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Regulatory Environment and Performance of Selected Pharmaceutical Companies in Anambra State, Nigeria

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Abstract
The study examines the relationship between regulatory environment and performance of pharmaceutical companies in Anambra State, Nigeria. The study utilized the descriptive survey research design. The population comprised top and senior management personnel from one healthcare products provider and drug manufacturer in Awka metropolis. The study used the census technique and the sample comprised of the entire sixty-three employees from the two establishments. The study relied on primary data; obtained from a structured questionnaire. The questionnaire was designed in the Likert scale form. The data was analyzed using descriptive and inferential statistics. Pearson Product Moment Correlation Coefficient was used to validate the formulated hypothesis. The results showed that regulatory environment had a negative significant effect on organizational performance. Based on the findings, the study recommended among others that Government implements policies and measures that could trigger stability and reduce political risks. Managers should assess the strengths/weaknesses and opportunities/threats inherent in the environment and find ways of adapting to its changing nature.

Keywords: *Regulatory Environment, Regulatory Risk, Performance*

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I. Introduction

The organisational environment is a complex, multi-faceted and dynamic space organisations operate (Eruemegbe, 2015). Broadly, it refers to the aggregate of all factors or conditions and circumstances that influence or affect an organization (Adidu & Olanye, 2006). These factors may be broadly classified into two: internal and external factors. While, internal factors focus on that which are within the control of the company like product, organizational culture, leadership, and manufacturing (quality); the external factors includes such as social, environmental, technological, political, suppliers, competitors, government regulations and policies, etc., beyond the control of the company's management (Mwangi & Wekesa, 2017). Further authors have further sub-divided the external environment into two: directly interactive and indirectly interactive. While the former has a primary or firsthand impact upon the organization; the latter has a secondary or more distant effect upon the organization.

The regulatory environment is a subset of the external environment; and, refers to a variety of rules, regulations, policies, taxes, etc. that affect a business organisation. The regulatory environment has been identified as a controlling element for businesses to legally and freely function (Dixon, Gates, Kapur, Seabury, & Talley, 2006). It may be a directly or indirectly interactive force depending on the perceived impact on a business organisation. The regulatory environment may pose a threat or opportunity to an organisation which depends on its perceived impact. Koci (2018) observed that Government policies, supporting a dynamic business environment, create greater opportunities for all stakeholders. According to the African Development Report (2011) the legal and regulatory environment in Africa ranks amongst the least business-friendly in the world. The Report further identified "excessive business regulations, complicated permit procedures, and opaque tax assessment rules" among factors responsible for such regulatory issues.

Incessant regulatory changes by governments often creates a highly turbulent business environment; which, may pose difficulties for managers in forecasting demand or anticipating responses to marketing strategies (Klein, Frazier, & Roth, 1990). The World Bank Ease of Doing Business Report (2019) pointed out that one-third of all business regulatory reforms were recorded in the economies of Sub-Saharan Africa. This has greatly contributed to the decline in the 'Ease of Doing Business' index projection in the region. According to the World Bank Ease of Doing Business Report (2011), the estimated average rank of African countries on the ease of doing business index was 137 out of 183 economies, compared with 72 in Eastern Europe and Central Asia, 96 in Latin America and the Caribbean, and 87 for East Asia and the Pacific. Among the top perceived reasons for the score cited were corruption; customs and trade regulations; tax administration and rates; labour regulations; ease of getting operating permits and licensing; or the judicial system (African Development Report, 2011; World Bank Enterprise Surveys database, 2010). Presently, the Nigerian economy ranks 146 out of 190 economies in the overall Ease of Doing Business.

