

# UKWURU ECONOMICS

Ukw Econ. 2025; 25(10): 1-19. Published Online 2025 January 17

UkwEconID: USEcon1

## **BUSINESS PLAN FOR MANUFACTURING OF ACTIVE PHARMACEUTICALS INGREDIENT (API) IN WEST AFRICA: A CASE STUDY PLAN FOR NIGERIA.**

Ukwuru Jonathan Oga

### **ABSTRACT**

#### **Background**

This study focused on: Business plan for the Manufacturing of Active Pharmaceuticals Ingredient (API) in West Africa; A case study plan for Nigeria, an innovative program plan in the pharmaceutical industry to position Nigeria towards recognition in the global standard and competition. The research was undertaken, to; examine how the initiation and utility of API can be encouraged and managed to achieve the twin objectives of growth and competitive advantage on healthcare delivery in Nigeria and neighboring countries of West Africa.

#### **Method**

The researcher used both primary and secondary sources of data collection. Statistical tools as frequency distribution, tables, percentages, and Statistical package for social scientist (SPSS) version 23 were used in the analysis of data and test of hypotheses.

#### **Findings**

The findings in the test of hypotheses were the following; Initiation and utility of API cannot significantly be encouraged and managed to achieve the twin objectives of growth and competitive advantage on health care delivery both in Nigeria and neighboring countries of West Africa, Innovations in the use of API in Nigeria do not improve supply chain management platform in the highly competitive global health care delivery, Lockdown and related policies are not barriers caused by global pandemics (especially Covid-19) in the use of API in Nigeria as compared to other symptoms and diseases to income generation and employment, Skilled and unskilled personnel (manpower) requirements are not the core competences and elements of best practice in which technology could leverage for API production and use in Nigeria and Hidden talents and potentials to the production and use of API cannot be explored and managed to create value measurable to global standards and competition.

#### **Conclusion**

Public Private Partnership Initiative (PPPI) in the implementation of APIC schedules in Nigeria and West African countries is essential for achieving positive outcomes in the pharmaceutical industry.

## **Recommendations**

Initiation and utility of API can be encouraged and managed to achieve the twin objectives of growth and competitive advantage on health care delivery both in Nigeria and neighboring countries of West Africa by putting into practice a variety of programmes for API manufacturing.

**Keywords: API, Pharmaceutical, Manufacturing, Competitive advantage, West Africa.**

## **1.0 Introduction**

### **1.1 Overview of the Study**

The pharmaceutical industry plays a crucial role in the global healthcare system, particularly in ensuring the availability of high-quality, safe, and effective medicines. Central to this industry is the production of Active Pharmaceutical Ingredients (APIs), the biologically active components of drugs. APIs are the key components that ensure the therapeutic effectiveness of medicines, and their availability is critical for the production of a wide range of pharmaceutical products (Asante, 2017). However, many developing countries, including Nigeria, heavily rely on imported APIs, particularly from India and China. This dependency has resulted in several challenges, including higher production costs, supply chain vulnerabilities, and limited access to essential medicines (Adeyemi et al., 2018).

Nigeria, the largest economy in West Africa, faces significant barriers to local API production despite the growing demand for pharmaceutical products, particularly in response to prevalent diseases such as malaria and tuberculosis (Fortunak et al., 2016). The over-reliance on imported APIs has hindered the growth of the local pharmaceutical industry, making it difficult for Nigerian pharmaceutical companies to compete in both the domestic and global markets (Ogbinna, 2017). Moreover, the COVID-19 pandemic exposed the fragility of Nigeria's pharmaceutical supply chains, further emphasizing the need for local API manufacturing to strengthen the country's healthcare infrastructure (Ayo-Lawal et al., 2022).

This study aims to evaluate the feasibility and benefits of local API production in Nigeria. It will explore how Nigeria can leverage its market size, human capital, and strategic position in West Africa to establish a sustainable API manufacturing industry. The successful development of this sector could reduce Nigeria's dependence on imports, lower healthcare costs, create jobs, and enhance Nigeria's competitiveness in the global pharmaceutical market (Yusuff et al., 2022).

Nigeria's pharmaceutical industry is highly dependent on imported APIs, primarily from India and China, which account for about 60-80% of the raw materials needed for local drug production (Adeyemi et al., 2018). This dependence has created a range of challenges, including supply chain disruptions, inflated costs, and limited availability of essential medicines. The outbreak of the COVID-19 pandemic further exacerbated these problems, highlighting the vulnerabilities of relying on foreign sources for critical

healthcare components (Ayo-Lawal et al., 2022). The lack of local API production has also limited Nigeria's ability to address the growing healthcare needs of its population. The country's pharmaceutical sector has been unable to fully capitalize on the high demand for medicines to treat both communicable diseases like malaria and non-communicable diseases such as diabetes and hypertension (Ogbinna, 2017). Furthermore, the absence of local API manufacturing has resulted in higher production costs, making medicines less affordable for the general population and reducing Nigeria's competitiveness in the global pharmaceutical market (Nwude, 2013). The key issue, therefore, is the absence of a robust local API manufacturing sector in Nigeria, which limits the country's ability to produce affordable medicines, meet local demand, and compete internationally. This study seeks to develop a business plan that addresses these challenges by exploring the opportunities for local API production in Nigeria and the steps necessary to achieve it (Ekeigwe, 2019).

The primary objective of this research is to develop a comprehensive business plan for the local production of APIs in Nigeria. The specific objectives are as follows:

## **2.0 Methodology**

### **Research Methods**

This study utilized semi-structured questionnaires and interviews as the primary methods of data collection (Patton, 2015). The questionnaire will include both closed-ended and open-ended questions, focusing on key themes such as the feasibility of local API production, regulatory challenges, and market opportunities. The interviews were conducted with pharmaceutical manufacturers, government officials, and policymakers who are directly involved in the pharmaceutical sector in Nigeria (Bryman & Bell, 2015).

### **Time Horizon**

Given the limited time frame available for this study, a cross-sectional time horizon was employed. This approach allowed the researcher to gather data from respondents at a specific point in time, providing a snapshot of the current state of API production in Nigeria. While a longitudinal study might offer insights into how perceptions and practices evolve over time, the cross-sectional design is appropriate for the purpose of this research due to the constraints of time and resources (Sekaran & Bougie, 2016).

### **Data Collection**

This study used primary data, collected through the distribution of questionnaires and the conduct of interviews. The primary data collected was supplemented with secondary data, drawn from academic journals, industry reports, and government publications, to provide a comprehensive understanding of the topic.

