A case study on the ecosystem for local production of pharmaceuticals, vaccines and biologicals

The Nigeria context
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Preface

The Local Production and Assistance (LPA) Unit in the Regulation and Prequalification Department (RPQ), Access to Medicines and Health Products Division (MHP), WHO, supports Member States (MS), particularly low- and middle-income countries (LMICs), to strengthen sustainable local production and technology transfer to improve timely, equitable access to quality, safe and effective essential medical products. The LPA Unit provides assistance and support to MS with an ecosystem-wide and holistic approach, such as fostering global coordination and partnerships, conducting ecosystem assessments for sustainable, quality local production, developing and implementing strategies/roadmaps, providing comprehensive capacity building and technical assistance, including for WHO Prequalification (PQ)/Emergency Use Listing (EUL), facilitating technology transfer (TT) and developing global resources on local production and TT.

A landmark resolution WHA74.6 on strengthening local production of medicines and other health technologies to improve access was adopted in the Seventy-fourth World Health Assembly, signalling globally the important role local production plays in improving access and strengthening health security. Within this mandate, the LPA Unit, developed a series of case studies on the ecosystem for local production of pharmaceuticals, vaccines and biologicals, with a focus on country context in the low- and middle-income countries. These case studies add to the existing repository of resources on strengthening local production and technology transfer of health products for countries to leverage upon when countries embark in these areas. The countries in this series are Bangladesh, Kenya, Nigeria, Pakistan, Senegal and Tunisia.

From July to September 2022, a series of interviews and consultative meetings, including a review of available literature, policies and other documents, and administration of a questionnaire, were performed. This case study is intended to report the collated information in areas such as available policies, initiatives, financing, regulatory system, patent protection system, research and development work, markets and capacity and preparedness to uptake local production of quality-assured pharmaceuticals, vaccines (including mRNA vaccines), and biologicals. The expectations and needs of these countries were also collected and included in the case study, along with proposed recommendations, for the reader to see various viewpoints towards strengthening sustainable local production and achieving universal health coverage and the Sustainable Development Goals.
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Secretary, Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria, Nigeria), Abdullahi Mustapha (Director-General, National Biotechnology Development Agency, Nigeria), Moses Njoku (Senior Research Fellow, Microbiology and Biotechnology Department, National Institute for Pharmaceutical Research and Development, Nigeria), Ijeoma Nwankwo (Director, Drug Evaluation and Research Directorate, National Agency for Food and Drug Administration and Control, Nigeria), Reuben Ocholi (Director, National Veterinary Research Institute, Nigeria), Emmanuel Ogwuche (Logistics and Commodities Program Manager, United States Agency for International Development, USAID Nigeria Office, Nigeria), Everest Okeakpu (Chief Operating Officer of Biovaccines Nigeria Ltd, Nigeria), Olumide Okunola (Senior Health Specialist, World Bank, Nigeria Office, Nigeria), Azuka Okwuraiwe (Chief Research Fellow, Nigerian Institute of Medical Research, Nigeria), Peters Oladosu (Assoc. Professor, Microbiology and Biotechnology Department, National Institute for Pharmaceutical Research and Development, Nigeria), Taiye Ologun (Director Pharmaceutical Services, Department of Food and Drug Services, Federal Ministry of Health, Nigeria), Tunde Salako (Director-General, Nigerian Institute of Medical Research, Nigeria), Walter Udokwelu (Assistant Chief Regulatory Officer, Post-Market Surveillance Unit, National Agency for Food and Drug Administration and Control, Nigeria), and Bello Yahaya (Head, Delivery Unit, Department of Logistics and Health Commodities National Primary Health Care Development Agency, Nigeria).