The Nigerian regulatory environment has witnessed a lot of changes over time (Eruemegbe, 2015). The Government has formulated several policies starting from the 80s Structural Adjustment Programme (SAP), Companies and Allied Matters Act (CAMA), and several other Corporate Governance Codes, among others. The Nigerian Code of Corporate Governance (2019) is regarded as the standard in the corporate landscape in Nigeria. The Code adopts a principle-based approach in specifying minimum standards of practice that companies should adopt (Proshare, 2019). Another significant regulatory reform was the requirement for publicly quoted companies to prepare accounts in line with International Financial Reporting Standards [IFRS] from 2012. This followed from the recommendation of the Federal Executive Council (FEC) in 2010, and was preceded with the enactment of the Financial Regulation Council of Nigeria Act (FRCN) in 2011; which transformed the Nigeria Accounting Standard Board (NASB) to Financial Regulation Council (FRC) (Okafor, Ogbuehi, & Anene, 2017). In addition, the Central Bank of Nigeria has instituted several banking reforms over the years. The reforms were directed towards financial intermediation, financial stability, and confidence in the system (Central Bank of Nigeria, 2012).

The pharmaceutical sector is vital to the growth and development of any nation. It plays a key role in the health of citizens. The pharmaceutical sector is a complex one, involving many different stakeholders such as the manufacturers themselves, national regulators, government ministries, wholesalers and others (United Nations Industrial Development Organization [UNIDO], 2011). The industry has grown at an average annual rate of between 10 and 15 percent over the last five years (Pharmaceutical Manufacturing Group of the Manufacturers' Association of Nigeria [PMG-MAN]). The relationship between a business and the environment is that of mutuality, that is, the environment exerts pressure on the business while the business, in turn influences some aspects of its environment (Akpoviroro & Owotutu, 2018; Ajayi, 2016). Threats such as new regulatory requirements, hostile shifts in market demands, revolutionary technologies and competitors make the business environment very fatal (Johnson, Scholes &Whittington, 2008).Thus, the survival of a business depends on its interaction with the environment; which may be constrained by regulatory forces (Adeoye & Elegunde, 2012). According to Musara and Gwaindepi (2014), even with the availability of resources, skills, and infrastructure, failure to address issues within the regulatory environment may hinder improvements in organisational performance. According to Adala (2014) the failure to adapt to changing regulatory requirements could have serious impact for a firm. Thus, managers are expected to be conscious of the environment and general trends in the economy in decision-making. Against this backdrop, the paper addresses the influence of regulatory environment on the performance of pharmaceutical firms in Anambra State. The study, therefore, is set out to address the following questions:

1. What factors within the regulatory environment constrain the performance of pharmaceutical companies in Anambra State?
2. To what extent has the regulatory environment hindered the performance of pharmaceutical companies in Anambra State?

II. Review of Related Literature

2.1 Conceptual Framework

2.1.1 Organisational Environment

The word "environment'' is derived from the French word "Environ" which means "surrounding". Harrison (1996) defines environment as all the conditions circumstances, and influences surrounding and affecting the development of the total organization or any of its internal systems. He argued that environment contains forces of complexity that are dynamic to varying degrees at differences, and under different circumstances. Atsegbua (2002) described environment as the system of abiotic, biotic and interact and simultaneous to which he adapts and transforms and uses in order to satisfy his needs. Organizations are ecological entities that have mutual relations with other entities in their environment where they operate as open systems and rely on their environment for their input and market for their end products (Mwangi & Wekesa, 2017). The environment of an organization may be described as "the pattern of all the external conditions and influences that affect its life and development" (Mintzberg, Lampel, Quinn, & Ghoshal, 2003).

The organizational environment is the set of forces surrounding an organization that have the potential to affect the way it operates (Davis & Powell, 2012). According to Duncan (1972) the external business environment refers to the totality of factors outside an organization that are taken into consideration by an organization in its decision making. These factors depend largely on the complexity and dynamism of the environment (Duncan, 1972; Dess & Beard, 1984). This, external business environment is classified as being stable when it does not show any changes, unstable when it shows relative changes and dynamic when it shows changes continuously (Aguilar, 1967). Organizations seek to manage the uncertainty imposed by their interdependence with the environment in two ways: (a) through internal strategies of adaptation and adjustment or organizational design and (b) through external environmental conditions which are important in effective strategic responses by organization (Mitchell, Shepherd, & Sharfman, 2011). According to Chidambaram and Alagappan (2002) business environment is very important to organsiations in the following ways:

a. **Determining Opportunities and Threats:** The interaction between the business and its environment would identify opportunities for and threats to the business. It also helps the business enterprises for meeting the challenges successfully.

b. **Giving Direction for Growth:** The interaction with the environment leads to opening up new frontiers of growth for the business enterprises. It enables the business to identify the areas of growth and expansion of their activities.

c. **Continuous Learning:** Environmental analysis makes the tasks of managers easier in dealing with agro-business enterprises challenges. The managers are motivated to continuously update their knowledge, understanding and skills to meet the predicted changes in realm of business.

d. **Image Building:** Environmental understanding helps the business organizations in improving their image by showing their sensitivity to the environment with which they are working.

e. **Identifying Firm's Strength and Weakness:** Business environment helps to identify the individual strengths and weaknesses in view of the technological and global developments.

