

Policies And Practice In Nigeria's Pharmaceutical Sector: A Mixed Methods Exploration of Stakeholders' Perspectives On Strategic Reforms

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Research

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Abstract

Background: Amongst other objectives, the National Drug Policy was designed to improve access to medicines, whilst also stimulating socioeconomic development. The policy was also intended to promote pharmaceutical research and development in Nigeria. Despite its criticality in the achievement of national Medicines' Security, evidence suggests a policy failure with consequent implications on attendant national health indices. This study aimed at assessing the views of pharmaceutical sector practitioners and other stakeholders, on the status quo as well as on strategies that can improve access to health whilst developing the sector.

Methods: Data were collected using questionnaires which were administered to stakeholders present during an event that focused on improving the Nigerian pharmaceutical sector. Questionnaires were completed and returned. Quantitative data were analyzed using Statistical Package for Social Sciences, whilst textual data were analysed using thematic analysis.

Results: Majority (48%) of the study participants indicated that current policy ecosystem was hostile for pharmaceutical sector growth and development. Also, a considerable proportion (97.3%) of the study participants indicated that increased investment in health research could stimulate the development of the pharmaceutical sector. Majority of the study participants indicated the need for collaboration between pharmaceutical companies, research institutes and the petrochemical industry.

Conclusions: This study consequently identified several critical factors that can stimulate development in the sector, including increased funding of research; stringent implementation of existing policies; and prioritization of pharmaceutical sector by government and other key stakeholders.

Background

The Nigerian pharmaceutical sector is a multibillion dollar industry with underutilized potential that can contribute to the economy as well as improve the quality of lives of its citizens. The pharmaceutical industry is therefore considered an important component of the manufacturing sector and has been reported as an important contributor to the Nation's Gross Domestic Product (GDP) [1]. About a decade ago, a seminal report enumerated 130 local drug manufacturers in Nigeria and identified that this represented about a third of the total pharmaceutical manufacturing capacity in the West Africa sub region [2]. Despite this apparent capacity, local manufacturing has not been perceived to make a commensurate impact on medicines' access in Nigeria [3]. Experts therefore identified that developing local pharmaceutical manufacturing capacity as a means of strengthening the sector, will enable it harness local raw materials and natural flora which are abundant in the country. This approach has been identified as one of the most sustainable pathways towards the development of new drugs as well as improving the availability of existing formulations [4]. Additionally, the approach can also help ensure the achievement of National Medicines' Security by reducing the inordinate dependence on importation of pharmaceutical products, especially those which local companies have the capacity to manufacture [5].

There is evidence that suggests that given the considerable manufacturing capacity in Nigeria, local production can satisfy up to three quarters of national medicines' needs [6]. Paradoxically, capacity utilization of the industry is below 30% and about 70% of medicines consumed in Nigeria are imported into the country [7]. The current status of the Nigerian healthcare sector where majority of the medicines used are imported is in direct contravention of the National Drug Policy. When it was formulated, the policy was designed to ensure that within a decade of its formulation, majority (70%) of national medicines' needs would be satisfied through local manufacturing. In line with the achievement of this objective, the National Drug Policy also sought to promote pharmaceutical research and development of raw materials for manufacturing pharmaceutical and related products. The policy further aimed at increasing availability of high quality, effective, affordable, and safe medicines, through various means [8, 9, 10].

The Medicines' Security concept is critical not only to how nations plan citizens' access to high quality, safe, and efficacious medicines, but also to the development of sustainable systems that address contextual socioeconomic needs such as unemployment, knowledge deficits and revenue generation [11]. Given that about 10 million people die every year due to poor access to essential medicines [12], and that Nigerians are disproportionately affected [13], understanding the interactions between pharmaceutical sector policies and practices, as well as their influence on access to healthcare is not only critical, but also expedient. So far, very few experts have sought to address this knowledge gap, for instance a decade old study which revealed that out of over 130 existing pharmaceutical manufacturing companies in Nigeria, less than half were in active operation [14]. A review of the extant literature revealed that no study has undertaken a robust and comprehensive interrogation of these critical issues in the context of contemporary challenges facing both the sector and the nation. This study therefore aimed at adopting a bottom-up approach in gathering insights into stakeholders' perspectives on policies and practice in Nigeria's pharmaceutical sector, and how they influence Medicines' Security and consequent access to healthcare.

Methods

2.1 Data Collection Procedure

The study participants were selected from stakeholders present at an event targeted at Nigerian pharmaceutical sector development. A questionnaire was designed for data collection, which was administered to stakeholders during the event. Questionnaires were completed and returned after completion. A convenience sampling strategy was employed [15], and this was achieved by administering the questionnaires to only those present at the event who agreed to complete the data collection tool. A total of 82 questionnaires were administered and the ethical principle of confidentiality was maintained throughout the data collection process. The purpose of the study was explained to the study participants and consent was obtained before the questionnaires were administered. The questionnaire was made up of socio-demographic items and items relating to relevant pharmaceutical sector development. A Likert scale of 1 to 5 was employed for some of the questions and they were represented as follows: 1 = Strongly

Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, and 5 = Strongly Agree. Other relevant open-ended items were included to enable the collection of relevant qualitative data.

2.2 Data Analysis

Questionnaires retrieved were coded into Statistical Package for Social Sciences (SPSS) version 21 for analysis [16]. Descriptive statistics was carried out, and association of responses with socio-demographic characteristics was determined using chi square test. A *p value* of 0.05 or less represented the threshold for statistical significance. Qualitative data collected from the open ended items on the questionnaire were subjected to thematic analysis [17].

Results

3.1 Demography

A total number of 76 questionnaires were completed and returned, giving a response rate of 92.68%. Female participants were in the minority as indicated by 30.3% of the sample. A quarter of the study participants were between the ages of 41 and 50 years, whilst those above 50 years represented the most populous proportion of the sample (38.2%). Occupationally, public and civil servants represented more than half of the study participants surveyed (63.2%), whilst politicians and policymakers represented the least (2.6%). Further details about socio-demographic characteristics are presented in Table 1 below.

Table 1: Socio-Demographic Characteristics

Variables	
n=76	N (%)
Gender	
Male	53 (69.7)
Female	23 (30.3)
Age	
18-30	9 (11.8)
31-40	16 (21.1)
41-50	19 (25.0)
51 and Above	29 (38.2)
Missing Data	3 (3.9)
Highest Education Level Achieved	
Diploma (OND)	1 (1.3)
First Degree (or HND)	29 (38.2)
Master's Degree	29 (38.2)
Doctorate Degree	16 (21.1)
Missing Data	1 (1.3)
Occupation	
Public/Civil servant	48 (63.2)
Business person	10 (13.2)
Politician or Policymaker	2 (2.6)
Development/International Agency	6 (7.9)
Others	7 (9.2)
Missing Data	3 (3.9)

3.2 Developing a Robust and Comprehensive Strategy

The healthcare system depends on medicines to function effectively, and the pharmaceutical sector is responsible for production and distribution of medicines necessary to achieve optimum results. From Fig. 1 below it can be seen that 93.5% of the study participants indicated that access to medicines should be the key goal of pharmaceutical sector development.

