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The influence of good distribution practice compliance on pharmaceutical supply chain performance in Nigeria

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Abstract

Good Distribution Practice (GDP) compliance is critical to ensuring the integrity, safety, and efficiency of pharmaceutical supply chains, particularly in developing economies where infrastructural and regulatory challenges persist. This study examines the influence of GDP compliance on pharmaceutical supply chain performance in Nigeria, focusing on four core dimensions: traceability and serialization, handling and packaging practices, storage and warehousing compliance, and quality control and monitoring. Adopting a survey research design, data were collected from 251 employees in logistics, supply chain, and sales/marketing departments of pharmaceutical companies in Nigeria. Descriptive statistics and simple linear regression analyses were employed to test the study hypotheses. The findings reveal that all four dimensions of GDP compliance exert a statistically significant positive effect on pharmaceutical supply chain performance, measured in terms of product availability, delivery reliability, quality integrity, and responsiveness. The study concludes that strengthening GDP compliance is of strategic importance to improving supply chain outcomes and safeguarding public health in Nigeria. It recommends enhanced regulatory enforcement, investment in traceability technologies, improved warehousing infrastructure, and continuous quality monitoring as pathways to achieving sustainable pharmaceutical supply chain performance.

Keywords: Good Distribution Practice; Pharmaceutical Supply Chain Performance; Traceability and Serialization; Storage and Warehousing; Quality Control; Nigeria

1. Introduction

The pharmaceutical supply chain encompasses interconnected activities involved in the production, storage, distribution, and delivery of medicines to end users while maintaining product quality, safety, and efficacy. In developing countries such as Nigeria, pharmaceutical supply chains remain highly vulnerable to infrastructural deficiencies, weak regulatory enforcement, and poor distribution practices, leading to medicine shortages, product deterioration, and the circulation of substandard and falsified medicines (World Health Organization [WHO], 2017).

Good Distribution Practice (GDP) represents an internationally recognized quality assurance framework designed to ensure that pharmaceutical products are consistently stored, handled, transported, and distributed under appropriate conditions. GDP guidelines, issued by bodies such as the WHO and the European Commission, emphasize documentation, traceability, quality management systems, and environmental controls throughout the distribution lifecycle (WHO, 2010; European Commission, 2013).

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In Nigeria, regulatory agencies such as the National Agency for Food and Drug Administration and Control (NAFDAC) and the Pharmacists Council of Nigeria (PCN) oversee pharmaceutical distribution activities. Recent initiatives, including national pharmaceutical traceability strategies, reflect growing regulatory commitment to GDP compliance. However, empirical evidence linking specific GDP dimensions to supply chain performance outcomes in Nigeria remains limited.

Pharmaceutical supply chain performance refers to the extent to which distribution systems ensure product availability, timeliness, quality assurance, cost efficiency, and customer satisfaction. Weak adherence to GDP standards has been associated with poor inventory management, increased wastage, delivery delays, and heightened risks of counterfeit medicines (Wamba Fosso et al., 2020; Gupta & Pathak, 2021). This study therefore investigates how compliance with GDP standards influences pharmaceutical supply chain performance in Nigeria.

Despite regulatory frameworks governing pharmaceutical distribution in Nigeria, significant challenges persist in ensuring effective GDP compliance. These challenges include inadequate storage infrastructure, poor transportation networks, inconsistent regulatory enforcement, limited adoption of traceability technologies, and weak quality monitoring systems. Consequently, the Nigerian pharmaceutical supply chain continues to experience inefficiencies, medicine shortages, and quality risks that undermine public health outcomes.

Existing studies largely focus on manufacturing practices or broad supply chain challenges without disaggregating GDP into measurable components or empirically assessing their performance implications within the Nigerian context. This knowledge gap constrains evidence-based policymaking and limits the ability of firms and regulators to prioritize interventions that enhance supply chain performance. Addressing this gap is essential for strengthening pharmaceutical distribution systems and ensuring reliable access to quality medicines in Nigeria.

The main objective of this study is to examine the influence of Good Distribution Practice compliance on pharmaceutical supply chain performance in Nigeria. Specifically, the study seeks to:

- Examine the effect of traceability and serialization on pharmaceutical supply chain performance in Nigeria.
- Assess the influence of handling and packaging practices, in line with GDP compliance, on pharmaceutical supply chain performance in Nigeria.
- Evaluate the effect of storage and warehousing compliance on pharmaceutical supply chain performance in Nigeria.
- Determine the influence of quality control and monitoring under GDP standards on pharmaceutical supply chain performance in Nigeria.

