openly mandated a “policy/requirement that key procurement functions and responsibilities are divided between different offices, committees, or individuals.”

Additionally, three nations (60%) formalized “guidelines for direct purchasing,” which covers basic procurement protocols. Conversely, only two countries (40%) provided open access to “standard operating procedures for the quantification committee (procurement committee)” and “guidelines for financial audits of the procurement unit.” However, a third nation achieved partial scores for both. Notably, no nations had a “published selection algorithm that includes product quality as a major factor,” representing a critical data gap on how clinical quality metrics are weighed against commercial variables, such as price, during final vendor selection.

**Table 1.** Standards-and-commitment indicators for public procurement.

| Governance and procurement function indicator                                                       | Country<br>A | Country<br>B | Country<br>C | Country<br>D | Country<br>E |
|-----------------------------------------------------------------------------------------------------|--------------|--------------|--------------|--------------|--------------|
| National framework establishing rules for public procurement of medicines                           | Y            | Y            | Y            | Y            | Y            |
| Institutional separation of key procurement roles across entities or individuals                    | Y            | Y            | Y            | Y            | N            |
| Existence of formalized procedures for forecasting and quantifying medicine needs                   | Y            | Partial      | N            | N            | Y            |
| Formal mandate documents defining responsibilities of tender evaluation or procurement award bodies | Y            | Y            | N            | Y            | Y            |
| Established rules governing supplier eligibility for participation in competitive bidding           | Y            | Y            | Y            | Y            | N            |
| Presence of standardized procedures regulating procurement workflows                                | Y            | Y            | Y            | Y            | Y            |
| Regulatory guidance for non-competitive/direct procurement mechanisms                               | N            | Y            | N            | Y            | Y            |
| Availability of an explicit selection framework incorporating quality as a decision criterion       | N            | N            | N            | N            | N            |
| Formal audit guidance applicable to procurement and financial oversight functions                   | N            | Y            | N            | Partial      | Y            |
| Documented national plan for procurement and supply chain management                                | Y            | Y            | N            | Partial      | Y            |

Note: Y = Yes, N = No.

To gauge how effectively these frameworks are operationalized, we evaluated seven decisions-and-results metrics within the purchasing domain (**Table 2**). Three countries (60%) maintained “a list/database of public sector medicines call for tenders.” However, only a single nation (20%) yielded “evidence that the procurement authority monitors supplier compliance with contracts,” “summary results of financial audits of the procurement unit,” or “a list of contracts for publicly

procured medicines exempted from tendering.” Furthermore, while no nation openly provided “a document with names and roles of appointed tender committee members publicly available,” one jurisdiction met the criteria partially. Similarly, only one country achieved partial compliance by providing “a list/database of purchased medicines (molecule, dose, formulation, manufacturer, volume, price, timeframe),” an essential data stream for evaluating public expenditure contexts.

**Table 2.** Decisions-and-results indicators for public procurement.

| Transparency and procurement accountability indicator                                                                                                                                       | Country<br>A | Country<br>B | Country<br>C | Country<br>D | Country<br>E |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|--------------|--------------|--------------|
| Documented evidence of post-award monitoring of supplier performance and contract compliance by the procurement authority                                                                   | N            | Y            | N            | N            | N            |
| Availability of an official registry of suppliers eligible for participation in public medicines procurement                                                                                | Partial      | Partial      | Partial      | Partial      | Partial      |
| Public disclosure of the composition and appointment details of tender committee members                                                                                                    | N            | N            | Partial      | N            | N            |
| Publication of summarized findings from financial audits conducted on procurement units                                                                                                     | N            | Y            | N            | N            | N            |
| Existence of a publicly accessible database of medicines procurement tenders issued by the public sector                                                                                    | N            | Y            | Y            | Y            | N            |
| Availability of a structured database of procured medicines, including product and transaction details (e.g., molecule, dosage form, manufacturer, quantity, price, and procurement period) | N            | N            | Partial      | N            | N            |
| Public listing of procurement contracts awarded without competitive tender processes (direct or exempted procurement)                                                                       | N            | N            | Y            | N            | N            |

Note: Y = Yes, N = No.