This case study was developed under the WHO Local Production and Assistance Unit’s mandates to support Member States in strengthening sustainable local production and technology transfer to improve access to safe, effective, quality and affordable medicines and other health technologies with funding from the Governments of China and France.
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>API</td>
<td>Active Pharmaceutical Ingredient</td>
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<tr>
<td>BSL</td>
<td>Biosafety level</td>
</tr>
<tr>
<td>BVNL</td>
<td>Biovaccines Nigeria Ltd.</td>
</tr>
<tr>
<td>CBN</td>
<td>Central Bank of Nigeria</td>
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<tr>
<td>COVAX</td>
<td>COVID-19 Vaccines Global Access</td>
</tr>
<tr>
<td>DER</td>
<td>Drug Evaluation and Research</td>
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<tr>
<td>DFi</td>
<td>Development Finance</td>
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<tr>
<td>DNA</td>
<td>Deoxyribonucleic acid</td>
</tr>
<tr>
<td>EML</td>
<td>Essential Medicines List</td>
</tr>
<tr>
<td>FPP</td>
<td>Finished Pharmaceutical Product</td>
</tr>
<tr>
<td>Gavi</td>
<td>The Vaccines Alliance (originally Global Alliance for Vaccines and Immunization)</td>
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<tr>
<td>GCP</td>
<td>Good clinical practice</td>
</tr>
<tr>
<td>GDP</td>
<td>Gross Domestic Product</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
</tr>
<tr>
<td>HVAC</td>
<td>Heating, Ventilation and Air Conditioning System</td>
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<tr>
<td>ICGEB</td>
<td>International Center for Genetic Engineering and Biotechnology</td>
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<tr>
<td>IFC</td>
<td>International Finance Corporation</td>
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<tr>
<td>IP</td>
<td>Intellectual property</td>
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<tr>
<td>LMICs</td>
<td>Low- and middle-income countries</td>
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<tr>
<td>MBN</td>
<td>May &amp; Baker Nig. Plc</td>
</tr>
<tr>
<td>M&amp;E</td>
<td>Monitoring and Evaluation</td>
</tr>
<tr>
<td>mRNA</td>
<td>Messenger ribonucleic acid</td>
</tr>
<tr>
<td>MSEZ</td>
<td>Medical special economic zone</td>
</tr>
<tr>
<td>NABDA</td>
<td>National Biotechnology Development Agency</td>
</tr>
<tr>
<td>NAFDAC</td>
<td>National Agency for Food and Drug Administration and Control</td>
</tr>
<tr>
<td>NAFEX</td>
<td>Nigeria Autonomous Foreign Exchange</td>
</tr>
<tr>
<td>NCLVB</td>
<td>National Control Laboratory for Vaccines and Biologicals</td>
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<tr>
<td>NDP</td>
<td>National Development Plan</td>
</tr>
<tr>
<td>NIPRD</td>
<td>National Institute for Pharmaceutical Research and Development</td>
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<tr>
<td>NMRA</td>
<td>National Medicines Regulatory Authority</td>
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<tr>
<td>NSI PSS</td>
<td>Nigeria Strategy for Immunization and Primary Health Care System Strengthening</td>
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<td>NVRI</td>
<td>National Veterinary Research Institute</td>
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<tr>
<td>PCN</td>
<td>Pharmacy Council of Nigeria</td>
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<tr>
<td>PQ</td>
<td>Prequalification</td>
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<tr>
<td>QMS</td>
<td>Quality Management System</td>
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<tr>
<td>RI</td>
<td>Routine Immunization</td>
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<tr>
<td>SIA</td>
<td>Supplemental Immunization Activities</td>
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<tr>
<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>TWG</td>
<td>Technical Working Group</td>
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<tr>
<td>UNICEF</td>
<td>United Nations International Children's Emergency Fund</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
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<tr>
<td>USP+PQM+</td>
<td>United States Pharmacopoeia Convention – Promoting the Quality of Medicines Plus</td>
</tr>
<tr>
<td>WBG</td>
<td>World Bank Group</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Executive summary

Nigeria is the most populous country in Africa with a growing gross domestic product but which depends on importation from other countries for supplies of vaccines and most pharmaceuticals.

The COVID-19 pandemic led to the development of the Economic Sustainability Plan in 2020 with several objectives, including ensuring business continuity, promoting manufacturing and local production at all levels and advocating the use of “Made in Nigeria” goods and services. This was seen as a way of creating job opportunities, achieving self-sufficiency in critical sectors of the economy and curbing unnecessary demand for foreign exchange.

