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Original Research

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Stakeholders' Perspective of Role of Policy and Legislation in Achieving Medicines' Security

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Abstract

Background: The role of the pharmaceutical industry in a country such as Nigeria in the provision of safe, high quality and efficacious pharmaceutical products to meet the healthcare need of the populace, cannot be over-emphasized. This study was undertaken to critically look at the issues affecting Medicines' Security in Nigeria. Methods: A selfcompletion questionnaire was used for data collection. The questionnaire was administered to participants of an Industry event in September 2017. Data collected were analyzed using Statistical Package for Social Science. Results: A total number of 800 questionnaires were administered to the participants and 529 of the questionnaires were included for analysis. Male participants (58.6%) were more than female participants, all age groups were well represented and more than a third of the respondents had first degree as their minimum qualification. Majority of the respondents (91.3%) indicated that Ministry of Health and its agencies were key to protecting the pharmaceutical sector, while slightly less of that proportion (79.1%) indicated that they patronized Nigeria pharmaceutical products. Almost all the participants (91.7%) supported the need for the local pharmaceutical industry to have access to sustainable funding and other incentives. A similar proportion (89.6%) of the respondents indicated that the local pharmaceutical industry should be prioritized in policy making and implementation. A significant proportion of the study participants (82.3%) indicated that access to medicines in Nigeria is a security issue. Conclusion: To ensure Medicines' Security and attain medicines selfsufficiency in Nigeria, radical policies must therefore be put in place, together with enabling good business and industrial environment by the government in order to protect, promote and grow the local pharmaceutical industry in Nigeria.

Keywords: Medicines' security; Access; Industry; Drugs; Pharmaceutical; Production; Products.

1. Introduction

1.1. Background

Medicines are output of the pharmaceutical manufacturing sector aimed at diagnosing, preventing, curing and treating disease, and they are considered essential when they are selected to meet the health care needs of majority of the population (World Health Organization, 2017). It is expected that people should have access to essential medicines at all times and in sufficient amounts (World Health Organization, 2003). This is however not the case in Nigeria and other similar settings, as many developing nations are currently faced with challenges associated with a lack of Medicines' Security. Access to essential medicines is a key indicator in the assessment of the viability of primary health care system in line with the Bamako Initiative (Chabot, 1988; Najmi, 1989). The National Drug Policy was introduced to improve the supply of affordable, safe and good quality medicines, as well as to ensure rational use of medicines. The policy was also designed to increase local production of essential medicines, stimulate export and ensure that all drugs in the National drug distribution system are safe, effective and of good quality. Other objectives include strengthening administrative, legislative, and regulatory controls of the importation, manufacture, procurement, storage, distribution, supply, sales and use of drugs, whilst promoting research on herbal medicines. The National Drug Policy also sought to promote pharmaceutical research and development for the purpose of production, compounding and formulation of pharmaceutical products (Federal Military Government, 1986; Ogbonna et al., 2015).

Although the target of the National Drug Policy was to ensure that 60% to 80% of the objectives were achieved before the end of 2008 (Kuti, 1992), more than a decade past this deadline, Nigeria still suffers seriously from a lack of Medicines' Security. About 70% of medicines in circulation in Nigeria are imported. Also, about 17% of generic medicines in circulation are either fake or substandard and about 30% of anti-malarials are faked despite the introduction of mobile authentication system introduced by the National Agency for Food and Drug Administration and Control (Abiodun, 1998; Adeoti, 2004; Ifudu, 2006).

Medicines' Security is an emergent concept which argues for better control of medicines production and distribution as a means of improving sustainable access to high quality, affordable healthcare for that population. Local manufacturing of medicines and related commodities are central to this concept (Adigwe, 2019; Akpa and Adigwe, 2018). Furthermore, emergent evidence from the articulation of the Medicines' Security concept indicates that local manufacturing of pharmaceuticals and related commodities can significantly boost socioeconomic development, especially in the areas of job creation, knowledge transfer and capacity building (Adigwe, 2018a).