Systemic performance hit its lowest point within the three metrics governing consequences and responsive actions (**Table 3**). Just one country (20%) actively maintained “a list of suspended suppliers that have not respected their contracts,” while another country achieved partial

compliance. Zero nations displayed any transparent record of “rulings from an independent formal appeals system on appeals filed by applicants who have their bids rejected” or “a list that details corrective measures enforced as identified through a financial audit.”

**Table 3.** Consequences-and-responsive-actions indicators for public procurement.

| Accountability and enforcement indicator                                                                      | Country A | Country B | Country C | Country D | Country E |
|---------------------------------------------------------------------------------------------------------------|-----------|-----------|-----------|-----------|-----------|
| Publicly available documentation of remedial or corrective actions resulting from financial audit findings    | N         | N         | N         | N         | N         |
| Publication of decisions from an independent procurement appeals mechanism addressing rejected bid complaints | N         | N         | N         | N         | N         |
| Existence of a published registry of suppliers suspended due to noncompliance with contractual obligations    | Partial   | Y         | N         | N         | N         |

Note: Y = Yes, N = No.

*Registration of medical products by national regulatory authority and characteristics of the regulatory-procurement interface*

Ideally, state purchasing bodies should directly leverage the evaluations of national regulatory authorities (NRAs) to verify whether a pharmaceutical product is safe for

public distribution. This workflow, however, requires NRAs to maintain transparent registries indicating which manufacturer formulations are authorized and which have failed quality controls. To determine whether purchasing authorities had access to this data, we scrutinized five metrics tracking NRA registration protocols and inter-agency workflows (**Table 4**).

**Table 4.** Indicators related to registration of medical products by NRAs and characteristics of the regulatory-procurement interface.

| Indicator                                                                                                                                                                                                      | Country A | Country B | Country C | Country D | Country E |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------|-----------|-----------|-----------|
| <b>Standards and commitments</b>                                                                                                                                                                               |           |           |           |           |           |
| Is prior national product registration mandatory before any public procurement process can proceed?                                                                                                            | Y         | Y         | Y         | Y         | Y         |
| Are there established rules and procedures governing the registration of medicines that have already passed earlier evaluation processes?                                                                      | Y         | Y         | Y         | Y         | Y         |
| <b>Decisions and results</b>                                                                                                                                                                                   |           |           |           |           |           |
| Do the drug regulatory authority and the procurement agency exchange information?                                                                                                                              | Y         | N         | N         | N         | N         |
| Is there a regularly updated (at least annual) national registry of all authorized pharmaceutical products, including details such as generic name, formulation, strength, and marketing authorization holder? | Y         | Y         | Y         | Y         | Y         |
| <b>Consequences and responsive actions</b>                                                                                                                                                                     |           |           |           |           |           |
| Is there an official database tracking medicines whose marketing authorization has been suspended or revoked?                                                                                                  | N         | N         | N         | N         | N         |

Note: Y = Yes, N = No.

All five jurisdictions demonstrated that “the public procurement agency requires national registration before procurement can be done” and maintained a “list/database of all pharmaceutical products registered in the country updated at least annually (and information categories available, e.g. generic names, dosage form,

strength, marketing authorization holder, etc.).” Theoretically, this baseline data allows purchasing agencies in all five nations to screen vendor eligibility based on whether a formulation holds active marketing clearance from the domestic NRA. Furthermore, every surveyed country possessed a formalized

“criteria/procedure for the registration of medicines that have undergone prior evaluation.” This indicates operational capacity for regulatory reliance, allowing these nations to fast-track market access for pharmaceuticals already validated by trusted external bodies, such as stringent regulatory authorities, WHO-listed authorities, or the WHO Prequalification Programme. This mechanism helps compensate for limited domestic oversight capacity. However, only one nation (20%) could prove active “information sharing activities between the drug regulatory agency and the procurement agency.” Crucially, zero NRAs maintained “a list/database of products that had their market authorization suspended or revoked.” This specific information deficit severely limits public purchasing

bodies’ ability to proactively block substandard drugs and non-compliant vendors from participating in future state tenders.

