

Limitations Impacting Local Manufacturing of Vaccines: A Nigeria Case Study.

By

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**A dissertation submitted in partial fulfilment of the requirements for MSc in
Pharmaceutical Business & Technology (QQI)**

Innopharma Labs Faculty of Science

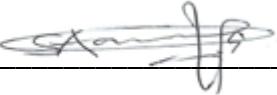
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August 2021.

DECLARATION

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I certify that the dissertation submitted to the department of Pharmaceutical Business and Technology at Griffith College, Dublin with the title "Limitations Impacting Local Manufacturing of Vaccines: A Nigeria Case Study", was compiled from results of my own research with appropriate acknowledgement and references.

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To God be the glory, Great things He has done.

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ABSTRACT

Vaccination is an age long science that has been proven to prevent some deadly diseases, especially in children below the age of 5 years. Therefore, it is empirical for any nation to stimulate the process of immunization and ensure that children and adults are protected from some of these infectious and deadly diseases. This will bring about a safe, healthy, and productive society where every individual within the system contributes their quota to the Gross Domestic Product (GDP) rather than treating the overall consequences of the lack of vaccination.

This research work was initiated to critically consider the limitations that impact local manufacturing of vaccines in Nigeria. A review of various literature from articles, journals, workshop presentations at different scientific conferences and other sources on related topics, to see trends and events as it relates to effort made in local vaccines manufacturing. From the literature reviewed, it was evident that most of the vaccines production are from developed countries like China, India, Russia, Vietnam, United States of America, Europe with very few Africa countries currently manufacturing vaccines locally.

In this research, qualitative method and Interpretivism philosophy of interviews arranged with experts on this subject matter were employed. Due to the prevailing pandemic ravaging the world, the researcher could not have a face-to-face interview with the identified experts contacted to be part of this research. Therefore, zoom meetings were set up and responses to the questions asked were all recorded and transcribed during the data analysis process. This process adequately ensured that the data collection process was effectively managed and with the use of thematic analysis, which is considered the most effective and preferred method used in qualitative data analysis based on its enormous benefits.

From the data analyzed using the answers provided by the experts interviewed in this research work, some findings inferred. There is no vaccine currently manufactured locally in Nigeria. Advocacy could be considered a strong tool in achieving local manufacturing of vaccines. There are available government policies on local manufacturing of vaccines, but the problem majorly is the lack of policy implementation. Although the pharmaceutical industries are willing to engage in local manufacturing of vaccines. Also, the challenges facing the pharmaceutical industries in achieving local manufacturing of vaccines are numerous but could be upturned with government support.

My researcher work has been able to identify some solution through the various recommendations and suggestions as discussed in chapter 5 of this dissertation. If these highlighted issues are implemented, then achieving local manufacturing of vaccines could be easily achieved and in good time.

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1.0 CHAPTER ONE: INTRODUCTION

1.1 BACKGROUND

This research work aims to study the limitations that impact local manufacturing of vaccines using Nigeria as a case study. The vaccine production started in Nigeria in 1924 in Vom, Plateau State with first animal vaccine and human vaccine came later in 1925 till 1991 when the vaccine production came to a stop due to facilities upgrade. This research is to provide answers to the research questions which will encourage local manufacturing of vaccines once again to boost our local content and tap from the over 120 registered manufacturing companies registered under the Pharmaceutical Manufacturing Group of Manufacturing Association of Nigeria (PMG-MAN)

Vaccines are usually administered to the body to stimulate the production of antibodies which in turn provide immunity to the body against one or several diseases. They are used for the prevention and control of infectious diseases and well over 20 different life-threatening diseases has been prevented with the use of vaccines (WHO, 2021a). This is made possible with the introduction of immunization scheme which is a by different non-governmental organization to support effort of the government to ensure the eradication of these deadly diseases which might affect children after birth.

The history of vaccination cannot be complete without mentioning vaccination against one of the deadly diseases called smallpox. This led to the discovery of other deadly infectious diseases such as measles, pertussis, diphtheria, tetanus, tuberculosis, and poliomyelitis tagged the six killer diseases. In addition to the above mentioned deadly diseases, within the last two decades, another vaccine was produced to prevent childhood against one of the major causes of pneumonia with pneumococcal and *Hemophilus influenza* type b vaccines (Abdulkarim *et al.*, 2011).

In line with the mandates of the world health organization (WHO) and other non-governmental organization such as United Nation Children and Education Funds (UNICEF) and Global Alliance for Vaccine and Immunization (GAVI), their mandates are to ensure immunization for all and also building capacity for local manufacturing of vaccines by different countries to guarantee local availability of vaccines for use thereby reducing death and elimination of vaccine preventable diseases (WHO, 2021a).

Therefore, it is imperative for individual country to develop local contents and increase capability by tapping into various opportunities available from these partners such as WHO, UNICEF, GAVI

and many others to build their local industries and strengthen their research and development (R & D), thereby promoting the local manufacturing of vaccine in Nigeria.

The need for a local content law (ACT) launched in 2010 by President Goodluck Ebele Jonathan (GCFR) have expressly supported the need for our indigenous pharmaceutical manufacturing industries to promote and improve the economic and social wellbeing of those engaged in vaccines manufacturing for vaccine security. This invariably will promote self-sufficiency in making raw materials available through backward integration of raw materials and other Active Pharmaceutical Ingredients (API) by strengthening our research and development through collaboration with universities and other academic institutions to encourage self-sufficiency or dependency.

1.2 AIMS AND OBJECTIVE

This research aims at developing a value-chain for local vaccine development, production, and distribution in Nigeria

The specific objective of the research is to:

- ❖ To find lasting solution for the local manufacturing of vaccines in Nigeria.
- ❖ To set up workable framework and plan of action towards re-establishing local manufacturing of vaccines in Nigeria.
- ❖ To promote and increase advocacy towards local manufacturing of vaccines among industry players.
- ❖ To identify the various challenges that are impacting local manufacturing of vaccines in Nigeria.

1.3 RESEARCH PURPOSE

The purpose of the research includes:

- ❖ To promote self-dependency and reduce the problem associated with sourcing vaccine outside Nigeria.
- ❖ State the need to increase access to vaccines in Nigeria.
- ❖ Come up with challenges which impact the local manufacturing of vaccines in Nigeria.
- ❖ Evaluate the current position regarding effort made towards local manufacturing of vaccines in Nigeria.

1.4 RESEARCH QUESTIONS

The following questions are expected to be answered by this research work to provide solution and way forward towards realizing these set goals. They are:

- ❖ What can be done to increase local manufacturing of vaccines in Nigeria?
- ❖ What are the challenges standing in between local manufacturing of vaccines in Nigeria?
- ❖ Are the government willing and ready to support the local manufacturing of vaccines in Nigeria?
- ❖ Would increase in advocacy promote the local manufacturing of vaccines in Nigeria?
- ❖ Are the Pharmaceutical industries ready to engage in local manufacturing of vaccines in Nigeria?

1.5 STRUCTURE OF STUDY

The researcher would be employing qualitative method of primary research in the collection of information from experts within the pharmaceuticals, government agencies, public and private organization who has adequate knowledge on the research topic, and information are obtained through recording of the zoom interviews recorded from the different sessions with the experts.

This research would be discussed in five different chapters comprises of introduction, literature review, research design and methodology, finding and discussion and finally recommendations and conclusion.

Chapter 1- This chapter provide a brief introductory aspect of this research work stating the research aims and objective, the research questions, and the conceptual framework of the research work.

Chapter 2- This is about literature review of publications or peer-reviewed articles to serve as the secondary information on related previous research work done by other researchers to throw more insight on the research topic.

Chapter 3- This chapter focus on the method of data collection. For this research, the researcher will be exploring a qualitative method of research to obtain the primary information from experts on the field who has the knowledge about vaccines development and manufacturing to give insight more on the research topic.

Chapter 4-The aim of this chapter is to analyze the data from the interviews which would be transcribed and then further analyzed. The qualitative data collected from the various zoom

interviewed held with the experts are transcribed and using thematic analysis would be carried out where patterns are defined, analyzed, and interpreted.

Chapter 5- This is the final chapter where various recommendations are discussed and conclusion drawn from the analyzed and interpreted data to give a lasting solution to most of the research questions. This conclusion will go a long way to give direction to concerned stakeholders if such recommendations could be implemented, it will give room for the development of domestic manufacturing of vaccine in Nigeria.

1.6 SIGNIFICANCE OF STUDY

The significance of this study is to develop local content and strengthen the manufacturing industries to utilize their full capacity through vaccine production. Also, it will enable the country to be prepared for any pandemic that may arise once the competencies are fully developed to handle the act of discovery, production, and distribution of vaccines in Nigeria. It is also a wakeup call to our government to further support local contents by creating enabling environment for our manufacturing industries to fully develop their full capabilities and encourage our government to conserve our country foreign reserve earning and channel such into other pressing areas towards infrastructural development. A lot still need to be done by our government to take a lead by encouraging investors and local manufacturers by supporting them with good policies that will create a more conducive environment to encourage and promote local manufacturing of vaccines in Nigeria.

1.7 CONCLUSION

The researcher is using exploratory research through qualitative research method to obtain primary information which will be used to answer some of the research questions which are highlighted above using experts' knowledge and opinions to throw more light into this research work. Domestic vaccines manufacturing may be the way out of the numerous problems found to be associated with vaccines manufacturing and distribution in Nigeria and with this research work, it will unravel what may likely be the way out of these problems and the next chapter will be review of literatures that are relevant to this study with in-depth understanding of the conceptual framework.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 PROCEDURE FOR THE DEVELOPMENT OF VACCINES IN THE WORLD

From information obtained from China as one of the emerging vaccine-producing countries, the government and private organizations are involved in the development vaccines to take care of local consumption and for export. The regulatory authority involved in the regulation of vaccines in China is the State Food and Drug Administration (SFDA). Also, provincial FDA collaborate with the SFDA to control the entire vaccine supply chain from production of the vaccines, trading, supply and administration (Hendriks *et al.*, 2010). The Chinese vaccine market are working assiduously to develop the local vaccine production and at the same time expanding their production capacity for international market by ensuring that they meet up the WHO prequalification guidelines for their factory certification which will benefit global access to vaccines.

In another research carried out to assess the importance of domestic vaccines manufacturing centers with emphasis on immunization programs, vaccine manufacturing and distribution, the importance of local vaccine manufacturing cannot be over-emphasized. This could be attributed to increase in vaccine research and development with a well-structured public healthcare system which is been encouraged globally. With effort from different countries to support domestic manufacturing of vaccine, still not enough to guarantee sufficiency for global needs. Countries such as USA, China, India, Canada, some nation in Europe and South America like Italy, France, Germany, Argentina, Netherland and Brazil manufactures vaccine employing Good Manufacturing Practices which should also be encourage in most developing countries to boost domestic manufacturing of vaccines (Rey-Jurado *et al.*, 2018).

In Vietnam, the production of vaccine for H5 influenza span between 2005-2011 was promoted as mass campaign for poultry vaccination which was biannual but was later suspended in 2011 due to antigenic drift in clade variant. The budget for the H5 avian influenza plan between 2014-2018 was about US\$39million of which poultry vaccination accounted for largest percentage of the amount. In addition, Vietnam is considered one of the rapidly growing country in term of its economies which has posed a major challenge consequently leading to withdrawal of external funding support to optimize healthcare system. The methodology adopted was qualitative approach which involved conducting series of interviews and meetings with notable stakeholders with different government agencies of influenza surveillance and research, pandemic

preparedness involving Nation Regulatory Authority along with other private vaccine manufacturers. The finding from the various interviews and roundtable meetings were discussed and recommendation and other action points implemented towards production of influenza vaccine in Vietnam (WHO, 2016).

Most developing countries are now building their countries capability in ensuring that they promote local manufacturing of vaccines through the development of bioprocessing technology and genetic engineering. With the new government health policy mandates, government of most of the developing countries are now supporting the local manufacturing of vaccines, which in long run, will reduce government spending on importation of vaccine to meet their needs to combat most pandemic and epidemic diseases. Today, most developing countries are investing huge amount of money to ensure domestic manufacturing of vaccines for cost reason and also for safety of their populations (Ronald A. Rader and Eric S. Langer, 2014). Furthermore, with the recent advancement in the use of modular technology in bioprocessing hardware will encourage the plug and play factories which will promote the transfer of technology to some of these developing countries to increase their capability in vaccine production with the use of cGMP quality level.

2.2 THE NIGERIA STORY: WAY FORWARD

Biovaccine Nigeria Limited is a joint venture agreement between the Federal Government of Nigeria (FGN) and May & Baker Nigeria Plc (MBN) and was incorporated in 2005 specifically to revive the vaccine production activity in Nigeria with MBN having 51% and FGN with remaining 49%. This is an example of PPP arrangement utilizing collaborative system of the government supporting the private sector. The objective is to ensure the production of safe, effective, and affordable human vaccines for the country thereby creating a hub in West African region to bring about reduction in the morbidity and mortality rate of vaccine preventable diseases which are common and endemic to our county Nigeria and other countries within the Africa. It is important that this arrangement is sustained and implemented because the Global Vaccine Alliance for Vaccines and Immunization (GAVI) may withdraw their funding to Nigeria because, Nigeria may surpass the criteria set by GAVI for her to continue to benefit thereby stopping the country from further benefit. Furthermore, it has become increasingly important for Nigeria to look inward and strengthen existing framework and also encourage more indigenous companies to join to increase the production capacity (BIOVACCINE NIG LTD, 2017).

In the light of the above, domestic vaccine manufacturing is currently being exploited by most developing countries. With the hit of COVID-19 pandemic, when most countries are yet to access the vaccine to stop the endless lockdown in most countries and death in other instances, if measures are not put in place to get people vaccinated as at when due, local-production of vaccine is prominent. In addition, the World Health Organization and other non-governmental organization are currently providing technical support to most developing countries to help set up working system and environment, which will support domestic manufacturing of vaccine in their individual countries with advantages in developing a cost-effectiveness solution and promoting local content. This research aims at unraveling reasons why Nigeria is still not among the countries that has not developed their domestic manufacturing capabilities and to put up recommendations which can support the development and implementation of domestic manufacturing of vaccines in Nigeria.

2.3 THE ROLE OF NATIONAL AGENCY FOR FOOD DRUG ADMINISTRATION AND CONTROL ON IMMUNIZATION

One of the mandates of National Agency for Food Drug Administration and control (NAFDAC) is to ensure that the vaccines that are made available for administration to the different categories of people are safe and of best quality. Vaccines are mostly administered to large number of healthy individuals and therefore must be of high quality to ensure that they meet up their desired goals.

To achieve this mandate, NAFDAC as the National Regulatory Authority (NRA) for vaccines must adhere strictly to the six critical WHO REQUIREMENTS. These Functions are:

1. Licensing and Registration of vaccines and other Biologics
2. Inspection
3. Laboratory assess/services
4. Lot Release (Laboratory services)
5. Post marketing surveillance
6. Clinical trial authorization.

In the quest to achieve excellence, the National Control Laboratory for Vaccines, and other Biologics (NCLVB) which is a unit under Laboratory Services Directorate of National Agency for Food and Drug Administration and Control (NAFDAC). Later, the National Vaccine Quality Control

Laboratory was commissioned 15th of February 1999 by the then Honorable Minister of Health Professor Debo Adeyemi. This laboratory mandate was to ensure safety, efficacy and potency through lot release of vaccines as stipulated by the six critical functions as recommended by the World Health Organization (NAFDAC, 2017).