The findings from this study are therefore in line with the paradigm shift that has now moved towards patient focused practice. Available evidence suggests that this approach is more efficient for improving access to healthcare for majority of the population.

The results from the study as indicated in Fig. 2 below revealed that almost all (96%) of the study participants agreed that the responsibility for initiating and driving development in the sector lays with the Government.

The role of Government in the development of the pharmaceutical sector can therefore be adjudged as critical, and the evidence emerging from this study can help provide policymakers with the necessary impetus for necessary reforms.

In Fig. 3 below, majority of the study participants indicated that increased investment in health research could stimulate the development of the pharmaceutical sector as 97.3% of the participants indicated “strongly agree” and “agree”.

The findings from the study in this thematic area is in tandem with the pressing need to build capacity in health research, particularly in Nigeria’s developing healthcare setting, where the gap is seemingly daunting.

3.3 Actualizing Potentials of Nigerian Pharmaceutical Sector

A favourable policy environment is an important factor for the growth of any sector. In this study, close to half (48%) of the study participants indicated that the current policy environment was not conducive for the growth of Nigerian pharmaceutical sector. Further details are presented in Fig. 4 below.

From the emergent findings from this study, the policy environment was perceived as hostile for the development of the sector. Without an in-depth understanding of the contributory factors, stimulating development in the sector will be difficult.

There are medicinal plants across different parts of Nigeria, and many herbal preparations are formulated from these abundant medicinal plants. Almost all (96%) the study participants however indicated that the potentials of phytomedicines and natural resources have not been fully explored. Details are presented in Fig. 5 below.

The fact that majority of the study participants indicated agreement with the stated item is a strong indication of a good understanding of the inherent potential of phytomedicines for both the pharmaceutical industry and the healthcare sector.

Currently, almost all the Active Pharmaceutical Ingredients (APIs) used in manufacturing medicines in Nigeria are imported and majority (92.1%) of the study participants indicated that there is need to partner with petrochemical industry to produce APIs. Further details are presented in Fig. 6 below.

Local production of APIs will significantly contribute to the assurance of Medicines’ Security and consequently improve access to healthcare in the country. Partnership between the petrochemical sector

and pharmaceutical sector stakeholders will also improve efficiencies in the achievement of Government's overarching objectives, especially with respect to diversification of revenue streams.

The production of raw materials for local production of medicines in Nigeria is an important factor with the capacity of boosting Nigerian economy and also create employment for its citizens. Almost all (96%) the study participants indicated that it is important to produce raw materials for the production of medicines in Nigeria. Further details are presented in Fig. 7 below.

Local production of various raw materials and manufacturing inputs will significantly contribute to the assurance of Medicines' Security, as it will domesticate a significant proportion of the pharmaceutical manufacturing value chain. Job creation, knowledge transfer and capacity building are some additional socioeconomic benefits that this initiative can achieve.

There is currently no local Nigerian pharmaceutical company on WHO prequalification list and majority (89.5%) of the study participants indicated the need for Nigerian organization to attain WHO prequalification as this can boost the development of Nigerian pharmaceutical sector. A breakdown of the participants' views is indicated in Fig. 8 below.

WHO prequalification enables Nigerian pharmaceutical companies participate in international procurement activities, particularly those funded by development partners. Attaining this status therefore increases market access for stakeholders in the sector.

Figure 9 shows responses of the study participants towards collaborating with research institutes. Almost all (97.3%) the participants indicated that pharmaceutical manufacturing firms should collaborate with research institutes so as to enhance their productivity.

The findings of the study in this area is in line with international practices, particularly in developed countries. Globally, there is an increasing emphasis on translation research, as a means of ensuring that resources committed to the knowledge industry actually ends up impacting on lives. In the case of the pharmaceutical sector, either as processes or as products.

3.4 Interests, Perceptions and Insights

From the findings, majority of the study participants were more interested in research and academics, compared to other aspects of the sector. On the contrary, the practice area which emerged as the least interesting to the study cohort was importation. It is however noteworthy that non-traditional areas such as policymaking, public health as well as supply chain and logistics emerged as areas of significant interest for the study cohort. Further details are presented in Table 2 below.

Table 2
Areas of interest by the participants

Item	N	Percent
Manufacturing	22	28.95
Supply Chain & Logistics	27	35.52
Investment	22	28.95
Hospital practice	27	35.52
Importation	10	13.16
Academics/Research	57	75.00
Public Health	31	40.79
Community Practice	17	22.37
Policy making	32	42.11
Traditional Medicine	18	23.68
NGO	18	23.68

Further to the descriptive statistical analysis undertaken on the data, more sophisticated statistical analyses such as cross tabulation were also undertaken. Findings shows that some of the responses of the study participants were influenced by their socio-demographic characteristics, as chi square test was significant for some of the items. A strong majority of public servants (95%) agreed that access to medicines should be the key goal of pharmaceutical sector development, compared to only half (50%) of policymakers that agreed with the same concept. This finding was statistically significant ($p = 0.007$) and for the first time in the extant literature, there is empirical evidence suggesting a possible dissonance between policy makers and policy implementers.

Another interesting finding that emerged at this level of analyses, was in relation to respondents' perceptions on strategies for actualizing the potentials of the Nigerian pharmaceutical sector. The findings indicated that participants' views differed significantly, based on their level of education. Whilst there was a strong agreement amongst degree holders and postgraduate respondents on the need for the pharmaceutical manufacturing firms to collaborate with research institute to enhance their productivity, only respondents who were not educated up to degree level disagreed with this strategy. This finding too was statistically significant ($p = 0.0001$) and provides desperate new insights into the role of educational qualification, as regards how government policies are formulated, implemented and understood.

Textual data provided by the study participants in relation to the development of the pharmaceutical sector were analysed thematically following the qualitative research paradigm. In relation to the development of the pharmaceutical sector, it emerged that the adoption of a collaborative approach involving all relevant stakeholders, was perceived as most appropriate for the Nigerian setting.

“...all stakeholders have to be involved to achieve a robust and comprehensive development” (Male Participant, Public Servant, above 51 Years).

“...continuous collaboration with other stakeholders would help improve the current situation” (Male Participant, Pharmacist, above 51 Years).

The study respondents further identified government as the key stakeholder responsible for articulating, driving and organizing the relevant reforms in the sector

“Government needs to demonstrate commitment to pharmaceutical sector as a national priority” (Male Participant, Public Servant, above 51 Years).

“...there must be a government structure to ensure policy implementation” (Male Participant, Development Sector Professional, 41–50 Years).