The survey questionnaire was designed to collect data on various aspects of API production, including the regulatory environment, financial barriers, and technological

capabilities. It included Likert scale questions to measure respondents' attitudes toward key issues, such as the feasibility of local API production and the impact of government policies. Open-ended questions will also be included to allow respondents to provide detailed responses on the challenges and opportunities they perceive in the industry (Bryman & Bell, 2015).

The sample population for this study consists of 75 pharmaceutical industry professionals and policymakers in Nigeria, selected using purposive sampling. Purposive sampling is appropriate for this study because it allows the researcher to select respondents who have specific knowledge and expertise relevant to the research objectives (Creswell, 2014). The sample included pharmaceutical manufacturers, government officials, regulators, and representatives from industry associations. This diverse group of respondents provided a comprehensive perspective on the challenges and opportunities for API production in Nigeria (Patton, 2015).

The data collection process involved distributing the questionnaire to the selected respondents via email, followed by in-depth interviews with a smaller subset of respondents. The interviews were conducted either in person or through video conferencing, depending on the availability and location of the respondents (Dillman et al., 2014).

## **Data Analysis**

The data collected was analyzed using qualitative content analysis to identify recurring themes, patterns, and relationships in the responses. Content analysis is suitable for analyzing open-ended responses, as it allows the researcher to categorize the data into meaningful themes (Krippendorff, 2018). Descriptive statistics, such as frequencies and percentages, were used to summarize the responses to the closed-ended questions. Additionally, the Statistical Package for Social Sciences (SPSS) was used to analyze the Likert scale data, providing insights into the general trends and attitudes of respondents toward local API production (Bryman & Bell, 2015).

## **Ethical Considerations**

This study will adhere to the fundamental principles of **research ethics**, ensuring that participants' rights are respected throughout the research process. Respondents will be informed about the purpose of the study and their right to withdraw at any point. Informed consent will be obtained from all participants before data collection begins (Flick, 2018). The study will also ensure confidentiality by anonymizing responses and securely storing the data collected, in compliance with data protection regulations (Kvale, 2007).

## **Limitations of the Methodology**

One of the key limitations of this study is the **time constraint**, which limits the ability to conduct a longitudinal analysis of changes in the pharmaceutical industry. Additionally, the use of purposive sampling may introduce some **selection bias**, as the sample is not representative of the entire population of pharmaceutical professionals in Nigeria.

However, the purposive sampling method is appropriate given the focus of the study on specific industry stakeholders with relevant expertise (Bryman & Bell, 2015). Furthermore, the reliance on qualitative data means that the findings may not be generalizable to the entire population of Nigeria's pharmaceutical industry. Nevertheless, the insights gained from this research will provide valuable information on the challenges and opportunities for local API production in Nigeria.

### 3.0 Results

Seventy-five (75) questionnaires were distributed using convenience sampling to gather information for this study, and all (75) were returned representing 100% response rate.

#### 3.1 Interpretation of Results

##### 3.1.1 Presentation of Socio-Demographic Characteristics of Respondents

Table 1: Description of the socio-demographic characteristics of the sample used.

Demographic Variable (n=75)	Category	Frequency	%
Gender	Male	51	68
	Female	24	32
Age Range	20-29yrs	15	20
	30-39yrs	23	31
	40-49yrs	31	41
	≥50yrs	6	8
Marital Status	Single	32	42
	Married	41	55
	Others	2	3
Educational Background	WAEC/OND/NCE	21	28
	HND/BSc	35	47
	MSc/MA/MBA/MPA	13	17
	PhD	1	1
	Professional Certificate	5	7

**Source: Researcher's field survey, 2022**

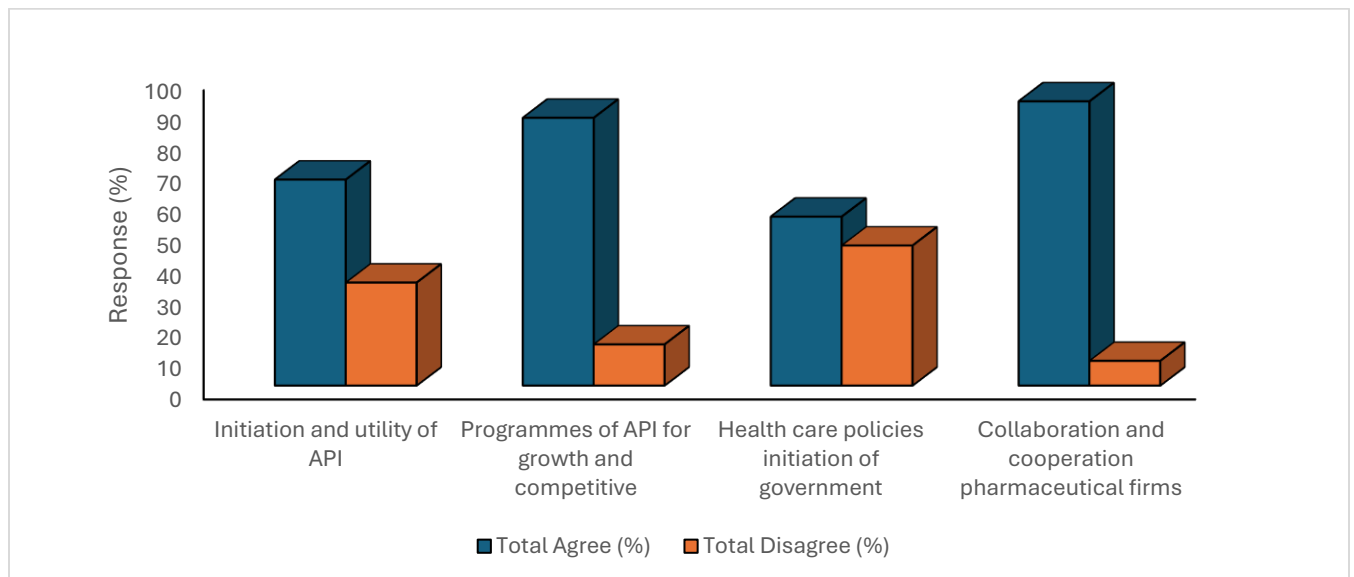
Table 1 presents a summary of the characteristics of the study participant (N=75). More male participated in the study (68%). Out of 75 participants, 41 of them were married representing (55%) and 35 (47%) had HND/BSc certificates while majority of them were within the age range 30-49 years.

### 3.2.2 How the initiation and utility of API be encouraged and managed to achieve the twin objectives of growth and competitive advantage on health care delivery both in Nigeria and neighboring countries of West Africa.