2.1.2 The Regulatory Environment and Organisational Performance

According to Kitching, Hart, and Wilson (2015) regulation can be defined "as a system of state-authorised and enforced rules, existing as texts in statutes or other legal instruments, possessing the power to shape social action and interaction by mandating or prohibiting action by agents (individuals and organisations), with such rules enforced by state agents…". They further note that regulation may take any form, such as:

i. acts of parliament;
ii. statutory instruments;
iii. rules, orders, and schemes made under statutory powers by ministers or agencies;
iv. licenses and permits issued under the central government authority;
v. codes of practice and guidance with statutory force; and,
vi. judicial and other enforcement body decisions, etc.

Regulatory risk is the risk of a change in regulations and laws that might affect an industry or a business (The Economic Times, 2019). According to Kansal (2015), regulatory risks imply the risk of changes in regulatory policies or legal framework of government which may render a business unprofitable. Examples may include import and export restrictions, price controls, stringent environmental laws or labour standards, preferential policy towards protection of domestic companies, etc.

Regulatory changes may occur when there is a change in the ruling government, or even when the pre-existing host government changes its priorities, or when the political system itself changes (Kansal, 2015). According to the Economic Times (2019) regulatory changes may cause significant changes in the framework of industries and businesses, changes in the cost structure, among others.

According to Agboli and Ukaegbu (2006) the interaction of an organization and its host environment can be examined from *three* strategic perspectives; *Firstly*, an organization can be viewed as importing various inputs (resources), such as human resources, capital, managerial, and technical resources. These resources are then transformed to generate output which takes the form of goods and services. *Secondly*, an organization may be regarded as a nexus of contractual relationship. It focuses on the demands and legitimate rights of different claimants such as employees, consumers, suppliers, stakeholders, government and the community. *Thirdly*, the organization can be viewed as operating in an external environment of opportunities and constraints.

Kitching, Hart, and Wilson (2015) observed that the regulatory environment creates 'variable firm-level performance effects' because of differing impacts on different organisations. Thus, regulation may enable or constrain business performance in various ways simultaneously. Mark and Nwaiwu (2015) observed that regulatory changes have the potential to promote or inhibit market competition.

2.1.3 Organisational Performance

According to Salem (2003) performance is defined as the "outcomes about work because they provide the strongest linkage to the strategic goals of an organization, customer satisfaction and economic contributions". Organizational performance is a measure of the change of the state of an organization, or the outcomes that results from management decisions and the execution of those decisions by members of the organization (Carton & Hofer, 2006). Lebans and Euske (2006) provide a set of definitions to illustrate the concept of organizational performance:

- Performance is a set of financial and non-financial indicators which offer information on the degree of achieving of objectives and results.
- Performance is dynamic, requiring judgment and by using a causal model that describes how current actions may affect future results.
- To define the concept of performance is necessary to know its elements characteristic to each area of responsibility.
- To report an organization's performance level, it is necessary to be able to quantify the results.

According to Richard, Devinney, Yip, and Johnson (2009) organizational performance encompasses three specific areas of firm outcomes: financial performance (profits, return on assets, return on investment, etc.), product market performance (sales, market share, etc.); and shareholder return (total shareholder return, economic value added).

2.2 Theoretical Framework

The study is anchored on the *systems theory*. Nwachukwu (2006) defines a system as "a set of interrelated and interdependent parts arranged in a manner that produces a united whole". A system can either be closed or open. A closed system does not allow for interactions between elements within the system and it's environment; while, an open system allows for interactions both within the system and outside it. Closed systems tend towards negative entropy with the likelihood of decaying due to the absence of exchanges with outside systems. The regulatory environment is part of the external environment of a business which interacts with the business and ultimately determines the performance.

