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Review Article

Africa's Path to Pharmaceutical Sovereignty and Renaissance: Building Champions at Home

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Abstract

For decades, African pharmaceutical markets have been shaped predominantly by multinational drug manufacturers, with indigenous firms occupying marginal positions due to structural rather than technical limitations. The gradual exit or downsizing of several multinational pharmaceutical companies across African markets between 2022 and 2024 was initially perceived as a systemic threat. However, emerging evidence from Nigeria and comparable African contexts indicates that this transition has catalysed regulatory strengthening, local industrial scaling, and renewed confidence in domestic pharmaceutical manufacturing. This article examines the evolving pharmaceutical landscape in Africa, with particular focus on Nigeria as a leading case study. It argues that disciplined regulation, credible standards enforcement, and strategic industrial alignment—exemplified by the roles of the National Agency for Food and Drug Administration and Control (NAFDAC) and the Pharmacists Council of Nigeria (PCN)—are laying the foundations for pharmaceutical sovereignty and continental renaissance.

Keywords: Pharmaceutical Sovereignty; Local Manufacturing; Regulation; Africa; Cardiometabolic Diseases; Industrial Policy

Introduction

Across much of Africa, including Nigeria, Kenya, Ghana, South Africa, and several Francophone countries, pharmaceutical markets have historically been dominated by multinational drug manufacturers. Market leadership, pricing structures, hospital procurement preferences, and even perceptions of medicine quality were shaped mainly externally. Indigenous pharmaceutical manufacturers existed, but their growth was constrained by regulatory fragility, limited access to capital, and weak market confidence, rather than by deficiencies in scientific capability.

Between 2022 and 2024, the gradual exit or downsizing of several multinational pharmaceutical companies across African markets marked a critical inflexion point. While initially interpreted as a looming crisis, this period has since revealed a structural realignment that is redefining pharmaceutical production, regulation, and market dynamics across the continent.

From multinational exit to African opportunity

Multinational exits from emerging markets often trigger legitimate concerns regarding medicine availability, brand continuity, and patient safety. These concerns are particularly acute within cardiometabolic therapy areas—hypertension, diabetes, and cardiovascular diseases—where long-term treatment continuity is essential, and supply disruptions carry significant morbidity and mortality risks.

Evidence from market intelligence analyses indicates that Nigeria mirrors a broader African reality characterised by:

- High cardiometabolic disease burden;
- Heavy reliance on out-of-pocket healthcare expenditure (approximately 80–90%);
- Concentration of essential molecules within a limited number of innovator brands; and
- Fragile supply chains susceptible to single-point failures.

When multinational Market Authorisation Holders withdraw, the risk extends beyond commercial gaps to systemic vulnerabilities. However, Nigeria's experience demonstrates that when such exits are proactively managed through regulatory coordination and industrial support, they can serve as catalysts for domestic capacity expansion rather than triggers of collapse.

Indicator	Observed Trend
Disease burden	Rising hypertension, diabetes, cardiovascular disease
Payment structure	80–90% out-of-pocket expenditure
Market structure	Concentration in few innovator brands
Supply chain risk	Vulnerable to single Market Authorisation Holders (MAH) exits
Opportunity	High demand for quality-assured branded generics

Table 1: Structural Characteristics of African Cardiometabolic Pharmaceutical Markets.

Source: PBR Life Sciences (2024) [1]; WHO (2023) [2].

Regulation as an enabler of market confidence

The pharmaceutical renaissance emerging in Nigeria—and increasingly relevant across Africa—cannot be adequately understood without recognising the pivotal role of regulatory transformation.

The National Agency for Food and Drug Administration and Control, along with the Pharmacists Council of Nigeria, have evolved beyond traditional gatekeeping roles to become market stabilisers and confidence-building institutions. Their regulatory approach integrates:

- Strengthened Good Manufacturing Practice (GMP) enforcement;
- Accelerated but rigorous product registration pathways;
- Enhanced post-market surveillance; and
- Professional regulation that reinforces trust at dispensing and retail levels.

PCN and NAFDAC's attainment of World Health Organisation Maturity Level 3 status and NAFDAC's admission as the 24th member of the International Council for Harmonisation represent more than symbolic milestones. They signal regulatory credibility capable of supporting industrial growth without compromising patient safety (WHO, 2022; ICH, 2024) [3,4].

