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From Policy to Practice: Evaluating the Impact of Regulatory Reforms on Nigeria's Local Pharmaceutical Industry

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Abstract

This article evaluates how Nigeria's recent regulatory reforms have translated from policy to practice within the local pharmaceutical manufacturing sector following attainment of WHO Global Benchmarking Tool Maturity Level 3. A descriptive cross-sectional survey of NAFDAC-licensed manufacturers engaged in production, quality assurance, and regulatory affairs was conducted to assess awareness, adoption, and perceived effects of core reforms—Good Manufacturing Practice (GMP), Quality Management Systems (QMS), and digital platforms such as the NAFDAC Automated Product Administration and Monitoring System (NAPAMS) and the Ports Inspection Data Capture and Risk Management System (PIDCARMS). The questionnaire, aligned to WHO-GBT indicators and demonstrating strong internal consistency (Cronbach's α = 0.82), comprised multiple-choice, Likert-scale, and open-ended items. Descriptive results showed high awareness and uptake of WHO-GMP (87.7%) and substantial engagement with NAPAMS (70.5%), but comparatively lower adoption of PIDCARMS (47.5%). Principal Component Analysis identified two latent dimensions: (i) optimism that reforms improve internal quality and operational outcomes, and (ii) tension between firms' confidence in compliance capacity and scepticism about the consistency of external enforcement. Reported barriers included the financial burden of GMP upgrades, uneven digital infrastructure, and user capacity constraints. Respondents credited reforms with strengthening compliance culture and improving product quality but cautioned that process-based milestones do not automatically yield market-level gains. Realising full public health and industrial benefits will require targeted SME support, phased implementation, transparent oversight, and sustained investment in digital readiness and outcome monitoring.

Keywords: *Compliance, Nigeria, Pharmaceutical Manufacturing, Regulation, Reforms, WHO-GBT.*

Introduction

The regulation of pharmaceutical products is fundamental to national health security, influencing not only the safety and efficacy of medicines but also the integrity of health systems, market competitiveness, and public trust. In many low- and middle-income countries (LMICs), systemic regulatory weaknesses have historically facilitated the proliferation of substandard and falsified (SF) medicines, undermining therapeutic effectiveness and contributing to adverse health outcomes, including antimicrobial resistance and treatment failure [15, 21]. Nigeria, as Africa's most populous country and a leading pharmaceutical market in the region, has long confronted this dual burden of the need to ensure access to quality medicines while overcoming regulatory fragmentation, poor

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enforcement capacity, and infrastructural limitations [1, 11].

In response to these challenges, Nigeria has initiated substantial regulatory reforms through its National Agency for Food and Drug Administration and Control (NAFDAC), guided by the World Health Organization's (WHO) Global Benchmarking Tool (GBT). The GBT is a structured framework used to assess the maturity of national regulatory systems across nine core functions, including market authorization, inspections, pharmacovigilance, and post-market surveillance [16]. In March 2022, Nigeria achieved Maturity Level 3 (ML3) for medicines and vaccines regulation, a designation that signifies the presence of a stable, well-functioning regulatory system with the capacity to ensure product quality, safety, and efficacy throughout the pharmaceutical lifecycle [17]. This milestone places Nigeria among a small group of African countries with regulatory systems deemed fit for international regulatory reliance and convergence mechanisms, such as the African Medicines Regulatory Harmonization (AMRH) programme and the forthcoming African Medicines Agency (AMA) [4].