2.3 Empirical Review

Akpoviroro and Owotutu (2018) investigated the impact of external business environment on organizational performance. The study utilized the survey research design. The sample comprised of 120 employees from three frozen fish companies. The study relied on primary data; obtained from a structured questionnaire. The data was analysed using multiple regression technique. The result showed that economic and political environment had a positive significant effect on organisational performance.

Eruemegbe (2016) investigated the impact of business environment on organisational performance of employees of Union Bank, Nigeria. The study utilized the survey research design. The sample comprised of 39 employees in Union Bank of Nigeria**,** Lagos branch. The study used primary data; obtained from a structured questionnaire administered. The data was analysed using Chi-Square technique. The results showed that several factors such as (teamwork, work based on contract, supervision based on leadership by example, provision of equipment, communication, love and belongingness, opportunity to undertake challenging task, identification with goal and overtime) were among factors that affected workers motivation and productivity.

Njoroge, Ongeti, Kinuu, and Kasomi (2016) examined the influence of external environment on performance of Kenyan State corporations. They examined three dimensions of external environment namely munificence, complexity and dynamism; while, performance was measured along all the indicators of the sustainable balanced scorecard. The sample consisted of 98 Kenyan State corporations. The study utilised primary data. The results revealed that external environment had a positive significant influence on all the indicators of performance.

Ajayi (2016) examined the impact of external business environment on organizational performance of Micro, Small and Medium Scale Enterprises (MSMEs) in Nigeria. The study relied on secondary data. The study finds from reviewed literature that external business environment (economic, political, legal, socio-cultural, demographic, natural, technological, global and financial) affect MSMEs. Secondly, there exists a relationship between environment and MSMEs performance in Nigeria.

Mark and Nwaiwu (2015) investigated the impact of political environment on business performance of multinational companies in Nigeria. The sample comprised of 27 manufacturing companies quoted on the Nigerian Stock Exchange. The study relied on secondary data; obtained from the Nigerian Stock Exchange Fact Book and World Development Indicators. The duration of the study was from 1999 to 2013. The data was analysed using multiple linear regression. The results showed that political environment had a negative significant impact on business performance of multinational companies.

Gado (2015) investigated the impact of business environment on company performance in Nigeria. The sample comprised the 20 most capitalised companies on the Nigerian Stock Exchange. The study relied on secondary data. The data was analysed using Ordinary Least Square and correlation. The results showed that the business environment affects performance of these companies. Specifically, government expenditure and inflation have positive impact while exchange rate and interest rate have negative impact.

Obasan (2014) examined the impact of business environment on the survival of small scale businesses in Nigeria. The study employed logistic regression technique to analyze primary data obtained through a structured questionnaire administered to eighty small scale businessmen and women operators in Ijebu North Local Government area, (Ogun State) South-West Nigeria. The result revealed that the model of logistic regression was able to predict the distribution of 72.15% of the observed values of the dependent variable as factors such inflationary trend; infrastructural facilities accessibility and government policy serve as barriers to business growth and survival.

Okeyo (2014) examined the effect of business environment on Small and Medium Enterprises (SMEs) in Kenya. The study utilised the cross sectional survey research design. The sample consisted of 150 enterprises randomly selected through stratification by business sector. The study relied on primary data; obtained via a structured questionnaire. The data were analysed using descriptive and inferential statistics. The results showed that the business environment had an overall impact on organizational performance.

Musara and Gwaindepi (2014) examined factors within the business regulatory environment that affect entrepreneurial activity in South Africa. The sample comprised of 153 new business owners in the Limpopo Province of South Africa. The study relied on primary data; obtained via a structured questionnaire. The data were analysed using t-test statistic, ordinary least squares and Spearman correlation methods. The results showed that regulatory factors (i.e., policy credibility, corruption, bureaucracy, and labour restrictions) had a negative significant effect on entrepreneurial activity. The variable policy compliance also had a negative but non-significant effect on entrepreneurial activity.

