

ENHANCING LOCAL PRODUCTION OF MEDICINES AND VACCINES IN NIGERIA

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BY THE



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List of Abbreviations

AFCFTA	African Continental Free Trade Area
AFDB	African Development Bank
AIDS	Acquired Immunodeficiency Syndrome
AMC	Advanced Market Commitments
AMG	Advanced
APIs	Active Pharmaceutical Ingredients
AVAREF	African Vaccine Regulatory Forum
BVNL	Biovaccine Nigeria Limited
COVID-19	Coronavirus Disease 2019
CBN	Central Bank of Nigeria
ECOWAS	Economic Community of West African States
GDP	Gross Domestic Product
GMP	Good manufacturing practices
NDP	National Drug Policy
NAFDAC	National Food and Drug Administration and Control
mRNA	Messenger RNA (Ribonucleic Acid)
MDAs	Ministries, Departments and Agencies
NHIS	National Health Insurance Scheme
NRAs	National Regulatory Agencies
SWOT	Strength Weakness Opportunities and Threats
PMG-MAN	Pharmaceuticals Manufacturers Group of Manufacturers of Nigeria
FIRS	Federal Inland Revenue Service
SHIAs	State Health Insurance Agencies
PAVM	Partnership for African Vaccine Manufacturing
PQS	Pharmaceutical Quality System
UNIDO	United Nations Industrial Development Organisation
USAID	The United States Agency for International Development
VAT	Value added tax
WHO	World Health Organisation

Executive Summary

This white paper examines the feasibility of domestic manufacturing of medicines and vaccines in Nigeria, summarising major constraints and enablers with some key recommendations for the government and stakeholders which will push Nigeria closer towards pharmaceutical self-sufficiency.

The COVID-19 pandemic brought growing consensus that for a developing nation like Nigeria, with approximately 70% of locally consumed medicines and vaccines imported into the country, to reach pharmaceutical self-sufficiency, domestic production is imperative. The Nigerian Economic Summit Group (NESG), as a dialogue partner with a keen interest in the health sector, convened a panel of experts at the 27th Nigerian Economic Pre-Summit event, held on the 29th of September 2021, on Enhancing Local Production of Medicines and Vaccines in Nigeria to closely examine the pharmaceutical industry in Nigeria with the aim of discussing key bottlenecks to local manufacturing and the support required from the government, development partners, and other stakeholders; setting goals for local pharmaceutical production—short term and long term; and articulating an action plan to guide agenda setting for domestic manufacturing of medicines and vaccines.

The panel discussion was facilitated by Dr. Nkata Chuku, Facilitator, NESG Health Policy Commission. It was composed of key stakeholders in the pharmaceutical sector, including Dr. Fidelis Ayebae, Chairman, Pharmaceuticals Manufacturers Group of Manufacturers of Nigeria (PMG-MAN); Mr. Samuel Ohuabunwa – President, Pharmaceutical Society of Nigeria (PSN); Dr. Abdu Mukhtar - Director of the Industrial and Trade Development Department, African Development Bank (AfDB); Mr. Mopa Esuga – Chief of Party, USAID Funded Promoting Quality of Vaccines Plus; and Mr. Patrick Ajah – MD/CEO, May & Baker (BioVaccines Ltd).

Nigeria has a large domestic market for medicines and vaccines, with regional integration bringing greater opportunities for the growth of the pharmaceutical sector. With a pharmaceutical manufacturing sector that has experienced steady growth, valued at about \$607 million in 2017 and an optimistic case for growth as high as \$3.6 billion by 2026, opportunities abound for significant expansion. However, there are key challenges facing the Nigerian pharmaceutical sector, including a poor infrastructural base, a technical skill gap, high cost of production, poor funding sources and a dysfunctional supply chain marred by corruption, which needs to be addressed for the nation to take advantage of existing opportunities.

The experts identified several key considerations that must be taken into account in order to accelerate domestic production. These include: improving the existing pharmaceutical production regulatory framework to catalyse manufacturing; improving the competitiveness of locally manufactured drugs and accelerating registration and prequalification; promoting a sustainable demand and supply system and government patronage for locally manufactured vaccines; and streamlining overlapping policies to ensure coordination across agencies. Other policy imperatives identified were: domesticating regional treaties and enhancing peer review, involvement of stakeholders to drive partnerships and technology transfer, and creating more effective and diverse funding sources.

In the case of manufacturing vaccines, there are multiple hurdles Nigeria needs to overcome in order to be prepared for local manufacturing. Before graduating to “form to finish” manufacturing, Nigeria could pursue a “backward integration” strategy through partnerships with multinationals in the sector which involve “filling and packaging” vaccine vials as an incremental path to production. This strategy creates an opportunity for the nation to engage in the COVID-19 vaccine manufacturing value chain similar to other countries such as South Africa and Morocco.

1. Introduction

Given its large market size, Nigeria has the potential to become a major player in the manufacturing and supply chain for pharmaceutical products in Africa. However, Nigeria still relies heavily on foreign supply of medicines and vaccines, with imports accounting for 70% of local drug consumption. Nigeria also imports most of the active pharmaceutical ingredients needed for local production (Fatokun, 2020).

Nigeria's high disease burden and mortality rates (see Tables 1 and 2) and the preponderance of falsified and sub-standard, often imported, drugs in the market indicate that more medical services and products will be needed to achieve better outcomes, thus making it more pertinent for the country to boost its capacity in manufacturing pharmaceuticals, vaccines and the other health product that it needs. The Nigerian government has committed to support local manufacturing of vaccines. Given the country's current limited involvement in the value chain for vaccine production, a considerable amount of planning and investments will be required to get the production of vaccines off the ground. Therefore, it is critical that while pushing for the local manufacturing of vaccines, the existing opportunities for significantly boosting the manufacturing of pharmaceuticals are recognised and leveraged to become self-sufficient in the provision of essential medicines.