The country also has the National Development Plan which recognizes the importance of the manufacturing sector as a driver of economic diversification in the country and therefore focuses on ensuring growth of manufacturing companies, including pharmaceutical manufacturing companies.

The focus of these government policies on the manufacturing sector resulted in the review of some policies and development of new ones to provide strategic direction for local manufacturing of pharmaceuticals and vaccines.

The Nigerian Pharmaceutical Manufacturing Industry

Nigeria has a reasonably-sized local pharmaceutical industry, estimated at about US$ 607 million in 2017, with a high possibility for growth to as high as US$ 3.6 billion in 2026 and opportunities for significant expansion.\(^1\) The country has about 170 functional local pharmaceutical manufacturing facilities; however, around 70% of medical products in the market are imported, stifling local production and increasing the prevalence of substandard and falsified medical products in the country.\(^1\)

Despite the growth of the industry, it is still plagued by several challenges – a major one being reliance on importation for most production inputs, including active pharmaceutical ingredients (API) and equipment.

In order to address these challenges, WHO launched the global messenger ribonucleic acid (mRNA) technology transfer hub to share the mRNA technology for COVID-19 vaccines with these countries. Nigeria is one of the first six African countries earmarked to receive this technology.\(^2\)

Survey of the ecosystem for local pharmaceutical and vaccine manufacturing in Nigeria

The survey was an information gathering exercise on the different components of the ecosystem for local manufacturing of pharmaceuticals and vaccines, with a focus on local manufacturing of mRNA vaccines. The report also highlighted ongoing efforts at boosting local manufacturing of these products and presents recommendations for improvement of the pharmaceutical manufacturing industry and reactivation of vaccine manufacturing in order to ensure self-sufficiency and security.

Although Nigeria has a viable local pharmaceutical manufacturing industry, there is no human vaccine manufacturing in the country. This survey is therefore a review of the components of the ecosystem as they relate to the existing pharmaceutical manufacturing industry, while leveraging this information to assess the preparedness and capacity of these components for the manufacturing of vaccines and other biologicals.
Methods applied in this survey include a review of available literature, policies and other documents, administration of a questionnaire to 75 existing pharmaceutical manufacturers, as well as face-to-face interviews and discussions with relevant stakeholders.

Overview of the ecosystem for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccines

Policies relating to local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccines
Industry-specific policies, and especially interventions that augment the business environment, are expected to offer better prospects for growth of the respective industry.

In Nigeria, several policies have been promulgated over the years to develop, promote, strengthen and sustain the country’s health system in order to achieve citizens’ access to required health services and ensure positive health outcomes. Proper implementation of these policies will promote local production of high-quality medicines, vaccines and other health commodities and technologies.

Policy implementation in the pharmaceutical sector
Most stakeholders in the pharmaceutical ecosystem agree that the available policies are adequate to promote the local manufacturing of pharmaceuticals, including vaccines if implemented as promulgated. Assessment of the implementation of these policies, however, indicates limited levels of implementation and therefore a lack of achievement of goals and objectives.

Some reasons said to be chiefly responsible for lack of implementation of local pharmaceutical manufacturing policies include the lack of political will, poor government commitment and allocation of required resources, and competing interests in the execution of policies, as well as biased leadership and lack of harmonization of policies across government agencies. Most respondents disagreed that lack of availability of local competence was responsible for poor implementation of policies relating to pharmaceutical manufacturing in Nigeria.

Incentives to promote and sustain local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccine production
Nigeria has several incentives in place to promote pharmaceutical manufacturing, and these incentives will also apply to local vaccine manufacturing, including of mRNA vaccines. It was noted by persons close to industry, however, that effective implementation, ease of access to and timeliness of accessing these incentives are the challenge. It was also noted that there is no robust mechanism for monitoring the implementation of these incentives.

Financing conditions and mechanisms for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccine production
The pharmaceutical industry is capital-intensive and requires significant investments in the construction of new plants and facilities, procurement of inputs and general operational costs. Current mechanisms and financial instruments being offered by government and finance institutions to meet the needs of local pharmaceutical manufacturers appropriately and, by extension, local vaccine manufacturers, were said by stakeholders to be inadequate and unfriendly in terms of accessibility and favourable interest rates.