For African regulators, the lesson is unambiguous: credible standards do not inhibit markets—they create them.

Regulatory Action	Impact
Strengthened GMP enforcement	Improved product quality and prescriber confidence
Accelerated registration pathways	Faster market entry for local manufacturers
Post-market surveillance	Sustained quality assurance
Professional regulation (PCN)	Restored trust at dispensing level
WHO ML3 and ICH membership	International regulatory credibility

Table 2: Regulatory Interventions Enabling Local Pharmaceutical Growth in Nigeria.

Source: WHO (2022); ICH (2024).

Structural growth beyond currency effects

Some analyses have attributed Nigeria's recent pharmaceutical growth primarily to currency depreciation and import substitution. However, market performance data contradicts this reductionist interpretation.

The observed growth reflects structural rather than nominal expansion, driven by:

- Prescriber confidence in quality-assured branded generics;
- Institutional procurement strategies favouring local manufacturers;
- Expansion of organised retail and digital pharmacy platforms; and

- Predictable, refill-driven revenue streams associated with chronic disease management.

These dynamics are not unique to Nigeria but are observable across African markets experiencing a rise in cardiometabolic disease prevalence. Nigeria's distinction lies in being an early and large-scale demonstration of this transition.

From import substitution to domestic mastery

Africa's pharmaceutical challenge has never been demand-side driven. Instead, it has stemmed from deficits in regulatory confidence, industrial coordination, and access to long-term capital.

Recent financial disclosures indicate that leading Nigerian pharmaceutical manufacturers, including Fidson Healthcare Plc, May and Baker Nigeria Plc, and MeCure Industries, recorded combined profits exceeding ₦15.7 billion over the nine months of 2025. MeCure's reported ₦60 billion revenue from Nigeria alone underscores a critical shift: local production is transitioning from contingency to default.

This evolution marks Africa's shift from basic import substitution to domestic pharmaceutical mastery, where medical security aligns with industrial development and economic resilience.

The continental opportunity under AfCFTA

The next strategic frontier extends beyond national success towards continental leadership. The African Continental Free Trade Area provides a platform for regional pharmaceutical hubs that can serve multiple African markets.

However, realising this opportunity requires addressing three imperatives at the continental scale:

- **Deepening industrial scale:** Patient capital is essential to support automation, research and development, and the manufacture of active pharmaceutical ingredients (APIs).
- **Export-oriented ambition:** African manufacturers must develop regulatory dossiers, brands, and quality systems that travel across jurisdictions.
- **Value-chain localisation:** APIs, excipients, packaging, and logistics must progressively relocate closer to African markets to stabilise costs and supply chains.

Cardiometabolic molecules such as gliclazide, indapamide, and perindopril-based combinations represent strategic entry points for durable African pharmaceutical franchises when regulatory guidance and industrial coordination align.

Pillar	Strategic Focus
Regulation	Standards-led market development
Industrial scale	Automation, R&D, API manufacturing
Capital	Patient, long-term financing
Trade	AfCFTA-enabled regional hubs
Value chains	Progressive localisation

Table 3: Strategic Pillars for African Pharmaceutical Sovereignty.

Conclusion: Africa's 2025 Inflexion Point

The pharmaceutical gains recorded between 2024 and 2025 should not be misconstrued as an endpoint. Instead, they mark the beginning of a structural transition. As macroeconomic conditions evolve and multinational re-entry narratives resurface, African pharmaceutical markets must already be sufficiently disciplined, credible, and competitive to withstand displacement [5].

Nigeria's experience—anchored by NAFDAC and PCN—offers a scalable blueprint for Africa: Protect standards, enable local champions, and scale with strategic intent.

If this trajectory is sustained, the lesson of 2025 will be unequivocal. Africa does not need to wait for multinational corporations to secure its pharmaceutical future. With credible regulation, disciplined indigenous industry, and continental ambition, Africa can build pharmaceutical champions that are fit for local realities and competitive globally.

Author Note

Prof. Lere Baale is a healthcare policy expert, pharmaceutical systems strategist, and academic leader with extensive experience in regulatory reform, industrial development, and health systems transformation across Africa.

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