COVID-19 has further revealed inherent weaknesses in Nigeria's health system. It has brought to the fore the dangers of relying on imports for most of the health products consumed in the country and the raw materials needed to produce them. Awucha et al. (2020) assert that at the height of the pandemic, the stock of medicines for chronically ill patients and some non-communicable diseases dropped to unacceptably low levels as most channels for importation experienced severe bottlenecks.

On the upside, the pandemic has also stimulated dialogue and action towards revitalising local manufacturing of medicines and vaccines and strengthening the sector's policy and regulatory framework. For instance, Nigeria has been exploring the feasibility of manufacturing COVID-19 vaccines locally, and the country was recently selected as one of six African countries that will receive the technology needed to produce mRNA vaccines. . The Federal government has also recently introduced a national vaccine policy, in addition to updating its national drug policy. The sector welcomed the Central Bank of Nigeria's (CBN's) N100 billion Health Sector Intervention Facility for COVID-19. The Pharmaceutical Society of Nigeria (PSN) reported that its members accessed over 90% of the intervention facility for expanding their businesses. However, much more is still required to achieve self-sufficiency in the manufacture of pharmaceuticals.

Nigeria needs to move quickly and take critical steps in enhancing local production to match and possibly outpace other African countries that are currently boosting the capacity of their pharmaceutical sector. By moving quickly and deliberately, Nigeria has the opportunity

¹See Bloomberg (2021). Nigeria Seeks \$30 Million for 1st Vaccine Plant in 30 Years
Available at: <https://www.bloomberg.com/news/articles/2021-08-19/nigeria-plans-vaccine-plant-30-years-after-closing-only-factory>

²Estimated based on data from McKinsey (2017). Winning in Nigeria: Pharma's next frontier

to become a major player in vaccine and medicine production, given its large local market and additional opportunities within the region. However, this will require the Nigerian government to proactively create an enabling environment, including support for meeting international standards and advanced market commitments (AMC) for medical products manufactured locally. This should include capacity development in local and international regulatory compliance, access to finance and foreign exchange and linkage with partners.

In addition to strengthening the health sector and improving service delivery and health outcomes, local manufacturing of pharmaceuticals will have significant economic benefits such as boosting job creation and contributing to GDP growth. The African Pharmaceutical market was estimated at \$20.7 billion in 2017, with imports accounting for 70%. This shows a significant opportunity for potentially growing Nigeria's export market in pharmaceuticals across the continent. Strengthening local production will also boost job creation and contribute to the government's job creation goals.

Section 2 examines the Nigerian pharmaceutical sector and its current performance. Section 3 presents an analysis of the strengths, weaknesses, opportunities and threats experienced by the sector. Section 4 examines structures and institutions which are needed to support the development of the sector. Section 5 provides expert recommendations for strengthening the sector and domestic capacity in pharmaceutical production. Section 6 concludes.



Table 1: Key Health Indices for Nigeria

Indices	Status
Maternal Mortality Rate	512 deaths/100,000 live births (2018 est.)
Infant Mortality Rate	67 deaths/1,000 live births (2018 est.)
Life Expectancy at birth	60.87 years (2021 est.)
Health Expenditure (% of GDP)	3.9% (2018)

Source: Nigeria Demographic Health Study, 2018; CIA world factbook

Table 2: Top 10 causes of most deaths in Nigeria

Cause of death	2009 ranking	2019 ranking	Percentage change 2009 – 2019 (%)
1	Malaria	Neonatal disorders	-0.9
2	Diarrhoeal diseases	Malaria	-30.9
3	Lower respiratory tract infections	Diarrhoeal diseases	-25.7
4	Neonatal disorders	Lower respiratory tract infections	-13.2
5	HIV/AIDS	HIV/AIDS	-8.4
6	Meningitis	Ischaemic heart disease	24.7
7	Ischaemic heart disease	Stroke	17.0
8	Stroke	Congenital defects	-1.4
9	Congenital defects	Tuberculosis	-11.5
10	Tuberculosis	Meningitis	-24.3

Top 10 causes of total number of deaths in 2019 and percent change 2009–2019, all ages combined

Source: Institute for Health Metric and Evaluation (IHME)

2. Nigerian Pharmaceuticals: Market Diagnostic and Local Production Situation Analysis

The COVID-19 pandemic further exposed the risk Nigeria faces by being “pharma-dependent” – dependent on foreign supply for pharmaceuticals. Out-of-pocket expenditure accounted for 76.6% of total health expenditure, according to National Health Account (2018). The risk faced by Nigeria is particularly high due to its dependence on imports for finished formulations and pharmaceutical inputs.

Nigeria’s health indices are currently ranked among one of the lowest globally, with all six pillars of the health system (service delivery, health workforce, health information systems, access to essential medicines, financing, and governance) being weak. In the context of this document, the access to essential medicines pillar is the area of focus. To emphasise its importance, one of the targets of the Sustainable Development Goals (Goal 3 Target 3.B) is directly linked to this. The goal is to: “Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.”

Nigeria has a National Drug Policy, developed in 1990 and revised in 2005 and 2021, with a goal “to make available at all times to the Nigerian populace adequate supplies of drugs that are efficacious, affordable, safe, and of good quality”, with overarching objectives that include ensuring the rational use of such drugs and stimulating local production of drugs and pharmaceutical raw materials through favourable policies and advocacy. In 2021, Nigeria launched its first national vaccine policy, the Nigeria Vaccine Policy, aimed at achieving vaccine availability and self-sufficiency through local vaccine production and ownership of vaccine supply chain management in the country.

The goals of the national drug policy, like those of many other health-related policies, have not been fully realised. It is critically important to examine the current state of the pharmaceutical sector in order to map out effective strategies that will enable the growth of the sector and consistency in access to essential medicines and vaccines. This underscores the need for this White paper. This section will highlight the major features of the pharmaceutical sector in Nigeria.

Nigeria has a sizeable local pharmaceutical industry, estimated at about \$607 million in 2017, with an optimistic case for growth to as high as \$3.6 billion in 2026 (Pharmexcil, 2017; McKinsey, 2017), but nearly 70% of medical products in the market are imported, according to NAFDAC, providing stiff competition for the scant local production and increasing the prevalence of substandard and falsified medical products in the country.