Regulatory system for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccine production
National regulatory system
The National Agency for Food and Drug Administration and Control (NAFDAC) and the Pharmacists Council of Nigeria (PCN) are the two organizations that make up the national regulatory system for medicines regulation in Nigeria, as assessed by the WHO Global Benchmarking Tool for National Regulatory Authorities. The regulatory system in place in Nigeria for regulation of medicines and imported vaccines was pronounced by WHO to be operating at Global Benchmarking maturity level 3 (ML3) in March 2022.(3)

NAFDAC is the national medicines regulatory authority of Nigeria with responsibility for most of the regulatory functions and has made serious efforts to achieve the feat despite challenges being experienced by the Agency. Finances from government subsidy to the agency are inadequate according to 52.8% of respondents who believed that the National Medicines Regulatory Authority (NMRA) was not adequately resourced.

Capacity and preparedness of the NMRA for regulation of local manufacturing of vaccines, including mRNA vaccines
NAFDAC has been regulating imported vaccines since the inception of the agency but has not been conducting National Regulatory Authority lot release because there is no local manufacturing of vaccines in the country. With the maturity of the agency and recent strides in regulatory system strengthening, the agency is poised for proper regulation of locally manufactured vaccines upon commencement of manufacturing in the country. Visibility of the available regulatory systems for vaccine manufacturing was, however, in doubt according to respondents.

Existing research and development (R&D) capability and in-country capacity for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccine production

Research and development of pharmaceuticals
Efforts in pharmaceutical R&D lead to the creation of new treatments and medicines and to improve people’s quality of life.(4) R&D of pharmaceutical products in Nigeria is a sector that would have been more vibrant but that is hindered by many challenges, as seen from the responses received from the questionnaire which indicate that most respondents agreed that the pharmaceutical industry is capable of R&D of pharmaceutical products if appropriately resourced. The role of government in improving pharmaceutical R&D in the country was emphasized by stakeholders because government’s continued investment in R&D, as in the wake of the COVID-19 pandemic, is a necessity for enhancement of the sector – though there was a note of caution that government policies should be consistent and should not work against R&D in the sector.

Research and development of vaccines and other biologicals, including mRNA vaccines
Nigeria has various institutions involved in R&D of vaccines at different levels, including the National Veterinary Research Institute (NVRI), the National Institute for Pharmaceutical Research and Development (NIPRD), the Nigerian Institute for Medical Research (NIMR), the National Biotechnology Development Agency (NABDA) and the Vaccine Development Consortium. These organizations have researched and developed vaccine candidates for diseases of public health importance but their activities are limited due to the paucity of funds to enable them to scale up their research discoveries.

Patent system for locally-manufactured pharmaceuticals, vaccines and other biologicals, including mRNA vaccines
The National Drug Policy appreciates the need for patent protection, but it emphasizes that such patent rights should not hinder Nigerians’ access to essential medicines. The policy therefore provides for coordination between the government ministries and agencies responsible for health, justice and trade to ensure that public health concerns are considered in international trade negotiations and agreements.

Respondents to the questionnaire were not sure if there were identifiable patent and intellectual property rights protection for novel research and product discovery with particular emphasis on vaccines and other biologicals. A minority of the respondents disagreed that the existing patent and intellectual property rights regime in the country offered any significant patent protection, and this sentiment was also expressed by some other interviewed stakeholders who felt that the inadequacies of the patent system in the country do not encourage innovation.

**Existing and potential technology transfer activities for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccines**

Technology transfer in pharmaceutical manufacturing is the process of transferring the information and technologies necessary to consistently manufacture a quality drug product from its inception in a laboratory to the stage when the product is fit for commercialization. Engagement with some local manufacturers during this survey revealed that there are several instances of previous and ongoing manufacturing arrangements between multinational companies and some local manufacturing companies for the manufacture of some frontline pharmaceutical products which involved transfer of the technology and facilities for producing these products.