Therefore, NAFDAC has the responsibility of ensuring that only safe and efficacious products are administered to the populace during immunization or vaccination. In addition, NAFDAC also have the mandate of registering, carrying out inspection and conducting appropriate laboratory tests to confirm the genuine nature of vaccines in respect to their potency. It is equally important that NAFDAC carries out quality checks on any manufactured vaccines but locally or imported before finally releasing them for administration to the populace. NAFDAC is currently undergoing the needed certification to attain the Stringent Regulatory Agency (SRA) level 4 to be able to have the needed power to regulate vaccines manufacturing in Nigeria.

2.4 PUBLIC PRIVATE PARTNERSHIP IN VACCINE DEVELOPMENT

According to World Health Organization (WHO), less than 10 Africa countries are involved in the local manufacturing of vaccine. They are South Africa, Tunisia, Egypt, Morocco, and Senegal among others. Most of these countries focuses on production for internal consumption and due to lack of capacity for export for now. One of the greatest challenges for vaccine market is the way the business is structured in Africa. Most of the Africa countries do not support patronizing other indigenous Africa countries which ought to support large scale of vaccine for export. Embarking on vaccine manufacturing domestically is a complex process with huge financial demand requiring long term vision. There is need to focus on innovative financing, regional regulatory capacity to ascertain quality, technology transfer, Good Manufacturing Practice facility design and product development partnership among others. Furthermore, it is important to adopt collaborative system to increase the vaccine manufacturing value chain and also encourage public private partnership to develop the vaccine domestic manufacturing thereby increasing production in Africa to encourage immunization of childhood diseases and control the outbreaks of infectious pathogens (WHO, 2021b).

Furthermore, the Nigeria vaccine industry is gradually being revive by the government by leveraging on Public Private Partnership (PPPs) to revamp the vaccine industry. The Research and development sector is beginning to gain a lot attention from government by investing 10billion

to back roll the vaccine manufacturing industry through the collaboration with PPP to encourage local manufacturing of vaccines in Nigeria.

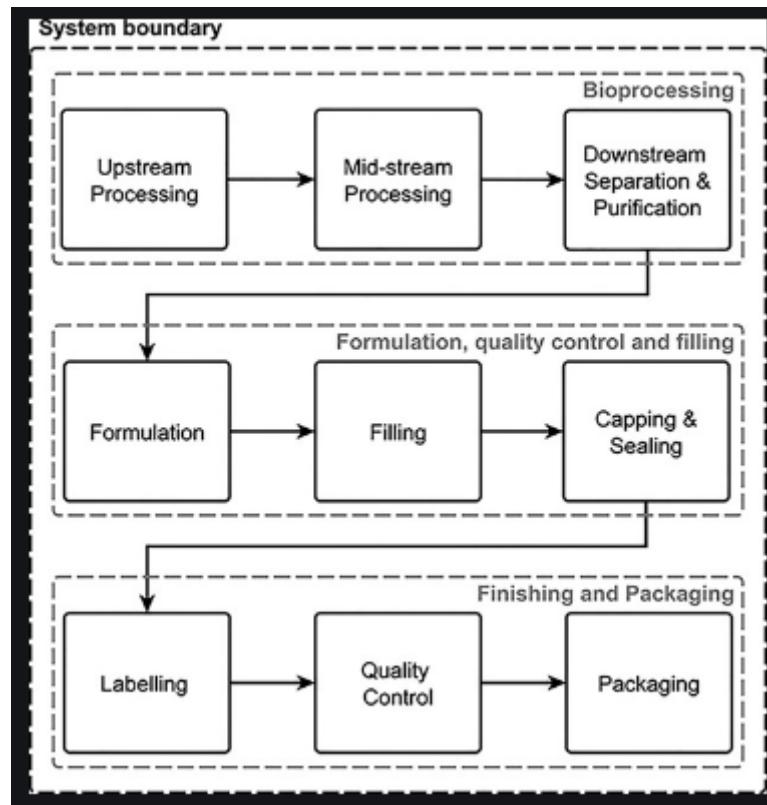


Figure 1 Complex vaccine manufacturing processes (adapted from: Emerging Technologies for Low-Cost, Rapid Vaccine Manufacture by (Zoltán Kis, Robin Shattock, Nilay Shah, Cleo Kontoravdi, 2018).

No Sub-Saharan African capacity

Countries with influenza vaccine production capacity in 2006 and following implementation of the WHO Technology transfer project

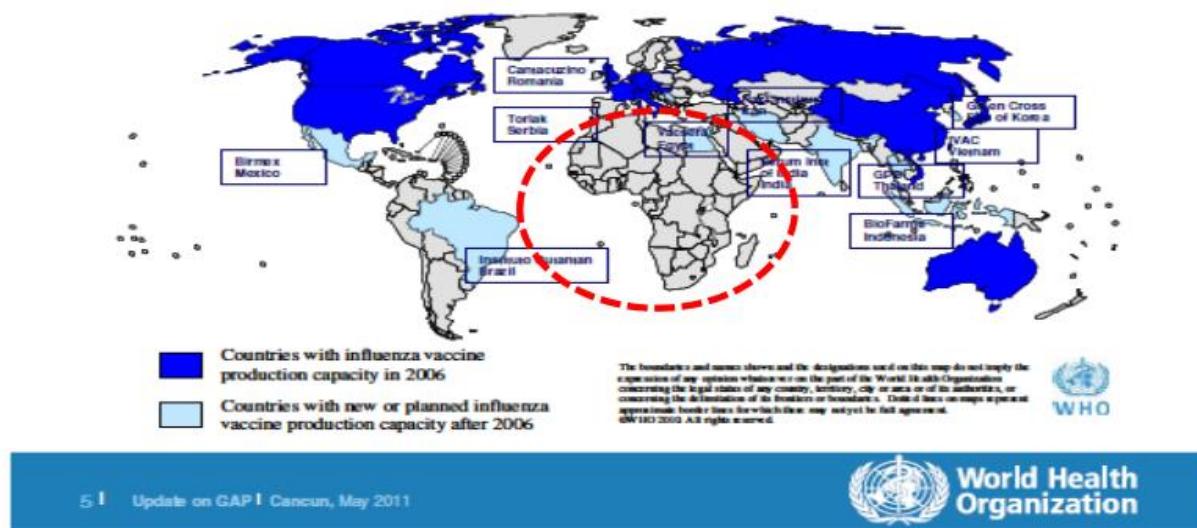


Figure 2 Countries with influenza vaccine production adapted from WHO initiative to increase global and equitable access to influenza vaccine in the event of a pandemic: supporting developing countries production capacity through technology transfer.



- **Senegal:** producer of prequalified vaccine (yellow fever).
- **Egypt:** DTP and some fill-finish
- **South Africa:** Fill finish
- **Tunisia:** very limited BCG and rabies
- **Ethiopia:** starting....

Figure 3 Current African manufacturers of Human Vaccines (Adapted from WHO initiative to increase global and equitable access to influenza vaccine in the event of a pandemic: supporting developing countries production capacity through technology transfer)

2.5 VACCINE MANUFACTURING IN AFRICA

Many Africa countries are yet to join the leagues of vaccines manufacturers in Africa even though Africa population contributes to about 17% of the world population. As at now, about 17 Africa countries are registered to be involved in vaccines manufacturing and out of these countries, only Senegal has developed its capability with WHO pre-qualified vaccine with capacity for export. This could be so worrisome thereby setting the need for Africa countries to form a united force to join hands to build capacity for vaccine manufacturing to protect growing Africa population against any form of pandemic such as Covid-19 and the common killer of childhood with infectious diseases (TOYIN ABIODUN *et al.*, 2021). This brought about the recent platform for most Africa countries to come together under the Tony Blair Institute of Global Change in April, 2021 coming up with a five key pointers focusing on developing Africa in vaccines manufacturing industries utilizing the right strategy managed by the apex body through development of innovative recommendations to achieving the set goals such as:

1. Exploring financial opportunities since vaccine manufacturing is a complex project with lot of financial involvement.
2. Working on generating and increasing demands.
3. Assessing and set up viability of manufacturing model to meet up production capability
4. Developing a workable system to strengthen the value chain in vaccine manufacturing.
5. Collaborating with developed biotech businesses that would support with technical competencies needed to drive local manufacturing of vaccines in Africa.

With these put in place, it will build individual country sufficiency and encourage export which will earn Africa countries more foreign earning to build infrastructural development and support local content in raw materials utilization (API) thereby developing and encouraging local content in Africa.

The healthcare budget of most Africa countries is not enough to fund the purchase of vaccines for vaccines preventable diseases, and this has led to high mortality rate of children death mostly below 5years. In time past, the mortality rate of children below five years due to measles was high due to high cost of vaccines in Africa. With the new wave in the local manufacturing of vaccines and other available collaborations in Africa are now chatting new course of action in making vaccines cost-effective and also equitable access to the developing countries (Elder, 2013)

2.5.1 Africa Vaccine Manufacturing Initiative (AVMI)

Africa vaccine manufacturing initiative (AVMI) is an African initiative with goal of partnering with various interest groups, organization and individuals who are passionate about developing a workable system of ensuring a viable vaccine manufacturing framework in Africa to promote improved access to quality, safe and efficacious vaccines and other biological products in Africa to combat infectious and deadly diseases (Africa Vaccine Manufacturing Initiative, 2013).

VISION

- To promote an Africa with sustainable vaccine manufacturing capacity that would meet the need of its people.

MISSION

- To promote the establishment of sustainable human vaccine manufacturing capacity in Africa.

ROLE OF CATALYST AND COORDINATOR IN AVMI

- To coordinate, support and promote various effort of vaccine manufacturing and partners who are passionate about ensuring that Africa succeed in rolling out its own vaccines and other biologicals products.
- To collaborate with Government and other private partners to create a conducive and enabling environment which will create a competitive and sustainable system for the manufacturing of vaccines and other biological products.

Strategic Objectives

High level Advocacy

- To mobilise the African continent, through progressive high level advocacy, to manufacture preventive and therapeutic vaccines and/or other biological products against diseases of public health importance in Africa

Facilitating partnerships

- To promote partnerships between African developers and manufacturers of vaccines and biologicals and other interested stakeholders who have a vision of Africa producing its own vaccines

Resource mobilization

- To attract and secure skills and financial resources for establishing vaccine manufacturing capacity in Africa

Skills Capacity Development

- To promote adequate scientific and technical capacity building of Africa's vaccine manufacturers in all aspects of production and distribution of vaccines and/or other biological products

Figure 4 Strategic objectives of Africa Vaccines Manufacturers Initiatives adapted from Microsoft PowerPoint-AVMI 9th January, 2013.

Manufacturer	Products	R&D	Manufacturing of drug substance	Fill & finish	Pack & label	Import for sale
IP Dakar	Yellow Fever					
Vacsena	BCG, Tuberculin, Tetanus, DTP, Typhoid, Cholera					
IP Tunis	BCG					
Biovac	BCG6, Measles6, Pneumococcal conj.3, Hepatitis B3, Hexavalent Vaccine7					
Aupen	Covid-19 candidate					
IP Maroc	BCG, DT, Yellow Fever, Typhoid, Influenza, Rabies					
EPH	Plan to produce vaccines					
Biovaccines	Plan to produce Hepatitis-B Plan to produce Tetanus Plan to produce DTP-Hep-B Plan to produce Yellow Fever Plan to produce Measles					
Innovative Biotech	HIV					
IP Algeria	Rabies					

Key: Work completed Work in progress or planning

Source: McGraw, FCDO, Pesa, Manufacturers' websites.

Figure 5 Companies in Africa operating manufacturing value chain (Adapted from Tony Blair institute for global change on vaccine Manufacturing-Africa-what it takes and why it matters on April 1 2021.

2.6 VACCINE AVAILABILITY AND MANUFACTURING

One of the major challenges with the Low- and Middle-Income Countries is access to vaccines and Africa countries are coming together to chart a way forward to ensure equitable access to safe and effective vaccine especially COVID-19 vaccines in time like this when most countries are still looking forward to making vaccines available to their population to have herd immunity to the virus. During the 21st Annual General Meeting held by Developing Countries Vaccine Manufacturers' Network (DCVMN) in November 2020 due to COVID -19 pandemic, this brought

about increased collaboration among developing countries vaccines manufacturers to strategized and come forward with different plan such as Access to COVID-19 tools Accelerator (ACT-A) to strengthen the COVAX facility which was geared towards making 2billion COVID-19 vaccine available by the end of 2021 (Pagliusi *et al.*, 2021). This also led to the regulatory authority granting emergency use authorization targeted to achieve rapid approval of safe and effective vaccines.

Through the meeting held by DCVMN, lot of challenging issues such as vaccines stability with the cold chain and storage, barcoding of the primary package and data management used in decision making. They are overcoming these challenges will increase availability and equitable access to vaccines among member states.

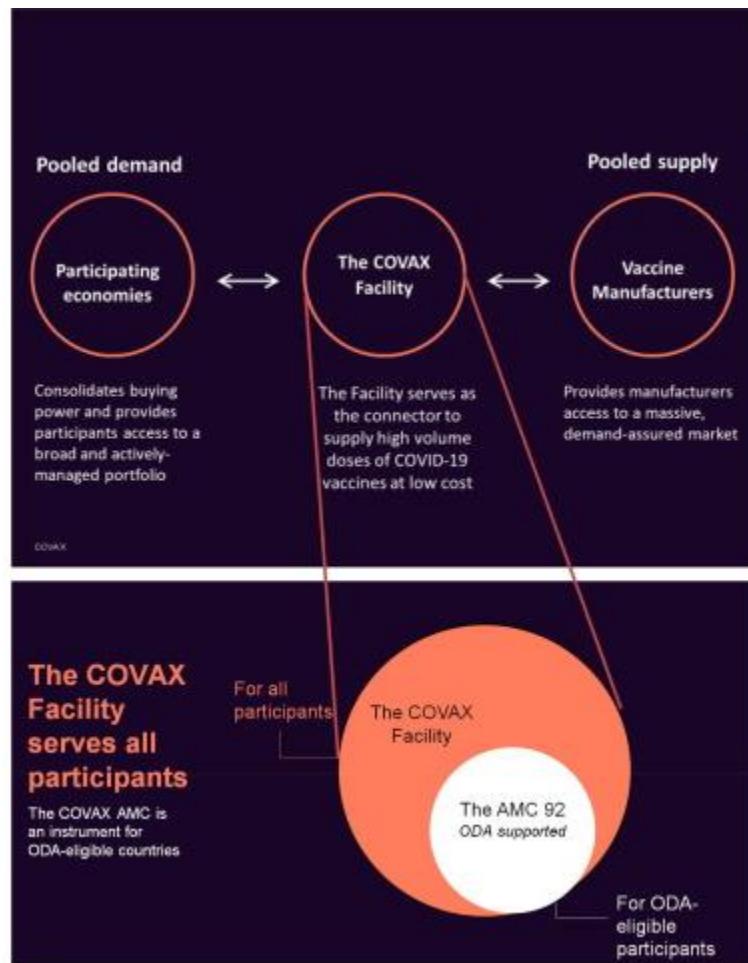


Figure 6 COVAX facility focused on transparency, global access and impact (Adapted from vaccine for a healthy future: DCVMN Annual General Meeting 2020 Report)

2.7 TECHNOLOGY TRANSFER IN THE MANUFACTURING OF VACCINES

The Developing Country Vaccine Manufacturers (DCVMs) are now using available alternative platforms to bring about cost reduction to some vaccines such as recombinant Hepatitis B Vaccines (HBV) and Human Papilloma Virus Vaccines (HPV) which is caused by cervical cancer which is one of the leading causes of female cervical cancer with high mortality rate worldwide. Lack of access to the routine gynecological screening has been identified as one of the major causes of death due to cervical cancer in Low- and Middle-Income countries (LMIC). In addition, the high cost of the vaccine could be another reason why large number of women has been found to be involved in death as a result of cervical cancer mostly in the LMIC (Padmanabhan *et al.*, 2010).