Nigeria's significant dependence on importation of medicines has been associated with its current difficulties in achieving Medicines' Security. This is due to the perceived negative impact that being overly reliant on importation has on the Country's capacity to locally produce of pharmaceuticals for Nigerians. The role of local pharmaceutical manufacturing in a country such as Nigeria, in the provision of safe, quality and efficacious pharmaceutical products to meet the healthcare need of the populace has therefore been identified as critical (Ogaji J. I. et al., 2014).

In Nigeria, companies who manufacture medicines include local firms and multinationals. Over the years, in line with the National Drug Policy, both classes were identified as being active in the local manufacture of medicines. However, evidence suggests that an increasing number of multinationals no longer manufacture in Nigeria, but rather seem to prefer engaging in the importation of finished pharmaceutical products. Researchers have identified a nexus between this sort of attrition of local manufacturing and subsequent increase in importation on one hand, and the increased threat to Medicines' Security, for instance, increased risk of spurious substandard products (Kristin and Olatubosun, 2002).

It is acknowledged that undertaking strategies to assure Medicines' Security has the potential to increase access to healthcare especially as indicated by the National Drug Policy. This approach is also invaluable to improving key socioeconomic objectives. Despite this, very little research has been undertaken in this critical area. Some reports have explored the relationship between good governance and access to essential drugs (Cohen *et al.*, 2007; NAFDAC, 2011), however, no study has yet explored how roles and activities of policymakers and other critical actors influence the achievement of Medicines' Security. Furthermore, there was little evidence in the extant literature, that Medicines' Security concerns had been explored from the oft ignored but critically important perspective of the pharmaceutical industrial sector. This study was therefore undertaken to explore stakeholders' views and experiences regarding various critical issues relevant to Medicines' Security in Nigeria, especially from the pharmaceutical industrial sector.

2. Methods

A self-completion questionnaire was developed to explore the views and opinions of stakeholders in pharmaceutical manufacturing industry on the challenges in the pharmaceutical manufacturing sector and the possible solutions. The questionnaire was administered to stakeholders that participated in an industry event that took place in Lagos, Nigeria in September 2017. Completed questionnaire copies were retrieved from the participants. Convenience sampling approach was adopted in data collection (Ilker *et al.*, 2016; Sedgwick, 2013).

A 12-item stem consisting of 5 points response scale as well as socio demographic characteristics was developed for the survey questionnaire. Items included in the questionnaire covered protection, patronage, funding, and special status. The questionnaire was pre-faced as follows: 1 = strongly disagree, 2 = disagree, 3 = Neutral, 4 = agree, and 5 = strongly agree.

The retrieved usable copies of the questionnaire were entered into Statistical Package for Social Science (SPSS) for analysis. The analysis conducted include descriptive and inferential statistics (Bryman and Cramer, 2002). A *P* value of 0.05 or less represented the threshold for statistical significance.

3. Results

A total number of 800 questionnaires were administered to the participants and 529 of the questionnaires was included for analysis. Male participants (58.6%) were more than female participants, all age groups were well represented and more than a third of the participants had first degree as their minimum qualification. Other relevant details are presented in table 1 below.

Table-1. Socio Demography

Variables n=529	N (%)
Gender	
Male	310 (58.6)
Female	75 (14.2)
Missing Data	144 (27.2)
Age	
18-30	91 (17.2)
31-40	114 (21.6)
41-50	135 (25.5)
51 and Above	93 (17.6)
Missing Data	96 (18.1)
Highest Education Level Achieved	
Diploma (OND)	136 (25.7)
First Degree (or HND)	198 (37.4)

Master's Degree	146 (27.6)
Doctorate Degree	14 (2.6)
Missing Data	35 (6.6)
Occupation	
Public/Civil servant	53 (10.0)
Business person	182 (34.4)
Politician or Policymaker	26 (4.9)
Development/International Agency	18 (3.4)
Others	85 (16.1)
Missing Data	165 (31.2)
Nationality	
Nigerian	459 (86.8)
Non-Nigerian African	5 (0.9)
Asian	59 (11.2)
European	2 (0.4)
Missing Data	4 (0.8)

3.1. Protection of the Local Pharmaceutical Industry in Nigeria

The protection of the local pharmaceutical industry is vital to the development of the pharmaceutical sector. Although the participants accepted that the executive and the legislature should protect the pharmaceutical industry in Nigeria, their opinion was that majority of the responsibility lay with the Ministry of Health. Further details are presented in figure 1 below.

