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Local Production of Active Pharmaceutical Ingredients (APIs) in West Africa: A Survey of Stakeholders' Perception and Views

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Abstract

Background: The pharmaceutical sector in West Africa is faced by challenges due to limited domestic capacity for production of medicines and heavy reliance on imports. Local pharmaceutical manufacturers face challenges such as high cost of doing business, poor infrastructure, and lack of standardized equipment. This study aims to assess the perception towards local manufacturing of Active Pharmaceutical Ingredients (APIs) in West Africa and explore strategies to improve access to medicines and achieve self-reliance in the region.

Methods: A cross-sectional survey was conducted amongst stakeholders that attended a conference targeted at improving local manufacturing of APIs in West Africa. Online and physical data were collected through the use of a validated questionnaire. Retrieved data were analyzed using Statistical Package for Social Sciences version 25. Data were presented in form of tables, frequencies, percentages and chi square analysis was used for inferential statistics.

Results: A total of 191 valid responses were received. Close to half (48.2%) of the stakeholders were female, majority of the study participants were between the ages of 18 and 40 years and were educated up to bachelor's degree level (62.8% and 58.1% respectively). The majority of participants (85.5%) acknowledged significant gaps in access to medicines and essential pharmaceutical commodities in West Africa. Over two-thirds of the respondents (83.3%) believed that West Africa is suitable for cost-effective production of quality medicines and majority of them (83.0%) were willing to patronize locally manufactured APIs.

Conclusion: Findings from this study identifies significant gaps with access to medicines and essential pharmaceutical commodities in the region and suggests the need for more strategic investments and policy action towards the promotion of local API production in the region.

Keywords: Local production, Active pharmaceutical ingredients, Stakeholders' perception, Self-reliance, West Africa

INTRODUCTION

Active Pharmaceutical Ingredients (API) can be defined as any biologically active substance within a drug that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease (U.S. FDA, 2017). APIs are used in the production of pharmaceutical drugs, including tablets, capsules, injections, and other forms of medication. They are typically manufactured by pharmaceutical companies and sold to other companies, who use them to produce finished dosage forms of medicines (Ehsan et al 2022). However, despite the importance of APIs in drug production, available evidence still suggests that the majority of raw materials and active pharmaceutical ingredients required for the production of medicines in West Africa are imported (Ekigwe, 2019).

According to a report, pharmaceutical companies in India accounts for over 70% of APIs and finished drug products consumed in the region (BusinessDay, 2021). This substantial dependence of West Africa on drug imports has however resulted in several challenges which undermine the achievement of medicines' security. Amongst other constraints, supply chain complications, infiltration of counterfeit medicines into legitimate drug supply, as well as high cost of pharmaceuticals have been identified in this regard (Pharmaapproach 2021). To address these challenges, it is therefore expedient that local API production across West Africa is catalysed. West Africa's pharmaceutical business relies significantly on imported Active Pharmaceutical Ingredients (APIs), posing substantial hurdles to drug security, price, and accessibility (Odeniyi and Adeyemi, 2015). The COVID-19 pandemic highlighted the weaknesses in the region's pharmaceutical supply chain. Despite West Africa's potential for low-cost domestic API manufacturing, poor infrastructure, high production costs, and insufficient government assistance have stifled expansion.

Several challenges however limit domestic API production capacity in the region with poor infrastructures and high production cost as two key underlying factors (West African Health Organization, 2018). These factors increase the cost of doing business and make it difficult for local manufacturers to compete with imported products. In Nigeria, the cost of energy is a major concern for manufacturers, as the country heavily relies on fossil fuels for power generation and the cost of electricity failure in Nigerian manufacturing sector is quite high. (World Health Organization (WHO), 2000). The absence of government incentives such as free land, research and development funding, technology incubation centers, tax holidays or rebates, and access to low-interest loans to encourage local production of medicines in West Africa further constitutes to these challenges (The African Union Commission 2012). These statements are consistent with reports in a study which indicated that several challenges such as limited research infrastructure, inadequate funding, shortage of skilled personnel, and reliance on imported raw materials hinder the domestic production of APIs in West Africa (Danraka and Abdulmujeeb 2023).