Enyioko (2012) examined the effect of interest rate policies on the performance of banks in Nigeria. The sample comprised of 20 banks that emerged from the consolidation exercise. The study relied on secondary data; obtained from published accounts of the banks and from the Central Bank of Nigeria (CBN). The data were analysed using linear regression and error correction models. The results revealed that interest rate policies have not improved the overall performances of banks significantly.

Adeoye and Elegunde (2012) examined the impact of external business environment on organisational performance in Nigeria. The sample consisted of 3 companies in the food and beverage industry. The study relied on primary data; obtained from questionnaires. The data were analysed using multiple regression analysis. The results revealed that external business environment (political, economic, socio-cultural, technological, *etc.*) impact on organisational performance (effectiveness, efficiency, increase in sales, achievement of corporate goals *etc.*).

Machuki and Aosa (2011) investigated the effect of the external environment on corporate performance. The sample was drawn from 23 companies listed on the Nairobi Stock Exchange. The study relied on primary data; obtained from a structured questionnaire. The results revealed that the overall effect of external environment on corporate performance was statistically not significant.

III. Methodology

3.1 Research Design

The study adopted descriptive survey research design. This research design entails gathering information regarding perceptions through the use of questionnaires from a sample of respondents. The design was considered suitable because the intent of the researcher is to describe the effect of regulatory environment on the performance of pharmaceutical companies. Thus, the dependent variable was performance and the independent variable was regulatory environment.

3.2 Population of the Study

The population is defined as all the members of a real or hypothetical set of people, events or objects to which a researcher wishes to generalize the results of the study (Borg & Gall, 1989). The population of the study was drawn from top and senior management staff of two firms operating in Awka metropolis: Juhel Pharmaceuticals and Grafil Healthcare providers. The two firms had offices located in Awka, the capital of Anambra State. The details are shown in the table below:

Table 1: Population distribution

S/No.	Company name	Admin Personnel
1.	Juhel	44
2.	Grafil	19
	Total	**63**

Source: Field Survey (September, 2019)

3.3 Sample Size of the Study

The sample size refers to the proportion of the population under study utilized to test and provide information on the whole. However, since the study population is relatively small, a census was undertaken instead of sampling. According to Lodico, Spaulding and Voetgle (2010), a census is whereby a researcher surveys the entire realistic population; and, is a method appropriate when the realistic population is not too large.

3.4 Methods of Data Collection

The study relied solely on primary data. The data was collected using a self-constructed questionnaire. The questionnaire was designed in the Likert-type scale statements. The questionnaire comprised of two sections: Section A, to obtain personal information of the respondent and, Section B to obtain information on items related to the study objectives. The response options were Strongly Agree (SA), Agree (A), Indifferent (I), Disagree (D), and Strongly Disagree (SD). The scores were weighted as follows (SA: 5), (A: 4), (I: 3), (D: 2), and (SD: 1) respectively.

3.5 Methods of Data Analysis

The data were analysed using descriptive and inferential statistics. Descriptive statistics comprised the mean and standard deviation. The inferential statistics was performed using Pearson's correlation coefficient. Correlation is an inferential statistical technique that helps determine whether there is an association between two variables (Ornstein & Lyhagen, 2016). The Pearson correlation coefficient is a measure of the strength of a linear association between two variables and is denoted by *r*. The hypothesis was tested at 5% significance level.

IV. Data Presentation and Analysis

The study relied on primary data which was analysed using the Statistical Package for Social Sciences (SPSS). The total number of questionnaires distributed was 63; however, 58 were fully completed and returned. This represents an approximate 92.1% success rate in questionnaire administration. The demographic information of the respondents is shown in the table below.

Table 2: Demographic information of the respondents

Demographic profile		Frequency	Percentage (%)
Age:	25-35	19	32.76
	36-45	29	50.00
45 & above		10	17.24
		58	**100**
Gender:	Male	34	58.62
	Female	24	41.38
		58	**100**
Highest Educational Qualification:	Secondary School	-	-
	Diploma (NCE, OND, etc.)	-	-
Bachelor Degree (HND, BSc, BA, etc.)		45	77.59
Post-graduate (PGD, MSc, PhD)		13	22.41
		58	**100**
Years of work experience:	1 - 5	32	55.17
	6 - 10	16	27.59
	11 - 15	7	12.07
16 & Above		3	5.17
		58	**100**

Source: Field Survey (September 2020)

The questionnaire consisted of eight items (12), 6 items measured regulatory environment and 6 items measured performance. Each item was rated on a 5-point Likert-type scale with response categories ranging from *strongly disagree* (1) to *strongly agree* (5). The reliability of the instrument was tested using Cronbach Alpha (α), which measures the internal consistency of a scale.