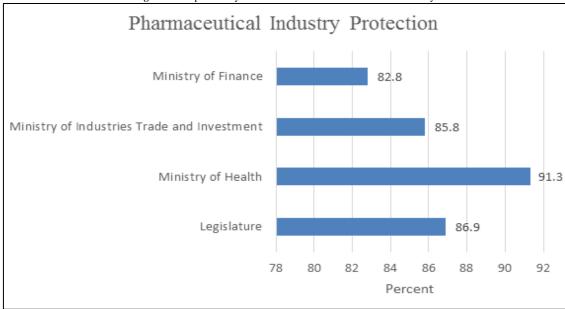


Figure-1. Responsibility for Protection of the Pharmaceutical Industry

Non parametric test was undertaken to compare the Ministry of Health's activities to protect the pharmaceutical industry in Nigeria with activities undertaken by other government ministries and the legislature. Mann-Whitney U test was statistically significant for other ministries and the legislature. See details in table 2 below.

Table-2. Mann-Whitney U Test

Items	Mann-Whitney U	Wilcoxon W	Z	<i>P</i> -Value
The Legislature is key in protecting the local	987.000	89818.000	-2.790	0.005
pharmaceutical Industry				
Ministry of Industry and its Agencies are key	434.500	60465.500	-3.506	0.0001
in protecting Local Pharmaceutical Industries				
Ministry of Finance and its Agencies are key	566.500	86471.500	-4.554	0.0001
in protecting the Pharmaceutical Industry				

3.2. Patronage of Nigerian Pharmaceutical Products

Patronage of Nigerian pharmaceutical products and materials is essential for the growth of the sector. The findings showed that 79.1% of the participants indicated that they patronized Nigerian pharmaceutical products and 8.6% of the participants did not patronize Nigerian pharmaceutical products. About a third of the participants indicated that Ministry of Health had not done enough to encourage patronage. However, more than a quarter of the

participants indicated lack of sufficient legislature to encourage patronage of Nigeria pharmaceutical products. Other details are presented in figure 2 below.

Patronage I Personally Patronise Nigeria Pharmaceutical Products Ministry of Health doing Enough to Encourage Patronage Sufficient Legislation for Patronage 30% 40% 50% 60% 90% 100% 70% ■ Strongly Agree ■ Agree ■ Neutral Disagree ■Strongly Disagree

Figure-2. Patronage

3.3. Cross Tabulation

A cross tabulation was done to determine association between the item "I personally patronize Nigerian pharmaceutical products" with "level of education". Findings from the result indicated that the level of education of the participants had influence on their patronage of indigenous pharmaceutical products. Chi square test was statistically significant with a P value of less than 0.05. See details in table 3 below.

Table-3. Cross-tabulation of Level of Education with Patronage

Level of Education	Yes	No	\mathbf{X}^2	DF	P-Value
Diploma(OND)	30 (62.5)	18 (37.5)	47.667	3	0.0001
First degree or HND	132 (91.0)	13 (9.0)			
Master's degree	107 (98.2)	2 (1.8)			
Doctorate degree	12 (100.0)	-			
Total	281(89.5)	33(10.5)			

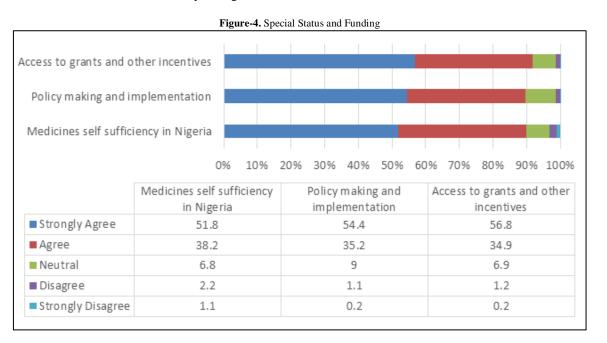
3.4. Access to Medicines

Majority of the participants (82.3%) indicated that access to medicines in Nigeria is a security issue. However, few of the participants (6.4) do not see access to medicines as a security issue in Nigeria. Further details are presented in figure 3 below.