The evidence from the existent literature therefore reveals that sustainability and growth of the West African pharma sector would highly depend on the presence of an enabling environment that supports the development of local manufacturing capabilities. To address these gaps, this study aimed at assessing the views and perception towards local manufacturing of Active Pharmaceutical Ingredients (APIs) in West Africa as this can provide insights for robust contextual strategies to improve access to medicines or to achieve medicine security across West Africa.

METHODOLOGY

A cross-sectional survey was undertaken in Abuja, Nigeria in the month of November 2022. The sample population consisted of all participants of a Conference targeted at improving local manufacturing of APIs in the West African region. A total of 191 stakeholders participated with 151 questionnaires administered in person and 40 questionnaires completed online. The data collection tool employed was a semi-structured questionnaire that had undergone face and content validation by an expert panel. A draft questionnaire was created to gather stakeholders' views and perceptions on local manufacturing of API. The questionnaire items were reviewed by a panel who made suggestions for changes, additions, and deletions. The questionnaire items were edited and reworded based on the feedback received. The questionnaire was designed to gain insights on measures that could help in understanding stakeholders' perspectives. The appropriateness, complexity, attractiveness, and relevance of the questionnaire were assessed. Data were collected using online and physical methods of questionnaire administration. Both online and physical questionnaires contained the same content and questions.

Online participants were sent the questionnaire via Google forms after seeking their consent with

adequate instructions about filling it. This was achieved by sending a web link which directed participants to the questionnaire when clicked. Each participant was followed up via attendance information taken at the Conference to ensure that the questionnaires were well filled and submitted. Hardcopies of the questionnaires were also distributed and administered to all participants physically present at the Conference after seeking their consent. As with the online questionnaire, adequate instructions and guidance were given. The filled questionnaires were retrieved from all participants before the end of the Conference. By employing a combination of online and physical methods, the survey aimed to capture a diverse range of perspectives and ensure inclusivity in the data collection process.

Ethical approval was obtained from Institutional Review Board of National Institute for Pharmaceutical Research and Development before the commencement of data collection. Participation in the study was voluntary as informed consent was sought prior to the administration of the questionnaire.

Statistical analysis

Following the importation of data collected into Statistical Package for Social Sciences software version 25, descriptive statistical analysis was carried out. Data obtained were presented tables showing frequencies and percentages. Associations between variables were tested using chi square. A *p*-value of 0.05 or less was considered the threshold for statistical significance.

RESULTS

Demography

The socio demographic data of the respondents are as presented in Table 1. Total responses were 191. Result show that the number of males (99; 51.8%) were slightly higher than female participants (92; 48.2%). The age of the participants was distributed across five different categories and participants within the ages of 31-40 years constituted the largest proportion (35.1%). A small percentage of respondents (5.8%) were above 60 years of age while majority (35.1%) fell within the age range of 31 and 40 years. The majority of participants had a Bachelor's degree (58.1%) as the highest educational level achieved. In terms of the sector of practice, the largest group of participants were those practicing in the public sector (42.9%), followed by the private sector (35.9%) and development agencies (12.6%).

Table 1: Distribution of Respondents' socio-demographic characteristics

Variables n = 191	N (%)
Gender	
Male	99 (51.8)
Female	92 (48.2)
Age (Years)	
≤ 30	53 (27.7)
31-40	67 (35.1)
41-50	36 (18.8)
51-60	19 (9.9)
Above 60	11 (5.8)
Undisclosed	5 (2.6)
Highest Educational status	
Diploma	10 (5.2)
Bachelor's Degree	111 (58.1)
Master's Degree	40 (20.9)
Doctorate Degree	21 (11.0)
Others	1 (0.5)
Neutral	8 (4.2)
Sector of practice	
Government Sector	82 (42.9)
Private Sector	68 (35.6)
Development Agency	24 (12.6)
Others	2 (1.0)
Neutral	15 (7.9)

Overview of the West African pharmaceutical sector and medicine production

Majority of the respondents (85.5%) were in agreement that there is a significant gap in access to medicines across West Africa as shown in Table 2. Similarly, the table shows that poor access to essential pharmaceutical commodities in West Africa was indicated by about 87.0% of the study population. Access to new therapeutics was also considered a major challenge by over two-thirds (82.4%) of the study population, and a considerable proportion of the sample (83.3%) indicated that west Africa is suitable for cost-effective production of quality medicines. Further details are represented in Table 2 .