Table 3: Reliability statistics

	N	**Cronbach Alpha (α)**
Regulatory environment:	6	.771
Performance:	6	.872

Source: SPSS Ver. 24

The items were sub-divided into two subscales, the regulatory environment subscale consisted of 6 items [Questions 1-6] the Cronbach Alpha (α) value was .771; and, the business performance subscale consisted of 6 items [Questions 7-12] the Cronbach alpha (α) value was .872. The overall Cronbach Alpha (α) for the 12 items was .790; thus, the instrument showed a high degree of internal consistency.

Table 3: Reliability statistics

Regulatory environment					
Item description	**Min.**	**Max.**	**N**	**Mean**	**Rank**
Labour restrictions	1	5	58	3.21	6th
Corruption	1	5	58	3.73	4th
New industry regulations	1	5	58	3.49	5th
Compliance costs	1	5	58	4.04	2nd
Government bureaucracy	1	5	58	3.91	3rd
Taxes	1	5	58	4.23	1st
Organisational performance					
Item description	**Min.**	**Max.**	**N**	**Mean**	**Rank**
Increased profitability	1	5	58	4.00	2nd
Service delivery/quality	1	5	58	4.02	1st
Cost reduction	1	5	58	3.91	3rd
Goal accomplishment	1	5	58	3.44	6th
Degree of innovation	1	5	58	3.65	5th
Employee emoluments	1	5	58	3.76	4th

Source: SPSS Ver. 24

4.1 Analysis of Hypotheses:

H_1: There is a significant relationship between regulatory environment and organisational performance of pharmaceutical companies in Anambra State.

The Pearson correlation result is shown in the table below:

Table 4: Pearson correlation between regulatory environment and performance

		RE	PERF
RE	Pearson Correlation	1	-.839
	Sig. (2-tailed)		.004
	N	58	58
PERF	Pearson Correlation	-.839	1
	Sig. (2-tailed)	.004	
	N	58	58

Source: SPSS Ver. 24

The table shows that the correlation coefficient (PPMC) is -.839; and, negative. Thus, regulatory environment is negatively correlated with organizational performance and significant ($p<.05$). Since, the p-value .004 is less than the chosen alpha value .05; the study concludes that regulatory environment has a significant negative relationship with organizational performance. Therefore, the null hypothesis is rejected and the alternate accepted.

V. Conclusion and Recommendations

The study examined the influence of regulatory environment on organizational performance. A survey of respondents of pharmaceutical companies in Anambra State was conducted. The respondents identified among others that taxes, compliance costs and Government bureaucracy were the three most prominent regulatory challenges posed in business environment. The empirical data analysis revealed that regulatory environment had a negative effect on business performance. The Pearson Correlation Coefficient showed a negative value of -.839; and, p value less than .05. Hence, the study concludes that regulatory environment is a significant factor affecting pharmaceutical companies in Anambra State. Based on the findings, the study makes the following recommendations:

1. Creating an enabling environment for organizations to operate is a crucial factor which determines performance; hence, it is highly recommended that Government implement policies and measures that could trigger stability and reduce political risks. An enabling environment leads to greater levels of investment by the private sector, more wealth, job creation and poverty alleviation (Adeoye & Elegunde, 2012). Regulatory agencies are advised to develop resolution mechanisms for tackling contradictory regulatory influences which may impair organizational performance.
2. In other to effectively manage her organizations, Companies should carefully have an assessment of strengths/weaknesses and opportunities/threats inherent in the environment and finding a way to adapt to its changing nature. Managers are advised to tap into regulatory reforms to seek out new market opportunities, process and product innovations in order to contribute to higher levels of performance (Kitching, Hart, & Wilson, 2015).

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