**Table 2: Initiation and utility of API**

S/N	Statement (n=75)	SA (4)	A (3)	D (2)	SD (1)	TA (%)	TD (%)	Decision
1	Initiation and utility of API can significantly be encouraged and managed to achieve the twin objectives of growth and competitive advantage on health care delivery both in Nigeria and neighboring countries of West Africa.	22	28	10	15	67	33	Agreed
2	Programs of API is inevitable for growth and competitive edge on health care delivery in Nigeria.	40	25	9	0	87	13	Agreed
3	Health care policies initiation of government on API is value relevant for growth and standards to manufacturing drug in Nigeria.	24	17	18	16	55	45	Agreed
4	Private and public pharmaceutical firms' collaboration and cooperation is needed in the use of API in curbing monopolistic trend in drug production in Nigeria.	42	27	5	1	92	8	Agreed

SA=Strongly Agree, A=Agree, D=Disagree, SD=Strongly Disagree, TA=Total Agree, TD=Total Disagree, Decision Rule: Agree if TA $\geq$ 50%, Disagree if <50%



**Fig 1: A multiple bar chart showing Initiation and utility of API**

Data displayed on Table 2 and fig 1 indicate that all the TA scores ranged from 55% to 92%. This infers that the initiation and utility of API can be encouraged and managed to achieve the twin objectives of growth and competitive advantage on health care delivery both in Nigeria and neighboring countries of West Africa by putting into practice the programmes of API, health care policies initiation of government on API, and collaboration and cooperation of private and public pharmaceutical firms.

### **How innovations in the use of API in Nigeria improve supply chain management platform in the highly competitive global health care delivery**

**Table 3: Innovations in the use of API**

<b>S/N</b>	<b>Statement (n=75)</b>	<b>SA (4)</b>	<b>A (3)</b>	<b>D (2)</b>	<b>SD (1)</b>	<b>TA (%)</b>	<b>TD (%)</b>	<b>Decision</b>
1	Innovations in the use of API in Nigeria improves supply chain management platform in the highly competitive global health care delivery.	22	20	22	11	56	44	Agreed
2	Electronic transaction (E-commerce) in the use of API on drug manufacturing in Nigeria promotes health care delivery as global competitiveness	22	22	16	15	59	41	Agreed
3	Human capital development improves the use of API in Nigeria's supply chain management	36	28	11	0	85	15	Agreed
4	Advancement in science and technology (e.g., effective laboratory facilities) is a survival strategy in API for firm's drug production in Nigeria	23	18	13	21	55	45	Agreed

SA=Strongly Agree, A=Agree, D=Disagree, SD=Strongly Disagree, TA=Total Agree, TD=Total Disagree, Decision Rule: Agree if TA $\geq$ 50%, Disagree if <50%

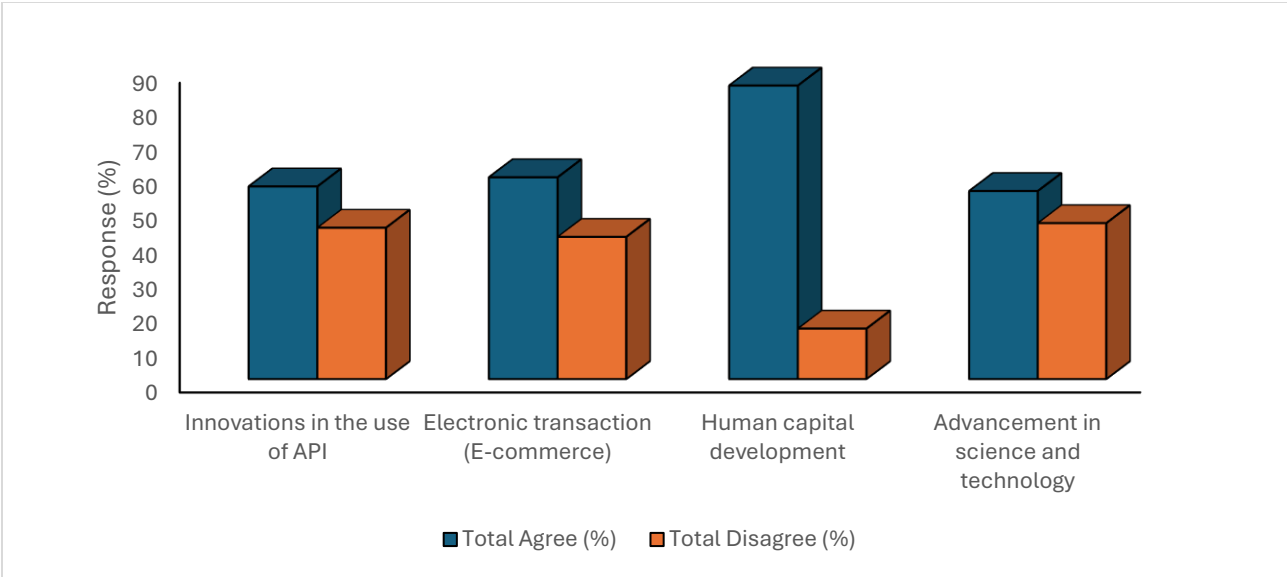


Fig 2: A multiple bar chart showing innovations in the use of API

Data presented on Table 3 and fig 2 reveal that all the TA scores ranged from 55% to 85%. This deduces that innovations in the use of API in Nigeria improve supply chain management platform in the highly competitive global health care delivery through electronic transaction (e-commerce), human capital development and advancement in science and technology.

**The barriers caused by global pandemics (especially Covid-19) that limits consensus of API usage in Nigeria as compared to other symptoms and diseases to income generation and employment.**

Table 4: Barriers caused by global pandemics

S/N	Statement (n=75)	SA (4)	A (3)	D (2)	SD (1)	TA (%)	TD (%)	Decision
1	Lockdown and related policies are barriers caused by global pandemics (especially Covid-19) in the use of API in Nigeria as compared to other symptoms and diseases to income generation and employment.	37	32	6	0	92	8	Agreed
2	Lockdown in commercial activities resulting from global pandemic negatively affect the use of API to produce drugs as income generation and employment.	49	23	3	0	96	4	Agreed
3	Economic crisis of trade sanctions between nations (e.g., Nigeria and China) caused by covid-19 negates the use of API for drug production, hence losses of income and unemployment laboratory.	51	21	3	0	96	4	Agreed
4	Apathy to massive laboratory discoveries of much substance to produce drugs on diseases (e.g., covid-19, HIV/AIDS, etc.) equates with not using API for drugs in Nigeria.	41	23	10	1	85	15	Agreed