Table 2: Respondents' general views on west African pharmaceutical sector and medicine production (n = 191)

Views	Strongly disagree (%)	Disagree (%)	Neutral (%)	Agree (%)	Strongly agree (%)
Significant gap exists in access to medicines in west Africa	10(5.4)	8(4.3)	9(4.8)	87(46.8)	72(38.7)
Significant gap exists as it relates to access to essential pharmaceutical commodities in west Africa	5(2.7)	7(3.8)	12(6.5)	80(43.2)	81(43.8)
Access to new therapeutics is a major challenge for west African countries	2(1.1)	11(5.9)	20(10.6)	76(40.4)	79(42.0)
West Africa is suitable for cost-effective production of quality assured medicines	3(1.6)	9(4.8)	19(10.2)	69(37.1)	86(46.2)
Philanthropist support pharma sector research and development in west Africa	23(12.3)	43(23.0)	50(26.7)	38(20.3)	33(17.6)

Perceptions towards local production of APIs in West Africa

Table 3 shows the results of a survey on local production of active pharmaceutical ingredients (APIs) in West Africa. The majority of respondents agreed that manufacturing APIs in the region could improve access to medicines (95.7%), increase medicine affordability (90.4%), and benefit associated local industries and businesses (91.9%). However, respondents were less convinced that international support for local production of APIs in the region is adequate (A total of 51% either disagreed or strongly disagreed) or that collaboration among West African nations in this area is sufficient (54.9%). Most respondents were willing to patronize locally manufactured APIs (82.9%) and believed that the region has the technical capacity for local production of APIs (60.1%).

Table 3: Respondents' Perceptions towards local production of APIs in West Africa

Perception	Strongly disagree (%)	Disagree (%)	Neutral (%)	Agree (%)	Strongly agree (%)
Countries in the west African region have the capacity to address challenges associated with active pharmaceutical ingredients production	6(3.2)	15(8.0)	21(11.2)	77(41.2)	68(36.4)
Manufacturing of active pharmaceutical ingredients in west Africa can improve access to medicines in this region.	2(1.1)	3(1.6)	3(1.6)	60(32.1)	119(63.6)

International support for local production of active pharmaceutical ingredients in west Africa region is adequate	36(19.1)	60(31.9)	40(21.3)	30(16.0)	22(11.7)
Efficient local active pharmaceutical ingredients production can also benefit associated local industries and businesses	1(0.5)	2(1.1)	11(5.9)	62(33.5)	108(58.4)
Local production of active pharmaceutical ingredients in west Africa can increase medicine affordability in this region	1(0.5)	3(1.6)	14(7.4)	61(32.4)	109(58.0)
Collaboration among west African nations on active pharmaceutical ingredients manufacturing can improve local production of drugs	2(1.1)	3(1.6)	13(6.9)	55(29.3)	115(61.2)
Collaboration in the area of local production of active pharmaceutical ingredients among west African countries is adequate	37(19.8)	67(35.8)	32(17.1)	33(17.6)	17(9.1)
I am willing to patronize locally manufactured active pharmaceutical ingredient	2(1.1)	3(1.6)	27(14.4)	80(42.6)	76(40.4)
West African countries have the technical and qualified persons, technologies and capacity for local production of active pharmaceutical ingredients	9(4.8)	29(15.5)	35(18.7)	75(40.1)	39(20.9)

Determination of Association between variables using Chi square analysis

Table 4 displays the results of a cross-tabulation between the highest educational status of respondents' perceptions towards significant gaps with access to medicines in West Africa. The results show a relationship between the two variables with a p-value of 0.037 and X^2 value of 22.024. The p-value of 0.037 indicates that there is a statistically significant association between the two variables. The data suggests that the higher the educational status of the respondents, the higher the tendency for them to agree with perceptions towards the issue of significant gaps with access to medicines in West Africa and vice versa. The table shows 10% of those with Diploma strongly disagreeing with the perception while no respondent with Doctorate degree strongly disagreed. Conversely, only 20% of those with Diploma strongly agreed with the perception and as high as 71.4% of those with Doctorate degree strongly agreed.