The use of technology transfer model to countries like India, Cuba, China, and Brazil has brought about reduction in the price of some of these vaccines and donor aided vaccine purchase from agencies such as UNICEF and GAVI made these vaccines accessible in LMIC thereby demonstrating their capacity to make vaccine available at low cost and still meeting international quality standards. This is brought about by the intellectual property right which must be signed by these countries. This agreement prevents DCVMs a complete autonomy to produce vaccines which would be sold locally or internationally without due approval or agreement to the company with the patent right.

2.8 VACCINE ROLLOUT BY GOVERNMENT OF NIGERIA & PRIVATE SECTOR PARTICIPATION

Nigeria's planned vaccine distribution needs to create a National control Centre reporting directly to the Presidential Task Force (PTF) on Covid-19 led by Mr. Boss Mustapha. An assessment of supply chain preparedness, maturity levels and areas of weakness. Lean mechanism for continuous improvement which will continuously carry out assessment of the vaccine supply chain and identify areas of constraint or capacity constrained resources (work streams under threat of becoming constrained). The National Control Centre will act as the drumbeat of the Covid-19 vaccine supply system.

This will involve 6 Phases for consideration.

1. Demand generation,
2. Production - Manufacture/purchase,
3. Information Technology / Data,

4. Distribution, Transportation, Logistics.
 5. Cold storage,
 6. Training and capacity building for key players in the vaccine distribution network.
- 1) **Demand Generation** - The government will need to mobilize the public to receive vaccination. The assumption that the populace already knows about the Corona Virus and why the Corona vaccine is needed is erroneous. Consequently, the following private sector participation is needed.
- a) Civil Society Organizations,
 - b) TV Stations with local and International reach (AIT, Channels, Multichoice DSTV, Kwese TV) - these will help mobilize the populace with extensive reach. In traditional African setting the "*Village Town Crier*" announces invitations to a meeting or a decree by the king. The multichannel TV and radio stations play the role of town criers.
 - c) The support of religious leaders and worship centres will need to be brought on board to give confidence to the citizens.
 - d) Social media channels and platforms will utilize what are known as *Social media influencers* to change the narrative and garner positive opinion towards the vaccination exercise.

These will serve to engage the Nigerian people in debates and information sharing, disprove myths, conspiracy theories, superstitions, and rumors about vaccines. The federal government cannot solve this crisis alone. The peoples trust must be gained.

- 2) **Local Vaccine Manufacture Vs Purchase / In-house Production Vs Outsource:** - Vaccine distribution is all about making the right type of vaccines available at the last mile, Just-in-Time, at the right quality, right dose, in the right cold storage condition and at the right cost. Thus, the decision on whether to manufacture or purchase will be based on a cost benefit analysis. Pharmaco-economics come into play here. The Government may choose to exploit the COVAX facility on its MOU for the Biovacines project to strengthen local manufacture of Covid-19 vaccines.

Innovative Biotech Nigeria (IBNL) is currently partnering with two United States companies to develop and manufacture COVID-19 vaccines for clinical trials and use in the country and Africa with a plan to set-up a factory in Nigeria to enable us domesticate vaccine production in the country.

Also a vaccination campaign should also provide tools for safety protocols:

- i) PPE-Personal protective gear, facemasks, disposable gloves
- ii) Hand sanitizers
- iii) Health and hygiene education using public health experts

A larger portion of these is currently produced by private companies. The government will need to incentivize and exploit local capacity for manufacture of PPE, sanitizers, and facemasks. Some of those incentives are already in place with the Central Bank of Nigeria's (CBN) grants and low interest loans to Manufacturers in the Health sector value chain. AfDB - Africa development Bank grant facilities, IDA (International development Association) and multilateral development Banks should grant facilities and grant support to for development of private sector Vaccine manufacturing value chain. There should be a government initiative to give certification in Platinum, Gold and Silver to private owned corporate bodies that have partnered with the government in the Covid-19 Vaccination program.

3) **Information Technology/Data:** The national control centre is to link Vaccine production in Lagos, Ogun, Kaduna states with national demand considering that 2 doses within a 3 weeks' gap is required. The centre will publicly share data around key response indicators: Metrics and metric-driven public health guidance which will be essential to accessing the priority populations. Ensuring Data Driven distribution mechanism. Enhance federal agencies' collection, production sharing, and analysis of, and collaboration with respect to data to support an equitable distribution and administration of COVID-19 Vaccine shots, security, and supply chain preparedness.

- Track a range of performance measures and data including cases, testing, vaccinations, and hospital admissions, and will make real-time information readily available to policy makers at the federal, state, and local level.

- The NCDC and NPHCDA will maintain a public dashboard of Vaccine dose supplies to states and local governments at a granular level and match it against vaccinations. I dashboard will show vaccine storage quantity at state and local government level against daily number of doses administered so that Nigerians can remotely gauge the level of inoculation/vaccination in their own communities and communities of interest (such as that of siblings). This will create confidence and help people make informed choices.

- 4) **Distribution** - (Determine A Distribution Requirements Plan (DRP): This will be followed by a Capacity Requirements Plan (CRP) to determine gaps in the supply chain and areas for improvement. A Value Stream Mapping (VSM) will show Bottleneck areas for continuous improvement in the national distribution system (logistics, transportation, Carriers, Distribution Inventory management, road network, security, Supply Chain Visibility). All these will be based on private owned Information Technology / EDI Electronic Data Interchange (Electronic Data storage and retrieval Systems) - private sector data mining for forecasting, server farms, leveraging private telecom firms, electronic payment platforms.
- 5) **Transportation;** Third Party Logistics (3PL) and Fourth Party Logistics (4PL) service providers should play a key role in Transporting Cold-stored vaccines because they have historically played a major role in the health care sector and are known for efficiency, responsiveness, reliability, flexibility, robust and are performance driven. Examples are GHSC-PSM's Chemonics, DHL, MDS Logistics, TSL Logistics, RedoxCorp shipping and Logistics, Coca Cola and GIG Logistics. Special agreements should be signed by Africa leaders to ease vaccine supply chain. This can be captured in a review of the African Continental Free Trade Agreement (ACFTA)

a. Drone Delivery Services:

- Australian drone company, Swoop Aero, is working with the Democratic Republic of the Congo's head of public health on delivering a Covid-19 vaccines using a drone delivery network it has developed in the country.
- Germany based Wingcopter, which develops transport drones for Health and humanitarian operations has also partnered with UNICEF'S African Drone and Data Academy to train local youth in drone operations (Nathan Ohiomokhare, 2021)

- 6) **Cold storage:** Vaccines are cold chain. This implies cold storage not only during distribution and warehousing but also in health facilities and point of care. This requires provision of other customized logistic tools which enable cold storage and handling especially considering Africa's very hot climatic conditions. The strategic advisory to the government will need to
- ✓ Determine national cold storage warehousing capacity - save cost by leveraging private sector warehousing and distribution capacity.
 - ✓ Decide on Centralized cold storage versus decentralized storage at National and state logistics levels.
 - ✓ Determine operational aspects of the Push system - Based on milestone achieved by states in vaccination phase. i.e. 2 doses (1st phase then 2nd phase).
 - ✓ Partner with multinationals Coca-Cola, Pepsi, fruit, and beverage production companies which have large cold storage facilities. The catch would be a tax incentive, corporate social responsibility, early off-take of products. The National Warehousing Advisory Committee of NPSCMP (National Product Supply Chain Management program) will need to champion such an initiative.
- 7) **Training, capacity building and Monitoring and supportive supervision/ Human Capital Management** (For key players in the Vaccine distribution network): Vaccine management is a highly technical work, and many players will be involved nationwide. To ensure uniformity of content across board private sector Human resource management partners will need to be engaged not only for training but in performance management, Monitoring and supportive supervision.
- 8) Goal number 2 on President Joe Biden's *Covid-19 Response and Pandemic preparedness strategy* document is the mounting of a safe effective and comprehensive vaccination campaign. (The National strategy has 7 goals).

2.9 CONCEPTUAL FRAMEWORK

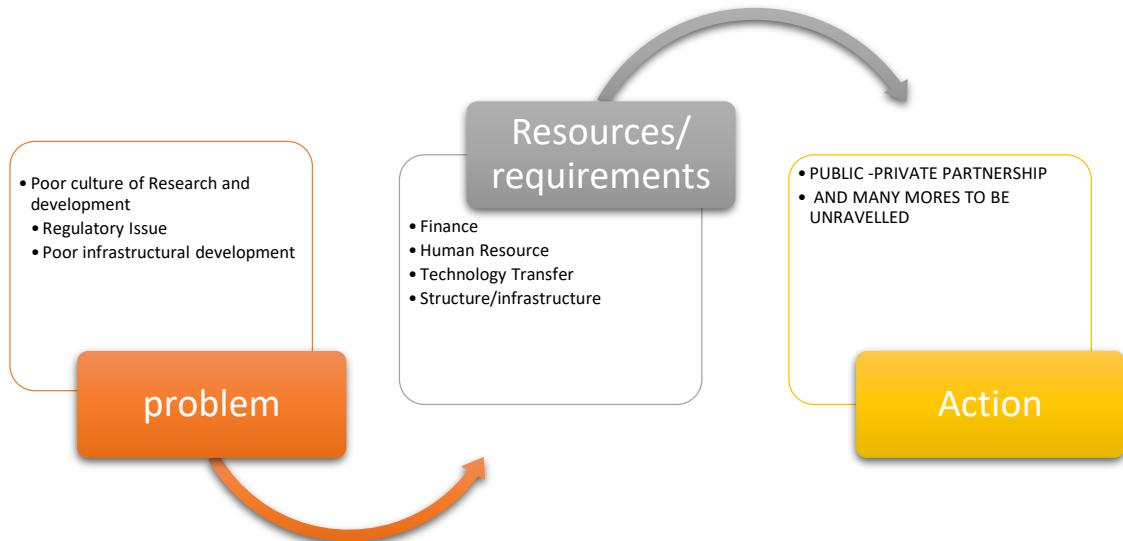


Figure 7 Conceptual framework developed by the author.

From the literature review, lot of efforts are being channeled into promotion of local vaccine manufacturing with lot of technical support from various non-governmental organization such as WHO, UNICEF, GAVI and many others to increase support for individual countries willing to embark on domestic manufacturing of vaccine in their countries.

This research will use the knowledge gathered from the literature review to examine various opportunities available to Nigeria to further support the local manufacturing of vaccine and to investigate various bottlenecks which has impacted local manufacturing of vaccine in Nigeria thereby coming up with recommendation that can assist individuals, private organization, joint ventures partnerships and government to take the next step to re-awaken local vaccine manufacturing in Nigeria.

The element named problem in the conceptual framework shows the problems found to be associated with the Nigeria inability to locally manufacture vaccines as expressed in the literature review. The major problems identified are poor culture of research and development, constraint due to regulatory issues and lack of infrastructural development among other reasons. To get

more information on this, the researcher will be interviewing experts within the vaccines industries to further unravel detailed information in this area.

Furthermore, the element named requirements/resources explained what could be needed to ensure that we have the enabling environment to implement the local manufacturing of vaccines in Nigeria. The major requirements which could be identified from analysis done from the literature review are financial resources, human resources, technology transfer and adequate infrastructural development to meet up with the requirements for local vaccine manufacturing in Nigeria.

Finally, the element named action are the needed action plan which must be implemented to guarantee movement in the right direction. The researcher would be utilizing the various expert opinions to provide answers to necessary actions that could positively impact on Nigeria to actualize the dream of locally manufacturing of vaccines based on the numerous advantages which has been enumerated in the previous chapter.

3.0 CHAPTER THREE: RESEARCH METHODOLOGY

3.1 OVERVIEW

This chapter will explain the methodology employed in achieving the research objectives. Below is a tabulated summary of the methodology employed for this research work.

PART	PRIMARY DATA	APPROACH
1.	RESEARCH METHOD	QUALITATIVE METHOD
2.	RESEARCH PHILOSOPHY	INTERPRETIVISM
3.	INTERVIEW ACCESS	ZOOM INTERVIEWS
4.	DURATION OF INTERVIEW	15-45 MINUTES OF ZOOM CONVERSATION
5.	RESPONDENTS	EXPERTS WITHIN THE VACCINES, PHARMACEUTICAL INDUSTRY, ACADEMIA AND OTHER RELATED INSTITUTIONS.

The respondents are experts within the vaccines, pharmaceutical industry and related organization who has distinguished themselves in the pharmaceutical industries, government agencies, non-governmental organization, academia, and other related institutions with good knowledge of local vaccines manufacturing and related issues.

3.2 RESEARCH METHODOLOGY

This section is very key to the overall success of this research work. The choice of research method must be justified and should also be in tangent to the research objectives. There are numerous methods which could be used as a system of data collection, but the researcher chose qualitative method via zoom interview as a mode of gathering data. This method is considered a more effective means of gathering information considering the time frame within which research work must be conducted and completed and the distance involved in getting access to the selected respondents who are not within the reach of the researcher.

Finally, because of Covid-19 pandemic ravaging the entire world as at the time of this research work, does not give free access for a one-on-one interview which might even take much more time when compared to the zoom interview option chosen which remains the best choice taking

everything into consideration. More on this, zoom interviews were scheduled at different times with each of the selected experts.

The interview aimed to explore relevant information from the experts digging into their knowledge repository and personal perception. On the various interview questions asked from them and their responses and recorded and transcribed to bring out the various information gathered from them, and these data was later analyzed using “Themes” to segment their responses.

The data gathered were placed under various themes and this gave the researcher an in-depth knowledge to give a sustainable conclusion. Through these data gathered, if critically examined, it would afford the researcher to come up with recommendation and conclusion on the study.

3.3 RESEARCH PHILOSOPHY

This explains a belief system of how data are to be gathered, analyzed, and used. It goes further to explain the source, nature and development of knowledge gained. It talks about the development of knowledge and the nature of the knowledge. The research philosophy is depending on the facts which are provided by the experts based on their knowledge which would be important and useful in achieving the purpose of the study.

This research explores the Interpretivism philosophy which uses the concept of understanding and interpreting social world and its context through individual set of meaning or perspective (Saunders *et al.*, 2009). These methods such as interview, observation and analysis of some existing text has been used by naturalist.

In this research work, Interpretivism was employed using qualitative method to gather information from selected experts to explore their thoughts and gain insight from their wealth of knowledge of the research focus. The data collected were recorded and transcribed to be able to make meaningful observation and recommendation without any influence, addition or subtraction to the data collected. There was no element of bias in this research because the research was independent of the researcher and there was no personal influence from the researcher in compliance to the ethics guiding this research work.