SA=Strongly Agree, A=Agree, D=Disagree, SD=Strongly Disagree, TA=Total Agree, TD=Total Disagree, Decision Rule: Agree if TA $\geq$ 50%, Disagree if <50%

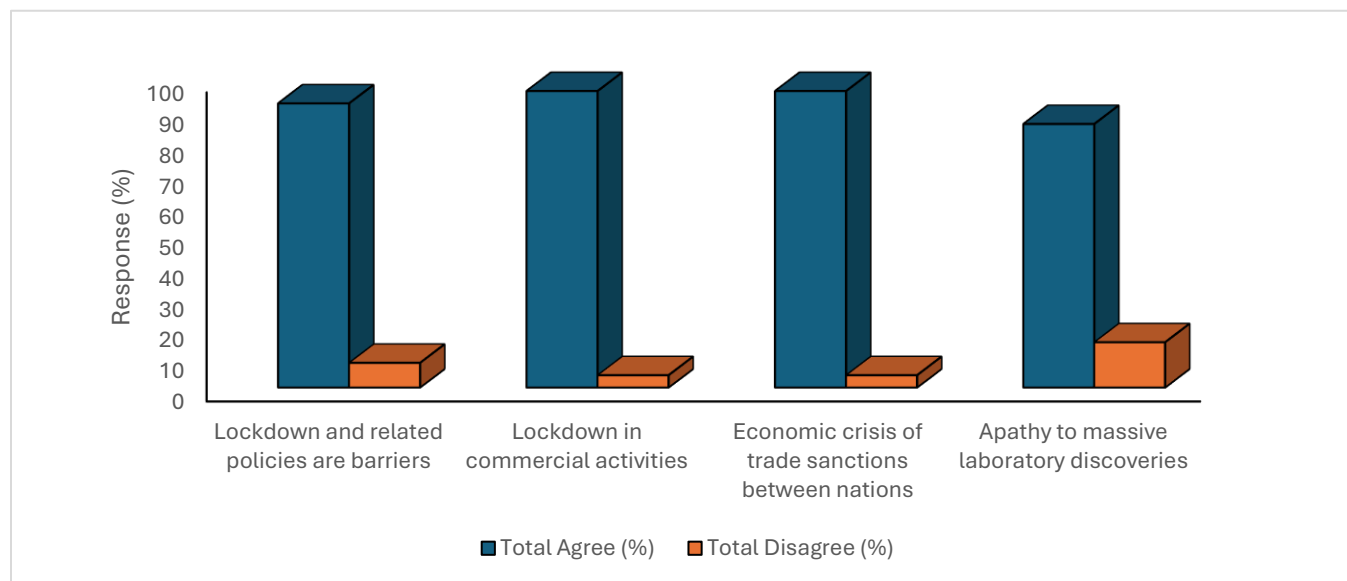


Fig 3: A multiple bar chart showing barriers caused by global pandemics

Data showed on Table 4 and fig 3 indicate that all the TA scores ranged from 85% to 96%. Meaning that the barriers caused by global pandemics (especially Covid-19) that limits consensus of API usage in Nigeria as compared to other symptoms and diseases to income generation and

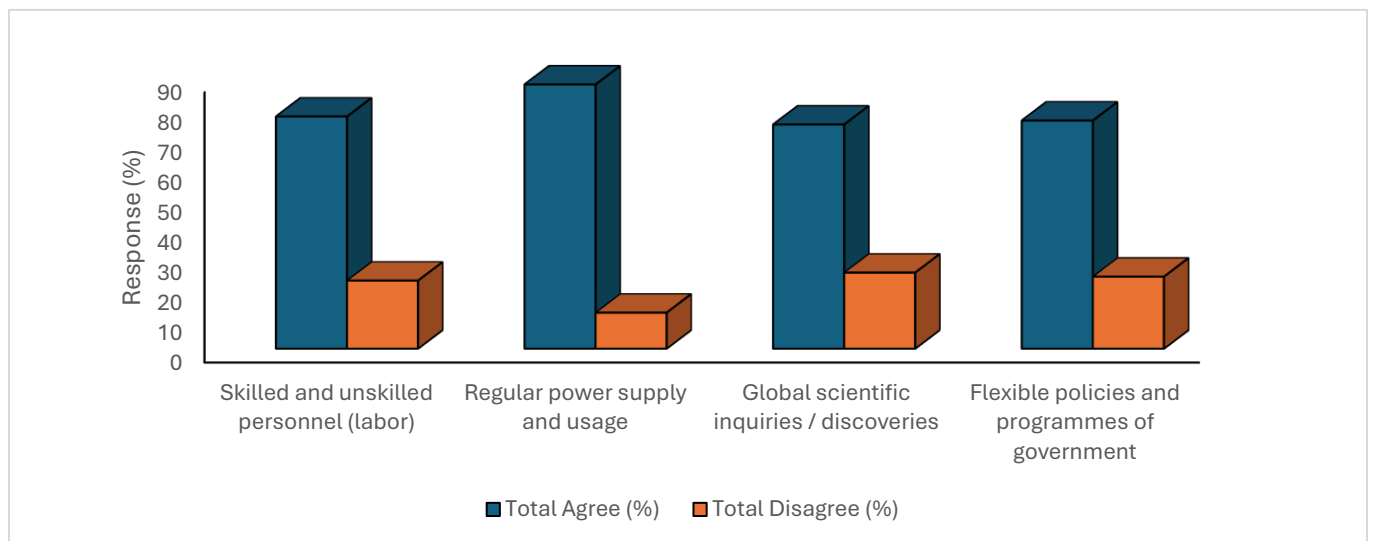
employment include economic crisis of trade sanctions between nations, and apathy to massive laboratory discoveries of much substance to produce drugs on diseases.