The following hypotheses will be tested:

- H01: Traceability and serialization have no significant effect on pharmaceutical supply chain performance in Nigeria.
- H02: Handling and packaging practices under GDP compliance have no significant effect on pharmaceutical supply chain performance in Nigeria.
- H03: Storage and warehousing compliance do not significantly influence pharmaceutical supply chain performance in Nigeria.
- H04: Quality control and monitoring under GDP standards have no significant influence on pharmaceutical supply chain performance in Nigeria.

2. Literature Review

2.1. Good Distribution Practice (GDP)

Good Distribution Practice refers to the set of quality assurance principles and guidelines that govern the distribution, storage, and transportation of pharmaceutical products to ensure that their quality and integrity are maintained throughout the supply chain (WHO, 2010). GDP covers activities beyond manufacturing, including warehousing, order fulfillment, transport, documentation, and recall management.

Key elements of GDP include quality management systems, personnel training, premises and equipment standards, temperature control, traceability, and risk management. Effective GDP implementation minimizes the risks of

contamination, degradation, diversion, and counterfeiting, thereby protecting patient safety and enhancing supply chain reliability (Ali et al., 2023).

2.2. Pharmaceutical Supply Chain Performance

Pharmaceutical supply chain performance reflects the ability of distribution systems to deliver medicines efficiently, reliably, and safely to healthcare providers and patients. Performance indicators commonly include product availability, lead time, delivery accuracy, inventory efficiency, quality assurance, and customer satisfaction (Ivanov & Dolgui, 2020).

In the pharmaceutical context, performance is closely linked to regulatory compliance and process quality. Weak distribution practices often result in stock-outs, wastage, and compromised medicine quality, whereas strong GDP compliance enhances transparency, responsiveness, and trust across the supply chain (Ying et al., 2021).

2.3. Traceability and Serialization

Traceability refers to the ability to track pharmaceutical products throughout the supply chain, while serialization involves assigning unique identifiers to individual product units. These mechanisms enhance supply chain visibility, support recalls, and combat substandard and falsified medicines (Sarkar, 2024). In Nigeria, national traceability initiatives spearheaded by NAFDAC aim to strengthen regulatory oversight and improve supply chain performance.

2.4. Handling, Packaging, Storage, and Quality Control

Proper handling and packaging protect pharmaceutical products from physical damage and environmental exposure during distribution. Storage and warehousing compliance ensure that medicines are kept under controlled conditions that preserve their efficacy. Quality control and monitoring involve systematic inspections, environmental monitoring, and corrective actions to ensure ongoing compliance with GDP standards (WHO, 2010).

This study is grounded in the Resource-Based View (RBV) and Institutional Theory. RBV, advanced by Penrose (1959), Wernerfelt (1984), and Barney (1991), posits that firms achieve sustained competitive advantage through valuable, rare, inimitable, and non-substitutable resources. In this context, GDP compliance systems, such as traceability infrastructure, quality monitoring, and skilled personnel, are viewed as strategic resources that enhance pharmaceutical supply chain performance.

Institutional Theory, developed by Meyer and Rowan (1977) and DiMaggio and Powell (1983), and further elaborated by Scott (2008), explains how regulatory, normative, and cognitive pressures shape organizational behavior. Here, compliance with GDP standards is seen as a response to regulatory mandates and the need for legitimacy. Thus, Institutional Theory explains why firms adopt GDP practices, while RBV explains how these practices improve performance.

However, empirical studies indicate a positive relationship between regulatory compliance and supply chain performance; Wamba Fosso et al. (2020) found that compliance with logistics standards improves operational efficiency and service quality. Adeyeye et al. (2023) reported that pharmaceutical traceability initiatives enhance monitoring and reduce counterfeit risks. However, few studies provide Nigeria-specific empirical evidence on the disaggregated effects of GDP dimensions, underscoring the contribution of the present study.

3. Methodology

3.1. Research Design

This study adopted a quantitative cross-sectional survey research design. The design was considered appropriate because it enables the collection of standardized data from a defined population at a single point in time and facilitates statistical examination of relationships between variables. The study sought to determine the effect of Good Distribution Practice (GDP) compliance dimensions on pharmaceutical supply chain performance; therefore, a quantitative approach allowed for objective measurement and hypothesis testing.

3.2. Population of the Study

The population comprised employees working in logistics, supply chain management, warehousing, quality assurance, and sales departments of selected pharmaceutical manufacturing and distribution companies operating in Nigeria. The total accessible population was 251 staff members across the selected firms.

3.3. Sample Size and Sampling Technique

Given the relatively manageable population size, a census sampling technique was adopted, where all 251 employees were included in the study. The census approach eliminates sampling error and increases the representativeness of the findings. It also enhances statistical power in regression analysis.