Figure-3. Access to Medicines In Nigeria context, I believe access to medicines is a security issue 50 43.4 38.9 40 30 20 11.3 10 4.8 1.6 0 Strongly Agree Disagree Strongly Agree Neutral Disagree

3.5. Special Status and Funding

From figure 4 below, almost all the participants (91.7%) supported the need for local pharmaceutical industries to have access to grants and other incentives, 89.6% of the respondents indicated that local pharmaceutical industries should be prioritized in policy making and implementation, and they further supported the need for stakeholders to strive towards medicine self-sufficiency in Nigeria.



4. Discussion

A number of insightful findings relating to Medicines' Security emerged from the study. In terms of the demographic data, more males participated in the study than females and this corroborates the findings by Ekpenyong *et al.* (2018) which reported more males in the Nigeria pharmaceutical workforce. All the predetermined age groups were well represented in the age category. This is an indication of robust knowledge, and opinion sharing between the older and younger generation on the challenges in the Nigeria pharmaceutical industries and ways to improve the Nigerian pharmaceutical industries. Majority of the participants had a minimum of first degree, this is expected as the data were collected during an industry event focused on the pharmaceutical sector and the minimum requirement to practice pharmacy in Nigeria is BPharm degree (Ogaji J. and Ojabo, 2014). Collectively, individuals not in government or civil service constituted the majority of the participants. This is a true reflection of the Nigerian pharmaceutical manufacturing industry, given the private sector nature of the industry.

In this study, it emerged that the majority of the participants indicated that access to medicines was a security issue in Nigeria, this finding is buttressed by previous findings that reported lack of access to essential medicines to the Nigeria populace and its consequent deleterious effects on the health of Nigerians (Kolawole, 2012; Kristin and Olatubosun, 2002; Ogbonna et al., 2015). Nigeria is the most populous country in Africa with its population accounting for a significant proportion of people living in the West African region (Akinyemi, 2014). Nigeria is however associated with high birthrate, high illiteracy, low investment and large scale of unemployment (Adebayo, 1999; Onah, 2001). These poor socioeconomic indices have continued to counter numerous efforts being put in place towards ensuring access to essential medicines in the country. Findings from previous studies have shown some correlation between issues around availability of medicines with irrational use of medicines as health care providers will tend to make do with the available medicines (T'Hoen, 2003; Uzochukwu et al., 2002; World Health Organization, 2020). Similarly, studies have reported that about 50% of people in developing countries lack access to essential medicines (Oxfam, 2006; T'Hoen, 2003). What this implies is that promoting the rational use of medicines will therefore improve access to medicines (Alfa and Adigwe, 2014). Most importantly however, findings from this study validate the emergent Medicines' Security concept which strongly supports local manufacturing as a means of improving access to health, as well as catalyzing the reversal of the downward trend of poor socioeconomic indices (Adigwe, 2018a; 2018b).

With respect to the protection of the pharmaceutical industry in Nigeria, findings from this study show that Ministry of Health is perceived as being most responsible for protecting the local pharmaceutical industries in Nigeria, and these findings were statistically significant. Although the legislature is responsible for law making, findings from this study suggest that the Ministry of Health needs to be proactive in formulating relevant policies protective of the local pharmaceutical industry in Nigeria especially as this Ministry is responsible for the regulation of the pharmaceutical sector in Nigeria as evidenced by the regulatory activities of Pharmacist Council of Nigeria and National Agency for Food and Drug Administration and Control (Amadi and Amadi, 2014; Government of Nigeria, 2005; Olatunji, 2014; Oseni, 2019; Pharmacists Council of Nigeria (PCN), 2001). Findings from this study further indicate that the Ministry of Health is perceived to be responsible for collaborating with the legislature and other stakeholders towards the growth and development of the pharmaceutical sector in Nigeria. Some of the policies

made by the government to boost local production of drugs include the 20% import adjustment tax on some groups of imported drugs which can be adequately produced by local manufacturers (Brandspur, 2018). Many developing countries have policies in place which excludes locally manufactured products from being imported. Ghana has no fewer than 49 pharmaceutical products on import prohibition list, believing that doing so would help to fast-track the development of its own local manufacturing firms (Bokpe, 2017). Similar policies may be considered in Nigeria to ensure Medicines' Security which is crucial to improving access to healthcare, as well as stimulating socioeconomic development including job creation, knowledge transfer and revenue generation.