**The core competences and elements of best practice on which technology could leverage for API production and use in Nigeria.**

**Table 5: Core competences and elements of best practice**

S/N	Statement (n=75)	SA (4)	A (3)	D (2)	SD (1)	TA (%)	TD (%)	Decision
1	Skilled and unskilled personnel (labor) requirements are the core competences and elements of best practice in which technology could leverage for API production and use in Nigeria.	8	50	15	2	77	23	Agreed
2	Regular power supply and usage are inevitable for adequate use of API for drug production in Nigeria.	19	47	9	0	88	12	Agreed
3	Global scientific inquiries / discoveries of raw materials are value relevant for the use of API in drug production and consumption in Nigeria.	24	32	16	2	75	25	Agreed
4	Flexible policies and programs of government on quality health delivery serve as best practice on the use of API for drug production in Nigeria	24	33	14	4	76	24	Agreed

SA=Strongly Agree, A=Agree, D=Disagree, SD=Strongly Disagree, TA=Total Agree, TD=Total Disagree, Decision Rule: Agree if TA $\geq$ 50%, Disagree if <50%



**Fig 4: A multiple bar chart showing core competences and elements of best practice**

Data displayed on Table 5 and fig 4 show that all the TA scores ranged from 75% to 88%. This implies that the core competences and elements of best practice on which technology could

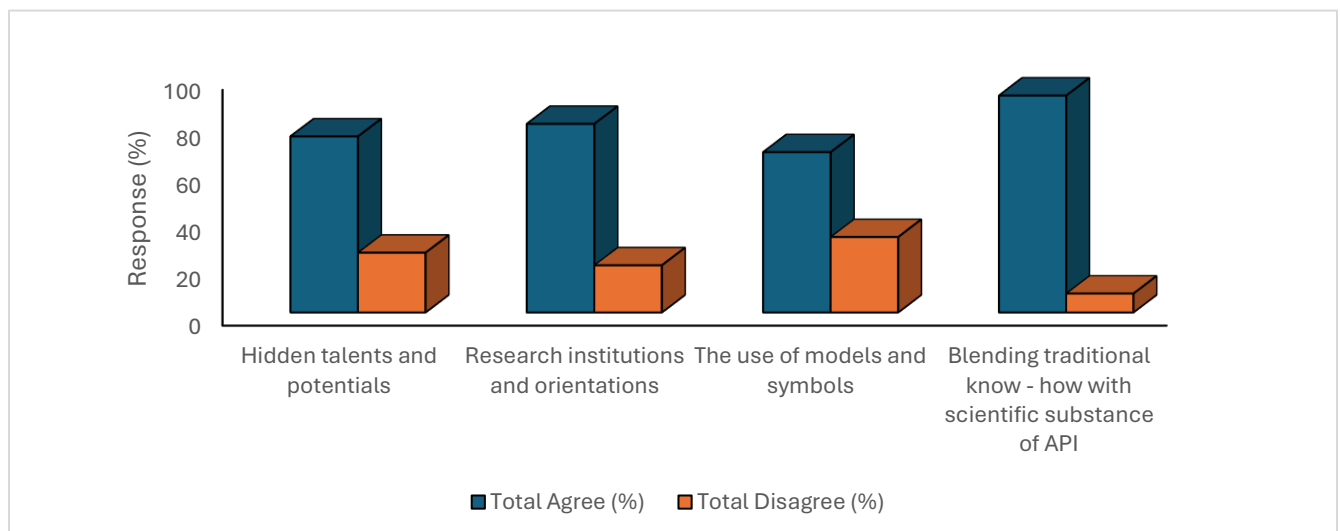
leverage for API production and use in Nigeria are regular power supply and usage, global scientific inquiries/discoveries of raw materials, and flexible policies and programmes of government on quality health delivery.

**How hidden talents and potentials to the production and use of API be explored and managed to create value measurable to global standards and competition**

**Table 6: Hidden talents and potentials to the production and use of API**

S/N	Statement (n=75)	SA (4)	A (3)	D (2)	SD (1)	TA (%)	TD (%)	Decision
1	Hidden talents and potentials to the production and use of API can to a large extent be explored and managed to create value measurable to global standards and competition.	19	37	15	4	75	25	Agreed
2	Research institutions and orientations on the use of API to produce medicinal products in Nigeria are indispensable as global standards and competition.	19	41	14	1	80	20	Agreed
3	The use of models and symbols (i.e., intellectual property) are potentials to the practice of the use of API for drug production in Nigeria amidst global competition.	26	25	20	4	68	32	Agreed
4	Blending traditional know - how with scientific substance of API for drug production in Nigeria creates value measurable to global expectations.	37	32	6	0	92	8	Agreed

SA=Strongly Agree, A=Agree, D=Disagree, SD=Strongly Disagree, TA=Total Agree, TD=Total Disagree, Decision Rule: Agree if TA $\geq$ 50%, Disagree if <50%



**Fig 5: A multiple bar chart showing hidden talents and potentials to the production and use of API**

Data presented on Table 6 and fig 5 indicate that all the TA scores ranged from 75% to 92%. This deduces that hidden talents and potentials to the production and use of API can be explored and managed to create value measurable to global standards and competition through orientations on the use of API to produce medicinal products, use of models and symbols (intellectual property), and blending traditional know - how with scientific substance of API.

### 3.2.3 Research Hypotheses

**Hypothesis 1:** Initiation and utility of API cannot significantly be encouraged and managed to achieve the twin objectives of growth and competitive advantage on health care delivery both in Nigeria and neighboring countries of West Africa

**Table 7: Friedman's test for significant impact of Initiation and utility of API on twin objectives of growth and competitive advantage**

Variable (n=75)	Mean Rank	$\chi^2$ (p-value)
Initiation and utility of API can significantly be encouraged and managed to achieve the twin objectives of growth and competitive advantage on health care delivery both in Nigeria and neighboring countries of West Africa.	2.19	33.34 ( $<0.001$ )
Programmes of API is inevitable for growth and competitive edge on health care delivery in Nigeria.	2.87	
Health care policies initiation of government on API is value relevant for growth and standards to manufacturing drug in Nigeria.	2.05	
Private and public pharmaceutical firms' collaboration and cooperation is needed in the use of API in curbing monopolistic trend in drug production in Nigeria.	2.89	

The Chi-square value 33.34 with degree of freedom 3 from the Friedman's test infers that the hypothesis that Initiation and utility of API cannot significantly be encouraged and managed to achieve the twin objectives of growth and competitive advantage on health care delivery both in Nigeria and neighboring countries of West Africa is rejected ( $p < 0.05$ ). Therefore, initiation and utility of API can significantly be encouraged and managed to achieve the twin objectives of growth and competitive advantage on health care delivery both in Nigeria and neighboring countries of West Africa.

**Hypothesis 2:** Innovations in the use of API in Nigeria do not improve supply chain management platform in the highly competitive global health care delivery

**Table 8: Friedman's test for significant impart of the use of innovations in API on supply chain management**

Variable (n=75)	Mean Rank	$\chi^2$ (p-value)
Innovations in the use of API in Nigeria improves supply chain management platform in the highly competitive global health care delivery.	2.37	20.64 ( $<0.001$ )
Electronic transaction (E-commerce) in the use of API on drug manufacturing in Nigeria promotes health care delivery as global competitiveness	2.31	
Human capital development improves the use of API in Nigeria's supply chain management	3.03	
Advancement in science and technology (e.g., effective laboratory facilities) is a survival strategy in API for firm's drug production in Nigeria	2.29	

The Chi-square value 20.64 with degree of freedom 3 from the Friedman's test deduces that the hypothesis that innovations in the use of API in Nigeria do not improve supply chain management platform in the highly competitive global health care delivery is rejected ( $p < 0.05$ ). Consequently, innovations in the use of API in Nigeria improves supply chain management platform in the highly competitive global health care delivery.