Stakeholders believe that, given the right conditions and the availability of the necessary support, the existing and potential technology transfer activities and capabilities in the Nigerian pharmaceutical manufacturing and research space have great potential for the uptake of transfer of technology for mRNA vaccines in Nigeria.

**Challenges for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccine production**

Nigeria has a functional local pharmaceutical manufacturing industry but this faces many challenges that hinder it from progressing. Some of the challenges highlighted by stakeholders include inadequate financing mechanisms to support local manufacturing of pharmaceuticals and vaccines, poor implementation of policies, lack of supporting infrastructure for local manufacturing of pharmaceuticals and vaccines, an inconducive business environment, absence of a workforce competent to support local manufacturing of pharmaceuticals and vaccines (including mRNA vaccines), unguaranteed government patronage for vaccines, and inadequate support for the R&D sector to boost development and local manufacturing of pharmaceuticals and vaccines.

**National strategy for strengthening local production of pharmaceuticals, vaccines and other biologicals**

The Nigerian government has a number of strategies in collaboration with key stakeholders to strengthen local manufacturing of pharmaceuticals and vaccines with some focus on mRNA vaccines, including implementation of the National Drug Policy and the Nigerian Pharmaceutical Sector Strategic Plan. The government has also begun plans for local manufacturing of active pharmaceutical ingredients and reactivation of local vaccine manufacturing through the implementation of the Nigeria Vaccine Policy. Efforts have also been made to start the operations by Biovaccines Nigeria Ltd. (BVNL), in addition to cautious discussions with other private-sector companies who have expressed interest in local vaccine manufacturing.
Acceleration of research into vaccines of public health interest is also ongoing with the recent activities of the Vaccine Development Consortium.

**Initiatives to strengthen local production of pharmaceuticals, vaccines and biologicals, including mRNA vaccines, by supporting partners**

Several of Nigeria’s support partners of the country have ongoing initiatives specifically to strengthen local manufacturing of pharmaceuticals and vaccines. Some of these partners include WHO, USAID, the United States Pharmacopoeia – Promoting the Quality of Medicines Plus (PQM+), the World Bank and Bloom Public Health.

**Objectives and expectations of being a spoke of the mRNA technology transfer hub**

The Hub and Spoke model enables more efficient use of scarce resources, thereby reducing overhead costs. It ensures faster delivery of goods, increases workforce productivity, optimizes work planning, reduces logistical costs and enables consistent pricing.(7)

As one of the spokes to receive the mRNA technology from the hub in South Africa, Nigeria expects that the transfer of technology will reap the above benefits for the country, in addition to capacity-building of staff in the manufacturing processes for mRNA vaccines so that the knowledge may be deployed for the manufacture of other vaccines as well as those for COVID-19.

**The country’s next steps towards local manufacturing of vaccines, including mRNA vaccines, and areas of support from WHO**

The Government of Nigeria has committed to making Nigeria a hub for production of quality, safe, affordable and efficacious vaccines and is therefore taking the necessary steps to achieve this objective. The country will, however, need support from development partners for conducting a situational analysis, ecosystem mapping, a business plan and roadmap for vaccine development in the country. There will be a need for adequate laboratory and pilot production facilities for the research organizations, advocacy to enable harmonization of research and engender synergy between researchers and industry practitioners, as well as provision of funds to enhance vaccine research.

**Manufacturers and market information**

There is a cause for concern in that, despite the high disease burden, Nigeria has no human vaccine manufacturer as the country’s vaccine needs are met through importation with support from international organizations like Gavi and UNICEF. The support from Gavi will, however, be withdrawn by 2028 and this has led to the development of the Nigeria Strategy for Immunization and Primary Health Care System Strengthening (NSIPSS) which is a 10-year strategy document that defines the country’s plan for transition from Gavi support.

It is hoped that the transfer of mRNA technology to BVNL will springboard human vaccine manufacturing in Nigeria, thereby positioning the country as a regional/global hub for supply of vaccines, with a potential for greater growth of the industry and its consequent contribution to Nigeria’s economic development.