“Government should not take sole responsibility on investing but private companies, international organizations should partake and partner in drug production” (Female Participant, Public Servant, 18–30 Years).

In addition to outlining government’s role and responsibilities, the findings from the qualitative part of the study further corroborated findings from the quantitative aspect, particularly with respect to identifying the need for partnership with the private sector and with development partners.

From the study participants’ perspective, there was a need for the Nigerian Pharmaceutical sector to embrace emergent new technologies in various aspects of the sector as a catalyst for the overarching development of the sector.

“Adaptive technology should be put in place properly to improve the development of the Pharmaceutical Sector” (Female Participant, Public Servant, 18–30 Years).

“...many researches [sic] conducted are not transformed into products” (Male Participant, Public Servant, above 51 Years).

In addition to the need to integrate new technologies in the Nigerian setting, participants also identified a lack of a framework that supports translational research, resulting in a situation where most research output are left on the shelf.

Another important theme that emerged in the qualitative aspect of this study was the hitherto unexplored socioeconomic potential of the pharmaceutical sector

“Leveraging on local research outcomes should be considered by pharmaceutical industries to support local production” (Male Participant, Public Servant, 31–40 Years).

“The potential of Nigeria pharma sector is large and if tapped, it will increase the economic indices of Nigeria” (Female Participant, Public Servant, Above 51 Years).

The findings from the thematic analysis have identified associations between quality local manufacturing and national economic growth. These linkages between strengthening local manufacturing through contextual research, and achieving socioeconomic objectives such as revenue generation, job creation and capacity building, is at the very core of the Medicines' Security concept.

Discussion

4.1 Demography

Of a total of 76 study participants, a third were females suggesting that the event was dominated by males. This is a reflection of the current Nigeria labour force [18]. One-tenth of the study participants were between the ages of 18 to 30 years, suggesting a considerable inclusion of an age bracket traditionally associated with innovative and fresh ideas [19]. The consequent implication is the increased potential of interventions that can catalyze the development of the sector. Close to a quarter of the study participants had a doctorate degree, whilst more than half of them indicated that they had a post graduate degree. This implies that the study participants had considerable research experience, as such, it is possible that their views and experiences are evidence-based. Available evidence suggests that doctorate degree holders can play vital roles in establishing good policies in various relevant settings [20]. It is logical to therefore infer, that despite the relatively small sample size of the study, the high quality of the sample together with the qualitative analysis of the textual data provides some insight as to the value of the novel findings that emerged from the study. These insights can consequently support policymakers and other stakeholders develop contextual strategies to improve Nigerian pharmaceutical sector.

4.2 Assuring Medicines' Security

Majority of the study participants indicated that access to medicines should be the key goal of pharmaceutical sector development. This finding is critical for government stakeholders and policymakers. An earlier study had identified that weaknesses in healthcare provision in Nigeria were associated with lack of Medicines' Security in that setting [5]. The findings from this study, despite focusing on pharmaceutical sector development, corroborates an overarching systematic objective of improving access to medicines. Furthermore, the thematic analysis provided evidence that deepens the socioeconomic aspects of the Medicines' Security concept. The correlations between local manufacturing underpinned by contextual research and stimulation of critical indices economic, represents a novel finding in the study area.

Over the years, the issue of access to affordable essential medicines in healthcare systems has been a matter of concern worldwide [21]. Studies have revealed that the health of a country's general population is significantly affected by access to healthcare and availability of medicines [12, 22]. It is therefore important for policymakers, practitioners and other stakeholders in the sector to continuously explore novel mechanisms to enable the achievement of medicines' security. What this study adds, is the identification of development partners and the corporate sector as key stakeholders, plus the need for collaborative working in policy articulation, development and implementation.

In this study, study participants indicated the need for government to increase investment in health research as a way of stimulating the development of the sector. A similar finding was previously reported by Sun *et al.* [23] in China. For policymakers, it is important to look at funding holistically with a view of exploring other alternative sources for funding health research. Also, it is important to fully implement existing policies which have prospects of developing Nigerian pharmaceutical sector. There are existing policies that can catalyze the development of the pharmaceutical sector, if well implemented. An example of such policies is the National Drug Policy [9]. The National Drug Policy set a target of 70% for local manufacturing of medicines consumed in Nigeria, however there is little evidence that this target has been achieved, after more than a decade of implementation. This perhaps emphasizes study participants' exhortation of the improved collaboration and active participation of critical stakeholders in the articulation, development and implementation of pharmaceutical sector policies. Although this study represents the first time a collaborative, multi-stakeholder participation is being promoted for the entire policy value chain in the Nigerian pharmaceutical sector, aspects of this strategy have been identified as sufficiently effective in earlier findings by Witty [24].

4.3 Harnessing Potentials in Nigerian Pharmaceutical Sector

Findings from this study identified current policies as hostile for pharmaceutical sector development, suggesting desperate and urgent reforms to stimulate necessary development. Despite the challenges faced by the sector, majority of the study participants were of the view that the Nigerian pharmaceutical sector possesses significant potentials especially in the area of phytomedicines and natural resources. These are resources, which when properly harnessed can activate the production of APIs, excipients and other pharmaceutical raw materials. This finding is in line with other previous studies that indicated the need to focus on exploring medicinal plants and other natural resources to improve access to healthcare services [25, 26]. A significant proportion of all medicines were derived from plants and today, many pharmaceutical classes of drugs include a natural prototype [27]. Traditionally, herbs and phytomedicines have provided very useful synthetic clues for orthodox medicines [28]. Medicinal plants have also been recognized as an unparalleled source of molecular diversity for drug discovery and development [29]. Whilst this work provides evidence that validates advantages associated with phytomedicines, the heightened interest in research revealed in the study represents an opportunity to develop contextual strategies that can appropriately harness these opportunities.

Participants in this study indicated that manufacturers need to partner with the petrochemical industry to locally produce APIs and other raw materials. This can reduce inordinate importation, increase revenue generation, build capacity and create employment in various relevant settings [30]. With respect to WHO prequalification, there was a strong consensus among the study participants on the need for local pharmaceutical companies in Nigeria to consider this quality improvement approach. Presently, no local pharmaceutical firm in Nigeria is on the WHO prequalified list [31]. Achieving WHO prequalification by local manufacturers can boost development in Nigerian pharmaceutical sector. The WHO prequalification of medicines programme is a means of assessing quality, safety and efficacy of medicines undertaken in close collaboration with experts from national regulatory authorities of various member countries [32, 33]. One of the benefits for local manufacturing firms is the opportunity to participate in international

procurement opportunities by development partners who prohibit shortlisting of products without WHO prequalification.

Regarding collaboration, findings from this study indicates that collaboration between local pharmaceutical manufacturers and research institutes is necessary for achieving Medicines' Security, these findings are in agreement with a previous study [34]. Available evidence suggests that collaboration between pharmaceutical companies and research institutes is poor, and this has impacted the pharmaceutical sector negatively [1]. It is therefore urgent and important to initiate policy reforms that will promote collaboration between research institutes and local pharmaceutical companies. Successfully achieving this will expedite the translation of research activities into products and processes. This is particularly important at this point in time, given the increasing interest in research as indicated by the emergent findings of this study.