The attainment of ML3 was enabled following a series of institutional reforms undertaken between 2018 and 2022. These included the implementation of a Quality Management System aligned with ISO 9001:2015 standards; modernization of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) inspections; digitization of registration and port clearance via platforms such as NAFDAC Automated Product Administration and Monitoring System (NAPAMS) and Ports Inspection Data Capture and Risk Management System (PIDCARMS); and the legal codification of traceability systems for pharmaceutical products [4, 5, 9, 14, 18]. Collectively, these initiatives aimed not only to enhance regulatory efficiency but also to stimulate local pharmaceutical manufacturing by fostering a more predictable, transparent, and supportive regulatory environment. While these reforms constitute significant policy achievements, their success in transforming the local pharmaceutical sector remains empirically under-examined. Regulatory milestones are typically celebrated through process-oriented metrics such as updated guidelines, system audits, or inspector training but these indicators do not always reflect industry outcomes or operational realities on the ground [6, 13]. Nigerian pharmaceutical manufacturers, which are mostly small- and medium-sized enterprises (SMEs) [10], continue to encounter significant barriers in implementing new regulatory standards. These include the high costs of facility upgrades required for GMP compliance, the technical complexity of digital submission platforms, and uneven enforcement across regions [3, 12]. Without assessing how these reforms are perceived and implemented by the industry actors they target, there is a risk of technocratic reform that improves documentation without achieving substantive improvements in medicine quality or industrial competitiveness.

Evidence from other LMICs underscores the importance of stakeholder-informed evaluation in regulatory system strengthening. Studies from Ghana, Kenya, and Bangladesh indicate that successful regulatory reform relies on a balanced approach, combining top-down institutional mandates with bottom-up industry engagement, which ensures that manufacturers are both equipped and motivated to comply with evolving standards [7, 8, 12]. In Nigeria, while foundational studies emphasize the design of regulatory frameworks, fewer have explored implementation outcomes or firm-level perspectives. A robust example is provided by Akunne and colleagues [2], who utilized stakeholder engagement during a 2024 workshop to highlight barriers in pharmacovigilance adoption, including low uptake of digital platforms and weak feedback

mechanisms*:* underscoring the gap between policy design and practical implementation. Consequently, the responses of manufacturers to recent regulatory reforms, the challenges they encounter, and the real-world impacts on product quality and regulatory trust remain largely unexamined.

This study addresses these gaps by evaluating the perceived impact of regulatory reforms on Nigeria's local pharmaceutical manufacturing sector. Drawing on structured survey data from licensed manufacturers and regulatory officials, it investigates awareness and implementation of key reforms such as GMP guidelines, traceability regulations, and digital registration platforms alongside perceived challenges and sectoral benefits. The study aims to determine whether regulatory strengthening has translated into improved compliance, reduced prevalence of SF medicines, and enhanced competitiveness of locally produced pharmaceuticals. It contributes to a growing body of literature advocating for stakeholder-centred policy assessment and offers practical recommendations to align regulatory ambition with industry capability and public health outcomes.

Methods

This study employed a descriptive cross-sectional research design to examine the practical implications of regulatory reforms on Nigeria's licensed pharmaceutical manufacturing sector. The research was situated within the broader regulatory strengthening efforts following Nigeria's attainment of Maturity Level 3 (ML3) under the World Health Organization's (WHO) Global Benchmarking Tool (GBT) in 2021–2022 [16, 17]. The target population consisted of personnel from NAFDAC-licensed pharmaceutical manufacturing firms, specifically individuals in regulatory compliance, quality assurance, and production roles. Regulatory officers from external agencies were excluded to maintain focus on direct implementers of the reforms. Inclusion criteria required active employment within licensed firms and direct involvement in regulation-related tasks, while informal or unregistered manufacturers were excluded.

A 2023 WHO case study of Nigeria's local pharmaceutical manufacturing sector which included the regulatory framework covering reforms, pharmaceutical traceability and use of digital tools, among other issues, included a survey of 75 locally based manufacturers, of which 73 participated, yielding a 97.3% response rate [18]. This demonstrates strong engagement from industry stakeholders across the manufacturing sector. Data collection was conducted using a structured questionnaire, which was informed by WHO GBT indicators and scholarly literature on regulatory reform in LMICs [6, 15]. The instrument measured dimensions such as awareness and adoption of regulatory initiatives (GMP, QMS, NAPAMS, PIDCARMS), inspection experiences, cost and infrastructure constraints, and perceptions of reform effectiveness. It included multiple-choice questions, five-point Likert scale items, and open-ended questions. Content validity was ensured through expert reviews, and a pilot test with 15 industry professionals led to minor refinements. The final instrument demonstrated high internal consistency (Cronbach's alpha = 0.82).