#### *Summary of overall procurement landscape*

The combined data across the assessed nations (**Figure 1**) demonstrate that, while general performance on procurement and registration indicators was moderate, outcomes varied significantly across the three indicator categories. Performance across the standards-and-commitments indicators was predominantly high; by contrast, outcomes for the decisions-and-results indicators were lower, and the weakest performance was observed in the consequences-and-responsive-actions indicators.

| Indicators                |                                     | Countries              |                         |                       |                          |                          |
|---------------------------|-------------------------------------|------------------------|-------------------------|-----------------------|--------------------------|--------------------------|
|                           |                                     | Country A              | Country B               | Country C             | Country D                | Country E                |
| <b>Public procurement</b> |                                     | <b>Moderate (8/20)</b> | <b>Moderate (13/20)</b> | <b>Low (6.5/20)</b>   | <b>Moderate (8.5/20)</b> | <b>Moderate (7.5/20)</b> |
|                           | Standards and commitments           | High (7/10)            | High (8.5/10)           | Moderate (4/10)       | High (7/10)              | High (7/10)              |
|                           | Decisions and results               | Low (0.5/7)            | Moderate (3.5/7)        | Moderate (3.5/7)      | Low (1.5/7)              | Low (0.5/7)              |
|                           | Consequences and responsive actions | Low (0.5/3)            | Moderate (1/3)          | Low (0/3)             | Low (0/3)                | Low (0/3)                |
| <b>Registration</b>       |                                     | <b>High (4/5)</b>      | <b>Moderate (3/5)</b>   | <b>Moderate (3/5)</b> | <b>Moderate (3/5)</b>    | <b>Moderate (3/5)</b>    |
|                           | Standards and commitments           | High (2/2)             | High (2/2)              | High (2/2)            | High (2/2)               | High (2/2)               |
|                           | Decisions and results               | High (2/2)             | Moderate (1/2)          | Moderate (1/2)        | Moderate (1/2)           | Moderate (1/2)           |
|                           | Consequences and responsive actions | Low (0/1)              | Low (0/1)               | Low (0/1)             | Low (0/1)                | Low (0/1)                |

**Figure 1.** Overall performance landscape for indicators related to the interface of the registration and procurement of medical products. Classification of high/moderate/low follows the instructions in WHO’s Pharmaceutical System Transparency and Accountability Assessment Tool: green indicates a country met > 66% of indicators in a certain area (high); yellow, 33%-66% (moderate); and red < 33% (low) [26].

When a country fulfilled an indicator, a value of 1 was assigned; partial fulfillment, 0.5; and failure to meet the indicator, 0.

In this investigation, publicly available documentation was utilized to examine the intersection of regulation and procurement across five African nations. This specific cohort of five countries represents a selection of the more effectively functioning healthcare systems within sub-Saharan Africa. Nonetheless, critical areas for optimization were identified to fortify the regulatory-procurement interface and improve accessibility to high-quality medical products.

Policy and statutory frameworks designed to facilitate optimal procurement practices (as demonstrated by the standards-and-commitments indicators) were frequently established in these nations; however, the practical implementation and enforcement of these mechanisms (as reflected in the decisions-and-results and consequences-and-responsive-actions indicators) remain primary areas requiring development. This does not imply that optimal practices were universally adopted for standards-and-commitments benchmarks. For instance, public guidelines governing the direct acquisition of medical products were available in only three of the five

nations. When numerous medical products are granted exemptions or are acquired directly without competitive bidding, the publicly established procurement protocols may be frequently bypassed, thereby introducing risks to product quality [14].

Furthermore, regarding the decisions-and-results indicators, only one nation published a registry of contracts for publicly procured medications that were exempt from standard tendering processes, which limits transparency into when deviations from standard procurement procedures are authorized. In terms of consequences-and-responsive-actions indicators, no nation published a directory or database of medical products with suspended or cancelled market authorizations, and only a single country provided a comprehensive register of suspended suppliers that failed to honor their contractual obligations. In the absence of these registries, it becomes challenging for state authorities to penalize, and for the public to identify, entities that circumvent the public procurement framework [14, 25].

Notwithstanding the need to prioritize product quality in procurement decisions, a shortage of public information on how product quality influences medical product selection was documented. No publicized algorithms explaining how quality benchmarks are integrated into procurement selection were identified in any of the surveyed nations. Without this data, evaluating how quality is weighted against other variables in procurement choices remains impossible. If quality considerations are marginalized in favor of price as the primary selection benchmark, manufacturers of superior-quality products face diminished incentives to participate in a country's bidding process, as they are likely to lose contracts to less expensive, lower-quality alternatives [16, 21].