3.4 RESEARCH STRATEGY

Having critically examined the seven (7) different types of research strategy, the researcher chose survey method in form of interview to gather the much-needed data which is required for the study. Taking a close look at the topic "*Limitations impacting local manufacturing of vaccines: A Nigeria case study*" is more of an exploratory research which will involve gathering expert's opinions based on their knowledge in focus. As seen from the literature review the enormous benefits which could be found to be associated with local manufacturing of vaccines, although a very complex process but with immense benefits. Currently, a lot is going on with the African countries to develop a hub for local vaccines manufacturing especially currently when Covid -19 is still ravaging the world and vaccines are yet to be available to most developing countries therefore necessitating the proactive step to make vaccines more accessible to the people.

The Researcher chose survey through interviewing of experts who were carefully selected based on their expert's knowledge to provide information which could be beneficial to the course of this study. The participants are duly informed of the purpose of the research and the confidentiality of their various responses.

3.5 COLLECTION OF PRIMARY DATA

The collection of primary data was done through interview. The questions were developed by the researcher in line with the research objectives. The primary research represents a qualitative research method which was done in a semi structured interview where participants give their honest answers to the questions asked by the researcher based on their expert knowledge. All questions administered during the interview were carefully structured without any form of ambiguity and in line with the objectives of the research.

The interview process gave the researcher new insight and perspectives with more information in relation to the research focus and objectives. The researcher used his interviewing skills to probe for more answers from the participants to be able to exhaustively get adequate information from the participants.

3.6 PROCEDURE AND SAMPLE

For this research work, both primary and secondary data were collected. The primary data were collected from identified experts who has good grasp of the research focus areas based on their vast knowledge on the research topic. Because of the present Covid-19 pandemic, face to face interview was practically impossible thereby giving room for interview to be conducted via zoom meetings. This therefore prevented the researcher inability to measure the participants' non-verbal communication such body language, tone of voice, gestures and other related parameters as may be required.

The secondary data was gotten from previous research work done on the topic and finding out more on other vital elements which were involved in the research. This information was accessed via journals, articles, thesis, and books which were accessed via different websites. The participants were asked for their verbal approval of their willingness to participate before proceeding.

3.7 ACCESS AND RESEARCH ETHICS ISSUES

For this research work, both primary and secondary data were collected. The primary data were collected from identified experts who has good grasp of the research focus areas based on their vast knowledge on the research topic. Because of the present Covid -19 pandemic, face to face interview was practically impossible, thereby giving room for interview to be conducted via zoom meetings. This therefore prevented the researcher inability to measure the participants' non-verbal communication such as body language, tone of voice, gesture and other parameters as may be required. The secondary data was gotten from previous research work done on the topic and finding out more on other vital elements which are involved in the research. This information was accessed via journals, articles, thesis, and books which were accessed via different websites.

The participants were asked for verbal approval of their willingness to participate before proceeding with the interview and none of the participant gave a repulsive comment because they all demonstrated good knowledge of having the research conducted to contribute to the body of knowledge.

3.8 APPROACH TO DATA ANALYSIS

The best approach which has been identified for analyzing data from the interview is using *thematic analysis*. This offer a systematic, flexible, and accessible approach to analyze the data which are obtained from the various interview after transcribing them. This method of analyzing qualitative method involves the researcher coding the qualitative data to identify themes or patterns which are considered for further analysis. Thematic Analysis could be flexible because it is not tied to any research philosophy. In addition, the advantages found to be associated with the use of thematic analysis are enormous because it gives room for grouping of data based on themes and categories which will help in data analysis which would assist in answering the research questions.

The participants' responses were transcribed with emphasis on patterns and coding the responses.

3.9 CONCLUSION

The methodology adopted for this research work was Interpretivism philosophy, the researcher employed a qualitative approach for the purpose of the study. The data collection was majorly through zoom interview with the experts in the pharmaceutical industry and other related areas who has requisite knowledge in the research focus area and a total of 11 participants were interviewed in this research work.

The data collected Was analyzed using thematic analysis which is considered the most appropriate method and then compared to the conclusions gotten from most of the literature reviewed. The researcher employed qualitative approach as an exploratory tool to gain insight on various key elements which are key to the research questions in relation to limitations impacting local manufacturing of vaccines in Nigeria and further gaining other insight on the topic based on the vast experience of the experts interviewed.

The various responses and analysis are well set out in Appendix D with further discussion of the findings in chapter 4.

Having critically explained the methodology adopted for this research in this chapter, all the various responses and finding evaluated with the use of this method will therefore be analyzed in the next chapter.

4.0 CHAPTER FOUR: FINDINGS AND ANALYSIS

4.1 OVERVIEW

In our previous chapter, the researcher gave a full account of the methodology used for the purpose of this research work and gave reason for the choice of methodology adopted for this research work. The researcher explores the Interpretivism philosophy through a vibrant engaging of qualitative approach. Therefore, this chapter will be focusing on analyzing all findings from the research work.

In this chapter, the researcher will be evaluating the findings from the interviews carried out looking at the major areas such as what could be done to facilitate the local manufacturing of vaccines in Nigeria, challenges standing in between making vaccines manufacturing locally available in Nigeria, evaluating the readiness/ willingness of the government to support local manufacturing of vaccines in Nigeria. Other areas are whether advocacy could be a strong tool to support local manufacturing of vaccines and finally are the pharmaceutical industries ready to engage in local manufacturing of vaccines in Nigeria.

Therefore, as a way of analyzing the data obtained from the various interview session, the research employed the use of *Thematic Analysis*, which may be used irrespective of whether you employed a deductive, inductive, or adductive approach with the research question more likely to be firmly established and the research objectives may be used to derive themes which are derived from the data collected. This is done by occurrence and re-occurrence of themes to explore related to our research interest. Thematic analysis is therefore said to be more flexible because it is not tied to a particular research philosophy and whether you are adopting an objectivist or subjectivist position.

In addition, after the interviews are written as notes, or produced in form of transcript of an interview, it is essential to produce a summary of the key points that have emerged from undertaking this activity. Therefore, a transcript summary compresses long statements into briefer ones in which the statement is been rephrased into few words.

4.2 FINDINGS (QUALITATIVE DATA)

Listed below are some findings from this research work. These are:

1. There is no human vaccines currently manufactured in Nigeria.
2. Advocacy could be regarded as a strong tool in achieving local manufacturing of vaccines.
3. Available government policies need to be backed with government support to deliver on local manufacturing of vaccines.
4. The pharmaceutical industries are ready to engage in local manufacturing of vaccines in Nigeria.
5. The challenges facing the local manufacturing of vaccines in Nigeria are enormous but could be overcome.

FINDING #1: THERE IS NO HUMAN VACCINES CURRENTLY MANUFACTURED IN NIGERIA

Going back memory lane from history, vaccine production started in Nigeria back in 1924 from available information gathered from the literature review and came to a stop in 1991 due to facilities upgrade. Both Animal and Human vaccines were produced then but became moribund due to government inability to fund and upgrade the facilities used in the manufacturing of vaccines due to technology advancement.

EVIDENCE:

Based on the findings from this interview, it is crystal clear that Nigeria has a long way to go to attain the level of self-sufficiency in local vaccine manufacturing. From the responses from the interviews, it was evidence that Nigeria do not currently manufacture vaccines, but history has it that the country at some time manufactured both animal and human vaccines until the factory was shot down in 1991 for upgrade and till date, it has never seen the light of the day. All participants attested to the fact that currently; no human vaccine is being manufactured but the country at some time do engage in local manufacturing of vaccines in Nigeria.

ANALYSIS:

From evidence which are available from the literature review that there is a reawakening all over the world now especially with the Covid-19 pandemic which has brought debilitating diseases to most people with increasing number of death due to the untoward effect of the virus. Most countries are now going back to their drawing board to engage and promote local vaccines

manufacturing to increase access and improving self-sufficiency. As expressed by the World Health Organization (WHO), there are lot of partnership ongoing among Africa countries to form united forces and join hands to ensure the local manufacturing of vaccines are promoted to increase access to vaccines among the Africa population. In addition, the Nigeria vaccine industry is gradually being revamp by the government trying to leverage on public private partnership strategy through collaboration and engagement to increase access to vaccines in Nigeria. Also, there are lot of limitations found to seriously impacted local manufacturing of vaccines in Nigeria and most of these challenges are discussed by the participants and will be discuss later.

Therefore, this research work further confirmed by the participant responses that no human vaccines are currently being manufactured in Nigeria but there are lot of efforts going on to revamp that sector of the economy especially at this time when Covid-19 has taught everyone lessons on the need to engage in local manufacturing of vaccines looking at the enormous benefits that are found to be associated with it.

FINDING # 2: ADVOCACY IS A STRONG TOOL THAT CAN BE USED IN ACHIEVING LOCAL MANUFACTURING OF VACCINES IN NIGERIA

Advocacy can be considered as a strong tool which could be used to achieved local manufacturing of vaccines in Nigeria. Lot of advocacies are currently going on in Nigeria in the face of this current Covid-19 pandemic that is ravaging the world now to brainstorm on way forward and promoting local of vaccines to increase access to vaccines that could be used as preventive measures in vaccinating large population of people to attain the herd immunity status. This advocacy may be among government agencies, development partners, investors, pharmaceutical manufacturers to come together and strengthen collaboration towards achieving the set goals and objectives. To this end, this research work confirmed that advocacy is considered as a strong tool that help to support the desire to bring to limelight the local manufacturing of vaccines in Nigeria and other developing countries in Africa.

EVIDENCE:

From the interviews responses, attached in Appendix D, advocacy is majorly considered by all the participants as a vital tool to fast-track local manufacturing of vaccines in Nigeria. The participants equally stressed the importance and need to carry out advocacy to the relevant institutions and agencies of government to ensure that all necessary stakeholders collaborate to chat a common agenda and strive towards realizing the goal of local manufacturing of vaccines in Nigeria. The relevant institutions to which this advocacy should be targeted to are:

- PMG-MAN (Pharmaceutical Manufacturing Group of Manufacturing Association of Nigeria) and NAFDAC as regulating agency
- Government
- Ministry of Health, Ministry of industry, trade and investment, Ministry of foreign affairs, Ministry of science and Technology, Ministry of Finance,
- Other government agencies such as Central Bank of Nigeria, Nigeria custom services, Federal Inland Revenue.
- National programme on immunization, National primary healthcare development agency (NPHCDA).
- National sovereign wealth investment company, Bank of industry, Global Investment financiers.
- Local manufacturers, Pharmaceutical importers
- Petrochemical industries like NNPC, TOTAL, EXXON MOBIL etc.
- National institutes of pharmaceutical research and development
- The power brokers and renounced investors like Aliko Dangote, Oba Otudeko and many others
- Development partners such as WHO, UNIDO, World bank etc.

ANALYSIS:

From the data from the interviews carried out, going by the numerous institutions and agencies listed above, there is incontrovertible evidence to show that advocacy is a very vital tool that helps to achieve the milestone of local manufacturing of vaccines in Nigeria. These institutions are the major stakeholders and when the right advocacy carried out to the right institutions at appropriate time and given the necessary follow up and with right policies in place, it will boost

local manufacturing of vaccines which would bring about the most desired end point. From our literature review also, the World Health Organization (WHO) is doing the expected advocacies by partnering with relevant institutions and agencies and through collaboration and support will help to build the capacity to develop their local manufacturing of vaccines in Nigeria. It is evidently clear that there is need to drive advocacy in the right direction with these government agencies and developmental partners because it would strengthen the synergy of interest and bring about collaborative development among all the stakeholders that has been identified to bring about the result in achieving local manufacturing of vaccines in Nigeria.

FINDING # 3: AVAILABLE GOVERNMENT POLICIES NEED TO BE BACKED WITH GOVERNMENT SUPPORT TO DELIVER ON LOCAL MANUFACTURING OF VACCINES

The issue of government policies as an enhancer to achieving local manufacturing of vaccines is a crucial one which cannot be undermined. Government is the biggest player in the business of increasing the Gross Domestic Product (GDP) of a country and this can only be achieved with the right policies on ground to create the enabling environment which is needed to achieve the set goals. Without the backing of the government to provide the incentives, the environment, and the political will to bring about the implementation of those policies, such environment might not be conducive to achieve the framework that could bring about the right return on investment with the needed support from government to drive the policies in the right perspective.

Furthermore, policies that will support local manufacturing of vaccines are necessary to be put in place to strengthen and create the right atmosphere and enabling environment for the investors and pharmaceutical industries to operate. Without the right policies in place, it likens to car without an engine which cannot move except with the right functional engine. The problem with the government policies in Nigeria is not the unavailability of policies as expressed by some the participants but it has to do with policies summersault meaning those policies are just cosmetics and do not have the necessary relevancy because of lack of proper implementation of those policies in place. There is need to make sure that government also throw their weight behind these policies and make them implementable by giving the policies the push and support to be able to bring about right innovations that will support and deliver on the local manufacturing of vaccines in Nigeria.

EVIDENCE:

There is available evidence to show the presence of various government policies in place to support local manufacturing of vaccines in Nigeria. From the data collected from the interviews with the participants, which they all agreed to the fact that there are government policies whether good or bad but the issue with most of these policies that are mostly used in Nigeria such as the National drug policy of 2005, the National Vaccination Policy and the recent policy on intervention funds released by the Federal Ministry of Finance in conjunction with the Central Bank of Nigeria to the Ministry of Health was set aside to be accessed by indigenous pharmaceutical industries to support local manufacturing of drug products in Nigeria. However, the funds could not be easily accessed by the indigenous pharmaceutical companies because of policy summersault which has indeed made the policy to be referred to as been generic due to lack of implementation and follow up from the necessary quarters.

Additionally, as part of proven evidence to show the availability of government policies in Nigeria, there is another policy tagged “Executive order” to prioritize and patronize locally manufactured product from Nigeria. But as reported by one of the participants, he said *“government still enjoy patronizing foreign manufacturers due to reasons best known to them rather than encouraging and supporting indigenous manufacturers to improve and develop local capacity”*.

Conclusively, the major problem with government policies is not the lack of good policies but that of lack of implementation and policies summersault which has led to inadequacies of such policies and therefore critically affecting the working of achieving the set target of local manufacturing of vaccines and other medicinal products in Nigeria.

ANALYSIS:

The response from the participant gave more insight into perspective of government policies in Nigeria. As shown by the evidence given above, it crystal clear that the problem with the Nigeria government system as relates to policies is not the absence of these policies but more with lack of policy implementation. From the literature review done by the most of countries presently manufacturing vaccines in the developed and developing countries, there are enough evidence from those countries of the existence of good policies which has the backing of the government

to support such policies to work through proper implementation of such policies. Some of these countries are India, United States of America, Vietnam, China, Tanzania, Senegal, United Kingdom, Russia to mention but few.

This finding has helped the researcher to better understand the need for proper implementation of policies as a key driver in achieving local manufacturing of vaccines in Nigeria.

FINDING # 4: THE PHARMACEUTICAL INDUSTRIES ARE READY TO ENGAGE IN LOCAL MANUFACTURING OF VACCINES IN NIGERIA

From time immemorial, the Nigeria pharmaceutical industries are saddle with the responsibility of ensuring the manufacturing of high quality, safe and efficacious drug products to the consuming public. Most of the pharmaceutical industries are building and increasing their capacity to meet up with the local manufacturing of these products and prevent the over dependency of the pharmaceutical industries on the foreign manufacturers. With developmental agencies such as World Health Organization (WHO), United Nation Children Emergency fund (UNICEF) and other similar agencies are actively collaborating with most indigenous pharmaceutical industry to develop their capacity and become a holder of Good Manufacturing Practice (GMP) which is a needed qualification for indigenous manufacturing companies to make room for their products to be marketed in other countries outside the shores of Nigeria.