Table 4: Association between respondents' highest educational status and their perception on the significant gaps with access to medicines in West Africa

Highest educational status	Perception on the significant gaps with access to medicines in West Africa					X^2	*p*-value
	Strongly Disagree (%)	Disagree (%)	Neutral (%)	Agree (%)	Strongly Agree (%)		
Diploma	1(10.0%)	0 (0.0%)	1(10.0%)	6(60.0%)	2(20.0%)	**22.024**	**0.037**
First degree	7(6.3%)	8(7.2%)	7(6.3%)	55(49.5%)	34(30.6%		
Master's degree	1(2.6%)	0(0.0%)	1(2.6%)	17(43.6%)	20(51.3%)		
Doctorate degree	0 (0.0%)	0(0.0%)	0(0.0%)	6(28.6%)	15(71.4%)		

Table 5 provides the results of a cross-tabulation analysis between the respondents' level of education and their perceptions towards the efficient local manufacturing of active pharmaceutical ingredients (API) in West Africa. The results show that there is a significant association between the two variables (X^2= 28.928; p-value=0.016). Participants with higher levels of education (Master's degree and Doctorate degree) were more likely to agree that efficient local API production can benefit associated local industries and business compared to those with lower levels of education (Diploma and First degree).

Table 5: Association between respondents' highest educational status and their perception on benefits for associated local industries through efficient local API production

Highest level of education	Benefits for associated local industries through efficient local API production					X^2	*p*-value
	Strongly Disagree (%)	Disagree (%)	Neutral (%)	Agree (%)	Strongly Agree (%)		
Diploma	0(0.0%)	0 (0.0%)	1(11.1%)	4(44.4%)	3(33.3%)	**28.928**	**0.016**
First degree	0(0.6%)	2(1.8%)	6(5.5%)	35(31.8%)	67(60.9%		
Master's degree	1(2.5%)	0(0.0%)	4(10%)	10(25.0%)	25(62.5%)		
Doctorate degree	0(0.0%)	0(0.0%)	0(0.0%)	8(38.1%)	13(61.9%)		

DISCUSSION

The socio demographic data of the respondents showed that both genders were well represented, the age brackets cut across both the young and the old and their educational status cut across various cadres. Respondents from various sectors of practice also participated in the study. This makes it interesting and possible to determine possible associations that may result due to the demographics of the respondents. It also gives the result obtained from this study a diverse view from different angles. The findings of the study showed that there is a significant gap in access to medicines and essential pharmaceutical commodities in West Africa, and access to new therapeutics is a major challenge, corroborating it with a study by Adebisi *et al*., (2022) which reports that that there is a significant gap in access to medicines and essential pharmaceutical commodities in West Africa. While this may be due to some underlying factors which may include limited pharmaceutical industries, high costs of raw materials, overdependence on countries abroad for medicines, poor supply chain systems, lack of government investment in the pharmaceutical sector, unfavorable manufacturing conditions, limited health workforce, lack of sustainable health financing mechanisms, lack of infrastructures and technical know-how, low investment on research and development, and circulation of fake and counterfeit medicines among others.

The study further reveals that the potential for cost-effective production of quality assured medicines in West Africa is positively perceived, and most respondents are willing to patronize locally manufactured APIs. This perception is good as it shows that stakeholders are ready to encourage any entity willing to venture into this aspect because patronage is a vital aspect of business growth and development. However, participants were less convinced that philanthropic support for the pharma sector's research and development in West Africa is adequate. This was in accordance with a study by Agyepong *et al*. (2011), which discusses the

challenges of health research and development in Africa, including the limited funding and support for research and development in the pharmaceutical sector. This directly or indirectly causes shortage of APIs which should be used in medicine production, in turn, can lead to a lack of effective treatments and interventions for diseases that disproportionately affect the African population. The limited funding and support for research and development in the pharmaceutical sector can also have significant consequences, corroborating it to a study by Simpkin., (2021) noted that despite the existence of production facilities in West Africa, there was a lack of investment in local production capacity for essential medicines which limits the capabilities of local industries resulting in over-reliance on imported drugs.