Table 3: Import Dependence of Nigeria Drug Market

DRUGS PRODUCTS REGISTERED BY NAFDAC			
	2012	2013	2014
Imported	2,082	2,336	2,768
Local	523	570	557
Total	2,605	2,906	3,325

Source: NBS Summary Report of Food and Drug Administration and Control in Nigeria 2012-2014

Nigerian pharmaceutical manufacturers produce a range of products, including liquid preparations, tablets, capsules, ointments, lotions, creams and ophthalmic preparations. The installed capacity for these product classes is provided in Table 4 below. A breakdown of the sector reveals the industry is mostly dominated by over-the-counter medicines at 43.1% and the generic sector at 38.9%, while patented medicine stands at 12% (Pharmexcil, 2017).

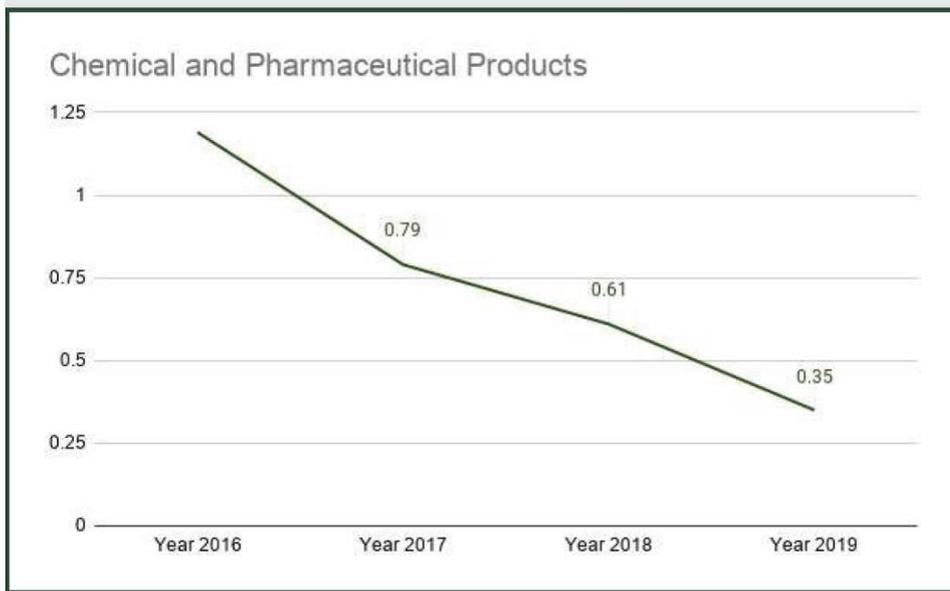
Table 4: Installed capacity of Nigerian Pharma manufacturers, 2010

<i>Products</i>	<i>Installed capacity/year</i>
1 Analgesics	
Tablets	40 billion
Syrup/suspension	70 million litres
Ointments/Balms	700 million tubes
2 Antimalarials	
Tablets	8 billion
Capsules	5 billion
Syrups	50 million litres
3 Antibiotics	
Tablets	20 billion
Capsules	20 billion
Syrups	40 million litres
4 Antiretrovirals	
Tablets	20 billion
Syrups	30 million litres
5 Vitamins	
Tablets	50 billion
Capsules	40 billion
Syrups	80 million litres
6 Antitussive syrups	45 million litres
7 Infusions	500 million litres
8 Antacids	
Tablets	30 billion
Syrups	50 million litres
9 Antiseptics / Disinfectants	60 million litres
10 Injectables	400 million vials

Source: UNIDO Pharmaceutical Sector Profile Nigeria, 2011

There are currently over 130 registered pharmaceutical manufacturers in Nigeria. However, the proportion of those actively involved in manufacturing continues to dwindle. In 2008 the total revenue of the top 20 pharma manufacturers in Nigeria was estimated at \$505M. However, many of these manufacturers have since exited the pharmaceutical manufacturing space in Nigeria. Evidence also suggests declining growth in the sector, as shown in Figure 1 below. The chemical and pharmaceutical products sub-sector growth rate in 2017 was 0.79% and declined to 0.61% and 0.35% in 2018 and 2019, respectively.

Figure 1: Growth of chemical and pharmaceutical products



Source: NBS Nigerian Gross Domestic Product Report – Q4 2019

A major challenge in the pharmaceutical manufacturing sector is reliance on the importation of most of the inputs required for production. Currently, all active pharmaceutical ingredients (APIs) required by the local industry are imported. In August 2021, Emzor pharmaceuticals recently announced its intent to commence the production of APIs for antimalarial, ushering in the long journey to the critical backward integration required by the sector. As with APIs, the local industry is largely reliant on imported excipients. Siyanbola et al. (2012) noted that only 25% of excipients are produced domestically, in addition to most primary and secondary packaging materials.

The reliance on imported inputs results in a substantial, often unmet, demand for foreign exchange to procure those inputs; delays occasioned by transport, customs, and NAFDAC regulatory formalities; high susceptibility to global supply chain shocks, such as occurred with the COVID-19 pandemic and an inability to compete with imported, finished products on price terms given the continuous devaluation of the local currency.

3. SWOT Analysis

Figure 2 shows a summary of the Strength, Weakness, Opportunities and Threats (SWOT) analysis of the sector.

Weaknesses and Threats

The Nigerian pharmaceutical manufacturing sector faces several challenges, including low-capacity utilisation, a weak financial base, a high cost of production, corruption across the value chain, and difficulty in meeting World Health Organization (WHO) prequalification criteria (UNIDO, 2011). These issues have stifled the development of the sector. Limited access to finance has hindered the ability of the pharmaceutical sector to scale up production and take advantage of existing opportunities, such as the large African market. This has brought about a vicious cycle of restricted access to finance and limited ability to scale up production.