**Hypothesis 3:** Lockdown and related policies are not barriers caused by global pandemics (especially Covid-19) in the use of API in Nigeria as compared to other symptoms and diseases to income generation and employment

**Table 9: Friedman's test for significant impart of Lockdown and related policies on the use of API**

Variable (n=75)	Mean Rank	$\chi^2$ (p-value)
Lockdown and related policies are barriers caused by global pandemics (especially Covid-19) in the use of API in Nigeria as compared to other symptoms and diseases to income generation and employment.	2.35	15.52 (0.001)
Lockdown in commercial activities resulting from global pandemic negatively affect the use of API to produce drugs as income generation and employment.	2.65	

Economic crisis of trade sanctions between nations (e.g., Nigeria and China) caused by covid-19 negates the use of API for drug production, hence losses of income and unemployment laboratory.	2.71	
Apathy to massive laboratory discoveries of much substance to produce drugs on diseases (e.g., covid-19, HIV / AIDS, etc.) equates with not using API for drugs in Nigeria.	2.29	

The Chi-square value 15.52 with degree of freedom 3 from the Friedman's test implies that the hypothesis that lockdown and related policies are not barriers caused by global pandemics (especially Covid-19) in the use of API in Nigeria as compared to other symptoms and diseases to income generation and employment is rejected ( $p < 0.05$ ). Thus, lockdown and related policies are barriers caused by global pandemics (especially Covid-19) in the use of API in Nigeria as compared to other symptoms and diseases to income generation and employment

**Hypothesis 4:** Skilled and unskilled personnel (manpower) requirements are not the core competences and elements of best practice in which technology could leverage for API production and use in Nigeria

**Table 10: Friedman's test for significant impart of Skilled and unskilled personnel**

Variable (n=75)	Mean Rank	$\chi^2_3$ (p-value)
Skilled and unskilled personnel (labor) requirements are the core competences and elements of best practice in which technology could leverage for API production and use in Nigeria.	2.24	6.44 (0.002)
Regular power supply and usage are inevitable for adequate use of API for drug production in Nigeria.	2.65	
Global scientific inquiries / discoveries of raw materials are value relevant for the use of API in drug production and consumption in Nigeria.	2.59	
Flexible policies and programmes of government on quality health delivery serve as best practice on the use of API for drug production in Nigeria	2.53	

The Chi-square value 6.44 with degree of freedom 3 from the Friedman's test shows that the hypothesis that skilled and unskilled personnel (manpower) requirements are not the core competences and elements of best practice in which technology could leverage for API production and use in Nigeria is rejected ( $p < 0.05$ ). Therefore, skilled, and unskilled personnel (manpower) requirements are the core competences and elements of best practice in which technology could leverage for API production and use in Nigeria.

**Hypothesis 5:** Hidden talents and potentials to the production and use of API cannot be explored and managed to create value measurable to global standards and competition

**Table 11: Friedman's test for significant impact of hidden talents and potentials to the production and use of API**

Variable (n=75)	Mean Rank	$\chi^2_3$ (p-value)
Hidden talents and potentials to the production and use of API can to a large extent be explored and managed to create value measurable to global standards and competition.	2.19	15.04 (0.003)
Research institutions and orientations on the use of API to produce medicinal products in Nigeria are indispensable as global standards and competition.	2.87	
The use of models and symbols (i.e., intellectual property) are potentials to the practice of the use of API for drug production in Nigeria amidst global competition.	2.05	
Blending traditional know - how with scientific substance of API for drug production in Nigeria creates value measurable to global expectations.	2.89	

The Chi-square value 15.04 with degree of freedom 3 from the Friedman's test shows that the hypothesis that hidden talents and potentials to the production and use of API cannot be explored and managed to create value measurable to global standards and competition is rejected ( $p < 0.05$ ). Hence, hidden talents and potentials to the production and use of API can be explored and managed to create value measurable to global standards and competition.

## 4.0 Discussion

### Discussion of Key Findings

The findings from this study provide significant insights into the potential for local Active Pharmaceutical Ingredient (API) production in Nigeria, as well as the barriers that hinder the development of this sector. A key finding is the urgent need for Nigeria to establish a sustainable API manufacturing industry to reduce its reliance on imports and strengthen its pharmaceutical sector. As highlighted by Fortunak et al. (2016), local API production is crucial for enhancing Nigeria's healthcare system, improving access to affordable medicines, and reducing the country's vulnerability to global supply chain disruptions. This study confirms that, despite the significant market demand and economic potential, several challenges remain in developing local API manufacturing, including regulatory barriers, inadequate infrastructure, and limited technical expertise.

One of the most pressing issues revealed by the study is the high cost of importing APIs, which significantly increases the price of pharmaceuticals in Nigeria (Adeyemi et al., 2018). This has direct implications for the affordability of medicines and limits access for low-income populations. The over-reliance on imported APIs, particularly from India and China, makes Nigeria's pharmaceutical industry highly vulnerable to global supply chain disruptions, as witnessed during the COVID-19 pandemic (Ayo-Lawal et al., 2022). The

study's findings suggest that establishing a local API manufacturing industry could lower production costs and improve the availability of essential medicines in Nigeria.

The results also indicate that Nigeria's pharmaceutical industry has the potential to meet both domestic and regional demand for pharmaceuticals, given the country's large population and its strategic position within the West African region (Yusuff et al., 2022). However, the industry is currently constrained by several factors, including the lack of government incentives for local manufacturers, high production costs, and inadequate technical capacity (Osaze, 2014). These challenges highlight the need for comprehensive policy reforms that will support local production, improve regulatory frameworks, and provide financial incentives to encourage investment in the pharmaceutical sector.

#### **4.2 Barriers to Local API Production**

The study identifies several key barriers to local API production in Nigeria, many of which are consistent with previous research in the field. One of the main barriers is the lack of adequate infrastructure to support pharmaceutical manufacturing (Nwude, 2013). Pharmaceutical companies in Nigeria face high operational costs due to unreliable electricity supply, poor transportation networks, and limited access to high-quality raw materials. These infrastructural deficiencies make it difficult for local manufacturers to produce APIs at competitive prices, which, in turn, discourages investment in the sector (Ayo-Lawal et al., 2022).