The survey was administered over a six-week period from March to April 2025, using a mixed-mode strategy. Approximately 60% of responses were collected via secure online forms, while the remaining 40% were obtained through in-person visits by trained researchers. All participants received an information brief and provided informed consent either digitally or in writing. Participation was voluntary and anonymous.

Data analysis was conducted using IBM SPSS Statistics Version 25. Descriptive statistics (frequencies, percentages, means, and standard deviations) were employed to

summarize demographic and response trends. Principal Component Analysis (PCA) was utilized to reduce multicollinearity and identify latent constructs within ordinal Likert-scale data, providing deeper insights into stakeholder perceptions.

Ethical approval was secured from the University of Ibadan/University College Hospital Research Ethics Committee. Additional permissions were obtained from individual firms, and ethical protocols ensured participant confidentiality and informed consent throughout the study.

Results

From Table 1 the majority of respondents were pharmacists (36.6%), followed by regulatory affairs (26.8%) and quality assurance officials (22.8%). Very few respondents identified as CEOs or held specialized roles such as plant managers or GMP instructors, indicating the sample was heavily weighted toward operational and compliance-focused staff.

Table 1. Demography Summary of Respondent Role/Position

Roles/Position	Frequency	Percentage
Pharmacist	45	36.59
Regulatory Affairs official	33	26.83
Quality Assurance official	28	22.76
Production official	6	4.88
CEO	3	2.44
Quality Control analyst.	1	0.81
Admin	1	0.81
GMP Instructor	1	0.81
Regulator	1	0.81
Plant Manager	1	0.81
Director	1	0.81
Superintendent Pharmacist	1	0.81

Figure 1 shows that respondents were drawn from a range of career stages. The largest share had between 6 and 15 years of experience, suggesting the sample had a solid professional background suitable for evaluating regulatory reforms.

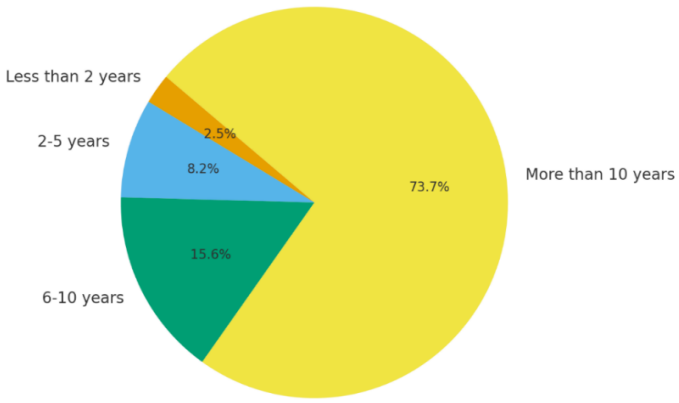

Figure 1. Demography Summary for Years of Experience in the Pharmaceutical Sector

Table 2 below shows that awareness and adoption of regulatory reform initiatives were highest for WHO GMP standards (87.7%), followed by NAPAMS (70.5%) and PIDCARMS (47.5%). This suggests widespread exposure to core GMP reforms, but relatively lower engagement with digital traceability tools like PIDCARMS.

Table 2. Level of individual Awareness/Adoption Rates for each Reform Initiative

Initiative	**Frequency**	**Percentage**
WHO GMP Standards	107	87.7
NAPAMS	86	70.49
PIDCARMS	58	47.54

The PCA in table 3 below revealed two key components. Component 1 reflects general perceptions of reform impact on quality and operational outcomes, while Component 2 contrasts confidence in internal compliance with skepticism about regulatory effectiveness. Together, they provide insight into how manufacturers perceive and navigate reforms.