Although there are over 120 pharmaceutical manufacturers operating in Nigeria, only four manufacturers have obtained the WHO Good Manufacturing Practices (GMP) certification, according to PMG-MAN (2021), constraining the ability of manufacturers to participate in international tenders and the export market. Like other manufacturing sectors in the country, pharma manufacturers self-supply utilities such as power using industrial generators and industrial boreholes for water supply. These utilities accounted for as high as 40% of the overall production cost. However, some of the major challenges in the pharmaceutical sector are discussed in more detail below.

Lack of policy consistency and coherence

There is an absence of policy clarity in ensuring the sustainability of local pharmaceutical manufacturing. Experts also hold that there has been a long-standing challenge of the absence of cohesive and targeted policies across the different regulators of the pharmaceutical manufacturing industry. This has led to implementation inconsistencies which derail the National Drug Policy's (NDP's) strategic intent to boost local production of pharmaceuticals. For example, the Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMGMAN) recently decried the tax regime by the Federal Inland Revenue Service (FIRS), where VAT is paid on pharmaceutical raw materials. In contrast, no VAT is levied on finished products, rendering the achievement of the NDP's objectives implausible.

Given the multiplicity of regulators and government stakeholders involved in the pharmaceutical manufacturing value chain, a targeted policy regime orchestrated by the highest levels of government is required to ensure coherence and implementation across relevant MDAs.

Additionally, there appears to be weak regulatory strength to ensure the implementation of regulatory policies. NAFDAC's import prohibition list outlines pharmaceutical products manufactured locally which are banned from importation into Nigeria and attempts to confer some protection for local manufacturers. Regardless, there are several instances where these banned and imported products are brought into the country and displayed side by side with locally manufactured drugs.

In order to attract investment into the sector, it is essential that the business environment minimises investment risk. The high cost of setting simple line production - at about N5 billion and complex manufacturing such as infusion at well over N10 billion, takes deliberate policy framing, which does not serve political interests to guarantee sustainability and security of investments to attract investors into the pharmaceutical sector.

A dysfunctional supply chain and logistics

There are numerous unregulated players in Nigeria's supply chain and logistics sector, which indicates the presence of inadequate monitoring of this market segment. In the same vein, although Nigeria has a large in-country market, it has yet to integrate sufficiently for regional export. In addition, the pharmaceutical distribution and supply policy direction provided in the National Drug Distribution Guideline is not fully operational. When operationalised, the policy seeks to improve the distribution and supply of health products and the roles and responsibilities of stakeholders.

High cost of production and inability to compete in the international market

The local manufacturing industry in Nigeria is unable to compete globally. According to a study by the AfDB, the cost per unit of production for pharmaceutical manufacturers in Africa is 60% higher than in countries such as India and China. The COVID-19 shock awakened the country to revive manufacturing, as indicated by the CBN Health Sector Intervention Fund. Although a welcome development, the additional challenge of foreign exchange scarcity meant that manufacturers were still faced with significant barriers to accessing raw materials and machinery.

Similarly, bureaucratic bottlenecks in customs formalities during importation have been known to delay the commencement of production, increasing overall costs for manufacturers. This contributes to Nigeria's low cost-competitiveness compared with global manufacturers in China and India.

Inability to secure guaranteed offtake of products

Vaccines are mainly procured by governments and multi-lateral agencies with close to zero private markets. Therefore, prospective manufacturers will need government guarantees on the procurement of their products to find production lucrative. Similarly, the inability of manufacturers to secure guaranteed offtake of commodities for public health programmes in HIV, Malaria and Tuberculosis from government and development partners also constitute a disincentive to production.

Poverty and substandard medicines

There is growing poverty in Nigeria with its cascading consequences on crime and the proliferation of an informal medicine market characterised by substandard and cheaper products. The low cost of substandard products makes them more accessible to poor Nigerians. This, in turn, weakens the competitiveness of genuine products in the formal market.

The National Health Insurance Scheme (NHIS) was launched in 2004. In furtherance of its goal to facilitate financial access to quality healthcare for all Nigerians, it recently devolved some of its responsibilities to newly established state health insurance agencies (SHIAs). The NHIS and SHIAs are mostly funded through enrollee contributions and given the informal nature of the country's economy, have achieved very low coverage levels (estimated at less than 10% of the population). The poor health insurance coverage in the country further exacerbates the low demand for good quality pharmaceuticals.

To turn the tide, there is a dire need for a robust social protection system towards incremental poverty reduction, improving the security of lives and property, and strengthening pharmaceutical price control policies to keep prices affordable.

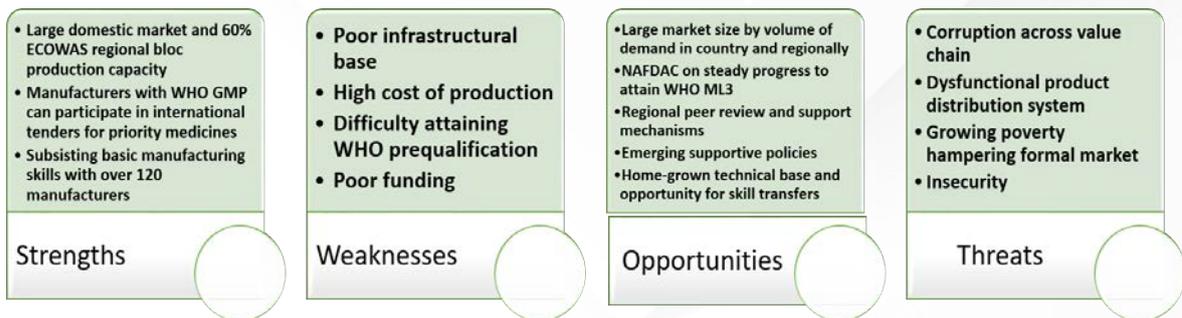
Strengths and Opportunities

Nigeria is well-positioned to engage in the value chain for medicines and vaccine manufacturing. In addition, with high vaccine demand in Africa and domestically, Nigeria can become a major player in the value chain. There are several existing strengths and opportunities which can be harnessed to improve sectoral performance, as enumerated below:

- Although more effort needs to be directed at policy implementation, political commitment towards attaining local drug and vaccine production sufficiency is growing;
- The government's NHIS has provided a potentially sustainable financing option for healthcare. However, coverage is still very low. Strengthening coverage presents an opportunity to improve access to healthcare and expand the market for health technologies;
- A huge potential market considering Nigeria's population and, by extension, the African market through the framework of the African Continental Free Trade Area (AfCFTA);
- Availability of highly qualified indigenes, professionals, research experts and professionals in existing pharmaceutical companies;
- Existing partnerships with development institutions to anchor on such as the Promoting the Quality of Medicines Plus (PQM+) Program. This program has supported the increased supply of locally manufactured quality-assured medical products for maternal, newborn, and child health and malaria. It has also supported several local pharmaceutical manufacturing companies in achieving WHO prequalification status. .
- The signing of a Memorandum of Understanding (MoU) on the 5th of November, 2020, between the Federal Government and Biovaccine Nigeria Limited (BVNL). This led to a joint venture for the local production of vaccines between the Federal Government and May & Baker Nigeria Limited (FMoH, 2020).
- The AfDB is proposing pharmaceutical hubs across the regions of Africa. According to the Bank, Nigeria has the potential to become a hub for the West African region if it moves quickly to solidify its position in the region as a major producer of pharmaceutical products. The AfDB is planning to contribute \$3 billion to support this initiative.

- A huge potential vaccine market exists in Nigeria, estimated at about \$208 and \$175–220 million locally and within the ECOWAS bloc, respectively. Similarly, the local market for routine and supplemental immunisation vaccines between 2018 and 2028 is projected at \$2.7 billion.

Figure 2: Production drivers SWOT analysis



As the pharmaceutical sector makes strides in overcoming some of the existing challenges it faces, leveraging on its strengths and taking advantage of the significant market opportunities, the sector can experience considerable growth in the short to medium term. By increasing the production of competitively priced quality medicines and vaccines, Nigeria will be well-placed to broaden its export base and expand its foreign exchange earnings. A growing pharmaceutical sector will support job creation, economic growth and economic stability. The next section examines issues facing the sector in more detail and identifies strategies for promoting its development.

³PQM+ is a U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention (USP) to sustainably strengthen medical product quality assurance systems in low- and middle-income countries (LMICs).

4. Promoting Local Manufacturing

The following key elements are critical in facilitating the local production of pharmaceuticals and in the expansion of the sector.

1. **Agenda setting and national coordination framework:** To bolster medicines and vaccines production in Nigeria, there is a need for strategic agenda setting, coordination and political will around the manufacture of pharmaceuticals. A National Co-ordination and Advisory Framework would enable centralised coordination and provide a clear and coherent methodology for coordinating national resource mobilisation for local production of medicines and vaccines. AstraZeneca vaccines, produced in India, made an integral part of vaccine rollout in sub-Saharan Africa. India's feat can be traced to the strategic agenda and policy direction contained in India's National Vaccine Policy. Adopting such a framework would enhance the robustness of the National Drug Policy and contribute to achieving policy objectives.

The national coordination framework will need to identify and lay down a plan for engaging with stakeholders, the Ministries, Departments and Agencies (MDAs), i.e., the Ministry of Finance, Ministry of Trade and Investment, Nigerian Customs Service etc., required to facilitate effective implementation of the national agenda. Given the high profile and criticality of the roles of these agencies, a presidential mandate might be required to convene them towards coordinating policy setting, planning and implementation.

As Nigeria strategises on the pathway towards a pharmaceutical manufacturing revolution, it is best to focus on a core set of medicines and avoid the pitfall of employing scarce resources in different directions in a manner that impedes scale. For example, the agenda might prioritise the production of pharmaceuticals that target diseases or conditions that constitute a major mortality/morbidity burden in the country and which promote health security.

While production is underway, demand and supply strategies such as the creation of awareness to reduce vaccine hesitancy, guaranteed offtake agreements with vaccine manufacturers, coordinated government procurement (across federal and state governments), and supporting vaccine procurement by non-governmental organisations need to be put in place to ensure that the vaccines and medicines being produced have a favourable market to thrive in.

2. **Financing (Resource Mobilisation):** Local vaccine production in Nigeria will require effective public-private blended financing to address financing barriers. Innovative financing strategies are required to expand the resource envelope beyond government grants. Local manufacturers should benefit from expanded funding sources such as for-profit investor funding and development grants.

Pharmaceutical companies with a strong competitive position and/or credit rating stand a good chance of raising the required funds for expansion through issuing financial instruments. Emzor pharmaceutical, for example, successfully raised an initial issue of N15 billion in Series 1 Senior Unsecured Bond Issuance from its 50 billion Bond Issuance Programme . However, smaller industry players may not have the capacity to raise the required funds. This segment can benefit from blended finance with government and infrastructure guarantees, respectively.

Tax waivers and relief mechanisms and demand-side assurance through Advanced Market Guarantees (AMC) may attract local and international investors to tap into pharmaceutical manufacturing and the vaccine production value chain, given the large Nigerian and regional market.

- 3. Enhancing regulatory capacity and production quality:** National regulatory agencies (NRAs) such as NAFDAC in Nigeria are the gatekeepers for the medical products supply chain with a mandate to oversee the quality, safety, and efficacy of vaccines. NAFDAC's recently published report placed the agency at WHO's maturity level 2. To secure WHO prequalification for vaccine licensure, an NRA has to attain level 3 maturity.

Regional peer review mechanisms can propel the capacity development of NRAs. In 2006, the WHO created the African Vaccine Regulatory Forum (AVAREF) - an informal capacity-building platform aimed at improving the regulatory oversight of interventional clinical trials being conducted in Africa. To this end, Nigeria ought to harness regional frameworks such as the AVAREF.

Producing pharmaceutical products which meet the standards of foreign regulatory agencies such as the Food and Drug Agency in the United States and the European Medicines Agency in the European Union would enhance the profile of the pharmaceutical sector and promote the export of locally produced pharmaceuticals. This is particularly important given the opportunity of a converged African market provided by the AfCFTA.