Another significant barrier is the regulatory environment in Nigeria, which is often described as cumbersome and inefficient. According to Osaze (2014), the regulatory framework for pharmaceutical manufacturing in Nigeria is fragmented, with multiple government agencies involved in the approval and oversight processes. This complexity creates delays in obtaining licenses and approvals, thereby slowing down the establishment of local API manufacturing plants. The findings of this study confirm that streamlining the regulatory process and improving coordination between regulatory agencies could facilitate the growth of the API industry in Nigeria.

Moreover, the study reveals that there is a shortage of skilled labor in Nigeria's pharmaceutical sector, particularly in the area of API production (Ogbinna, 2017). The technical expertise required to produce APIs at scale is limited, and many pharmaceutical companies lack the necessary training and knowledge to adopt advanced manufacturing technologies. This shortage of skilled labor is further exacerbated by the lack of specialized training programs and educational institutions focused on pharmaceutical manufacturing in Nigeria (Ekeigwe, 2019).

The study also highlights financial barriers, including the high cost of capital and limited access to affordable financing for pharmaceutical manufacturers (Nwude, 2013). Many local manufacturers struggle to secure the funding needed to invest in API production facilities, purchase raw materials, and cover operational costs. The high-interest rates charged by commercial banks in Nigeria further compound this issue, making it difficult for companies to expand their operations or invest in new technologies (Ayo-Lawal et al.,

2022). Addressing these financial challenges will require government intervention, including the provision of low-interest loans and financial incentives to support local manufacturers.

### **4.3 Opportunities for Growth and Development**

Despite the barriers identified, the study reveals several opportunities for the growth and development of Nigeria's API manufacturing industry. One of the most promising opportunities is the potential for public-private partnerships (PPPs) to support local pharmaceutical production (Fortunak et al., 2016). By partnering with private sector organizations, the Nigerian government can leverage additional resources and expertise to develop the infrastructure, technical capacity, and regulatory frameworks needed to establish a sustainable API industry. For example, collaborations between government agencies and private pharmaceutical companies could lead to the establishment of manufacturing hubs or industrial parks dedicated to API production (Osaze, 2014).

Additionally, Nigeria's large and growing population presents a significant market opportunity for the pharmaceutical industry. With a population of over 200 million people, Nigeria has one of the highest demands for pharmaceuticals in Africa (Ayo-Lawal et al., 2022). Meeting this demand through local production, rather than relying on imports, could create a robust domestic pharmaceutical industry capable of serving both local and regional markets. Moreover, by producing APIs locally, Nigeria could reduce its reliance on international suppliers and mitigate the risks associated with global supply chain disruptions.

Technological advancements also present a major opportunity for Nigeria's pharmaceutical industry. As noted by Ewurum (2014), innovations in pharmaceutical manufacturing technologies can significantly improve the efficiency and cost-effectiveness of API production. Investing in modern manufacturing technologies, such as process automation and advanced quality control systems, could help Nigerian pharmaceutical companies compete with international manufacturers and produce APIs that meet global standards. Furthermore, fostering research and development (R&D) in the pharmaceutical sector could lead to the discovery of new APIs and drug formulations that address the specific health needs of the Nigerian population (Yusuff et al., 2022).

### **4.4 Policy Recommendations**

Based on the findings, several policy recommendations are proposed to facilitate the development of Nigeria's API manufacturing industry. First, the Nigerian government should prioritize the creation of a conducive regulatory environment by streamlining the approval processes for pharmaceutical manufacturing and improving coordination between regulatory agencies (Osaze, 2014). This would reduce delays in obtaining licenses and approvals, thereby encouraging more pharmaceutical companies to invest in local API production.

Second, the government should provide financial incentives to support local manufacturers, such as offering low-interest loans, tax breaks, and subsidies for API production facilities (Nwude, 2013). These incentives would help reduce the financial burden on pharmaceutical companies and encourage investment in the sector. In addition, the government could establish a dedicated fund to support research and development in the pharmaceutical industry, particularly in the area of API production.

Third, the government should invest in infrastructure development, particularly in areas such as electricity supply, transportation, and access to raw materials. Improving infrastructure would reduce operational costs for pharmaceutical manufacturers and make local API production more competitive (Adeyemi et al., 2018). Furthermore, the establishment of industrial parks or manufacturing hubs dedicated to pharmaceutical production could help address some of the infrastructural challenges faced by the industry (Osaze, 2014).

Finally, addressing the skills gap in Nigeria's pharmaceutical sector is critical for the growth of local API production. The government, in collaboration with educational institutions and private sector organizations, should invest in specialized training programs to develop the technical expertise required for API manufacturing (Ogbinna, 2017). Establishing partnerships between universities, research institutions, and pharmaceutical companies could also help foster innovation and knowledge transfer within the industry (Ekeigwe, 2019).

## **5.0 Conclusion and Recommendations**

### **5.1 Conclusion**

This study has examined the potential for establishing a sustainable Active Pharmaceutical Ingredient (API) manufacturing industry in Nigeria and identified key challenges, opportunities, and strategies for overcoming the barriers to local production. The findings underscore the critical need for Nigeria to reduce its reliance on imported APIs, which currently hampers the pharmaceutical sector's ability to produce affordable medicines and meet domestic healthcare demands. By fostering a robust local API production industry, Nigeria could improve the availability of essential medicines, enhance its healthcare system, and contribute to regional economic growth (Fortunak et al., 2016).

The challenges associated with local API production in Nigeria are significant, ranging from inadequate infrastructure and high production costs to regulatory inefficiencies and a shortage of skilled labor (Nwude, 2013). These challenges are compounded by the lack of government incentives and financial support, which discourages investment in the pharmaceutical sector. However, the study also reveals substantial opportunities for growth, particularly through public-private partnerships, technological advancements, and the development of policies that support local production (Osaze, 2014).

Given Nigeria's large population and strategic position within the West African region, the establishment of a local API industry could position the country as a major player in the

pharmaceutical sector, not only meeting domestic needs but also serving the broader regional market (Ayo-Lawal et al., 2022). The findings suggest that with the right investments in infrastructure, regulatory reforms, and financial support, Nigeria has the potential to build a vibrant pharmaceutical industry that contributes to both public health and economic development.