Conclusion

Existing policies within the National healthcare context are unlikely to enable the achievement of Medicines' Security in Nigeria. New insights from stakeholders' perspective propose urgent bottom-up policy reforms led by Government but underpinned by robust and comprehensive multi-stakeholder engagement at all developmental and implementation stages. Additionally, increased collaboration between pharmaceutical companies, research institutes, and the petrochemical industry was identified as critical for the production of APIs, excipients, phytomedicines and other inputs. Consequently, the sector must begin to look inwards as regards harnessing local resources available within the country for the development of contextual interventions and solutions.

The development of contextual and responsive policies that can help address vulnerabilities in the pharmaceutical sector will go a long way in repositioning the local pharmaceutical industry, and consequently contribute to the achievement of Medicines' Security and Universal Health care in Nigeria. This study has demonstrated the need for critical attention to be given to contextual pharmaceutical sector research and the adoption of new technologies and processes, as catalysts in their achievement.

Despite the small sample size, this study has adopted a novel mixed methods approach to provide new insight into critical policies expected to drive development in Nigeria's pharmaceutical sector, especially from Stakeholders' perspectives. Further research is however required to deepen some of these emergent findings, as well as to determine specific barriers preventing the implementation of existing policies which have the potentials to catalyze development of Nigerian pharmaceutical sector.

Declarations

Ethics approval and consent to participate: This study was conducted after securing ethical clearance from the Institutional Review Board of National Institute for Pharmaceutical Research and Development. Consent was obtained from the participants before administering the questionnaire to them.

Consent for publication: Not applicable

Availability of data and materials: The datasets used and analysed during the current study are available from the author on reasonable request.

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Competing interests: There is no competing interest.

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Authors' contributions: Not applicable.