- 4. Technical skills:** There are obvious challenges to vaccine manufacturing in Nigeria. Probably most important is the lack of technical expertise at the three levels of vaccine production - upstream, downstream and fill and finish. Skills transfer and collaborations between multinationals and local manufacturers will be essential in improving production capabilities. Regulatory expertise will also be required to secure vaccine production approval. The expertise of Nigerians in the diaspora can be utilised for upskilling and training home-grown human resource to drive the vaccine production industry.

The USAID PQM+ program has supported improvements in the quality of locally produced medicines by providing technical assistance and supporting

⁴See GCR (2020). GCR Accords an Indicative Rating to Emzor Pharma Funding SPV PLC's Series 1 Bonds. Available at: <https://gcratings.com/announcements/gcr-accords-an-indicative-rating-to-emzor-pharma-funding-spv-plcs-series-1-bonds/?print=pdf>

regulatory improvement. There needs to be a commitment to adhering to global standards to ensure that the quality of pharmaceutical products is maintained. Medicine manufacturers have also been given technical support in the adoption of GMP through the USAID PQM+ program. The government can support the rollout of such technical assistance to promote the development of the sector.



5. Recommendations

5.1 General Recommendations

- **The Federal Government should actively patronise local vaccines and provide an enabling environment for local medicine production:** For local manufacturers to make the significant investments needed for production and expansion of operations, there needs to be an assurance of sustained demand for their products. There is a need for government procurement of vaccines. For other pharmaceutical products, the government needs to provide an enabling environment through coherent policy statements across MDAs, consistent, multi-sectoral policy execution, possible tax breaks and incentives, and the utilisation of special economic zones.

At present, the rollout of the NHIS is very low. It presently only covers 3% of the population. In addition, only 5% of the Nigerian population have pre-paid health insurance coverage (Okpani & Abimbola, 2015). Further rollout of the national health service programme will support demand for health products. Expanding the enrolment of Nigerians beyond the formal sector will significantly reduce the financial barrier to accessing health care.

- **Infrastructural development:** One of the main problems facing the local manufacturing industry in Nigeria is the lack of quality infrastructure, which has amplified the industry's production costs. Due to high manufacturing costs, finished products manufactured locally are often unable to compete in price with imported products, where manufacturers benefit from infrastructural availability and significant economies of scale. The industry is not cost-effective, making China and India dominate the African market with their cheap products. Therefore, all stakeholders must be engaged in developing quality infrastructure that will make the industry cost-competitive.
- **Strengthen the existing pharmaceutical production regulatory framework to increase manufacturing competitiveness and accelerate registration, prequalification, and production:** Strategic implementation frameworks for the 2021 National Drug Policy and Nigeria Vaccine Policy hinge on strong political will, coordinated national oversight, and capabilities for peer review and sustainability. Institutional capacity building and executive orders for ease of registration processes with regulatory agencies and reduced formalities with customs can promote the efficiency of the sector. Improving the ease of registration and reducing bureaucracy will lower delays, support production and the expansion of operations.

There are numerous unregulated players in the supply chain and logistics sector, which calls for increased guidance and monitoring. In addition, given the high technicality in the manufacturing of pharmaceutical products, there is a great need for capacity and logistical support for stakeholders across the supply value chain that ensures proper monitoring for adherence to quality and good manufacturing practices.

- **Streamline overlapping policies to ensure coordination across tiers of government and agencies:** There is a need to recognise the link between ease of doing business and policy stability and coordination among agencies. As experts have stated, to promote domestic pharmaceutical manufacturing, all government agencies should be supportive of manufacturing efforts while avoiding unnecessary bureaucracies. The government has a role to play in coordinating the different departments, ministries and agencies, such as the Nigerian Customs Service, Federal Ministry of Health and the Federal Ministry of Finance, to ensure cohesion in their activities.
- **Domesticate regional instruments and enhance peer review to increase production and promote export:** Nigeria should fast-track the domestication of regional instruments such as the Partnership for African Vaccine Manufacturing (PAVM). Similarly, developing and deploying regional peer review mechanisms for research and development will build the capacities of regulatory agencies and support the international competitiveness of local manufacturers.
- **Involvement of stakeholders to drive partnerships, improve the data ecosystem, and transfer technology:** Broad stakeholder participation is required to enable a holistic private sector drive for partnership between international and local manufacturers, with the government keeping close oversight and leading the collection and dissemination of reliable public health and market data.

Experts assert that partnerships and collaboration between local and foreign manufacturers are essential in bridging the skills gap in local production and bringing the desired technology transfer. In addition, collaborations between multinationals and local manufacturers will accelerate the adoption of global best practices and readiness for the export market.

The policy thrust should support these efforts by providing for market access, market-shaping, and incentives for technology transfer from multinational companies. Also, there should be a favourable regulatory environment to attract these multinationals, which would support local capacity building in vaccine manufacturing.

- **Develop more effective and diverse funding sources to spur local and international investment:** In order for Nigeria to leapfrog onto the global map of pharmaceutical manufacturers, it is necessary to expand funding sources available to local manufacturers, as well as improve financial regulations which ensure funding is appropriately utilised, supports transparency and addresses corruption across the value chain to attract international investment.

Experts at the 2021 Nigerian Economic Pre-Summit held that the first tranche of CBN's COVID-19 pharmaceutical funding was not sufficient to address the many

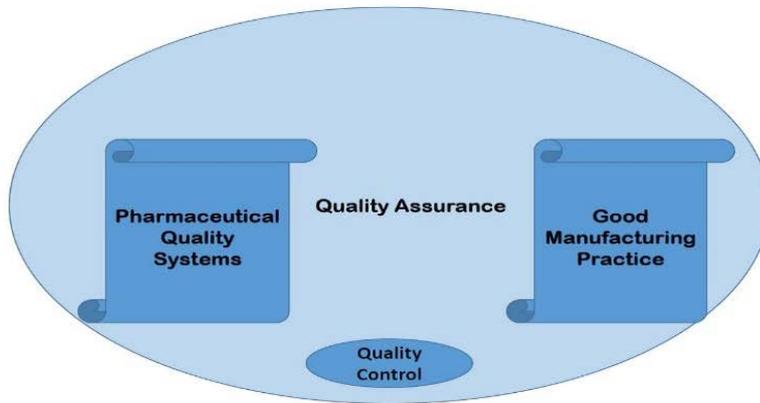
challenges plaguing the sector and called for more investment in keeping with the desired goal of making Nigeria pharmaceutical self-sufficient. There is a major funding gap for infrastructure and developing APIs, which can be filled by Development Finance Institutions such as the AfDB, African Finance Corporation and Afrexim.