In additional, our regulatory agency, National Agency for Food and Drug Administration and Control (NAFDAC) is currently upgrading to the stringent regulatory agency level 4 to be able to have the competency needed to regulate the vaccine industries.

Having this in mind, the pharmaceutical industries are now going into different collaboration with other foreign manufacturers to build partnership and develop their capacities in various areas to be able to measure up and look inward to begin technology transfer from other foreign partners and develop human capital to enable them run the local vaccines industry excellently without any hitch. However, our pharmaceutical industries are willing and also ready to engage in local manufacturing of vaccines if the right support and incentives are provided by the government to compliment investors preparedness and willingness to develop and make the vaccines industry a model for other Africa countries and the world at large to see.

EVIDENCE AND ANALYSIS:

The pharmaceutical Industries are willing to engage in local manufacturing of vaccines because this could be seen as a profitable investment despite the very complex procedure it may involve. The pharmaceutical investors are ready to deal if the right and enabling environment is provided by the government with the necessary back up incentives, it could translate into a profitable venture with a lot of big investors wishing to invest into it.

Additionally, from the data from the interviews, eight out of the eleven participants interviewed threw their weight behind the pharmaceutical industries willingness to engage in local manufacturing of vaccines. One of the participants said that "*the pharmaceutical industries are in business and will always want to invest their money in a place they are sure of having good returns on their investment*". While the three other participants see the vaccines industry as a risky business with most pharmaceutical industries or players not having enough technical expertise to manage the industry in term of the technicality. Another reason given for the pharmaceutical industries unwillingness is the problem associated with large capital involvement needed to start up the factory.

FINDING # 5 - THE CHALLENGES FACING THE LOCAL MANUFACTURING OF VACCINES IN NIGERIA ARE ENORMOUS BUT COULD BE OVERCOME.

From this research work, the major focus is to identify the various challenges which could be the stumbling block to achieving local manufacturing of vaccines in Nigeria. From the literature review, we could see clearer pictures from those countries that are currently manufacturing and why are they succeeding. These are some of the factors which could be attributed to why we are still not manufacturing vaccines in Nigeria because we are still lacking in most of these areas. These challenges would be discussed below and the need for us to brace up and put things in the right perspectives for us to join the leagues of countries that are manufacturing vaccines in Africa and the world at large.

Vaccine manufacturing is very complex to set up and there are lot of regulatory landscape issues which must be addressed by the pharmaceutical industries or the investors. There are key areas which must be get the needed certification and compliance with the regulatory agencies before you could have the approval to go ahead with your manufacturing. The facilities are usually hi-tech and must have the right expertise to manage the operation to ensure that the right

procedures and operations are carried out. Furthermore, partnership with other foreign manufacturers will guarantee support in term of training of human capital development and technology transfer which are very essential to get it done rightly than just doing trial by error.

EVIDENCE:

From the data analysis from the interview, the researcher was able to get the participants insight on limitations which could impact local manufacturing of vaccines in Nigeria. Below are some of the reasons which has been attributed to be the major challenges still drawing us back and preventing the country Nigeria not yet registered among the countries that are currently manufacturing vaccines. These challenges are hereby summarized below:

- The regulatory agency NAFDAC is yet to attain a Stringent Regulatory Agency (SRA) level 4 before they can be certified to be an agency that can supervise and regulate vaccines manufacturing in Nigeria.
- Government still enjoys patronizing foreign manufacturers due to reasons best known to them rather than encouraging and supporting indigenous manufacturers to improve and develop local capacity.
- There is no effort to encourage collaboration among different players as is the case in the developed countries such as Pfizer/BioNTech, Moderna/American government, Astra Zeneca/ Oxford University.
- Lack of technical know- how and infrastructural development
- Lack of patronage from government
- Lack of access to funds/ high cost of setting up/ High cost of funds (double digit interest rate of between 24-35%)
- Lack of human capital or expertise required to operate the process.
- Cost of acquiring land is very high for building factory
- Lack of favorable policies to drive local manufacturing of vaccines in Nigeria
- Lack of needed framework to access international partners in term of technology transfer to support local manufacturing of vaccines in Nigeria
- Lack of commitment from investors
- Reason due to unexplained bureaucracy
- Lack of the political will on the part of the government

- The issue of global conspiracy is also a major problem because the developed countries are looking forward to those highly populated countries such as Nigeria with population of over 200Million as a major market thereby preventing them from having access to local manufacturing of vaccines.

From the above, it is evidence that the challenges are quite enormous and overwhelming but with the determination and support on the part of the government, it will become a fierce and a thing of the past once these challenges are up-turned.

ANALYSIS:

The issue of local manufacturing of vaccines in Nigeria is really gathering momentum now since after the last Covid-19 pandemic that brought about reported cases of deaths most especially among the elites and some top government functionaries. This has set the tone to government to look inward and embark on total over-hauling of the health sector through various reforms and policies to support not just local manufacturing of vaccines but finding a way to support the indigenous pharmaceutical industries to achieve medicine security for the country with lesson from what happened with having government inability to access imported vaccines from other countries with the politics and bureaucracy encountered in getting access to vaccines for Nigeria citizens.

It is therefore pertinent to closely examine all these challenges and the various stakeholders involved should engage with the government and begin to find a lasting solution to all these bottlenecks to make local manufacturing of vaccine achievable within a shortest time because all hands must be on deck as there is need to strengthen our indigenous pharmaceutical industries to win this battle before them.

4.3 OVERALL DISCUSSION

The researcher objectives of carrying out this study are finding solution, examining the available framework policies, and evaluating the need to carry out advocacy to achieve local manufacturing of vaccines in Nigeria and these were well covered by the researcher through the information collected from the participants who has been able to provide insight into these key areas and speaking based on their intellectual knowledge and from experiences.

Furthermore, the fact remains that Nigeria has not fully been able to locally manufacture vaccines but already taken step to address most of the challenges listed above as hindrances to achieving this fit but with the support from government providing the needed conducive environment and incentives, this would soon become a thing of the past.

The first finding revealed and confirmed that currently, there is no manufacturing of vaccines going on in Nigeria at the moment, but a lot of efforts are being channeled towards preparing to kick start the local manufacturing of vaccines with the support from government and public private partnership going on to upturn the present state of the industry into the achievement of that fit of locally manufacturing of vaccines in Nigeria. This therefore confirm the secondary data from the literature review on the present state of domestic vaccines manufacturing in Nigeria which is an agenda being pursue by government and indigenous pharmaceutical industries as at today.

The second finding revealed the need for advocacy which has been considered a necessary tool towards attaining local manufacturing of vaccines. From the analyzed data from the interviews based on the participants' responses has indicated the needed agencies and institutions where this advocacy should be targeted. These can be seen in the appendix D at the end of the project write-up. It has also been proven that the government has a major role to play to ensure that the local manufacturing of vaccines in Nigeria is achieved with support from them. To this end, it further agreed to the secondary data from the literature review on the need for government support to fast track the objective of this research as seen in most of the developed countries with partnership intervention of the government and other stakeholders.

The third finding also revealed the need to ensure that the right policies are in place and there is also the need for government to ensure they back up those policies with support in term of driving the implementation. This was confirmed by one of the participants that said "*Our problem has never been lack of policies but the problem associated with implementing those policies*". This finding is also in agreement with the secondary data and discussed in my literature review on the need for having fundamental framework policies which is driven by both the government and other stakeholders.

The fourth finding also revealed the willingness of the pharmaceutical industries who are the major players as evidence in the summation from the data analyzed from the interview responses attached as APPENDIX D. Although, two out of eleven participants do not support the willingness

of the pharmaceutical industries to want to engage in local manufacturing of vaccines because they see it as a very risky business and that they do not have the much-needed expertise required to initiate and manufacture vaccines locally. The literature review on Biovaccine is a clear evidence in agreement to the willingness of pharmaceutical industries to venture into domestic manufacturing of vaccines in Nigeria. Also, from information available from NAFDAC, some indigenous pharmaceutical industries are already carrying out lot of documentation to signify interest to become players in the vaccine industry.

The fifth finding revealed the various challenges facing local manufacturing of vaccines in Nigeria. These challenges are indication why Nigeria is not yet there and there is need by the government to create the much-needed environment and incentives to support the pharmaceutical industries to achieving this milestone. These challenges are quite enormous but can be overcome when government put their weight behind this course to support the manufacturers and investors by creating the right environment and needed incentives. The literature review delves into some of these challenges to agree with the findings from the primary data. It is very obvious that both the primary and secondary data are complementary to confirm the findings from this research work thereby showing the importance of having data from both sources.

4.4 CONCLUSION

From the various findings from above, it can be concluded that the pharmaceutical industries in Nigeria are currently undergoing transformation in preparation to take the bull by the horn and face the challenges limiting the effort towards achieving local manufacturing of vaccines in Nigeria. It is evidence from the research work that government is now willing to support the pharmaceutical industries to achieving this milestone once again by becoming registered member of countries manufacturing vaccines locally and lot is currently going on to change the picture and boost self-sufficiency and increase medicine security in Nigeria.

Taking everything into account, the government are becoming more responsive to support the pharmaceutical industries not only in local manufacturing of vaccines but also to provide incentives to guarantee medicine security which is now becoming major threat to Nigeria most especially during this recent Covid-19 pandemic. There seems to be a shining light at the end of the tunnel if the government becomes more responsive and provide the support and incentives to engage other stakeholders to drive this course, then Nigeria will be there in no time.

This chapter provide insight on the various findings as gotten from the interviews conducted and responses received from the participants. The next chapter, the researcher would further be discussing the implication of the study, the limitation of the study, likely suggestion for further research, the contribution of the research and concluding recommendations.

5.0 CHAPTER FIVE: CONCLUDING AND RECOMMENDATIONS

5.1 OVERVIEW

The last chapter gave a brief of key findings which came from the data analysis from the interviews based on the responses obtained from the participants. These findings are listed below:

1. There is no human vaccines currently manufactured in Nigeria.
2. Advocacy could be regarded as a strong tool in achieving local manufacturing of vaccines.
3. Available government policies need to be backed with government support to deliver on local manufacturing of vaccines.
4. The pharmaceutical industries are ready to engage in local manufacturing of vaccines in Nigeria.
5. The challenges facing the local manufacturing of vaccines in Nigeria are enormous but could be overcome.

This chapter will discuss the necessary implications of these findings, recommendations for further studies and the limitations that were faced during this research work will be discussed in detail.

5.2 IMPLICATIONS OF FINDINGS FOR THE RESEARCH QUESTIONS

The research questions from these studies are:

1. What can be done to increase local manufacturing of vaccines in Nigeria?
2. What are the challenges standing in between local manufacturing of vaccines in Nigeria?
3. Are the government willing and ready to support the local manufacturing of vaccines in Nigeria?
4. Would increase in advocacy promote the local manufacturing of vaccines in Nigeria?
5. Are the Pharmaceutical industries ready to engage in local manufacturing of vaccines Nigeria?

Based on the focus and the structuring of the questions used for the interview, the research questions are embedded in those questions answered by the participants to be able to give their

insight in addressing some of these questions and the data analysis using thematic analysis which provides answers to these research questions asked.

Firstly, to address the issue of what could be done to increase local manufacturing of vaccines in Nigeria. Below are some of the proposed solutions to address this problem.

- Government must be ready to collaborate with other players such as Indian government collaborated with serum institute of India
- Government must be willing to patronize and give assurance to investors in Nigeria regarding guaranteed patronage
- Government must make sure that their regulatory agency attains that level of stringent regulatory agency (SRA)
- Need for infrastructural development
- Need to provide needed incentives to attract technical expertise to move down to Nigeria to support the course/ need for government to wake up from their slumber
- There must be a deliberate policy framework/ policy coherency to drive local manufacturing of vaccines in Nigeria
- Government must be willing to support by giving incentives to encourage investors such as tax holiday, subsidized land etc.
- There must be industrial park arrangement that allow for entry cost to be low because it will be shared between government and investors

Secondly, considering the challenges standing in between local manufacturing of vaccines, these challenges has been enumerated in the previous chapter and they are seen as high-level issues which must be dealt with for us to graduate and be recognized as one of the local manufacturers of vaccines in Africa and the world at large.

Thirdly, are the government willing to support local manufacturing of vaccines in Nigeria? This question has been extensively dealt with in the previous chapter based on the findings from the data analysis from the responses and the summary being that a lot rest on the government table to provide the conducive environment and incentives to support the pharmaceutical industries to achieving this milestone. From these responses collected from these interviews, there are enough evidence to prove that the government are now ready to support local pharmaceutical industries in achieving this set objective.

Fourthly, would increase in advocacy be an important tool in achieving local manufacturing of vaccines in Nigeria. The researcher has also evaluated and discussed this in previous chapter based on the data analyzes from the information collected from the participants. It is evidence from this research work that advocacy is key to achieving local manufacturing of vaccines in Nigeria as discussed in the previous chapter.

Finally, whether the pharmaceutical industries are ready to engaged in local manufacturing of vaccines in Nigeria. Most participants believed that the pharmaceutical industries are willing to engage in local manufacturing of vaccines provided the government are willing to support by providing the enabling environment and incentives needed to have a healthy transition. Just three participants had a contrary opinion that the pharmaceutical industries are not yet ready because vaccines manufacturing is a risky business, and it requires a lot of technical expertise which may not be available in the country.

In conclusion, the researcher believed that the research questions were all well answered based on findings gotten from the study.

5.3 CONTRIBUTIONS AND LIMITATION OF RESEACH

This research work has really reemphasized the need for and importance of the government to really put their weight behind the indigenous pharmaceutical industries in Nigeria by ensuring that they provide the right framework policies to support the indigenous pharmaceutical industries in Nigeria. This research work also has been able to expose the inadequacies which has caused severe setbacks to the pharmaceutical industries because most of the government policies are not favorable to the development of these industry.

However, the pharmaceutical industries still have a long way to go if truly the country want to be recognized as developing the local content and therefore encouraging the local manufacturing of vaccines, then all hands must be on deck to collectively put heads together and strives toward achieving this course. The government must be at the Centre of this fight and provided the enabling environment to attract investors and provide incentives to encourage the pharmaceutical manufacturers and other players to set the ball rolling and engage with foreign partners to actualize this dream.

The contributions of the participants are overwhelming and encouraging to have provided insight to this research work by answering questions on those focus areas thereby providing the various

insight which has led to the data generated to enable the researcher to come up with all these findings, recommendations and suggestion going forward.

The limitations faced during this research work are minimal and could be attributed to the prevailing economic condition especially at this time when the entire world is still battling with the adverse effect of Covid-19 pandemic and the economic is gradually re-opening and with people also struggling to have their lives back. As we all are aware of the limitation cause as an effect of management strategy of protecting their staff leading to most people resulting to embrace the option of working from home therefore making most government and private sectors workers inaccessible and absence from their duty post. Although, the researcher must go extra length to do follow up on the identified participants out of 15 participants initially contacted, only 11 participants finally responded to attend the zoom meeting representing 73.3% which was an excellent performance overall.

In addition, limitation which could be attributed to the time frame within which the research work must be delivered could also be a contributing factor because having as much as 6months would have given more time to contact more participants and recruit them to be part of the research work. Finally, my inability to visit Nigeria during the period of this research work could also be considered as a limitation because it would have afforded me the opportunity to interact with more opinion leaders and stakeholders needed for this research work.