Similarly, this study highlighted the need for more strategic investment and policy action to promote local production and reduce reliance on imported drugs to improve medicine security in the region. It's corroborated by another study by Ekeigwe, (2019) that showed that political will and policy action were necessary to strengthen the local pharmaceutical manufacturing sector in West Africa. These findings suggest the need for more strategic investment and policy action to promote local production and reduce reliance on imported drugs. It can limit the ability of African researchers and pharmaceutical companies to conduct clinical trials, develop new drugs, and improve the quality of existing ones. Additionally, interventions to address the gaps in access to medicines must be tailored to meet the needs of different demographics.

This survey also found widespread agreement on the need for greater access to medications and pharmaceutical commodities in West Africa. The majority of respondents felt that local APIs production may lower medicine costs, promote related sectors, and increase medicine security. This may be true because it tends to eliminates or reduces the complexity associated with importation of this APIs including port issues, exchange rates, and forex issues among others. These stated issues cause difficulty in accessibility to the APIs as well as very high costs. However, there were concerns about insufficient international funding and collaboration among West African countries. The findings are consistent with earlier research by Danraka and Abdulmujeeb, (2023) which emphasized the need for strategic investments, governmental reforms, and improved infrastructure to enhance local pharmaceutical Research and Development for sustainable manufacturing.

Furthermore, the study found that there is a statistically significant association between educational attainment and access to medicines, with respondents having higher levels of education reporting greater access to medicines than those with lower levels of education. This shows that level of education impacts directly on understanding the respondents. The study recommends that policymakers and stakeholders should develop an environment for active pharmaceutical ingredient (API) production and local pharma manufacturing in Africa, and Ghana and Nigeria can be used to help other West African countries develop their local pharmaceutical industries. The study highlights the importance of education and training in the pharmaceutical industry, which could contribute to the higher levels of support for local manufacturing among those with higher education levels as cited in by OECD (2007). Corroborating it with a study by (Ogada *et al* 2020) that supports the idea that Ghana and Nigeria have a considerable amount of experience in the pharmaceutical manufacturing industry, which can be used to help other West African countries develop their local pharmaceutical industries.

Ghana, for example, has a relatively advanced regulatory system that can offer services in regulatory science to train regulators from other countries in the region. This suggests that those with higher levels of education who have had exposure to the pharmaceutical industry may be more likely to support local manufacturing of active pharmaceutical ingredients, as they understand the potential benefits and have seen it in practice in countries like Ghana and Nigeria. The fact that Ghana is offering training to pharmacists and postgraduates also highlights the importance of education and training in the pharmaceutical industry, which could contribute to the higher levels of support for local manufacturing among those with higher education levels.

Recommendations include Policy and Regulatory Support - Governments should provide incentives such as tax breaks, research funds, and subsidies to API makers. Policy interventions that address the gaps in access to medicines and promote local production of active pharmaceutical ingredients (APIs) in West Africa will enhance access, affordability, and local industry development while leveraging international support and regional collaboration and increased investment in research infrastructure, funding support, capacity building programs, and initiatives to promote local production of API can help overcome these obstacles and unlock the full potential of West Africa's pharmaceutical industries.

Infrastructure Development - Investment in industrial zones, power supplies, and standardized manufacturing facilities is critical.
Regional Collaboration - West African countries should expand cooperation to share resources, expertise, and regulatory frameworks.
Education and Workforce Training - Increased pharmaceutical education and technical training can boost the region's manufacturing capabilities.
Increased Investment - Funding from the public and commercial sectors should be devoted toward domestic API production in order to reduce reliance on imports and assure pharmaceutical self-sufficiency.

CONCLUSION

Generally, respondents have positive perceptions and views which can assist in promoting and actualizing local production of APIs in the West African region. The findings from this study suggest that higher levels of education are associated with a more positive perception of access to medicines and the benefits of local API production. This highlights the importance of education in shaping individuals' perceptions and beliefs in regards to healthcare services. The results provide valuable insights for public health policies aimed at improving access to medicines and promoting the benefits of local API production in West Africa.

The study also emphasized major gaps in pharmaceutical availability and the possibility for indigenous API production in West Africa. While there is considerable support for domestic manufacturing, obstacles such as limited infrastructure, high production costs, and insufficient legislative assistance persist. Addressing these concerns through strategic investments, regulatory changes, and regional coordination is critical for improving pharmaceutical self-sufficiency and lowering reliance on imports.

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