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Figures

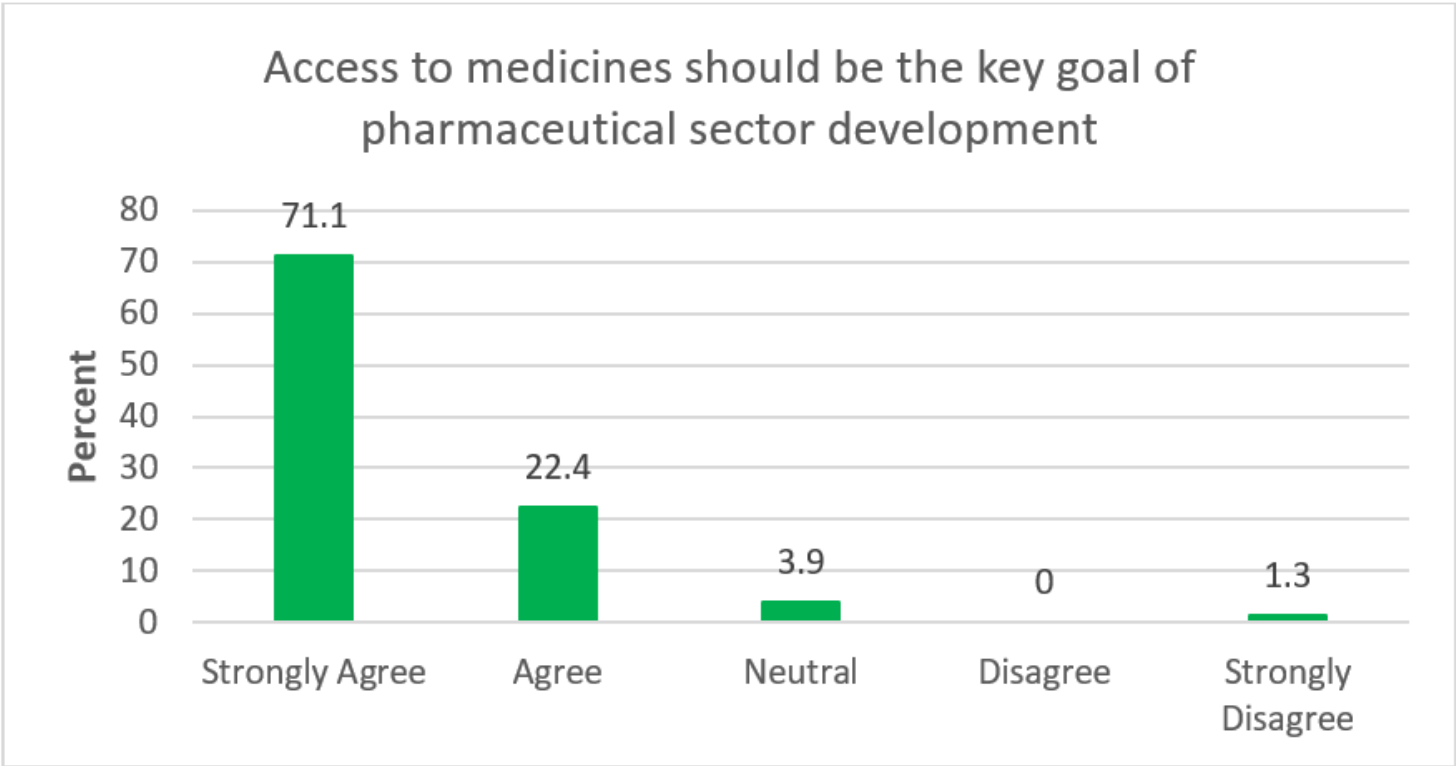


Figure 1

Access to Medicines

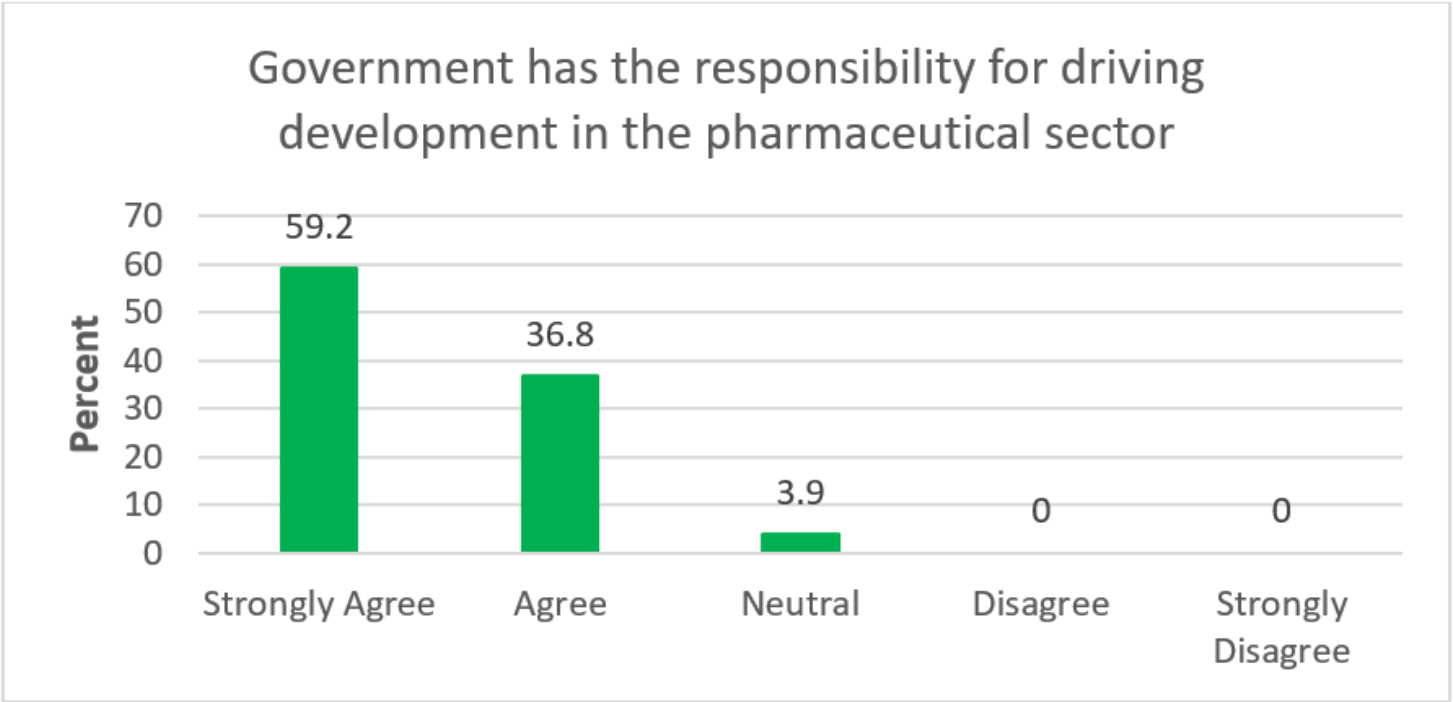