- **Enhance continuous capacity strengthening for manufacturers and regulatory agencies:** Design, develop and deploy a continuous capacity-building framework for manufacturers and regulatory agencies in line with global best practices and international regulations such as the WHO's maturity level and GMP. NAFDAC needs to attain level 3 of global benchmarking tools in order to engage in vaccine production and facilitate the export of our pharmaceutical products.
- **Monitoring and Evaluation (M&E):** M&E in the pharmaceutical manufacturing sector comes with a cascade of quality improvement processes with Quality Assurance (QA) as the guiding principle that covers all aspects that might impact the quality of finished pharmaceutical products (WHO, 2006). QA is established through synergistic best practice approaches, including Pharmaceutical Quality Systems (PQS), Good Manufacturing Practice (GMP), and Quality Control (QC) (see Figure 3). Therefore, in order to maintain credibility in locally manufactured pharmaceutical products, the government and stakeholders must put in place a continuous monitoring and evaluation mechanism that adheres to the aforementioned best practices.

Quality assurance seeks to ensure prescribed pharmaceutical products meet the desired effect on end-users, protect the client from accidental administration of incorrect or contaminated medication, and ensure all products conform to regulations. In an attempt to maximise profit while maintaining quality standards, pharmaceutical manufacturers rely on PQS, which comprises eight pillars designed to provide high-quality finished pharmaceutical products (Petropoulou, 2018).

GMP ensures consistent pharmaceutical product control and quality standards in conformity with their intended use in keeping with product specification and authorisation (WHO, 2016). To this end, GMP ensures products meet the safety, quality, and efficacy needs of end-users. Thus, GMP is essential in all stages of the manufacturing process.

Figure 3: Synergy of QA with PQS, and GMP and QC



5.2 Feasible approach to vaccines production

Vaccine manufacturing is a complex process, and it requires varied resources at each stage of production. Figure 4 summarises the stages of the vaccine production value chain. The backwards integration model appears to be the most realistic approach to get on board the value chain of vaccine manufacturing due to the complexity involved. Experts in the field have supported this approach. It has also been adopted by other African countries which have developed capacity in this area.

Based on available resources and comparative advantage, stakeholders can deliberate on what particular phase Nigeria can begin with. Nigeria could start with packaging purchased products. The next stage in the vaccine value chain which can be incorporated is the filling and packaging of purchased products. South Africa started this phase with the COVID-19 vaccine before incorporating the more advanced process of form and filling.

Figure 4: A backward integration strategy to place Nigeria on the global vaccines production map



6. Conclusion

With its domestic expertise in the production of medicines, its large market, and access to the ECOWAS region, Nigeria has the potential to become a major manufacturer and exporter of medicines and vaccines. However, it needs to move quickly and take critical steps in enhancing local production in order to match the pace of other African countries currently increasing the capacity of their pharmaceutical sector. On the vaccine production front, Nigeria runs the high risk of being left behind as other African countries such as South Africa, Egypt and Senegal are taking the lead in the vaccine supply chain.

Efforts in promoting the development of the pharmaceutical sector, which the COVID-19 pandemic has spurred, need to be sustained for Nigeria to achieve self-sufficiency and sustainability. The government has a major role in supporting the sector by creating an enabling environment. The success of government policy in improving the procurement of local pharmaceutical products requires that local manufacturers are cost-competitive. This requires an enabling environment which facilitates the production and expansion of operations. Experts believe that local manufacturing is the only antidote to defeating the proliferation of substandard pharmaceutical products in the Nigerian market. However, the success of efforts to improve domestic demand for locally produced pharmaceuticals relies on the availability of competitively priced medicines.

The government also has a role to play in coordinating the different departments, ministries, and agencies relevant to the sector's performance. Expanding the coverage of the NHIS will support the development of the pharmaceutical sector. There also needs to be a clear commitment to procuring locally manufactured vaccines which supports the viability of investing in the sector.

Due to the significant capital outlay involved in the production of vaccines coupled with the low investment in health care in Nigeria, foreign investment is necessary for vaccine production to take off in a robust manner. Creating an enabling environment will be a key factor in attracting foreign capital. The government can also facilitate the involvement of foreign partners and international organisations, which will provide support for the adoption of internationally recognised manufacturing practices and regulatory standards.

In Nigeria, access to quality health care is low, contributing to poor health outcomes and low life expectancy. Developing the local pharmaceutical sector is necessary to ensure health security and access to essential medicines for the citizens. The sector is also highly lucrative due to Nigeria's large market, in addition to the potential to become a major regional supplier. This sector can also contribute to the government's export diversification efforts, as well as support economic development through increased investment and job creation. For Nigeria to realise the significant benefits that will ensue from developing the pharmaceutical sector, both demand and supply-side policies need to be consolidated.