Additionally, none of the five nations appear to release selection determinations broken down by purchased item—including data on the specific molecule, dosage, formulation, manufacturer, quantity, price, and schedule—though one nation offered a registry that partially fulfilled these criteria. Without explicit data on selected items, citizens face barriers in assessing whether basic quality standards are maintained and in holding governance structures accountable. Information about the manufacturer is vital because it enables verification of past major regulatory noncompliance (such as manufacturers associated with diethylene glycol poisoning). Furthermore, if a manufacturer exclusively

maintains authorizations in weakly regulated jurisdictions, this pattern may reflect a deliberate approach to circumvent stringent review, thereby threatening product quality (though certain reputable manufacturers specifically cater to LMIC markets) [28]. Data detailing the molecule, dosage, formulation, and manufacturing site are critical, as they enable verification of endorsements by stringent regulatory authorities, WHO-listed authorities, or the WHO Prequalification Programme. If a manufacturer produces an item with a molecule, dosage, and formulation that appear approved by one of these bodies, yet the firm does not declare this endorsement when seeking market authorization in an LMIC, this raises concerns about tiered manufacturing. Tiered manufacturing occurs when a manufacturer distributes identical molecules, dosages, and formulations of a drug to separate markets, while manufacturing the commodity under varying quality standards and in distinct facilities, depending on the level of supervision in the destination market [28]. When tiered manufacturing occurs, nations with compromised regulatory oversight are more susceptible to obtaining inferior iterations of a medical product.

Lastly, pricing data is essential because it enables inferences about product quality. For example, if a country's purchasing agency systematically acquires goods at or beneath the lowest tier of the price-per-unit spectrum on international pricing benchmarks, it may indicate compromised product quality. Constrained by limited finances and the necessity to minimize costs, procurement entities in low- and middle-income countries (LMICs) understandably prioritize price over other variables. Regrettably, this practice can exclude premium items from the market, as producers and distributors frequently sustain profitability by reducing manufacturing costs, including using cheaper raw materials or bypassing quality control protocols (potentially resulting in tiered manufacturing) [21].

We also identified a misalignment between the operations of national regulatory authorities (NRAs) and their corresponding purchasing agencies. This issue likely hinders procurement entities' ability to make well-informed determinations about product quality [14]. Within numerous African nations, procurement operates as a multi-stage workflow: it begins with a technical body, directed by NRA personnel, that designates the items to be obtained (generally utilizing the WHO's Essential Medicines List and registries of prequalified goods); it proceeds to a purchasing division, which

gathers commercial data from competitors; and it concludes with a commercial board that executes final buying choices. This division of responsibilities creates significant potential for purchasing decisions to diverge from medical product regulations and from NRA approvals and revocations [21, 30]. We observed transparent accounts of information-sharing practices between NRAs and purchasing bodies in only one of the five assessed nations.

Furthermore, none of the five NRAs published a register of commodities whose market authorizations were suspended or cancelled. This data is critical for assisting procurement agencies in avoiding the acquisition of falsified or substandard (SF) medications, and publishing such registries would likewise keep citizens informed about the quality of various medicines and producers. Codifying channels for data transfer between NRAs and purchasing bodies (e.g., through formalized information-sharing pacts) could help ensure procurement entities have the data needed to make optimal purchasing decisions.

Based on national performance across the benchmarks evaluated in this investigation, we suggest that an essential subsequent step to advance the competency and openness of national purchasing is for regulatory and procurement bodies to jointly formulate and publish comprehensive, quality-based selection benchmarks aligned with domestic pharmaceutical regulatory frameworks. Another critical action is for procurement agencies to publish current registries of acquired goods, complete with the primary product specifications detailed in this paper. Specialists have advocated for enhanced visibility of purchasing data, including cost and quality metrics, for many years [31]. One method to increase the availability of this data would be to use existing data-acquisition instruments or engineer new ones to incentivize nations to gather and distribute it in a uniform format. Open e-procurement architectures represent an encouraging approach to enhancing visibility into national purchasing workflows and decisions.