5.4 RECOMMENDATIONS FOR PRACTICE

This research work is to critically evaluate the pharmaceutical industries in term of the limitations which could impact local manufacturing of vaccines in Nigeria. Nigeria at some time was said to have manufactured vaccines both for human and veterinary use but the human vaccine factory became moribund when the facility closed for upgrade but never revived until now when concerted efforts are being put in place to get back on track.

The pharmaceutical industries should be ready now to engage other stakeholders whether government or private sectors and begin concerted effort to bring about collaborations and partnership because there is a lot to be put in place to ensure a proper vaccines facility is set up. These partnership and collaboration with other foreign manufacturers are welcome development and most be encouraged so as to shorten the lead time of attaining capability for local manufacturing of vaccines in Nigeria.

In addition, the government must be willing to throw their weight behind this project of actualizing this dream by being the focal point and ready to provide the conducive environment for the manufacturers to operate and provide the right policies which would support the actualization of encouraging local manufacturing of vaccines in Nigeria.

Moreover, the regulatory agency, National Agency for Food and Drug Administration and Control (NAFDAC) who is responsible for overseeing the regulatory issues must be seen to have the much-needed capability to regulate these industries. It is therefore statutory for NAFDAC to attain the Stringent Regulatory Agency (SRA) level 4 which is the statutory requirement for regulatory agencies to be able to give due approval to the pharmaceutical industries. From available information, NAFDAC is said to be at the last stage of this approval and would soon attain that status.

5.5 RECOMMENDATIONS AND SUGGESTIONS FROM THE STUDY

The researcher was interested in getting recommendations and suggestions from the participants going forward as steps in the right direction toward actualizing the dream of local manufacturing of vaccines and these are summarized below from the data analyzed from the responses obtained from the interviews.

They are:

- Government should also support NAFDAC to attain the stringent Regulatory Agency (SRA) level 4 to enable them to have the full potential to approve the manufacturing of vaccines in Nigeria
- Government should also assist to talk to multinationals to collaborate with Nigeria just like the collaboration of Indian government with serum institute of India/ government willingness to work with private sectors.
- Nigeria government should be ready to collaborate with other Africa countries such as central and west coast my manufacturing for them which are ready markets in Africa
- Need for infrastructural development.
- There must be tax incentives from government
- There is need for national policy blueprint/ Road map from government to work the talk
- Industrial clusters or park where the percentage can be shared between the government and manufacturers.

- The outcome of this research should not just be published in peer reviewed journals but try to seek audience with major stakeholders in government such that the recommendation gets to the policy makers that would implement the findings from the research.
- Access to low digit funds to scale up/upscale facilitates necessary for local manufacturing of vaccines in Nigeria
- The donor organization should be encouraged to patronize Nigeria vaccines to build local capacity and capabilities to develop local manufacturing of vaccines in Nigeria
- Government, private sectors, and pharmaceutical industries should get serious to invest in research and development and take ownership of the vaccine industry.
- Stability of policy direction
- Increase advocacy to all stakeholders involved.
- The PMG-MAN should talk to the government, and they must be willing to listen to them.
- There must be accountable leadership from government which will lead to increased productivity and government meeting the need of his people.
- The citizen should ensure that they have the right leaders in position that would be able to listen to the plight of the people by engaging in accountable leadership to serve the country rather than serving themselves.

5.6 RECOMMENDATIONS FOR FURTHER STUDIES

The researcher identified some other areas of studies in relation to this research work such as utilizing more participants such as between 25-50 to be able to cross fertilize ideas and being able to get more views regarding the research topic.

In addition, there might be need to segment the participants to have a cross sectional views of different opinion molders representing their sectors such as medical practitioners, laboratory scientists, academia, industrial pharmacists, government agencies such as Ministry of Health, National Primary Health Care Development Agency (NPHCDA), Developmental partners such as (WHO, UNICEF, UNIDO), Regulatory agency (NAFDAC), Research institutes and other relevant organization and groups to be able to compare their responses based on the interest they represent.

Finally, it is also important to examine the effect of government not providing the needed support and the consequences on local manufacturing of vaccines in Nigeria. These are further studies area will be available to research into in future and they are all not within the scope of this research work.

5.7 FINAL CONCLUSION AND REFLECTION

The researcher has done the much-needed literature review and search of related articles, journals, publications, and other past dissertation on related issues to give better insights on the research topic. This topic is a national issue drawing attention from various quarters based on the outcome of the Covid-19 pandemic and the need to provide vaccines to the people and population at large.

In addition, the entire research exercise was quite tedious but quite insightful and interesting because the participants exposed the researcher to new areas which are quite insightful and detailed as relates to global experience and other innovative ideas as relates to the topic of the research work.

The research was able to reveals the various challenges that are regarded as the stumbling block or clog in the wheel of progress of achieving local manufacturing of vaccines in Nigeria. Some of these problems are already known issues which has caused major setback to our indigenous pharmaceuticals industries, and they are also responsible for reasons why some multinationals are folding down or relocating their businesses from Nigeria. Coupled with the problem of insecurity in the country now, the nation is experiencing a difficult time now and this is really killing most investors now because the cost of doing business in Nigeria is becoming alarming on daily basis without a corresponding return on investment.

Taking everything into account, the ball still rests with the government to ensure that they provide the conducive environment and incentives and bring all stakeholders to a roundtable and chat a new course and provide the policy framework and a strategic plan which could be short, medium, and long term which the necessary political will and funding to back them up with the needed action.

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APPENDICES

APPENDIX A: COVERING LETTER TO SURVEY/INTERVIEW SUBJECT



Participant Information Letter

ATTENTION:

.....

PROJECT TOPIC- *Limitations impacting local manufacturing of vaccines: A Nigeria case study.*

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is **Omoniyi Sunday Adesanya** and a Master's student with the Pharmaceutical Business and Technology, Dublin under the faculty of Innopharma. I enrolled for this course to increase my knowledge and competency on the use of technology in the management of pharmaceutical technology as a way of optimising pharmaceutical business in Nigeria and its environ. We are doing this study to find lasting solution, setting up a workable framework plus plan and promotion cum increase advocacy on local manufacturing of vaccines in Nigeria.

The methodology to be employ in this research is through qualitative research method of data collection which will involve speaking to experts like you to give their honest opinions on various subject areas base on questions to be asked relating to local vaccines manufacturing in Nigeria. This research project is part of my course work in fulfilment of a master's award in Pharmaceutical Business and Technology from Griffith College, Dublin.

WHAT WOULD TAKING PART INVOLVE?

As we all know that being part of any research project will benefit the body of knowledge and also looking forward to having a change in the current situation of local vaccines manufacturing in Nigeria. This research will be utilising zoom platform to schedule meetings with the participants at different times for them to utilise their expert's knowledge to provide answers to various questions that will be asked by the interviewer. The interview will last between 20-25minutes and will be audio- recorded and the information would be transcribed after the interviews.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been selected based on your expert knowledge, your position and as player within the vaccines industry. You have been carefully selected because we are aware of the enormous deposits of information which we considered to be useful to help answer our research questions and at the same time to proffer solutions which would be helpful in achieving the aims and objectives of the research work.

DO YOU HAVE TO TAKE PART?

It is important we let you know that participation in this research project is totally voluntary, and you have the right to refuse participation, refuse to answer any question which you may deem not to be comfortable with and at the same time, you have the right to withdraw from participating at any time within the context of the interview.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

To the best of our knowledge, there is no associated risk involved in taking part in this research work but rather it is going to be of immense benefit to the body of knowledge and Nigeria as a developing country still trying to develop in the area of local vaccines development and at the same time utilising the manufacturing capacities of most of our pharmaceutical companies that are still performing below their full capacities. The benefits found in the local manufacturing of vaccines are enormous and are quite beneficial to the development of the Nigeria utilised in the case study. We hereby assure you of the utmost confidentiality of the information given according to the laid down ethics guiding the conduct of this research work.

WILL TAKING PART BE CONFIDENTIAL?

This type of research is an exploratory type which gives an insight on the subject matter. The information provided are not regarded as a sensitive information but confidentiality and anonymity of the participants would be maintained. The information would be analysed and recommendations compiled to summarized at the end of the project.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

The information provided will be stored and protected in the Griffith library for a period of 7years before it will be discarded and deleted from archive. A transcript of interviews in which all identifying information has been removed will be retained for a further two years after this. Under freedom of information legalisation, you are entitled to access the information you have provided at any time.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The research project is part of the requirement in partial fulfilment of an award of master's degree in pharmaceutical business and technology. This dissertation research projects, and their content will be made accessible in the college library and could potentially be made available in online e-journals or repository for future use by other students as contribution to the body of knowledge.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

For further details, please contact my project supervisor:

Dr Prosper Anaedu

Post Graduate Research Coordinator

Innopharma Faculty of Pharmaceutical Sciences

Griffith College, Dublin

Email – anaedup@innopharmalabs.com

Prosper.anaeedu@griffith.ie

Thank you.

APPENDIX B: SAMPLE SURVEY/INTERVIEW QUESTION

INTERVIEWING QUESTIONS

1. Can vaccination be used as a protection against some deadly and infectious diseases commonly found in infant, children and adult? IF YES WHY?
2. Could you please tell me some benefits found to be associated with vaccination?
3. Are vaccines currently being manufactured in Nigeria?
4. What are the challenges affecting local manufacturing of vaccines in Nigeria?
5. What can be done to increase access and facilitate the local manufacturing of vaccines in Nigeria?
6. Are the government willing and ready to support the local manufacturing of vaccines in Nigeria?
7. Are there favorable government policies in place to support local manufacturing of vaccines in Nigeria? If YES, list some that you know.
8. Would increase in advocacy promote the local manufacturing of vaccines in Nigeria? If YES, mention some organization to which this advocacy should be targeted to?
9. Are the Pharmaceutical industries ready to engage in local manufacturing of vaccines in Nigeria? If NO, mention reasons why pharmaceutical companies may not be interested?
10. Do Nigeria really have the technical expertise required for vaccines production? If YES, in which areas?
11. What are the benefits attributed to local manufacturing of vaccines in Nigeria?
12. Going forward, what are your suggestions and recommendation that can encourage local manufacturing of vaccines in Nigeria?

**APPENDIX C: SAMPLE COMPLETED SURVEY/INTERVIEW TRANSCRIPTION FOR EACH
PARTICIPANT**

PARTICIPANT INTERVIEW 1

QUESTION 1

ANSWER- YES- Vaccination is extremely important to prevent communicable diseases in infant, children and adult.

-Eradication of all these diseases makes not only Nigeria, Africa and the entire world free of these diseases.

QUESTION 2

-Prevention of communicable diseases in infant, children and adult

-To make the children useful to the world

-They uphold the health of the society, nation and the world at large.

QUESTION 3

CAPITAL NO (No human vaccine manufactured in Nigeria as at today)

QUESTION 4

-Caused by government, regulatory agencies religious believes, private sectors

1. The regulatory agent must attain a stringent regulatory agency (Level 4) before they can be certified to approve vaccine manufacturing.

2. Government encourages patronizing foreign manufacturers due to reasons best known to them rather than looking back into Nigeria system to look inward to improve local capacity and develop local manufacturing of vaccines in Nigeria

3. There is no effort to encourage collaboration among different players as is the case in developed countries such as Pfizer/ BioNtect, Moderna/ American government, Astra Zeneca/ Oxford university

QUESTION 5

1. Government must be ready to collaborate with other players such as Indian government collaborated with Serum Institute of India

2. Government must be given assurance to investors in Nigeria to patronize them and create enabling environment
3. Government must make sure that their regulatory agency attains that level of Stringent Regulatory Agency (SRA) LEVEL 4
4. There is the need to work with local and international researchers to research into local vaccines manufacturing in Nigeria

QUESTION 6

Government is NOW ready to support local manufacturing of vaccines

- Government have learnt their lessons from the last episode of Covid-19 pandemic that mostly affected the elites.

QUESTION 7

YES- Policies has always been there

One of the policies on vaccine is that minimum of 75% of medicines being consumed in Nigeria must be locally sourced and manufactured but they have never put any action behind it because a lot of government official are still paying lip service to that and would rather patronize Indians for reasons best known to them.

Ministry of health in conjunction with CBN setting asides about 10Billion naira for COVID -19 but the national assembly are saying the money is not meant for Covid -19 alone.

QUESTION 8

YES

- PMG-MAN (Pharmaceutical Manufacturing Group of Manufacturers Association of Nigeria)
- NAFDAC
- GOVERNMENT

QUESTION 9

YES

QUESTION 10

YES

- But the world has gone beyond localizing technical expertise

- Today, it's all about combined effort now to get things right. It's about collaboration with other foreign partners

QUESTION 11

- Ready availability of vaccines for all
- Creation of jobs for citizenry
- Wealth will be created for investors
- Creates opportunity for the export of vaccines to other Africa countries as a hub in Africa

QUESTION 12

- Government willingness to work with the private sectors
- Government should also support NAFDAC to attain the Stringent Regulatory Agency (SRA) Level 4 to enable them to have the full potential to approve the manufacturing of vaccines in Nigeria
- Government should also assist to talk to multinationals to collaborate with Nigeria just like the collaboration of Indian government with serum institute of India
- Nigeria government should also collaborate with other Africa countries such as central and west coast by manufacturing for them which are ready markets in Africa.

PARTICIPANT INTERVIEW 2

QUESTION 1

YES

-To expose the immune system to either dead or attenuated organisms, while the body is prepared to fight back

QUESTION 2

-Prevention of morbidity and mortality in infant, children and adults

QUESTION 3

Nobody currently manufactures vaccine in Nigeria

QUESTION 4

- Lack of infrastructures

- Lack of technical know-how
- Lack of patronage from government

QUESTION 5

- Need for infrastructures to be in place
- There must be ready patronage from government
- There is also the need for technical know-how to be in place

QUESTION 6

YES- The government are willing to suppose local manufacturing of vaccines due to ravaging effect of the last Covid-19 pandemic on the economy and country at large.

QUESTION 7

YES-

-Executive order to prioritize and patronize locally manufactured products
-There is an amount set aside by government through the CBN for pharmaceutical industries to access and develop their financial capability in local manufacturing of drug products

QUESTION 8

YES

- Ministry of Health
- CBN
- NATIONAL PROGRAMME ON IMMUNIZATION
- Nigeria Sovereign Wealth Investment Company
- Ministry of Finance
- Nigeria Custom Services

QUESTION 9

YES- They are interested and

NO---They are not ready Now

- Most pharmaceutical companies will be willing to involve in local manufacturing of vaccines but in term readiness, they are not all ready.

QUESTION 10

NO Technical expertise

QUESTION 11

Medicine/ Health Security

QUESTION 12

- Need for infrastructural development
- Need to have the required technical know-how
- Need to partner and collaboration with other partners
- Government support in term patronage
- Tax incentives from government

PARTICIPANT INTERVIEW 3

QUESTION 1

YES- Vaccination can be used as means of protection against deadly and infectious diseases.

QUESTION 2

- Containing of pandemic and spread of diseases
- Restoration of normalcy and good health
- Prevention of debilitating diseases and general maintenance of life

QUESTION 3

YES- Human vaccines are being manufactured in Nigeria until it became moribund in 1990. Also, veterinary vaccines are being manufactured somewhere in Jos

QUESTION 4

- Lack of access to funds
- High cost of funds
- Lack of infrastructural development

QUESTION 5

Government needs to wake up from their slumber

QUESTION 6

YES- On paper, we have policies that support local manufacturing of vaccines but the problem I implementation

- 98.7Billion has been disbursed by government but most pharmaceutical manufacturers are yet to access this funds due to very stringent conditions attached.

