

Assessing the impact of donor procurement guidelines on local sourcing of antiretrovirals and antimalarials in Nigeria's health sector

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ABSTRACT: Access to essential medicines, particularly antiretrovirals (ARVs) and antimalarials, is fundamental to the control of HIV/AIDS and malaria in Nigeria. International donors such as the Global Fund and USAID have significantly supported the country's health sector through funding and procurement of these commodities. However, donor procurement policies often prioritise international suppliers holding World Health Organisation (WHO) prequalification or U.S. Food and Drug Administration (FDA) approval. This preference, while aimed at ensuring quality, frequently excludes qualified local manufacturers who are certified by Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC). Such policies, though well-intentioned, may inadvertently constrain the growth of local pharmaceutical capacity and undermine national goals for a resilient and self-sustaining health supply chain. This study investigates the extent to which donor procurement guidelines affect local manufacturers' participation in the supply of ARVs and antimalarials in Nigeria. It further examines the implications for national drug security, health system sustainability, and local industry development. A mixed-methods design was employed, comprising quantitative data from 40 procurement officers in donor-funded NGOs and qualitative data from semi-structured interviews with 10 key stakeholders, including local manufacturers, donor representatives, and regulators. Quantitative data were analysed using SPSS for descriptive and correlation statistics, while thematic analysis was applied to qualitative responses. Findings indicate that over 85% of donor-funded procurement is awarded to international suppliers, primarily due to certification requirements. Local manufacturers, despite meeting national regulatory standards, are often excluded due to lack of WHO/FDA certification, limited access to donor tenders, and insufficient technical support. Additionally, international competitive bidding and long-term framework agreements disadvantage domestic firms. The study concludes that current donor procurement policies, while safeguarding quality, limit local pharmaceutical participation. It recommends technical assistance for WHO prequalification, conditional waivers for NAFDAC-certified firms, and policy reforms to promote local sourcing and enhance national drug security.

Keywords: Antimalarials, antiretrovirals, donor procurement guidelines, health supply chain, local pharma manufacturers, local sourcing, quality standards.

INTRODUCTION

Access to essential medicines such as antiretrovirals (ARVs) and antimalarials is vital to controlling HIV/AIDS and malaria, two of Nigeria's most pressing public health challenges (World Health Organisation [WHO], 2021). To support national health responses, international donor agencies, including the Global Fund, the U.S. President's

Emergency Plan for AIDS Relief (PEPFAR), and the United States Agency for International Development (USAID), have provided significant funding and health commodities over the years (The Global Fund, 2023; U.S. Department of State, 2023). These interventions are governed by strict procurement and supply chain policies

designed to ensure transparency, quality assurance, and cost-effectiveness (USAID, 2022).

However, these procurement frameworks frequently emphasise compliance with international certifications such as WHO Prequalification and U.S. Food and Drug Administration (FDA) approval. While these standards are essential for safeguarding product quality, they often marginalise capable local pharmaceutical manufacturers who meet national regulatory standards, such as Good Manufacturing Practice (GMP) certification from Nigeria's National Agency for Food and Drug Administration and Control (USAID, 2020). As a result, local firms are routinely excluded from donor-funded procurement processes (Chaudhuri and West, 2015; Nebot Giralt *et al.*, 2020).

This exclusion presents a dual challenge. First, it stifles the growth of Nigeria's domestic pharmaceutical industry by limiting access to donor-funded markets (UNIDO, 2011). Second, it undermines national drug security by increasing reliance on foreign suppliers and exposing the health system to global supply chain disruptions, as seen during the COVID-19 pandemic (Ogunleye *et al.*, 2020). These practices are misaligned with Nigeria's industrial policy goals, which prioritise pharmaceutical self-sufficiency and reduced import dependency (Federal Ministry of Finance, Budget and National Planning, 2021; Federal Ministry of Industry, Trade and Investment, 2020).

Despite investments in local production capacity, Nigeria continues to depend heavily on donor-funded imports for critical medicines. Donor procurement mechanisms, which often rely on long-term framework agreements and international competitive bidding, tend to favour foreign firms (The Global Fund, 2023). Perceptions of inadequate quality compliance by local manufacturers, despite a lack of empirical evidence, further compound their exclusion (Nebot Giralt *et al.*, 2020).

This study aims to empirically examine how donor procurement guidelines affect the participation of local pharmaceutical manufacturers in the supply of ARVs and antimalarials in Nigeria. The study addresses a critical knowledge gap by assessing the barriers posed by donor guidelines and exploring policy alternatives that can reconcile quality assurance with inclusive industrial growth. It contributes to the discourse on health sector reform and local content development by offering evidence-based insights into policy barriers and opportunities. The findings are expected to inform strategies for aligning donor practices with national development goals while maintaining global standards for quality and safety.

METHODOLOGY

Research design

This study employed a mixed-methods research design to assess the impact of donor procurement guidelines on the

participation of local pharmaceutical manufacturers in Nigeria. A mixed-methods approach was chosen to allow for triangulation of findings, integrating numerical data on procurement practices with in-depth stakeholder insights (Creswell and Plano Clark, 2018). This approach enhances the validity and depth of the study by combining quantitative breadth with qualitative depth (Tashakkori and Teddlie, 2010).