3.4. Sources of Data

Primary data were used for this study. Data were collected directly from respondents through structured questionnaires administered electronically. Secondary data from regulatory documents, WHO GDP guidelines, and existing literature were used to support conceptual and theoretical discussions.

3.5. Instrument for Data Collection

Data were collected using a structured questionnaire divided into two main sections:

- Section A captured demographic characteristics such as gender, years of experience, and department.
- Section B measured the study variables.

The independent variable (GDP compliance) was operationalized into four dimensions:

- Traceability and serialization
- Handling and packaging practices
- Storage and warehousing compliance
- Quality control and monitoring

The dependent variable, pharmaceutical supply chain performance, was measured using indicators such as product availability, delivery timeliness, inventory efficiency, and quality integrity.

All items were measured using a five-point Likert scale ranging from 1 (Strongly Disagree) to 5 (Strongly Agree).

3.6. Validity of the Instrument

Content validity was ensured through expert review by academics in supply chain management and professionals in pharmaceutical regulation. Their feedback helped refine ambiguous items and ensured that the instrument adequately captured GDP compliance and performance constructs.

Construct validity was supported through alignment of measurement items with established GDP guidelines and prior empirical studies.

3.7. Reliability of the Instrument

Reliability was assessed using Cronbach's alpha coefficient. The results indicated acceptable internal consistency for all constructs, with alpha values exceeding the recommended threshold of 0.70. This suggests that the instrument reliably measured the intended variables.

3.8. Model Specification

To examine the effect of GDP compliance on pharmaceutical supply chain performance, the following regression model was specified:

$$PSCP = \beta_0 + \beta_1 TRS + \beta_2 HPP + \beta_3 SWC + \beta_4 QCM + \varepsilon$$

Where: PSCP = Pharmaceutical Supply Chain Performance

TRS = Traceability and Serialization

HPP = Handling and Packaging Practices

SWC = Storage and Warehousing Compliance

QCM = Quality Control and Monitoring

β_0 = Intercept

β_1 - β_4 = Regression coefficients

ε = Error term

3.9. Method of Data Analysis

Data were coded and analyzed using statistical software. Descriptive statistics (mean and standard deviation) were used to summarize respondents' perceptions. Inferential statistics, particularly simple and multiple linear regression analysis, were employed to test the hypotheses at a 5% level of significance. The coefficient of determination (R^2) was used to assess explanatory power, while the F-statistic and p-values were used to determine statistical significance.

3.10. Ethical Considerations

Participation in the study was voluntary. Respondents were assured of confidentiality and anonymity, and the information provided was used strictly for academic purposes. Informed consent was obtained before data collection.

4. Results

4.1. Descriptive Statistics

Table 1 presents the descriptive statistics for the study variables. The results indicate generally high levels of GDP compliance and pharmaceutical supply chain performance among the surveyed firms. Mean scores for all GDP dimensions are above the benchmark mean of 3.00, suggesting that respondents largely agree that GDP practices are implemented within their organizations.

Table 1 Descriptive Statistics of Study Variables

Variable	Mean	Standard Deviation
Traceability and Serialization	3.87	0.68
Handling and Packaging Practices	3.92	0.64
Storage and Warehousing Compliance	3.78	0.71
Quality Control and Monitoring	3.95	0.60
Pharmaceutical Supply Chain Performance	3.89	0.66

The relatively low standard deviations indicate consistency in respondents' perceptions across the sampled firms.

4.2. Test of Hypotheses

Simple linear regression analysis was employed to examine the effect of each GDP compliance dimension on pharmaceutical supply chain performance.

4.2.1. Effect of Traceability and Serialization on Supply Chain Performance

Table 2 Regression Result for Traceability and Serialization

Parameter	Value
R	0.612
R^2	0.375
Adjusted R^2	0.372
F-statistic	148.62
p-value	0.000

The result shows that traceability and serialization explain approximately 37.5% of the variation in pharmaceutical supply chain performance. The model is statistically significant ($p < 0.05$), leading to the rejection of the null hypothesis. This implies that traceability and serialization have a significant positive effect on supply chain performance.

4.2.2. *Effect of Handling and Packaging Practices on Supply Chain Performance*

Table 3 Regression Result for Handling and Packaging Practices

Parameter	Value
R	0.645
R ²	0.416
Adjusted R ²	0.414
F-statistic	177.09
p-value	0.000

The results indicate that handling and packaging practices account for 41.6% of the variance in supply chain performance. The regression model is statistically significant, confirming that proper handling and packaging practices positively influence pharmaceutical supply chain performance.