Table 3. Principal Component Analysis (PCA) Result

	Component 1	**Component 2**
To what extent have inspection findings improved product quality in your organization	0.428497054	0.609588929
How have new regulatory requirements (e.g. as provided in published regulations and guidelines) affected your company's' operations?	0.441523765	0.025241259
Rate your organization's ability to comply with recent regulatory changes:	-0.350351066	0.749742835
Since recent reforms, have you observed any change in the prevalence of substandard or falsified medicines in the market?	0.455458654	-0.204369532
How effective have regulatory measures been in detecting or deterring substandard and falsified medicines	-0.539683783	-0.154541233

Discussion

The findings of this study offer a refined understanding of how recent regulatory reforms in Nigeria's pharmaceutical sector have been perceived, adopted, and operationalized by local manufacturers. These results, when situated within the broader literature, affirm both the promise and the limitations of policy-to-practice transitions in low- and middle-income regulatory environments.

The high levels of awareness and adoption of core regulatory initiatives particularly the WHO GMP standards (87.7%) and NAPAMS (70.5%) suggest that reforms have achieved

considerable reach among local pharmaceutical firms. This observation aligns with WHO case study findings showing significant improvements in GMP adoption and digital platform uptake following Nigeria's attainment of WHO Maturity Level 3 (ML3) *(18)*. Moreover, the widespread recognition of NAPAMS and WHO GMP reflects the effectiveness of NAFDAC's top-down dissemination strategy across key functions such as GMP training, electronic registration, and inspection standardization [11, 20].

However, the relative underutilization of PIDCARMS (47.5%) highlights implementation gaps in traceability systems, *a* trend reflected more broadly in LMIC regulatory settings. Studies have documented that digital platform adoption often falters due to limited user capacity, infrastructural constraints, and persistent process inefficiencies [12, 13]. This suggests that while policy architecture may be in place, effective system integration requires technological accessibility plus a robust support environment. Respondent-reported barriers, such as high costs, insufficient training, and human resource limitations, align with UNIDO's warning that regulatory reforms unsupported by targeted industrial backing risk further entrenching inequities, especially among SMEs [14]. The results of the PCA add further granularity. The first component, which grouped perceptions of product quality improvement, operational alignment, and reduced circulation of substandard medicines, reflects a broadly favorable view of reform impact. This is consistent with [15], who assert that reforms tied to internationally benchmarked regulatory maturity are most effective when they co-evolve with local quality assurance frameworks. On the other hand, the second component revealed a divide between internal readiness and external trust, with strong positive loading on firms' self-assessed compliance ability but weak confidence in the broader regulatory enforcement ecosystem. This dichotomy corroborates findings by [7], who argue that trust in regulation is not solely a function of rule clarity but also of enforcement consistency, perceived fairness, and regulator-industry engagement.

Moreover, the finding that SMEs are more likely to report cost-related and infrastructural constraints despite acknowledging the necessity of reforms reinforces the need for differential implementation strategies. As [8] observe, blanket regulatory requirements can be counterproductive unless accompanied by phased support schemes, technical assistance, and financial incentives that reflect firm-specific capacities.

Finally, while the PCA points to areas of reform success, it also reveals systemic gaps that merit policy attention. Limited use of digital traceability systems, uncertainty over the deterrent effect of regulatory inspections, and concerns over uneven implementation highlight the distance between policy design and practical realization. This reinforces the call by [6], along with recent WHO evaluations, which emphasize that effective regulatory impact is contingent on meaningful engagement with manufacturers, donors, and procurers to align regulatory design with implementation realities [19].

In summary, Nigeria's pharmaceutical regulatory reforms represent a substantive step toward strengthening market authorization, quality assurance, and post-market surveillance. Yet their effectiveness will ultimately depend on sustained industry engagement, targeted support for SMEs, and transparent enforcement mechanisms. Continued monitoring of manufacturer experiences, alongside responsive regulatory adjustments, is essential to converting policy success into systemic resilience and improved public health outcomes.