Study area

The research was conducted in Lagos, Ogun, and Anambra States, which are recognised as major pharmaceutical manufacturing hubs in Nigeria. These states were selected based on the concentration of pharmaceutical firms and their involvement in donor-supported health programs.

Study population and sampling

A purposive sampling technique was used to identify respondents with direct knowledge of donor procurement systems and local pharmaceutical production.

Quantitative component: Structured questionnaires were administered to 10 procurement officers and supply chain managers working in donor-funded programs, non-governmental organisations (NGOs), and health development agencies.

Qualitative component: 10 key informants were selected for in-depth interviews, including representatives from local pharmaceutical manufacturers, donor agencies, and officials from the National Agency for Food and Drug Administration and Control (NAFDAC). Purposive sampling is appropriate in exploratory and policy-oriented studies where the objective is to gather information from individuals with specialised knowledge (Palinkas *et al.*, 2015).

Data collection tools

Two main tools were used for data collection. The structured questionnaire was designed to capture information on procurement trends, supplier eligibility criteria, and challenges associated with local sourcing, while semi-structured interviews were conducted with key informants to explore contextual factors influencing procurement decisions, donor policies, and perceived regulatory challenges. Semi-structured interviews provide flexibility while maintaining focus on key themes (Kallio *et al.*, 2016), and structured questionnaires are effective for obtaining consistent and comparable data across a sample (Bryman, 2016).

Ethical considerations

Ethical approval was obtained from the USAID. All participants were briefed about the purpose of the study and provided written informed consent. Participation was voluntary, and data confidentiality and anonymity were strictly maintained, in accordance with ethical standards for research involving human subjects (Israel and Hay, 2006).

Data analysis

Quantitative data were analysed using SPSS version 25 to generate descriptive statistics (frequencies, percentages, means) and correlation analysis to assess the relationship between donor procurement criteria and local firm participation, while the qualitative data, transcripts from interviews, were subjected to thematic analysis, conducted using manual coding methods.

RESULTS

The procurement officer responds to donor guidelines and local sourcing

Findings from the structured survey administered to 20 procurement officers in donor-funded programs, as presented in Table 1, revealed a strong perception that donor guidelines significantly restrict the participation of local pharmaceutical manufacturers in Nigeria. A large majority (95%) of respondents confirmed that donor procurement frameworks require World Health Organisation (WHO) or U.S. Food and Drug Administration (FDA) certification as a condition for supplier eligibility. Only 5% indicated that national regulatory approval from the National Agency for Food and Drug Administration and Control (NAFDAC) was considered acceptable by donor procurement guidelines.

When asked about the extent of local sourcing, 95% of procurement officers acknowledged that less than 10% of their antiretroviral (ARV) and antimalarial stock was sourced from local manufacturers. This suggests a significant underutilization of domestic pharmaceutical capacity, despite the availability of locally certified manufacturers.

Regarding perceived barriers to local sourcing as presented in Table 2, respondents were allowed to select multiple options. The most frequently identified barrier was the lack of international certification (95%), followed by concerns about the risk of not meeting donor quality standards (85%), and a perception that donor agencies do not actively engage local manufacturers (75%). These findings underscore the structural challenges faced by Nigerian pharmaceutical firms in accessing donor-funded supply chains.

Correlation between donor requirements and local manufacturer participation

To further understand the relationship between donor procurement stringency and local manufacturer participation, a Pearson correlation analysis was conducted. Donor requirement stringency was measured on a five-point Likert scale ($M = 4.2$, $SD = 0.6$), while the level of local manufacturer participation was rated on the same scale ($M = 2.1$, $SD = 0.9$). Results show a statistically significant negative correlation ($r = -0.61$, $p < .05$), indicating that higher procurement stringency is strongly associated with lower participation by local manufacturers.

This inverse relationship suggests that stringent donor quality requirements, particularly those tied to international certifications, may systematically exclude capable local firms from procurement opportunities. Consequently, this reinforces dependency on foreign suppliers and undermines Nigeria's industrial policy objectives aimed at local content development and pharmaceutical self-sufficiency.

Regulatory officials highlighted that while NAFDAC is committed to building local capacity, it lacks influence over donor procurement decisions. Some informants suggested the establishment of transitional inclusion mechanisms, such as conditional waivers or partnerships with internationally certified firms.

DISCUSSION

The findings from this study provide empirical support for the argument that donor procurement guidelines, while established to ensure quality, transparency, and value for money, create significant barriers to the participation of local pharmaceutical manufacturers in Nigeria. The overwhelming majority of procurement officers (95%) reported that donor agencies require WHO or FDA certification for eligibility, effectively excluding firms that are only NAFDAC-certified. This corroborates previous reports that global health donors often prioritise internationally certified suppliers over nationally accredited ones (Bloom Public Health, 2023; Wirtz *et al.*, 2017).