QUESTION 7

YES

-The national drug policy of 2005 but the problem rest with implementation.

QUESTION 8

YES

- Government
- Manufacturers
- Importers

QUESTION 9

YES- Very ready

-It is business because investors will put their money where they can have good returns on investment provided the enabling environment is guaranteed.

QUESTION 10

YES- Human resources

QUESTION 11

- Drug security when drugs are manufactured locally
- Guarantees job security
- Encourages Technology Transfer

QUESTION 12

- Government needs to put his house in order and ensure that things are in the right perspectives
- Government needs to build and develop the enabling environment that will support local manufacturing of vaccines in Nigeria

- Government should come up with industrial parks where they will create the enabling environment for manufacturers to operate with the provision of needed infrastructures and other needed support to guarantee the much-needed conducive atmosphere.

PARTICIPANT INTERVIEW 4

QUESTION 1

YES- Very key in reducing morbidity and mortality especially in children under 5years in most developing countries like Nigeria

QUESTION 2

- It prevents morbidity and mortality rate in infant, children, and adults
- Guarantees the future generation through increase longevity
- Helps to improves the quality of life to increase the gross domestic products (GDP) by contributing their quota to the development of the country.

QUESTION 3

No vaccine is currently being manufactured in Nigeria. History only have it that Nigeria used to manufacture vaccines until the factory became moribund and the country manufactures veterinary vaccines in Jos but it's all in history as at today

QUESTION 4

- Lack of human capital or expertise required to operate this process are not available in the country.
- Cost of funds is high in Nigeria (double digit interest rate i.e 24-36% interest rates from Nigeria commercial banks)
- No guaranteed patronage from government
- Lack of infrastructural development like electricity
- The cost of acquiring land is very high for building the factory
- NAFDAC has not attained the required international regulatory standard called Stringent regulatory agency (SRA) which is a mandatory requirement stipulated by International regulatory body.

QUESTION 5

- There must be a deliberate policy framework to investigate local manufacturing of vaccines in Nigeria
- There must be guarantee from government for patronage (As up taker)
- Government must give various incentives to encourage investors such as tax holiday, subsidized land etc.
- There must be a deliberate effort for human resources with good curriculum which is adaptable to the industry through continuous training programme
- There must be infrastructural development
- There must be industrial park arrangement that allow for entry cost to be low because they are shared by government and manufacturers.

QUESTION 6

Government is willing to support the local manufacturing of vaccines in Nigeria, but readiness is really in doubt

QUESTION7

YES- There are few, but they are very generic

QUESTION 8

YES- Very important

- To Global investment financiers
- To Government to guarantee patronage

QUESTION 9

NOT READY

- It a risky venture and required some level of understanding in the vaccine industry
- Most will rather play the role of marketers and distributors as most pharmaceutical industries are very disadvantage in this area

QUESTION 10

YES

- There are lot of human capital experts both local and abroad who are vast and equipped with the technical know-how

QUESTION 11

- Vaccines security is guaranteed in term of read availability.

- It helps to respond to medium/long term plan especially during pandemic
- It helps to conserve/ preserve foreign currency
- It helps to build capacity within the vaccines market

QUESTION 12

- Need for national policy blueprint from government to walk the talk
- Infrastructural improvement
- Right incentives must be provided
- Industrial clusters or park where the percentage can be shared between the government and manufactures
- Funding must be accessible to manufacturers
- Government must guarantee patronage of the vaccines manufactured.

PARTICIPANT INTERVIEW 5

QUESTION 1

YES

There are empirical evidence standing close to century of the potency of vaccination as being a public health intervention in checking the spread of deadly diseases. Several decades ago, the eradication of smallpox was achieved using vaccination as a tool of public health. Also, several childhood diseases that has been kept in check using vaccination. The evidence is not in doubt that vaccination can be used to address infectious diseases and other public health menace and I can say categorically that vaccination can be used as a tool in protecting against deadly and infectious diseases.

QUESTION 2

There are two major benefits that can be attributed to vaccination in healthcare intervention

Vaccination is basically a preventive strategy which are more cost effective in the management of these diseases. The cost can be cost to life as well as cost to the healthcare system. There is empirical evidence to show that the number of people that will be susceptible to any infectious diseases would be less when a higher percentage are vaccinated. There is incontrovertible evidence to show that there is a big cost efficiency

in term of the amount of money that an individual or healthcare system will spend in treating these diseases when a large percentage are vaccinated.

There is also incontrovertible evidence to show that there is huge potential for vaccination to save lives in term of preventing the demographic from contracting the diseases or dying from the diseases as compared to when they are not vaccinated as to treat the diseases or battle with these diseases.

QUESTION 3

YES

There are veterinary vaccines being manufactured in Plateau state (National Institute of veterinary research in Jos).

But for human vaccines, currently NO but Nigeria has had significant vaccines manufacturing capacity for decades which was only degraded in 1990 in Yaba which played roles in eradicating small pox diseases and was short down for upgrade and has not been undertaken and vaccine manufacturing capacity unfortunately been degraded.

QUESTION 4

The biggest challenge is the lack of policy on ground to drive local manufacturing of vaccines in Nigeria

QUESTION 5

- There must be policies on ground to drive local manufacturing of vaccines in Nigeria
- There must be assurance from government to patronize local manufacturing of vaccines
- The funding of vaccines manufacturing project must be supported by government
- Providing a framework for local vaccines manufacturers to access international partners in term of technology transfer to support local manufacturing of vaccines in Nigeria
- Provision of adequate infrastructures such as power, good strategies, ease of regulatory landscape etc.

QUESTION 6

YES

Government are very willing to support local manufacturing of vaccines looking at the upstream and downstream involvement from government. There is a lot of work going on along the entire value chain of vaccines manufacturing locally.

QUESTION 7

This is an area that we have major setback because we are very reactive. We are not being proactive to put together a more robust framework with the entire stakeholders. Those favorable policies exist but they do not exist in a manner within a framework that will deliver a result to us within the time we need them. A multi sectorial framework would have been more ideal to bring all players on board and the key performance indicators would have been defined to move the country forward in the right perspective.

QUESTION 8

YES

- Ministry of industry, trade and investment
- Central Bank of Nigeria
- Ministry of Finance
- Ministry of foreign affairs for organizing collaborative meetings.
- Ministry of Science and Technology
- Government (Presidency)

QUESTION 9

YES

Most pharmaceutical industries are ready to engage in local manufacturing of vaccines

QUESTION 10

YES

The feather professionals are all available to support and give technical expertise in term of human capital development.

The Nigeria in diaspora is willing to come back to support the country if the right framework and incentives are available.

QUESTION 11

- Medicine security. This time last year, India banned the exportation of Active Pharmaceutical Ingredients (APIs) and that became a major threat to most countries to guarantee sustainable supply of safe, affordable, and high-quality medicine that will assure quality healthcare for their people.
- Other benefits are financial, technology transfer and forex generation.

QUESTION 12

- The outcome of this research should not just be published in peer reviewed journals but try to seek audience with major stakeholders in government such that the recommendation gets to the policy makers that would implement the findings from the research.
- There should be proactive approach towards policy making in the health sector especially in the area of vaccine development.
- Medicine security must be prioritized.

PARTICIPANT INTERVIEW 6

QUESTION 1

YES

Vaccination is an age long science that has proven to prevent some of the six killer diseases

QUESTION 2

- It helps in the protection of lives and guarantees future generations from death by preventing deadly and infectious diseases

QUESTION 3

NO

Vaccines are currently not manufactured in Nigeria. However, from history, vaccines had been manufactured previously until the factory became moribund

QUESTION 4

- Lack of infrastructure

- Lack of finance to bankroll the investment
- No enough human capital resources available
- Lack of good policies available to drive the industry by government
- Lack of guaranteed patronage from government

QUESTION 5

- There must be policy coherency from the government
- There must be guaranteed patronage from government
- The raw materials (APIs) must be sourced locally in Nigeria to prevent over dependency on foreign sourcing because of the various bottleneck involved in the supply chain difficulties encountered in moving raw material from abroad and the logistics involved to get them to the final warehouse where they would be required.
- There must be increased advocacy and engagement of our policy makers to provide the enabling environment for local manufacturing of vaccines to be seamless
- There must be meeting of all stakeholders to brainstorm and come up with a position paper that can change the face of things in the industry now and also having the right policies that will take us to the next level

QUESTION 6

YES

- Government are always willing to support local manufacturing of vaccines in Nigeria but the problem has to do with the readiness and the inability of government to put their weight behind the willingness. The issue has always been political statement with little or no action to back them up with the needed commitment.

QUESTION 7

YES

There are several policies on ground, but the problem has always been lack of implementation.

QUESTION 8

YES

There is always the need to carry out advocacy targeted at the level with the various stakeholders such as

- Ministry of health
- Ministry of trade and investment
- Ministry of finance
- Central bank of Nigeria
- The power brokers and renounced investors like Aliko Dangote, Oba Otudeko and many more
- The petrol-chemical industries such as NNPC, AGIP, TOTAL, EXCON-MOBIL etc.
- Ministry of foreign Affairs
- Bank of industries
- National Institute of Pharmaceutical Research and development
- Ministry of science and technology
- Federal inland revenue

QUESTION 9

YES

Some companies have started setting up their factories as we speak now to engage in local manufacturing of vaccines

QUESTION 10

YES

Nigeria has the technical expertise and human resources so far the much needed incentives are available to motivate the experts to work

QUESTION 11

- It brings about medicines security
- Improves the quality of life by reducing the morbidity and mortality rates in Nigeria
- It develops local content
- It brings about the development of local industries capability.

QUESTION 12

- There should be all inclusive and well-coordinated policy document on local vaccines manufacturing which will capture every policy makers'/stakeholders inputs in the area of

infrastructures, tax rebates, human capital development and patronage on the part of government to mention but few.

- Access to low digit funds to scale up /upscale facilities necessary for local manufacturing of vaccines in Nigeria
- The donor organization should be encouraged to patronize Nigeria so as to build local capacity and capabilities to develop local manufacturing of vaccines in Nigeria.

PARTICIPANT INTERVIEW 7

QUESTION 1

YES

Absolutely, vaccination can be used to prevent disease outbreak because it produces immunity against those pathogens that causes the diseases

QUESTION 2

- Protect recipient against those pathogens they are vaccinated against.
- It creates herd immunity among the population.

QUESTION 3

NO

- No vaccine is currently being manufactured in Nigeria.

QUESTION 4

- Lack of commitment from investors
- Lack of adequate infrastructures
- Could also be due to some unexplained bureaucracy

QUESTION 5

- Government needs to put their weight behind local manufacturing of vaccines in Nigeria
- Improved infrastructures
- Commitment on the part of investors

QUESTION 6

YES

- There is willingness on the part of the government to support local vaccines manufacturing of vaccines in Nigeria

QUESTION 7

YES

There are different policies on ground to support local manufacturing of vaccines in Nigeria

Q 8

YES

- NAFDAC
- NPHCDA- National primary health care development agency

QUESTION 9

YES

A lot of pharmaceutical industries are ready and willing to engage in local manufacturing of vaccines if the enabling environment are created.

QUESTION 10

YES

Lot of human capital resources both home and abroad and if incentives are available, they will come back to support the industry.

QUESTION 11

It will promote local access to vaccines use.

QUESTION 12

- If there is adequate support from government, it will stimulate a lot of investors to develop vaccines industry
- Need for infrastructural development.

PARTICIPANT INTERVIEW 8

QUESTION 1

YES- Vaccination can prevent the diseases thereby preventing death.

QUESTION 2

- Prevents diseases
- It increases productivity and reduces economic loss
- Reduces emotional stress

QUESTION 3

NO – Vaccines are currently not being manufactured in Nigeria

QUESTION 4

- Lack of technical know-how
- Lack of adequate infrastructures
- Lack of the political will on the part of government

QUESTION 5

- The government and other players (Pharmaceutical industries) should take responsibilities by investing in Research and Development with adequate support from government.

QUESTION 6

NO ANSWER- ASK GOVERNMENT OFFICIALS

QUESTION 7

No good policies on ground to support local manufacturing of vaccines

QUESTION 8

YES

- Government (Presidency)
- Ministry of Health

QUESTION 9

NO

- No investment in Research and development

QUESTION 10

YES, both locally and in diaspora

QUESTION 11

- Access to vaccines
- Cost in term of price

QUESTION 12

- Government, private sectors, and pharmaceutical industries should get serious to invest in Research and Development and take ownership of the vaccine industry.

PARTICIPANT INTERVIEW 9

QUESTION 1

YES- It has been proven over time that vaccination has helped in the prevention of deadly diseases in children most especially polio.

QUESTION 2

- Vaccination has prevented the damaging effects by preventing some of these deadly diseases.

QUESTION 3

NO- Human vaccines are currently not manufactured in Nigeria but history have it that Nigeria had manufactured vaccines both for local use and also for export to some Africa countries.

Also, veterinary vaccines are still being manufactured in Nigeria under National institute of veterinary research in Vom, Jos Plateau state.

QUESTION 4

- High cost involved to set it up.
- Lack of infrastructural develop
- Lack of technology know how.

QUESTION 5

- Government must provide enabling environment
- Government must provide the necessary incentives that will support the ventures
- Government must attract the necessary collaboration

QUESTION 6

YES- Government are very serious to revamp the sector through backward and forward integration.

- Natural vaccination policy
- National drug policy

QUESTION 7

- Natural vaccination policy
- National drug policy

QUESTION 8

YES-

- Ministry of Health
- Development partners such as WHO, UNIDO, World bank
- NAFDAC

QUESTION 9

Pharmaceutical industries would be willing to engage if the enabling environment is right

QUESTION 10

YES

- Both locally and in the diaspora provided the incentives are available.

QUESTION 11

- Ready available of the vaccines
- Economic value in term of increase in foreign reserve
- Creation of jobs

QUESTION 12

- Need to develop a road map for local vaccines manufacturing of vaccines.
- Adequate infrastructure either through industrial park
- Stability of policy direction
- Private sector engagement
- Advocacy to all stakeholders involved.

PARTICIPANT INTERVIEW 10

QUESTION 1.

YES

The evidence is there to prove the effectiveness of vaccination in the prevention of diseases.

QUESTION 2.

The benefits are enormous

- It is a cost-effective way of preventing diseases because it is ten times cheaper to use vaccines than curing the diseases.

QUESTION 3.

NO

But they used to be manufactured in Nigeria at Yaba but as at now, no vaccines are currently being manufactured in Nigeria

QUESTION 4.

- The problem of funding is a major issue
- Lack of infrastructural development such as power (Light)
- The issue of global conspiracy is also a major problem because the developed countries are looking forward to those highly populated countries such as Nigeria with population of over 200Million as a major market thereby preventing them from having access to local manufacturing of vaccines.

QUESTION 5.

- Government must show interest to support local manufacturing of vaccines by sacrificing sufficient resources to support local industries. Within the last 3years, government has started showing interest of their high level of awareness of the problem associated with medicine security risk, if nothing is done to address the issue taking a cue from the last Covid pandemic.

QUESTION 6.

The government are now willing and ready to support vaccine development in Nigeria. Government now has a partnership arrangement with May and Baker to manufacture

Biovaccine and they are ready by putting their weight behind the agreement with access to funding.