The international health community could reinforce the acquisition of quality pharmaceuticals by integrating pertinent metrics into prominent diagnostic tools and objectives. For example, new parameters necessitating comprehensive procurement data could be integrated into the WHO's Pharmaceutical System Transparency and Accountability Assessment Tool [26], and new metrics evaluating the maturity of a nation's regulatory-procurement interface could be incorporated into the

WHO's Global Benchmarking Tool [11]. Establishing product quality as a primary performance metric within major frameworks like the SDGs could help focus international attention on this domain, attracting funding and alternative forms of assistance.

Additionally, the international health community (WHO, World Bank, etc.) could foster optimal practices for the regulatory-procurement interface by replicating the specialized assistance it has previously provided to reinforce NRAs and regional regulatory bodies globally. Current international guidance is required on best practices for purchasing, including methodologies for selecting high-quality medical commodities and implementing optimal procedures at local, national, and regional levels [16]. Modernized and broader guidelines could target (1) selecting and auditing for product quality when regulatory capacity is constrained; (2) utilizing dependence on international and regional frameworks and networks to verify product quality; and (3) the statutes, strategies, and workflows regulatory and procurement agencies require to collaborate more effectively to guarantee quality. Naturally, it is equally important that regulatory and purchasing bodies are provided with the capital and institutional backing to enforce these statutes and codes [16, 24].

The international health community could likewise cultivate increased professional engagement and instruction at the intersection of regulation and procurement, given that many personnel at domestic purchasing agencies in Africa currently lack specialized expertise in pharmaceutical supply chain management [16, 30]. One strategy to advance this objective involves organizing a community of practice focused on domestic procurement of quality pharmaceuticals [16, 31]. Developing platforms for procurement and regulatory specialists (including chief pharmacists) to coordinate could also yield substantial utility [32]. Furthermore, purchasing specialists would benefit from targeted training or modules focused on quality-based selection in medical commodity procurement, potentially modeled after the World Bank's effective Health Systems Flagship Program and Course [16]. Finally, mentorship models and institutional trades between highly developed and developing initiatives have proven effective for NRA capacity optimization and could yield parallel benefits for procurement operations [16, 33, 34].

This investigation is subject to several significant limitations. First, in compliance with the WHO's Pharmaceutical System Transparency and

Accountability Assessment Tool, we relied on publicly accessible documentation to evaluate national performance on the chosen metrics. Consequently, we may have overlooked relevant data contained in records that are exclusively accessible upon formal request to the respective organizations or through interviews with key informants. Additionally, certain purchasing bodies and regulatory entities might fulfill an indicator without publicly archiving their operations in that sphere. Because domestic purchasing and regulatory entities operate on behalf of the state, we contend that data on these vital indicators ought to be accessible to the public—and that a lack of public data on these activities likely signals they are not being carried out. Second, we examined the regulatory-procurement interface within only five nations, several of which possessed some of the more robust healthcare systems in sub-Saharan Africa. This selection may have caused us to underestimate the severity of regulatory-procurement disconnects. In future research, it will be essential to evaluate procurement and registration benchmarks across a broader selection of nations. Third, there has been a noticeable shift toward decentralized public procurement within African nations [15]. To the extent that distinct procurement centers with varied protocols operate within the same nation, it can be difficult for a government to provide a cohesive characterization of its active procurement procedures. Finally, many citizens in LMICs depend on pharmaceuticals obtained through non-domestic purchasing agencies [35], such as those purchased in the private market, and our analysis does not encompass this domain. Although private-sector purchasing should, in theory, comply with the relevant NRA's determinations, regulatory monitoring remains difficult. Failures within this framework represent another major origin of SF pharmaceuticals in LMICs [36] and warrant rigorous examination.

## Conclusion

This investigation provides a cross-sectional overview of the regulatory-procurement interface across five African nations, compiled via a standardized instrument and publicly accessible, internet-based, English-language documentation. Resolving the shared difficulties identified in this research is becoming increasingly vital, particularly given the contemporary disparity in SF commodity volumes in Africa relative to the rest of the world. Additional elements, such as the transition toward

universal health coverage in Africa and the evolution of donor initiatives toward domestic governance, also render rapid intervention essential. In view of the common obstacles recorded in this study, we anticipate that our observations can help guide the dialogue surrounding the execution and enforcement of optimal practices at the regulatory-procurement interface (e.g., enhanced transparency regarding quality criteria and purchased drugs; data dissemination concerning authorized or procured SF goods), with the ultimate objective of expanding access to premium variants of pharmaceuticals in Africa and globally.

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