Conclusion

This study evaluated the awareness, adoption, and perceived impact of regulatory

reforms including GMP, QMS, NAPAMS, and PIDCARMS among licensed pharmaceutical manufacturers in Nigeria. Findings indicate that while awareness of core reforms is high, particularly for WHO GMP standards, adoption remains uneven, especially for digital systems such as PIDCARMS. Respondents largely acknowledged improvements in internal quality compliance and regulatory engagement, though concerns persist regarding implementation burdens, infrastructure deficits, and limited digital readiness.

Principal Component Analysis revealed two underlying dimensions: one capturing optimistic perceptions about quality and reform benefits, and another highlighting internal compliance capability amidst skepticism about enforcement consistency. These insights suggest that while policy frameworks have matured, their translation into consistent practice still faces organizational and systemic constraints. Future regulatory strengthening efforts must therefore be accompanied by targeted industry support especially for SMEs and responsive implementation strategies that promote trust, equity, and operational feasibility.

Strengths of the Study

This study's strength lies primarily in its methodological rigor and broad coverage of the target population. By achieving a response rate of 67.6% from Nigeria's 182 licensed pharmaceutical manufacturers, the study offers a comprehensive snapshot of industry perspectives. The inclusion of respondents from various regulatory and production roles enhances the diversity of insights, while geographical representation across different regions ensures contextual balance. The use of a structured, pre-tested questionnaire grounded in WHO GBT indicators and demonstrating high internal consistency (Cronbach's alpha = 0.82) reinforces the study's reliability. Additionally, combining descriptive statistics with Principal Component Analysis enabled both summary and in-depth pattern recognition, providing a robust framework for interpreting complex perceptions about reform implementation.

Weaknesses of the Study

Despite its strengths, the study is limited by its cross-sectional design, which captures perceptions at a single point in time and precludes conclusions about causality or change over time. The exclusion of informal or unregistered manufacturers, who represent a significant portion of Nigeria's pharmaceutical landscape, may narrow the generalizability of the findings to only formal-sector actors. Moreover, the absence of stratification by firm size or ownership structure means the study may have overlooked important variations in regulatory capacity, challenges, and resource availability. Another limitation stems from the reliance on self-reported data, which introduces the risk of social desirability bias or misrepresentation, particularly on sensitive topics such as compliance with regulatory standards.

Policy Implications

The findings from this study point to clear policy priorities for improving the effectiveness of pharmaceutical regulatory reforms in Nigeria. There is a need for differentiated implementation strategies that account for the varying capacities of manufacturers, particularly small and medium enterprises. Digital literacy and infrastructure support must be scaled to facilitate wider adoption of electronic platforms like PIDCARMS and NAPAMS. Additionally, regulatory agencies should consider offering phased or subsidized compliance programs to ease the cost burden associated with GMP and QMS adoption. Strengthening enforcement transparency, investing in regional regulatory support structures, and fostering ongoing dialogue between regulators and manufacturers will be essential for sustaining trust and driving long-

term reform adherence. These actions are critical to bridging the gap between policy formulation and practical implementation in Nigeria's pharmaceutical sector.

Competing Interest

The author declares that there are no competing interests related to this study. All data were collected, analyzed, and interpreted independently, and no external entity influenced the research process or findings.

Conflict of Interest

The author declares that there is no conflict of interest regarding the conduct of this study, the interpretation of its findings, or the preparation of this manuscript. The research was carried out independently, and no financial or personal relationships influenced its outcomes.

Ethical Approval

Ethical approval for this study was obtained from the University of Ibadan/University College Hospital Research Ethics Committee. Additionally, necessary permissions were obtained from the relevant individual firms. All respondents were informed of the study's objectives, assured of confidentiality, and provided written informed consent before participation, in accordance with the Declaration of Helsinki (2013 revision).

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Author Contribution

Khadijah O. Ade-Abolade served as the main author of this manuscript. Responsibilities included conceptualising the research idea, designing the study, developing and validating the data collection instrument, coordinating fieldwork, analysing the data, and interpreting the results. The author also wrote the manuscript, while it was revised critically for intellectual content and approved for final submission by the Co-Authors.

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