Figure 2

Government Responsibility in Driving Development

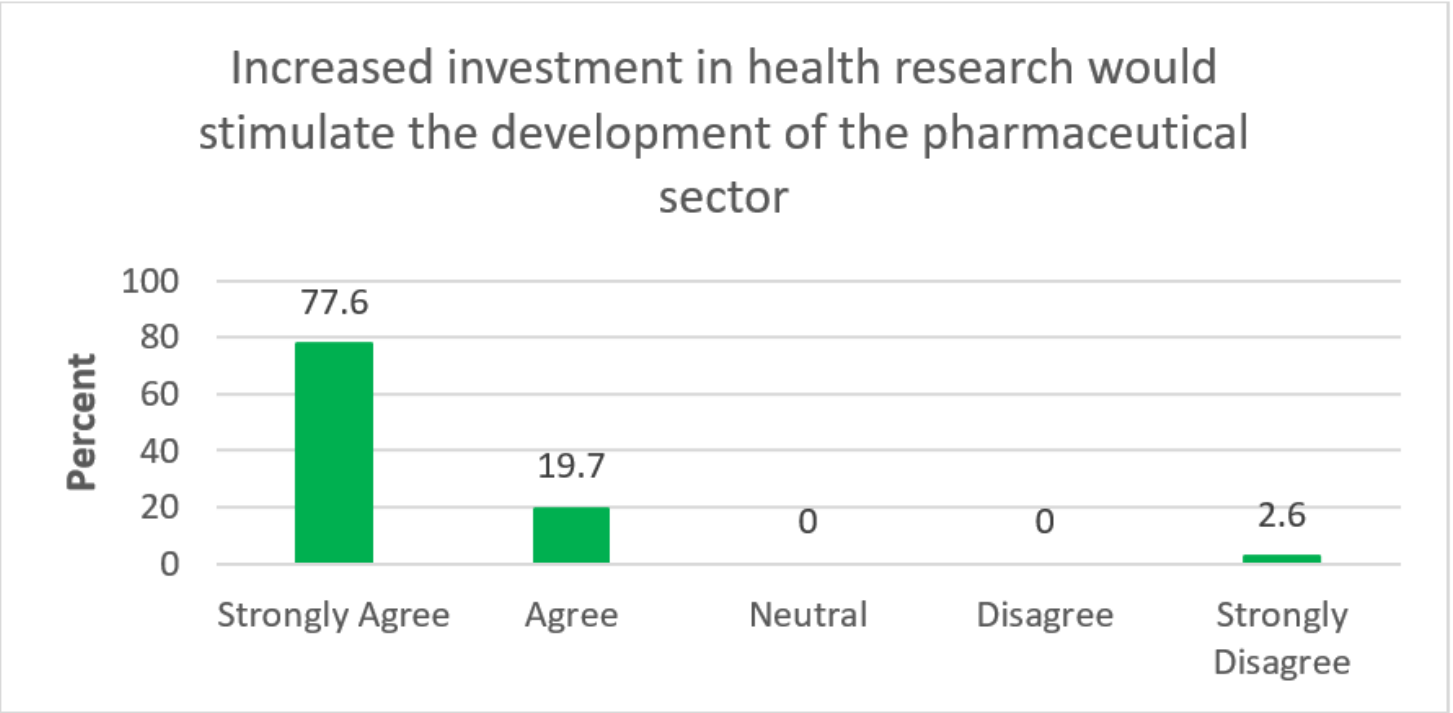


Figure 3

Investment in Health Research

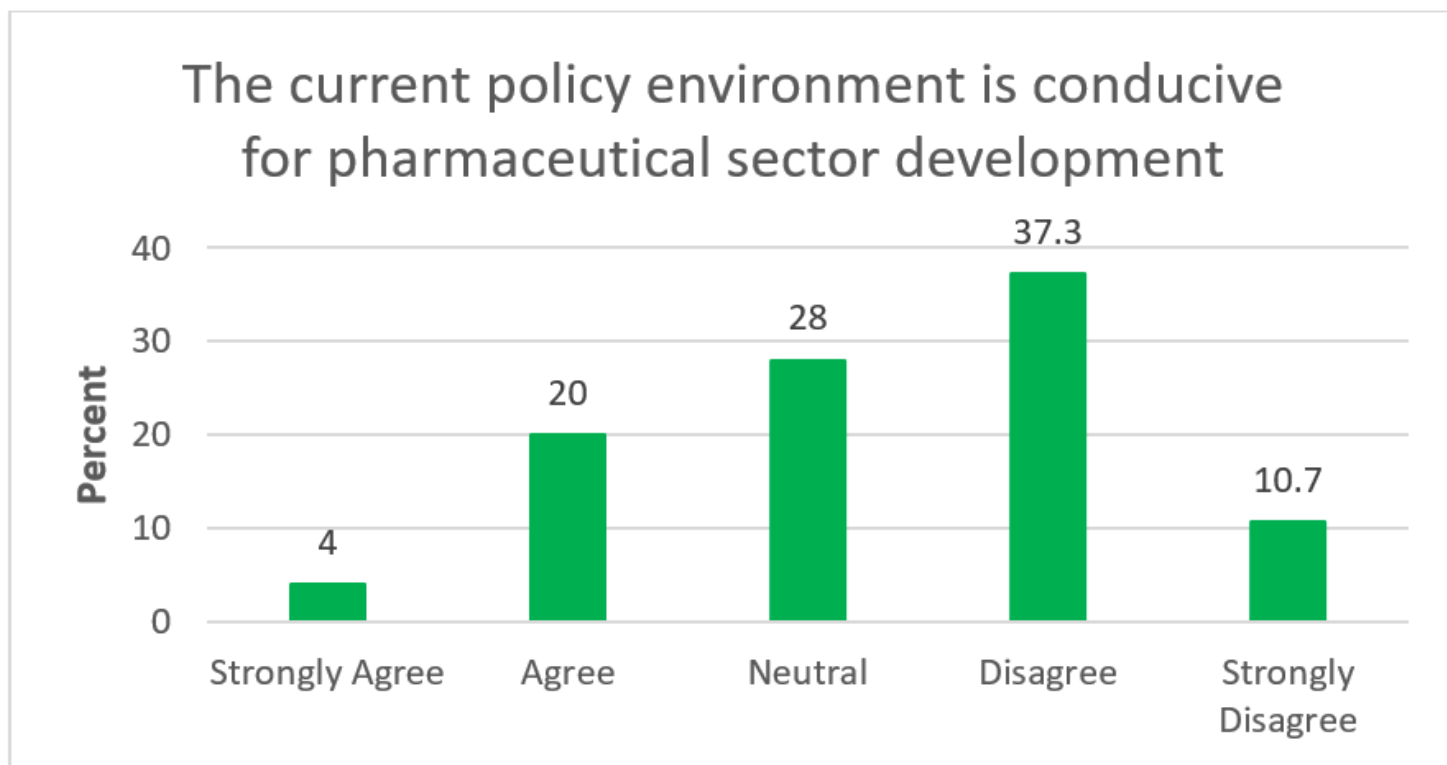