**Recommendations and conclusion**

This survey was intended to give an overview of the current situation of the different components of the ecosystem for local production of pharmaceutical products in Nigeria, and particularly for vaccines with a focus on mRNA vaccines. The report cannot be said to be totally exhaustive concerning all the relevant issues in the ecosystem; hence the recommendations and conclusions, some of which are stated here, should be interpreted with an appropriate degree of caution.


**Recommendations**

1. The government is advised to take ownership of its responsibilities in the health-care sector with little reliance on support partners in order to enable self-sufficiency, and also to take steps to improve inter-agency collaboration between government institutions to facilitate the harmonization of activities.
2. It is also recommended that proactive steps should be taken to reduce reliance on imports for production inputs, including a review of educational curricula to enable provision of competencies required for current industry needs.
3. There should be targeted utilization of available manufacturing capacity in the industry in order to boost performance.
4. The government is advised to consider the possibilities for local sourcing of critical manufacturing inputs as well as ways of addressing infrastructural needs of the industry.
5. The National Medicines Regulatory Authority and the R&D sectors should be strengthened through innovative use of funds from support partners.

**Conclusion**

Nigeria’s federal government has set out to achieve self-sufficiency in the supply of quality and affordable medicines and vaccines to the Nigerian people and, in collaboration with some key governmental and nongovernmental actors, has taken some steps in this direction. Addressing the identified challenges facing the local production of pharmaceuticals and vaccines, including mRNA vaccines, will go a long way to achieving the security, self-sufficiency and sustainability of medicines and vaccines as well as universal health coverage in Nigeria.
1 Introduction

1.1 The country

Nigeria is the most populous country in Africa, with a population of 208.3 million people and is the sixth most populous country in the world, accounting for around 2.7% of the world’s population in 2022. Nigeria is a lower-middle-income country, with a gross domestic product (GDP) of US$ 432.29 billion and a GDP per capita of US$ 2097.1 in 2020. The African Development Bank estimated the overall real GDP of Nigeria to have shrunk by 3% in 2020 and projected the economy to grow by 1.5% in 2021 and 2.9% in 2022.(9)

In the words of the WHO Director-General, Dr Tedros Adhanom Ghebreyesus, “No other event like the COVID-19 pandemic has shown that reliance on a few companies to supply global public goods is limiting, and dangerous. In the medium to long term, the best way to address health emergencies and reach universal health coverage is to significantly increase the capacity of all regions to manufacture the health products they need, with equitable access as their primary endpoint.” (10)

Africa, and particularly Nigeria, depends heavily on imports for the supply of vaccines and most medicines to meet its needs. It is estimated that less than 1% of vaccines consumed in Africa are manufactured within the continent while the majority come from India and the western countries.(11)

Nigeria is a major consumer of vaccines for the control of vaccine-preventable diseases. This is attributable to Nigeria’s large population and high infectious diseases morbidity and mortality, making it the largest market for vaccines in sub-Saharan Africa. Despite this, Nigeria has no human vaccine manufacturing in the country and therefore loses out on the opportunity to increase GDP, earn foreign exchange and strengthen the health sector.

In response to the COVID-19 pandemic, which created severe economic consequences around the world, in 2020 the Government of Nigeria developed the Economic Sustainability Plan. The objectives of this are to stimulate the economy by preventing business collapse and ensuring liquidity, promoting manufacturing and local production at all levels and advocating the use of “Made in Nigeria” goods and services, with the aim of creating job opportunities, achieving self-sufficiency in critical sectors of the economy and curbing unnecessary demand for foreign exchange which might put pressure on the exchange rate.(12) The Economic Sustainability Plan is based on three pillars, namely:

a. Real sector measures which comprise a mix of project and policy approaches that focus on the creation of jobs across the fields of agriculture and agro-processing, food security, housing construction, renewable energy, infrastructure, manufacturing and the digital economy. The aim is to safeguard existing micro-, small- and medium-scale businesses while ramping up local productive capacity by encouraging opportunities for innovation in the various sectors.

b. Fiscal and monetary measures with the overriding objective of keeping the economy active through cautiously planned regulatory interventions. These are designed to de-risk the atmosphere for local production and enterprise, stimulate external sources of funding, streamline existing debt commitments and boost investments in strategic sectors that are affected by the COVID-19 pandemic, while supporting the financial viability of the government.

c. Implementation of plans situated in the different ministries by ministerial implementation committees chaired by the responsible minister. The Ministerial Committee will be responsible for ensuring synergy between stakeholders – especially in the public and
private sectors. The committees should also drive specific projects, coordinate the entire sectoral value chain and ensure resolution of bottlenecks that are impeding implementation.