Patronage for local pharmaceutical products and other related aspects that contribute to market share are important factors that influence the growth and development of the local pharmaceutical industry. Although majority of the participants in this study indicated that they personally patronized Nigeria pharmaceutical products, an interesting finding emerged in this area. The level of patronage of the participants was associated with their level of education. The study revealed that the more educated people were, the higher the likelihood that they would patronize locally manufactured medicines. This finding was statistically significant and may be due to the fact that better educated people understood the intricate linkages between seemingly diverse policy areas such as local production, socioeconomic development and access to healthcare. Consequently, deliberate and continuous enlightenment of the populace is required, to enable a better understanding as to how patronage of locally produced pharmaceuticals stimulates national growth in various relevant areas. A third of the study population indicated that the Ministry of Health had not sufficiently encouraged patronage. About a quarter of the participants indicated the same sentiment as regards the lack of relevant legislation in the same area. It is therefore imperative for policies to be formulated that are targeted at ensuring that local pharmaceutical products are given priority in various aspects of legislation and policymaking. Asides the recommended prioritization in new policy formulation, there is also the need to periodically monitor, evaluate and reinvigorate the implementation of existing policies such as the National Drug Formulary, Essential Drugs List and the National Drug Policy (Cohen et al., 2007; Federal Military Government, 1986; Federal Ministry of Health and World Health Organization, 2005).

Regarding special status, there was a strong consensus among the study participants on the need for the local pharmaceutical industry to be accorded relevant growth and development linked concessions as well as other relevant incentives. This means that in addition to the recommended policy prioritization of the local pharmaceutical industry, there is also a need for all stakeholders to deliberately and collaboratively strive towards Medicines' Security in Nigeria. From this emergent evidence, policymakers and stakeholders may therefore consider ensuring that pharmaceutical companies have access to relevant support necessary for the acquisition of necessary equipment, capacity building and other inputs required to operate at the highest international standards.

Recently, some sector analysts reported the reduction of the domestic manufacturing capacity utilization of the Nigeria pharmaceutical sector to just about a fifth of the relevant installed capacity. This worrisome statistic was further complicated by indications that about a third of all local manufacturers communicating a shutdown of all production. Some contributory factors identified include inadequate access to funds, low patronage, unfair foreign competition, weak infrastructure, and unstable power supply (Brandspur, 2018). Articulating measures to achieve Medicines' Security would not only ensure a robust and comprehensive engagement with these issues, it would also promote healthy living, stimulate inclusive economic growth and productivity, as well as catalyze sustainable industrialization as enshrined in the United Nation's Sustainable Development Goals (Obina, 2019).

5. Conclusion

To ensure Medicines' Security in Nigeria, proactive yet contextual policies urgently need to be emplaced by government in partnership with other critical stakeholders, with a view to protecting, promoting and developing the local pharmaceutical industry. Additionally, the role of good business environment and effective industrial policies in catalyzing the growth of the sector cannot be overstressed. Prioritization of the sector and bestowment of special status, as indicated in this study can underpin an effective strategy that would ensure an expeditious emergence of a business and industrial milieu that supports the development of robust local manufacturing capacity.

Accessible and affordable funding alongside other similar fiscal incentives are a sine qua non for catalyzing growth and development required to ensure that the current potential of the industry can be harnessed to build a manufacturing hub of international standards. The most important outcome however would be National Medicines' Security which would significantly improve access to affordable, high quality healthcare, whilst also stimulating desperately needed socioeconomic consequences such as employment generation, knowledge transfer and improved revenue accruals.

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