QUESTION 7.

YES

- Still evolving but problems that necessitate not having them before are currently being addressed by government through constant dialoging and meetings with PMG-MAN and other astute pharmaceutical industries already working with the government.

QUESTION 8.

YES

- Ministry of health
- NIPRD
- NAFDAC
- NPHCDA
- Government

QUESTION 9

YES

- There are various indications that the pharmaceutical industries are ready and willing to engage in local manufacturing of vaccines in Nigeria. Already, the PMG-MAN are in discussion with government on way forward.

QUESTION 10.

YES

Nigeria both at home and abroad are all there to support Nigeria pharma industries by providing expertise but there must be incentives to motivate them to work.

QUESTION 11.

- The supply chain issue will reduce the lead time
- Employment opportunities
- Effect on the country GDP
- Increase research capability

QUESTION 12.

- The PMG-MAN should talk to the government, and they must be willing to listen to them.
- There must be accountable leadership from government which will lead to increased productivity and government meeting the need of his people.
- The citizen should ensure that they have the right leaders in position that would be able to listen to the plight of the people by engaging in accountable leadership to serve the country rather than serving themselves.

PARTICIPANT INTERVIEW 11

QUESTION 1

YES

It has been long established that vaccination are useful tools for preventing infections in the seven childhood diseases such as diphtheria, smallpox, measles and they have been found to help in the eradication of these diseases.

QUESTION 2

It protects people from gross infections by helping them to build their immunity against the pathogens

It helps to reduce mortality and morbidity rate in a country.

QUESTION 3

NO- As at today, no vaccine is currently being manufactured in Nigeria

QUESTION 4

- Lack of resources to invest in the industry because it is capital intensive
- No guaranteed patronage from government

QUESTION 5

- Government must provide the intervention funds
- The regulatory agencies such as NAFDAC and PCN do not have the required statutory power to carry out vaccines regulatory approval because they are yet to be accredited as a Stringent Regulatory Agency (SRA).

QUESTION 6

YES- But not backed up with financial commitment. Government needs to make funding more available to support the indigenous pharmaceutical industries

QUESTION 7

YES- There are policies on ground such as policy on intervention funding and that of executive order 5 of 2005 which support the patronage of locally manufactured medicinal products

QUESTION 8

YES

- Ministry of Health
- Ministry of trade and investment
- Ministry of Finance
- Presidency
- National Assembly

QUESTION 9

YES- Some have even started even building their plants

QUESTION 10

YES- Nigeria has the technical expertise and if need be, we can still get more expertise from the diaspora provided the right environment and incentives are in place.

QUESTION 11

- Assurance of patronage from Government
- Pioneer status of some companies and there will be preferential opportunity to engage in bilateral trade with other Africa countries

QUESTION 12

- Dedicated funding for vaccines from government
- Government must give guarantee for patronage
- Provide additional incentives, exemptions to enable manufacturers to stabilize in business for those taxes are levied
- Government should support in allowing manufacturers to be able to supply other Africa countries through the ACFTA (Africa Continental Free Trade Agreement).

APPENDIX D: HARMONIZATION OF DATA FROM TRANSCRIPTION ACROSS PARTICIPANTS BASED
ON INDIVIDUAL QUESTIONS

QUESTION 1- Can vaccination be used as a protection against some deadly and infectious diseases commonly found in infant, children and adult? IF YES WHY?

REPONSES-

- Vaccination is extremely important to prevent diseases in infant, children and adult
- Vaccination also ensures that the country Nigeria, Africa and the entire world becomes free from diseases
- Vaccination is a mechanism employed to help build the body defense responses
- Vaccination is key in reducing morbidity and mortality rate especially in children under 5 years in most developing countries like Nigeria
- There are empirical evidence standing close to century of the potency of vaccination as being a public health intervention in checking the spread of deadly diseases. Several decades ago, the eradication of small pox was achieved using vaccination as a tool of public health. Also, several childhood diseases have been kept in check using vaccination. The evidence is not in doubt that vaccination can be used to address infectious diseases and other public health menace and I can say categorically that vaccination can be used as a tool in protecting against deadly and infectious diseases.
- Vaccination is an age long science that has proven to be prevent some of the six killer diseases.

Absolutely, vaccination can be used to prevent diseases outbreak because it produces immunity against those pathogens that causes diseases. /The evidence is there to prove the effectiveness of vaccination in the prevention of diseases.

- It has been long established that vaccination are useful tools for preventing infections in the seven childhood diseases such as diphtheria, smallpox, measles and they have been found to help in the eradication of these diseases.

QUESTION 2- Could you please tell me some benefits found to be associated with vaccination?

- Prevention of communicable diseases in infant, children and adult
- Preventing the damaging effects by preventing some of these deadly diseases
- It helps to ensure that the children are useful to the world
- It helps to uphold the health of the society, nation and the world at large
- Prevention of morbidity and mortality rate in infant, children and adult
- Containment of pandemic and spread of diseases
- Restoration of normalcy and good health
- Prevention of debilitating diseases and general maintenance of life
- Guarantees the future generation through increased longevity
- Helps to improve the quality of life to increase the gross domestic product (GDP) by contributing their quota to the development of the country
- Vaccination is basically a preventive strategy which are more cost effective in the management of these diseases. The cost can be cost to life and also cost to the healthcare system. There is empirical evidence to show that the number of people that will be susceptible to any infectious diseases would be less when a higher percentage are vaccinated. Also, there is incontrovertible evidence to show that there is a big cost efficiency in term of the amount of money spent than an individual or healthcare system will spend in treating these diseases when a large population are vaccinated.
- There is also incontrovertible evidence to show that there is huge potential for vaccination to save lives in term of preventing the demographic from contracting the diseases or dying from the diseases as compared to when they are not vaccinated as to treat the diseases or battle with the diseases.
- It creates herd immunity among the population
- It increases productivity and reduces economic loss
- It reduces emotional stress.

QUESTION 3- Are vaccines currently being manufactured in Nigeria?

- NO- No human vaccine is currently being manufactured in Nigeria

- YES- Human vaccines was being manufactured in Nigeria before now until it became moribund in 1990. Also, Veterinary vaccines were being manufactured somewhere in Jos, Plateau state but not sure if they still do till today
- NO- No vaccine is currently being manufactures in Nigeria. History only have it that Nigeria used to manufacture vaccines until the factory shot down for upgrade.
- YES- Only veterinary vaccines are being manufactured in Plateau state by National institute of Veterinary Research in Jos.

QUESTION 4- What are the challenges affecting local manufacturing of vaccines in Nigeria?

- The regulatory agency NAFDAC is yet to attain a Stringent Regulatory Agency (SRA) level 4 before they can be certified to be an agency that can supervise and regulate vaccines manufacturing in Nigeria.
- Government still enjoy patronizing foreign manufacturers due to reasons best known to them rather than encouraging and supporting indigenous manufacturers to improve and develop local capacity.
- There is no effort to encourage collaboration among different players as is the case in the developed countries such as Pfizer/BioNTech, Moderna/American government, Astra Zeneca/ Oxford University.
- Lack of infrastructural development
- Lack of technical know-how
- Lack of patronage from government
- Lack of access to funds/ high cost of setting up
- High cost of funds (double digit interest rate of between 24-35%)
- Lack of human capital or expertise required to operate the process.
- Cost of acquiring land is very high for building factory
- Lack of favorable policies to drive local manufacturing of vaccines in Nigeria
- Lack of needed framework to access international partners in term of technology transfer to support local manufacturing of vaccines in Nigeria
- Lack of commitment from investors
- Reason due to unexplained bureaucracy
- Lack of the political will on the part of the government

- The issue of global conspiracy is also a major problem because the developed countries are looking forward to those highly populated countries such as Nigeria with population of over 200Million as a major market thereby preventing them from having access to local manufacturing of vaccines.

QUESTION 5- What can be done to increase access and facilitate the local manufacturing of vaccines in Nigeria?

- Government must be ready to collaborate with other players such as Indian government collaborated with serum institute of India
- Government must be willing to patronize and give assurance to investors in Nigeria regarding guaranteed patronage
- Government must make sure that their regulatory agency attains that level of stringent regulatory agency (SRA)
- Need for infrastructural development
- Need to provide needed incentives to attract technical expertise to move down to Nigeria to support the course
- There is need for government to wake up from their slumber
- There must be a deliberate policy framework/ policy coherency to drive local manufacturing of vaccines in Nigeria
- Government must be willing to support by giving the much-needed incentives to encourage investors such as tax holiday, subsidized land etc.
- There must be industrial park arrangement that allow for entry cost to be low because it will be shared between government and investors
- The funding of vaccine manufacturing project must be supported by government. Within the last 3years, government has started showing interest of their high level of awareness of the problem associated with medicine security risk, if nothing is done to address the issue taking a cue from the last Covid pandemic.
- The raw materials (APIs) must be sourced locally in Nigeria to prevent over dependency on foreign sourcing because of various bottlenecks involved in the supply chain difficulties encountered in moving raw materials from abroad and the logistics involved to get them to the final warehouse where they would be required.

- There must be meeting of all stakeholders to brainstorm and come up with a position paper that can change the face of things in the industry
- There must be commitment on the part of the investors
- The government and other players (Pharmaceutical industries and investors) should take responsibility by investing in Research and Development with adequate support from government.

QUESTION 6- Are the government willing and ready to support the local manufacturing of vaccines in Nigeria?

- Government is NOW ready to support the local manufacturing of vaccines because they have learnt their lessons from the last episode of Covid-19 pandemic that mostly affected the elites.

Government is willing to support local manufacturing of vaccines looking at the upstream and the downstream involvement from them. There is a lot of work going on along the entire value chain of local manufacturing of vaccines. Government now has a partnership arrangement with May and Baker to manufacture Biovaccine and they are ready by putting their weight behind the agreement with access to funding.

- Government is willing to support local manufacturing of vaccines in Nigeria, but the problem has to do with the readiness and the inability of government to put their weight behind the willingness. The issue has always been political statement with little or no action to back them up with the needed commitment.
- Government is now very serious to revamp the sector through forward and backward integration.

QUESTION 7- Are there favorable government policies in place to support local manufacturing of vaccines in Nigeria? If YES, list some that you know.

- YES, policies have always been on ground, but they are generic and lack implementation
- Policy on intervention funds released by the federal ministry of finance/ CBN to ministry of health to be accessed by pharmaceutical industries
- Executive order to prioritize and patronize locally manufactured products.
- National drug policy of 2005/ National vaccination policy

- No good policies on ground to support local manufacturing of vaccines.
- Still evolving but problems that necessitate not having them before are currently being addressed by government through constant dialoging and meetings with PMG-MAN and other astute pharmaceutical industries already working with the government.

QUESTION 8- Would increase in advocacy promote the local manufacturing of vaccines in Nigeria? If YES, mention some organization to which this advocacy should be target to?

YES- It was all agreed that increase in advocacy will promote and support local manufacturing of vaccines in Nigeria.

The institutions to be targeted are:

- PMG-MAN (Pharmaceutical Manufacturing Group of Manufacturing Association of Nigeria)
- NAFDAC
- Government
- Ministry of Health
- CBN
- National programme on immunization
- National sovereign wealth investment company
- Ministry of finance
- Nigeria custom services
- Local manufacturers
- Pharmaceutical importers
- Global investment financiers
- Ministry of industry, trade and investment
- Ministry of foreign affairs
- Ministry of science and technology
- Bank of industry
- Petrochemical industries like NNPC, TOTAL, EXXON MOBIL etc.
- National institutes of pharmaceutical research and development

- The power brokers and renounced investors like Aliko Dangote, Oba Otudeko and many others
- Federal inland revenue
- National primary healthcare development agency (NPHCDA)
- Development partners such as WHO, UNIDO, World bank etc.
- National Assembly

QUESTION 9- Are the Pharmaceutical industries ready to engage in local manufacturing of vaccines in Nigeria? If NO, mention reasons why pharmaceutical companies may not be interested?

- YES- Pharmaceutical industries are ready to engage in local manufacturing of vaccines in Nigeria. There are various indications that the pharmaceutical industries are ready and willing to engage in local manufacturing of vaccines in Nigeria. Already, the PMG-MAN are in discussion with government on way forward.
- NO- Most pharmaceutical companies will be willing to engage in local manufacturing of vaccines but in term of readiness, they are not all ready
- YES- It is business because investors will put their money where they can have good returns on investment provided the enabling environment is guaranteed.
- NO- It is a risky venture and required some level of understanding before venturing into it.
- NO- No investment in research and development.

QUESTION 10 - Do Nigeria really have the technical expertise required for vaccines production?

If YES, in which areas?

RESPONSES

- YES – Technical expertise has gone beyond been localized. It is more about collaboration with other foreign partners.
- NO- Nigeria do not have the much-needed technical expertise
- YES- There are lot of human capital experts both locally and in the diaspora who have the technical knowhow required. The Nigeria in diaspora is willing to come back to support the country if the right framework and incentives are available.

QUESTION 11- What are the benefits attributed to local manufacturing of vaccines in Nigeria?

RESPONSES

- Medicine security/ ready availability of vaccines
- It brings about job creation for citizenry
- It brings about creating wealth for investors
- Creates opportunity for the export of vaccines to other Africa countries as a hub in Africa
- Encourages technology transfer
- It helps to respond to medium/long term plan especially during pandemic
- It helps to conserve/preserve foreign currency
- It helps to boost local capacity with the vaccines market
- It improves the quality of life by reducing morbidity and mortality rate in Nigeria
- It develops local content
- It will promote local access to vaccine use
- Cost effectiveness.
- The supply chain issue will reduce the lead time
- Effect on the country GDP
- Increase research capability.

QUESTION 12- Going forward, what are your suggestions and recommendation that can encourage local manufacturing of vaccines in Nigeria?

RESPONSES

- There must be government willingness to work with private sectors.
- Government should also support NAFDAC to attain the stringent Regulatory Agency (SRA) level 4 to enable them have the full potential to approve the manufacturing of vaccines in Nigeria
- Government should also assist to talk to multinationals to collaborate with Nigeria just like the collaboration of Indian government with serum institute of India
- Nigeria government should be ready to collaborate with other Africa countries such as central and west coast my manufacturing for them which are ready markets in Africa
- Need for infrastructural development

- There must be tax incentives from government
- There is need for national policy blueprint/ Road map from government to work the talk
- Industrial clusters or park where the percentage can be shared between the government and manufacturers.
- The outcome of this research should not just be published in peer reviewed journals but try to seek audience with major stakeholders in government such that the recommendation gets to the policy makers that would implement the findings from the research.
- Access to low digit funds to scale up/upscale facilitates necessary for local manufacturing of vaccines in Nigeria
- The donor organization should be encouraged to patronize Nigeria vaccines to build local capacity and capabilities to develop local manufacturing of vaccines in Nigeria
- Government, private sectors, and pharmaceutical industries should get serious to invest in research and development and take ownership of the vaccine industry.
- Stability of policy direction
- Increase advocacy to all stakeholders involved.
- The PMG-MAN should talk to the government, and they must be willing to listen to them.
- There must be accountable leadership from government which will lead to increased productivity and government meeting the need of his people.
- The citizen should ensure that they have the right leaders in position that would be able to listen to the plight of the people by engaging in accountable leadership to serve the country rather than serving themselves.
- Government should support in allowing manufacturers to be able to supply other Africa countries through the ACFTA (Africa Continental Free Trade Agreement).