Prior to the COVID-19 pandemic in 2020, the Nigerian government had in place the Economic Recovery and Growth Plan 2017–2020. This plan elapsed, however, in December 2020 and a successor plan known as the National Development Plan (NDP) 2021–2025 was established. The NDP is a medium-term blueprint designed to unlock the country’s potential in all sectors of the economy for a sustainable, holistic, and inclusive national development.

The NDP is guided by four strategic objectives, namely: establishing a strong foundation for a concentric diversified economy; investment in critical physical, financial, science and innovation infrastructure; building a solid framework and enhancing capacities to strengthen security and ensure good governance; and enabling a vibrant, educated and healthy population.(13) The NDP recognizes the potential of the manufacturing sector, not only as a major source of economic growth but also as an important driver of concentric economic diversification and structural change. The plan therefore has provisions for reforms and for enabling business environment programmes focused on developing policies that ensure business growth for manufacturing companies, including the pharmaceutical manufacturing sector.

Nigeria’s relative strengths in attracting foreign direct investment include the large population size (which translates into a large domestic market), the government policy of economic liberalization, the promotion of public–private partnerships and collaboration with foreign establishments – all reflecting a potentially large future for the pharmaceutical market. Nigeria also remains a significant player in the Economic Community of West African States (ECOWAS) and will certainly benefit most from increased regional economic integration and support for regionally produced goods and services.(14)

One of the offshoots of the focus on the manufacturing sector regarding development of policies that ensure business growth, is the review of some relevant policies and development of new ones to provide strategic direction for local manufacturing of pharmaceuticals and other health commodities.

1.2 The Nigerian pharmaceutical manufacturing industry

The context in which pharmaceutical manufacturing takes place is generally determined by several key players who make up the “pharmaceutical manufacturing system”. These entities include the manufacturers, the National Medicines Regulatory Authority (NMRA), various government ministries, trade associations, finance organizations and other institutions that develop the human and material resources for this knowledge-driven sector.(15) The Nigerian pharmaceutical manufacturing system is no different from this general description.

Nigeria has a viable local pharmaceutical industry, estimated at about US$ 607 million in 2017, with a high possibility for growth to as high as US$ 3.6 billion in 2026 and opportunities for significant expansion.(1) Currently, the country has about 170 local pharmaceutical manufacturing facilities which operate at different levels of compliance and capacity. However, about 70% of medical products in the market are imported, thus stifling local production and increasing the prevalence of substandard and falsified medical products in the country.(1)

Despite the impressive growth of the local pharmaceutical manufacturing sector, current players face significant challenges. These include poor infrastructure, inconsistent government policies, low-capacity utilization due to stiff competition from imported brands, high production costs resulting
from dependence on imported production inputs, scarcity of the requisite technical skills, poor access to finance, and a lack of appropriate government incentives.

A major challenge in the pharmaceutical manufacturing sector that cannot be over-emphasized, is reliance on importation for most of the inputs required for production. Currently, all active pharmaceutical ingredients (APIs), excipients, significant quantities of packaging materials and manufacturing equipment required by the local industry are imported. This makes access to foreign exchange at business-friendly rates a critical input into local pharmaceutical manufacturing.