This exclusion is not due to a lack of capacity per se, but to procedural and policy constraints. Many Nigerian firms possess Good Manufacturing Practice (GMP) certification from NAFDAC and have upgraded their facilities to meet quality benchmarks, yet they remain ineligible for donor tenders (UNIDO, 2016). The significant underrepresentation of local manufacturers, where 95% of respondents noted that less than 10% of their ARV or antimalarial stock is locally sourced, highlights the inefficiency of this system in promoting national industrial goals.

The statistically significant negative correlation ($r = -0.61$, $p < 0.05$) between donor requirement stringency and local manufacturer participation reinforces this concern. It

Table 1. Responses from procurement officers on donor guidelines and local sourcing (N = 20).

Survey question	Response Option	Number of Respondents	Percentage (%)
Do donor guidelines require WHO/FDA certification?	Yes	19	95.0
	No	1	5.0
Do donor guidelines allow NAFDAC-certified firms?	Yes	1	5.0
	No	19	90.0
Is <10% of your ARV/antimalarial stock locally sourced?	Yes	19	95.0
	No	1	5.0
What are the barriers to sourcing locally? (Multiple responses allowed)	—	—	—
– Lack of international certification	Selected	19	95.0
– Risk of not meeting donor quality standards	Selected	17	85.0
– Donor agencies not engaging local firms	Selected	15	75.0

Note. Frequencies and descriptive statistics were analyzed using SPSS. Responses were coded (Yes = 1, No = 0) for statistical analysis.

Table 2. Correlation between donor requirements and local manufacturer participation.

Variable	Mean (1–5 scale)	Standard Deviation	Pearson Correlation (r)
Donor requirement stringency	4.2	0.6	–0.61*
Local manufacturer participation level	2.1	0.9	

Note. Pearson correlation is statistically significant at $p < 0.05$.

demonstrates that as procurement standards become more rigid and internationally oriented, the space for local firm participation diminishes. While such standards are essential for ensuring drug safety and efficacy, their rigid application without corresponding support for local capacity development can entrench supply chain dependencies and vulnerability to global shocks (NAFDAC, 2021; Mackintosh *et al.*, 2016).

Moreover, perceived barriers such as lack of international certification (95%), risks of not meeting donor quality expectations (85%), and lack of donor engagement with local firms (75%) reflect systemic challenges rather than individual firm inadequacies. These findings align with earlier literature noting that local suppliers in low- and middle-income countries (LMICs) often face structural exclusion from donor supply chains due to complex prequalification requirements and limited opportunities for capacity-building partnerships (Chaudhuri and West, 2015; WHO, 2020).

These procurement dynamics undermine national policy objectives such as those outlined in Nigeria's National Drug Policy, which emphasizes pharmaceutical self-reliance, local production, and reduced import dependency (Federal Ministry of Health, 2016). They also contradict global calls for more equitable and sustainable procurement practices that align with the WHO's local production framework (WHO, 2021).

Therefore, donor agencies and national stakeholders must co-develop context-sensitive procurement strategies that uphold quality without excluding competent local

firms. Blended certification frameworks, transitional support mechanisms, and preferential procurement quotas could serve as practical policy alternatives. Aligning donor practices with national regulatory systems while maintaining stringent pharmacovigilance could foster inclusive growth and enhance Nigeria's long-term drug security.

Conclusion

This study investigated the influence of donor procurement guidelines on the participation of local pharmaceutical manufacturers in Nigeria's supply chain for antiretrovirals and antimalarials. The findings reveal that stringent donor requirements, such as mandatory WHO prequalification and FDA certification, serve as barriers to entry for local manufacturers who, despite meeting national regulatory standards, are excluded from major procurement contracts. This exclusion not only hampers local industry growth but also compromises national health security by perpetuating reliance on foreign suppliers.

The study concludes that while the intent behind donor procurement guidelines is to ensure product quality and safety, their implementation often neglects the contextual realities and capabilities of local industries. Bridging this gap requires deliberate policy realignment and collaborative efforts among donors, government agencies, and the private sector to foster a more inclusive and resilient pharmaceutical supply chain.

Recommendations

To strengthen local pharmaceutical capacity and improve access to essential medicines, the following key actions are recommended:

1. Promote Inclusive Procurement Frameworks: Donor agencies should adopt tiered quality assurance systems that recognise NAFDAC-certified manufacturers progressing toward WHO prequalification and integrate local content policies into procurement guidelines.
2. Enhance Technical Support and Capacity Building: Both donor agencies and the Nigerian government should provide sustained technical assistance to local manufacturers, focusing on quality management, international certification, and regulatory compliance.
3. Strengthen National Regulatory Institutions: The Nigerian government should bolster NAFDAC's capacity to serve as a credible quality assurance authority and align its standards with global benchmarks to foster trust among donors.
4. Foster Industry Advocacy and Continuous Improvement: Local manufacturers must invest in quality systems, engage in policy advocacy, and proactively pursue international certifications, leveraging support from donors and regulators where available.

CONFLICT OF INTEREST

The author declare that they have no conflict of interest.

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