Figure 4

Current Policy Environment

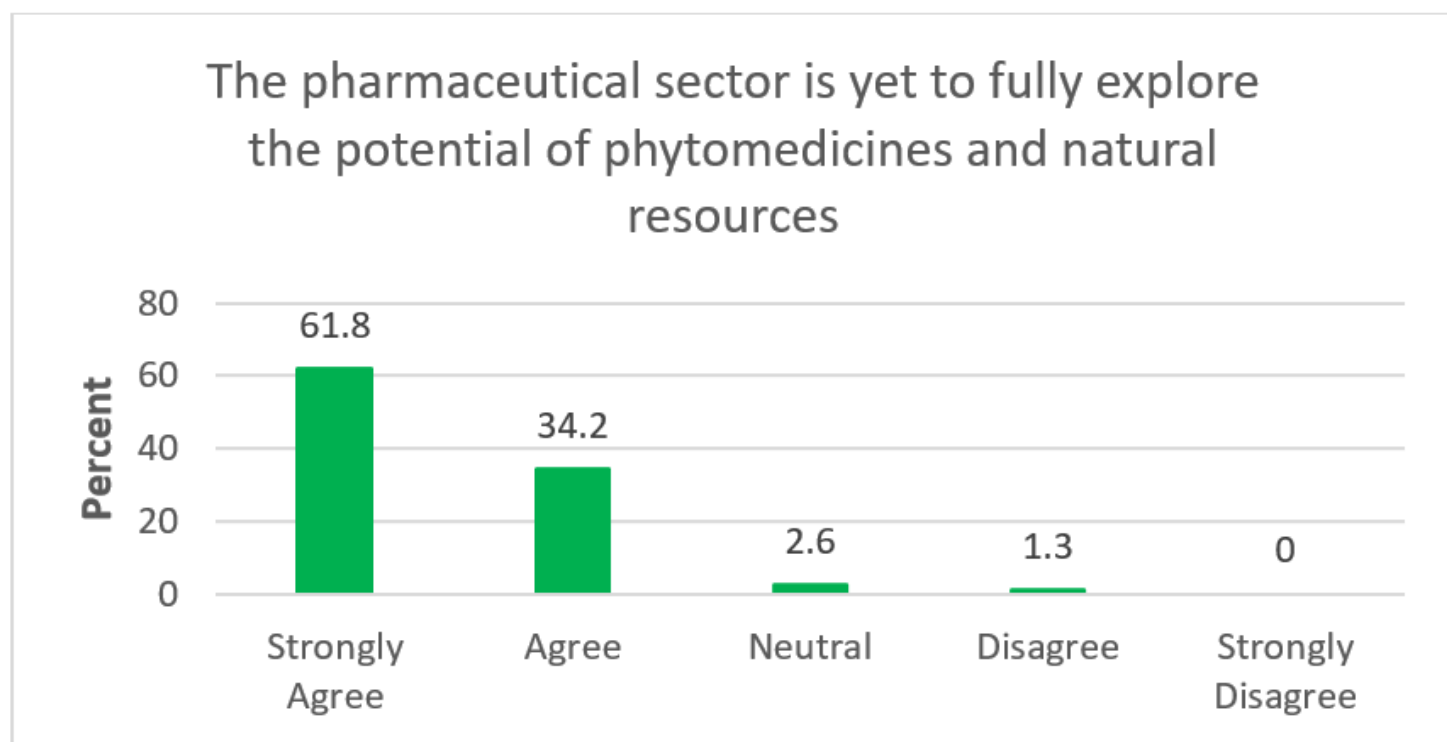


Figure 5

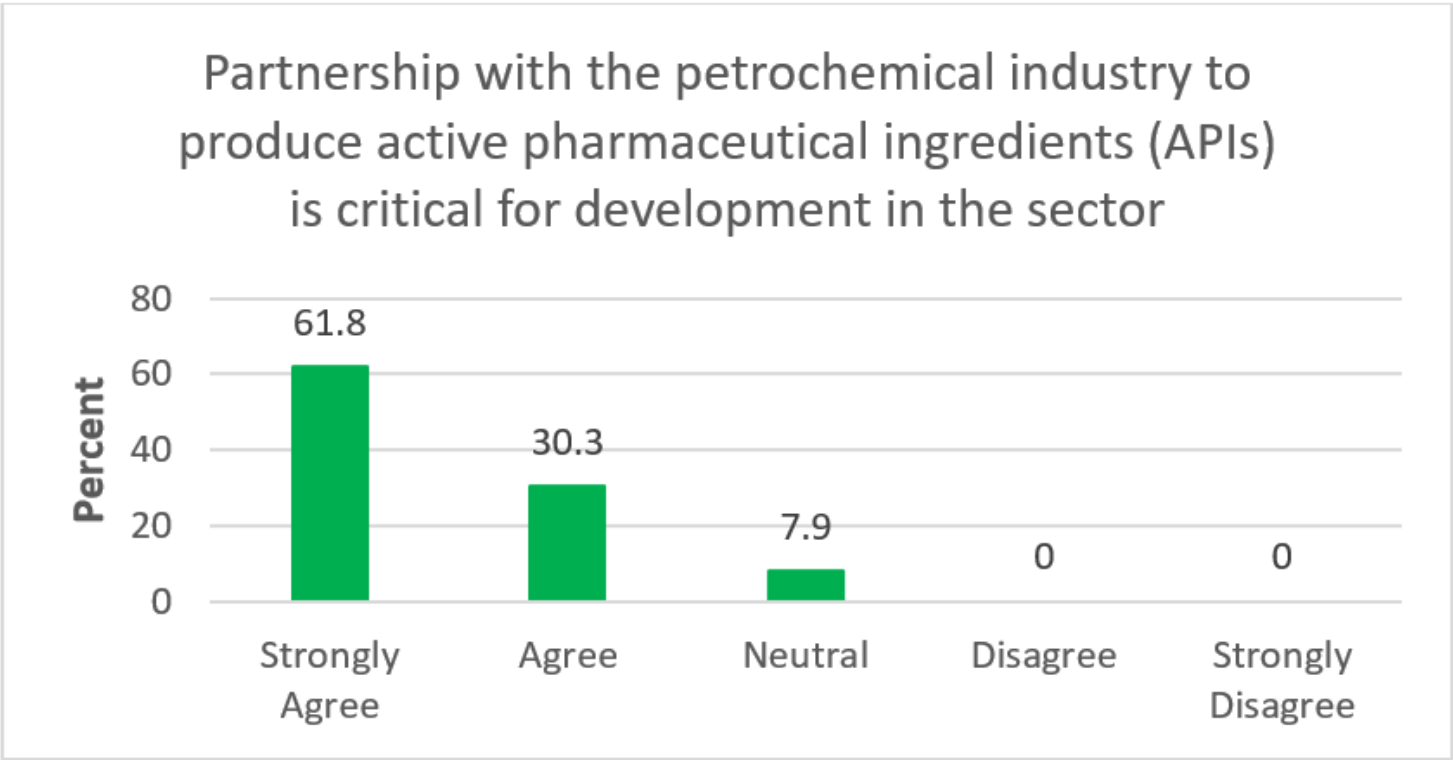


Figure 6

Partnership with Petrochemical Industry