## **5.2 Recommendations**

Based on the findings of this study, several recommendations are proposed to facilitate the development of the API manufacturing industry in Nigeria:

### **1. Strengthen the Regulatory Environment**

One of the most critical steps toward establishing a sustainable API manufacturing industry is to streamline Nigeria's regulatory framework. The government should prioritize regulatory reforms that reduce bureaucratic delays and improve the coordination between regulatory agencies involved in pharmaceutical production. Simplifying the approval processes for API manufacturing plants and reducing regulatory fragmentation would encourage more pharmaceutical companies to invest in local production (Osaze, 2014). Additionally, establishing clear and consistent guidelines for API production in line with international standards would improve the quality of locally produced APIs and enhance Nigeria's competitiveness in the global market (Yusuff et al., 2022).

### **2. Provide Financial Incentives and Support**

The government must implement policies that offer financial incentives to local pharmaceutical manufacturers. These could include low-interest loans, tax exemptions, and subsidies for companies investing in API production facilities (Nwude, 2013). By reducing the financial burden on pharmaceutical companies, the government can encourage more investment in the sector, particularly in the development of API production infrastructure. Furthermore, the establishment of a dedicated pharmaceutical development fund would support research and development (R&D) initiatives, fostering innovation and improving Nigeria's capacity to produce high-quality APIs (Fortunak et al., 2016).

### **3. Invest in Infrastructure Development**

To overcome the high production costs associated with API manufacturing, the Nigerian government must invest in critical infrastructure, including electricity, transportation, and access to high-quality raw materials. Improving the reliability of power supply and upgrading transportation networks would reduce operational costs for local manufacturers and make local production more competitive (Ayo-Lawal et al., 2022). Additionally, the creation of industrial parks or special economic zones dedicated to pharmaceutical manufacturing could provide manufacturers with the infrastructure and logistical support they need to scale their operations (Osaze, 2014).

### **4. Address the Skills Gap in the Pharmaceutical Sector**

Developing the technical expertise needed for API production is essential for the growth of Nigeria's pharmaceutical industry. The government, in collaboration with academic institutions and industry stakeholders, should invest in specialized training programs to equip pharmaceutical workers with the skills required for API manufacturing (Ogbinna, 2017). These training programs should focus on modern manufacturing technologies, quality control processes, and regulatory compliance. Partnerships between universities, research institutions, and pharmaceutical companies could also be established to promote knowledge transfer and foster innovation in API production (Ekeigwe, 2019).

## **5. Promote Public-Private Partnerships**

Public-private partnerships (PPPs) offer a promising avenue for developing Nigeria's API manufacturing capacity. By fostering collaboration between the government and private pharmaceutical companies, Nigeria can leverage additional resources and expertise to develop the necessary infrastructure and technical capacity for API production (Fortunak et al., 2016). PPPs could also facilitate technology transfer, enabling Nigerian manufacturers to adopt advanced pharmaceutical manufacturing technologies and improve their production processes. Furthermore, collaboration with international pharmaceutical companies could open up new markets for Nigerian-produced APIs, increasing export opportunities and driving economic growth (Osaze, 2014).

## **6. Encourage Research and Development (R&D)**

Finally, the government should prioritize investment in research and development (R&D) to stimulate innovation in the pharmaceutical sector. Establishing research centers focused on API development and fostering collaboration between pharmaceutical companies, universities, and research institutions could lead to the discovery of new APIs and drug formulations tailored to the specific health needs of the Nigerian population (Yusuff et al., 2022). Additionally, funding R&D initiatives could help improve the quality and efficiency of local API production, enhancing Nigeria's competitiveness in the global pharmaceutical market.

## **References**

- Adeyemi R.A., Joel A., Ebenezer J.T. and Attah E.Y. (2018). The Effect of Brain Drain on the Effect of Brain Drain on the Economic Development of Developing Countries: Evidence from Selected African Countries. *Journal of Health and Social Issues*. 7 (2): 66-76
- Asante, S.K. B (2017), *Regionalism and Africa's Development, Expectations, Realities and Challenges*, Great Britain; Macmillan Press Ltd
- Ayo-Lawal, R.A., Adelowo, C.M., Oyewale, A.A., Ejim-Eze, E.E., Omimakinde, E.A., Erhun, W.O., and Ukuoma, U. (2022). Mapping the strength of sectoral innovation system in the Nigerian pharmaceutical industry: Empirical evidence. *African Journal of Science, Technology, Innovation and Development*,
- Bryman A. and Bell E (2007) *Business Research Methods*. 2<sup>nd</sup> Edn Oxford University Press
- Abroad" *Organization Dynamics*, 9 (1) 42-63.

- Creswell, J. W. (2014). *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches* (4th ed.). SAGE Publications.
- Dillman, D. A., Smyth, J. D., & Christian, L. M. (2014). *Internet, Phone, Mail, and Mixed-Mode Surveys: The Tailored Design Method* (4th ed.). Wiley.
- Ekeigwe, A.A. (2019). Drug manufacturing and access to medicines: the West African story. A literature review of challenges and proposed remediation. *AAPS Open* 5, 3 (2019). <https://doi.org/10.1186/s41120-019-0032-x>
- Flick, U. (2018). *An Introduction to Qualitative Research* (6th ed.). SAGE Publications.
- Fortunak, J., Ngwozwana, S., Tsige, G-M., Tiffany, E., Watts, P., Emeje, M. and Nytko III, F.E. (2016). Raising the Technological Level: The Scope for API, Excipients, and Biologicals Manufacture in Africa. [https://link.springer.com/content/pdf/10.1007/978-1-137-54647-0\\_8.pdf](https://link.springer.com/content/pdf/10.1007/978-1-137-54647-0_8.pdf)
- Krippendorff, K. (2018). *Content Analysis: An Introduction to Its Methodology* (4th ed.). SAGE Publications.
- Kvale, S. (2007). *Doing Interviews* (1st ed.). SAGE Publications.
- Nwude, C (2013), Basic Principles of Financial Management- A First Course (3rd Edition), Enugu; Chuke Nwabude Nigeria
- Ogbonna BO. (2017). Leveraging pharmaceutical preparedness for epidemic outbreaks in the West African sub-region: a review. *MOJ Public Health* ;6(1):255–259.
- Osaze, E.B. (2014), Strategic Management in Nigeria – Text and Cases, Lagos; Maobic Print Nigeria Limited.
- Patton, M. Q. (2015). *Qualitative Research & Evaluation Methods* (4th ed.). SAGE Publications. Sekaran & Bougie, 2016).
- Sekaran, U. and Bougie, R. (2016) *Research Methods for Business: A Skill-Building Approach*. 7th Edition, Wiley & Sons, West Sussex.
- Yusuff, A.A., Akande-Sholabi, W. and Oluwatoyin, A.O. (2022). Therapeutic lifestyle strategies taught in Nigerian pharmacy schools. *West African Journal of Pharmacy*, 33 (1). 49.