4.2.3. *Effect of Storage and Warehousing Compliance on Supply Chain Performance*

Table 4 Regression Result for Storage and Warehousing Compliance

Parameter	Value
R	0.589
R ²	0.347
Adjusted R ²	0.344
F-statistic	132.41
p-value	0.000

Storage and warehousing compliance explain 34.7% of the variation in supply chain performance. The statistically significant p-value indicates that appropriate storage and warehousing conditions significantly enhance pharmaceutical supply chain outcomes.

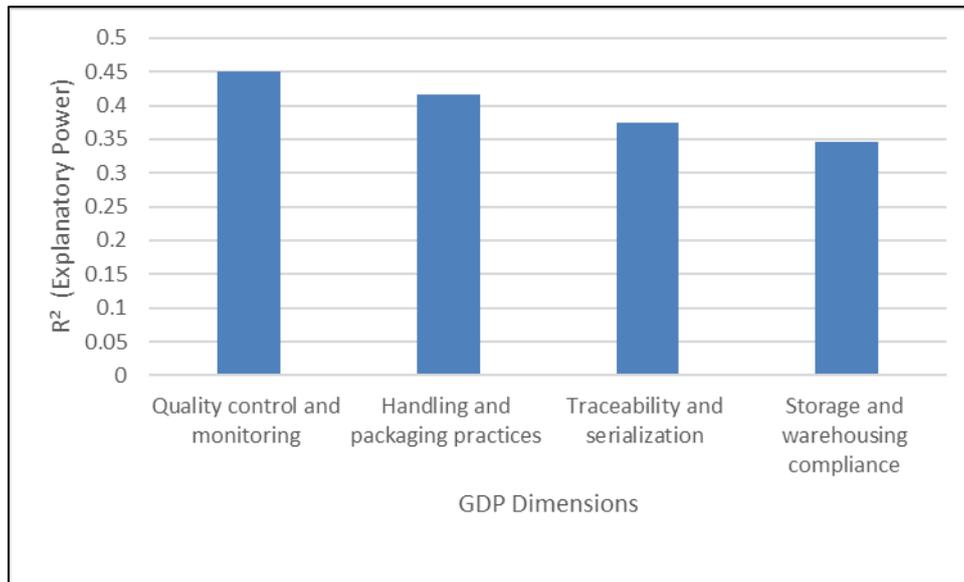
4.2.4. *Effect of Quality Control and Monitoring on Supply Chain Performance*

Table 5 Regression Result for Quality Control and Monitoring

Parameter	Value
R	0.671
R ²	0.450
Adjusted R ²	0.448
F-statistic	203.78
p-value	0.000

The results show that quality control and monitoring account for 45.0% of the variance in pharmaceutical supply chain performance. This dimension exhibits the strongest explanatory power among the GDP components, highlighting the critical role of continuous monitoring and quality assurance systems.

4.3. Comparative Influence of GDP Dimensions



(Bar chart illustrating R² values for traceability and serialization, handling and packaging practices, storage and warehousing compliance, and quality control and monitoring)

Figure 1 Comparative Effect of GDP Dimensions on Supply Chain Performance

Figure 1 illustrates the comparative explanatory power of GDP compliance dimensions on pharmaceutical supply chain performance. Quality control and monitoring exhibit the strongest effect ($R^2 = 0.450$), followed by handling and packaging practices ($R^2 = 0.416$), traceability and serialization ($R^2 = 0.375$), and storage and warehousing compliance ($R^2 = 0.347$).

5. Discussion of Findings

The findings of this study provide empirical evidence that compliance with Good Distribution Practice standards significantly improves pharmaceutical supply chain performance in Nigeria. The strong effect of quality control and monitoring underscores the importance of systematic inspections, temperature monitoring, and corrective actions in maintaining product integrity. The results also highlight the growing importance of traceability and serialization in improving transparency and reducing risks associated with counterfeit medicines.

Overall, the results affirm that GDP compliance is not merely a regulatory obligation but a strategic tool for enhancing efficiency, reliability, and public health outcomes in the pharmaceutical supply chain.

6. Conclusion

The study concludes that Good Distribution Practice compliance significantly influences pharmaceutical supply chain performance in Nigeria. Compliance with GDP standards enhances operational efficiency, product quality, and reliability of medicine distribution. This study provides empirical evidence on the disaggregated effects of GDP compliance dimensions on pharmaceutical supply chain performance in Nigeria, contributing to both academic literature and policy discourse.

Recommendations

- Regulatory agencies should strengthen enforcement of GDP standards and harmonize oversight functions.
- Pharmaceutical firms should invest in traceability and serialization technologies.
- Improved storage and cold-chain infrastructure should be prioritized.
- Continuous quality control and monitoring systems should be institutionalized.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare that there is no conflict of interest to be disclosed.

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