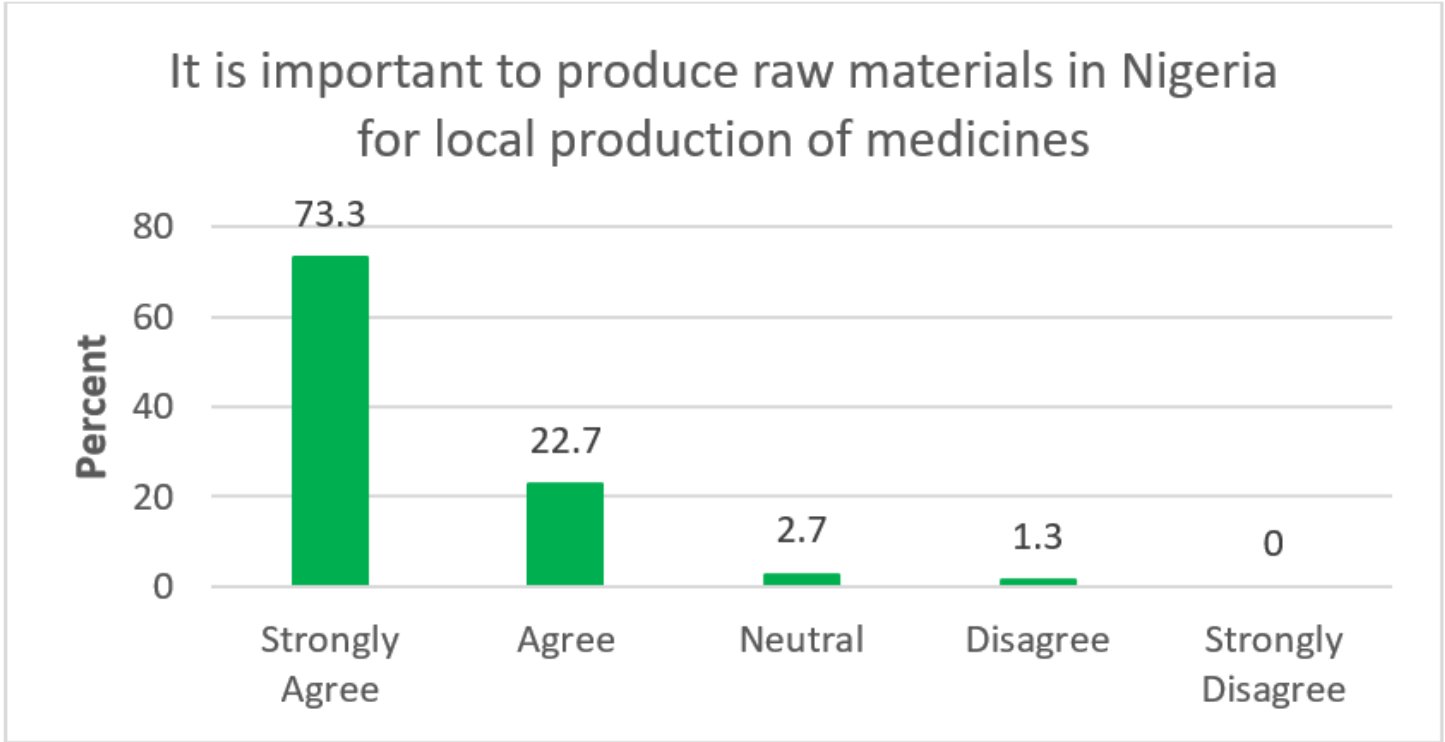


Figure 7

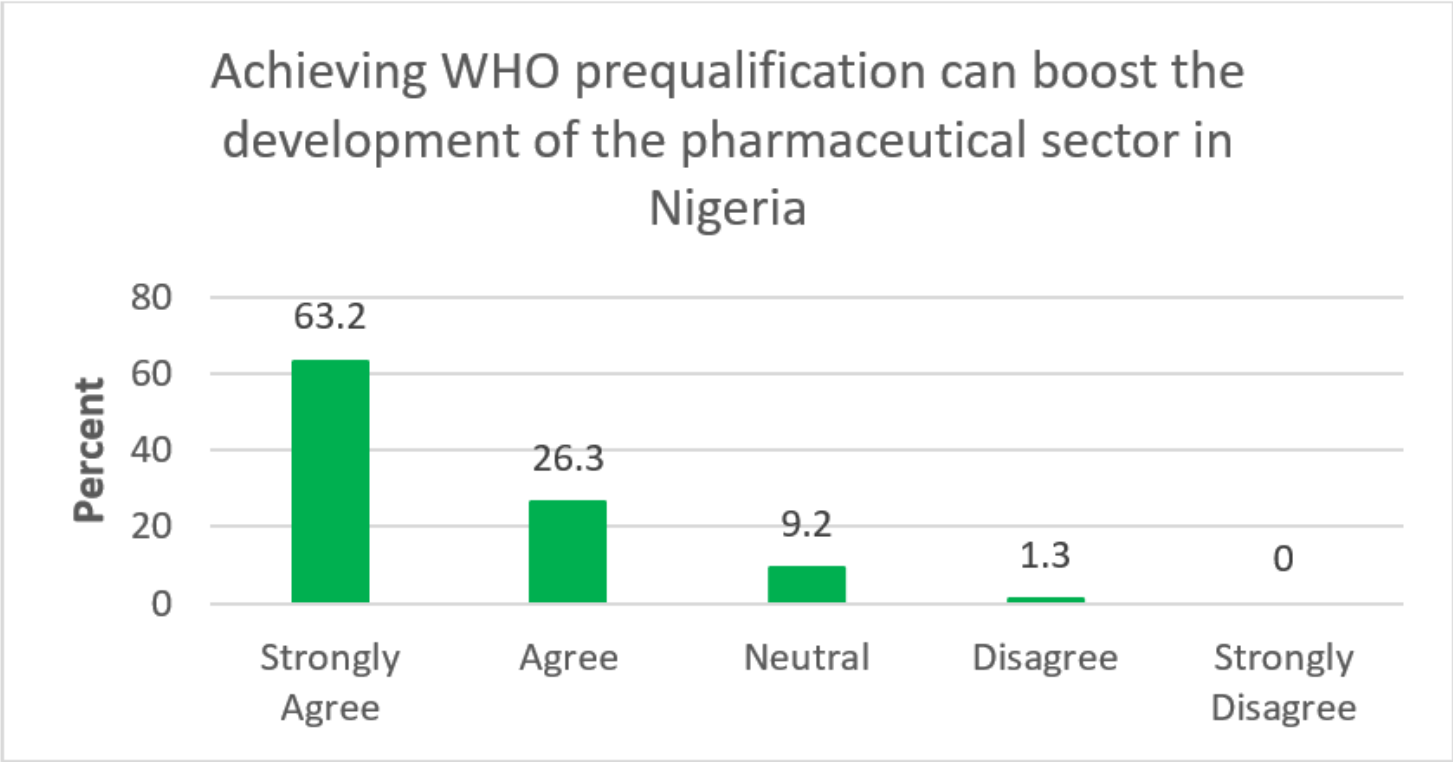


Figure 8

WHO Prequalification

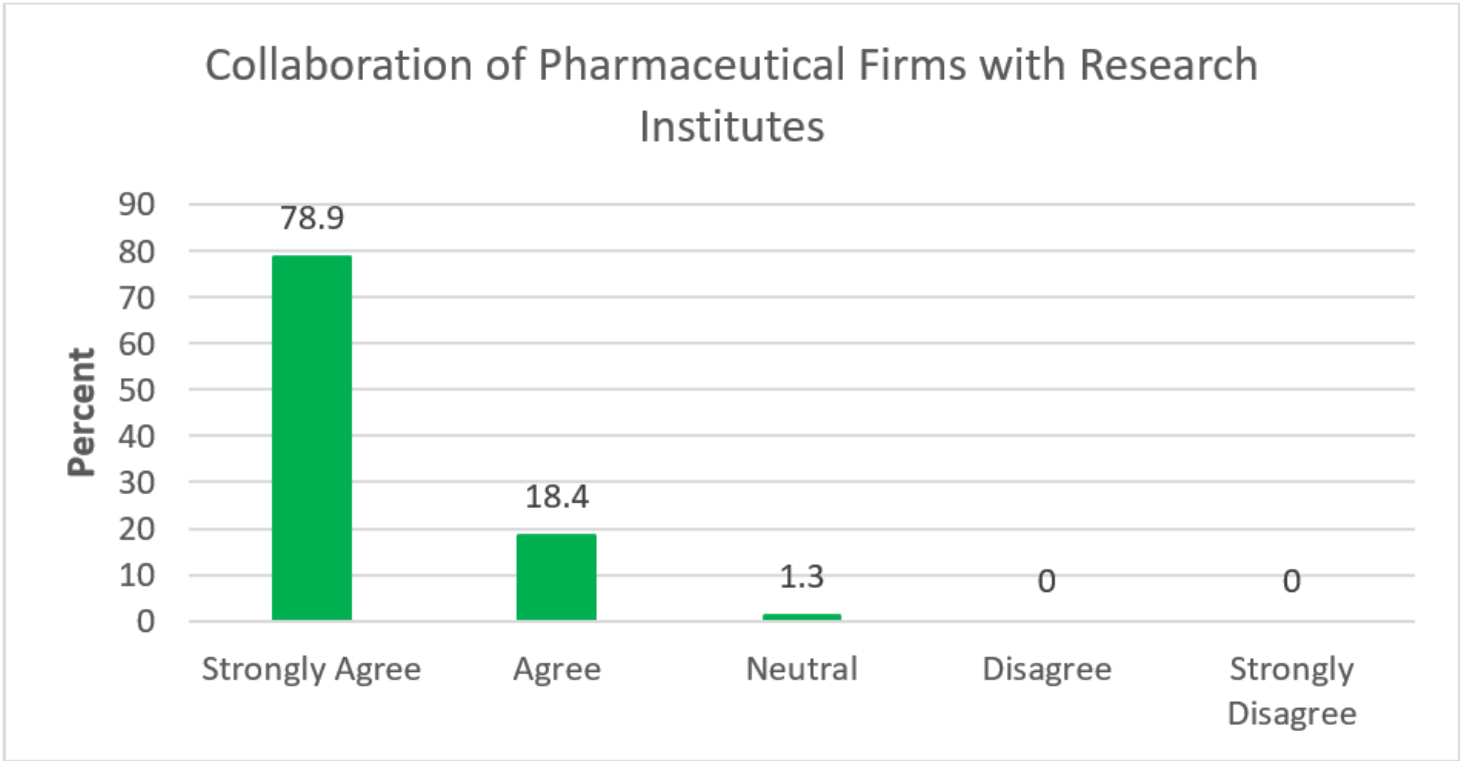


Figure 9