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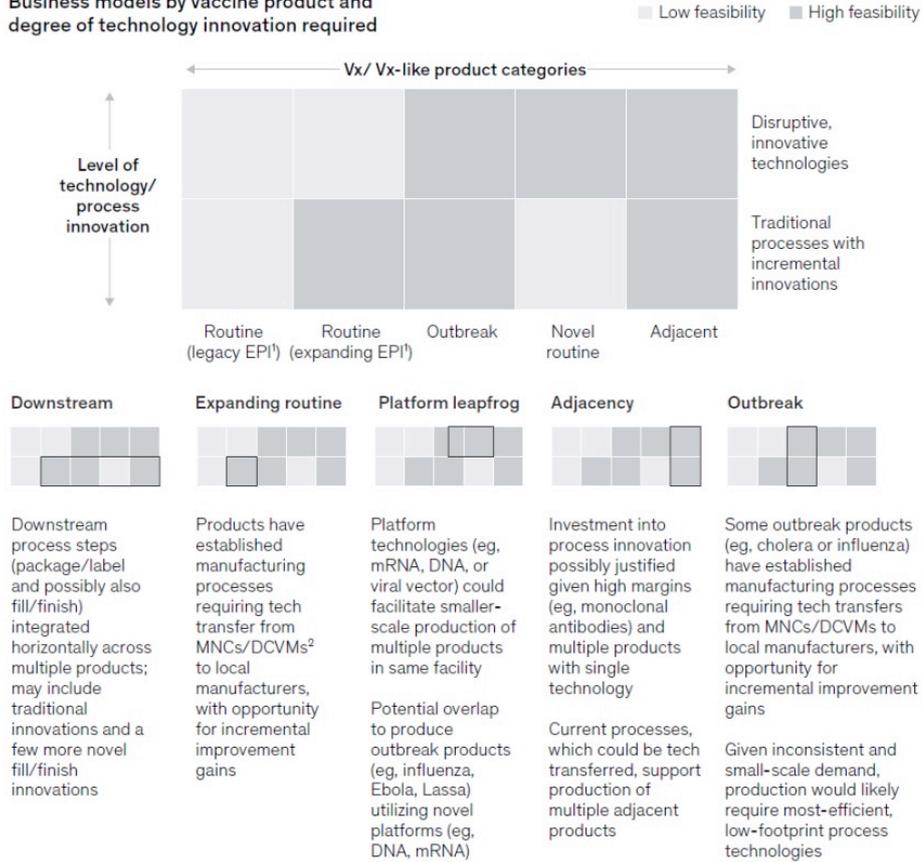
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Appendices

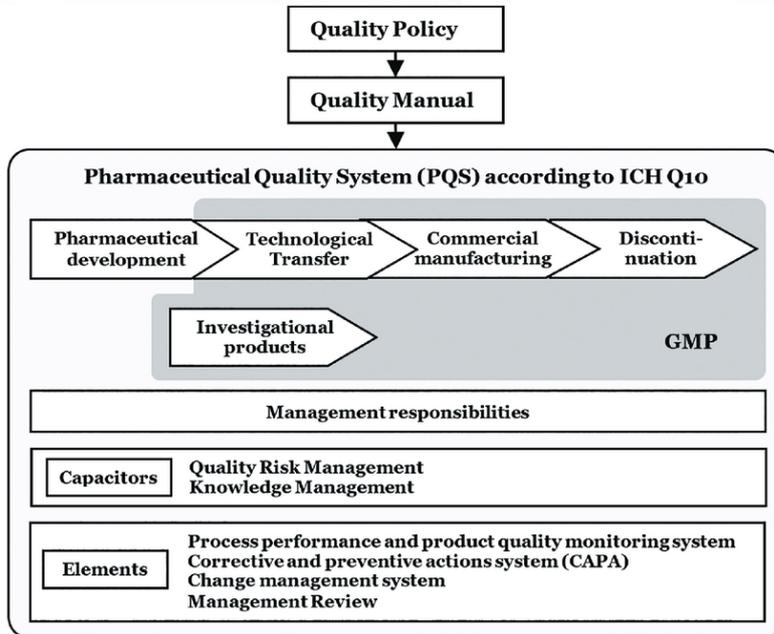
Five models for vaccine manufacturing and distribution may be viable.

Business models by vaccine product and degree of technology innovation required



¹Expanded program on immunization, WHO.
²Multinational companies/developing-country vaccine manufacturers.
 Source: Expert interviews; McKinsey analysis

Source: Mckinsey and Company, 2021



Structure of International Council on Harmonisation Q10 PQS

Adapted from: Botet, Jordi. (2018). Pharmaceutical Projects: Walking along the Risk Management Line

- Establishment of a steering committee and working groups, or other form of governance structure, to provide the necessary direction, monitoring and review of the implementation process
- Ongoing training, support and strengthening (as required) of NAFDAC to further build its capacity to assess and monitor manufacturers with regard to their level of GMP compliance and implementation of their CAPAs
- Development of an approach for re-assessment and re-categorization of FPP manufacturers as they improve from their current manufacturing practices to compliance with WHO GMP. Under the regional GMP roadmap framework a process that includes an element of regional collaboration with regards to re-assessment is envisaged
- Training of manufacturers with regard to WHO GMP requirements
- Development of appropriate, time-limited incentive packages
- Access to affordable finance for manufacturers, especially in the context of GMP compliant construction/modification of manufacturing sites
- Training and provision of new personnel with sufficient GMP-related skills and general industrial pharmacy knowledge, to meet the HR needs of both pharmaceutical manufacturers and relevant supervisory/regulatory bodies
- Promotion of partnerships and knowledge sharing between industrial pharmaceutical Manufacturers

Nigeria Roadmap to GMP proposed by the West African Health Organisation 2019

ABOUT THE NESG

The NESG is an independent, non-partisan, non-sectarian organisation, committed to fostering open and continuous dialogue on Nigeria's economic development. The NESG strives to forge a mutual understanding between leaders of thought so as to explore, discover and support initiatives directed at improving Nigeria's economic policies, institutions, and management.

ABOUT THE HEALTH POLICY COMMISSION

The overarching mandate of the Health Policy Commission (HPC) is to serve as a platform for public-private dialogue to drive reforms that guarantee not only health for all but health by all in the Nigerian health system. This necessitates that resources for health are evenly distributed and that essential health care is accessible to everyone while acknowledging that the attainment of a well-developed and better health sector will involve a shared commitment between the government and its national and international partners. This mandate is subsumed under the goal of attaining a Universal Health Coverage (UCH), which is one of the Sustainable Development Goals by the year 2030.

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