In the area of vaccine manufacturing, the landscape in low- and middle-income countries (LMICs) is evolving continuously. The current need for LMICs is to manufacture their own vaccines which would enable them to have supply security, control over production scheduling and sustainability, control of costs, socioeconomic development, and a rapid response to local epidemics and other emerging diseases. However, the critical elements for the establishment of vaccine production capacity differ from country to country. The challenges in developing countries relate to ensuring the local availability of experts, constant sources of raw materials, consumables, equipment, market access and import policy, as well as having solutions to intellectual property rights issues, a regulatory framework in Good Manufacturing Practice (GMP) inspection, and long timelines for dossier review and approval. Other critical aspects include the construction of facility, financial support, and acquisition of technology.(2)

Efforts are now being made by organizations such as WHO to enable vaccine manufacturing in LMICs through the launch of the global mRNA technology transfer hub which aims to share technology and technical knowledge with local producers to scale up manufacturing capacity for COVID-19 vaccines. However, the work is largely being done without help from major vaccine developers.

In February 2022, WHO announced that Egypt, Kenya, Nigeria, Senegal, South Africa, and Tunisia would be the first countries involved in the mRNA hub. Nigeria had in the past engaged in local production of vaccines between 1940 and 1991. The vaccine production unit in Yaba, Lagos, manufactured vaccines against smallpox, rabies, and yellow fever for both local use and for export to neighbouring countries in western Africa.(16) However, the facility was closed in 1991 for supposed turnaround maintenance work which has still not been carried out. Currently, the only ongoing vaccine manufacturing in Nigeria is for animals (i.e. veterinary vaccines).

1.3 Survey of the ecosystem for local pharmaceutical and vaccine manufacturing in Nigeria

This survey is an information gathering exercise on Nigeria’s ecosystem for local production of pharmaceutical products, including vaccines, with a focus on mRNA vaccines. The purpose of this report is to give an overview of the current situation of the different components of the ecosystem for local manufacturing of pharmaceuticals, vaccines and other biologics with some focus on mRNA vaccines.

The survey covered a review and analysis of the components of the ecosystem for pharmaceuticals and vaccines manufacturing, such as: policies that hinder or promote local manufacturing; incentives from government or other sectors for manufacturers and investors to promote and sustain production of vaccines, including mRNA vaccines and other pharmaceuticals; financing conditions and mechanisms in the country for manufacturers to produce pharmaceuticals and vaccines; the existing regulatory system; current R&D capability and capacity in the country; patents/intellectual property rights systems; as well as existing and potential technology transfer activities in the country. The survey also included analysis of bottlenecks and challenges for local mRNA vaccine production, as well as an existing and/or potential national strategy, and a roadmap and action plan for strengthening local production of pharmaceuticals, including mRNA vaccines and other biologics. The report
highlighted some ongoing efforts at boosting local manufacturing of pharmaceuticals and vaccines by support partners, as well as recommendations for improvement of the local pharmaceutical manufacturing sector and the commencement and sustainability of local vaccine manufacturing to enable self-sufficiency in medicines and vaccines.

The pharmaceutical industry in Nigeria has grown over the years and there are now over 170 pharmaceutical manufacturers, mostly owned by local entrepreneurs. Because of the lack of human vaccines and biologicals manufacturing in Nigeria, the survey leveraged a review of the components of the ecosystem as they relate to the existing pharmaceutical manufacturing industry to gain insight into the preparedness and capacity of these ecosystem components for the manufacturing of vaccines and other biologicals and the sustainability of vaccine manufacturing when it eventually begins.

The survey was conducted through a review of available literature, policies and other documents, the administration of a questionnaire to existing pharmaceutical manufacturers, and face-to-face interviews and discussions with relevant stakeholders.

The stakeholders with which discussions and interviews were held include the following:

a. Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN)
b. Biovaccines Nigeria Ltd. (BVNL)
c. United States Pharmacopoeia – Promoting the Quality of Medicines Plus (USP-PQM+)
d. Pharmacy Council of Nigeria (PCN)
e. Bloom Public Health
f. National Veterinary Research Institute (NVRI)
g. Federal Ministry of Health
h. National Biotechnology Development Agency (NABDA)
i. National Primary Health Care Development Agency (NPHCDA)
j. National Institute for Pharmaceutical Research and Development (NIPRD)
k. National Agency for Food and Drug Administration and Control (NAFDAC)
l. Chairman, West African Pharmaceutical Manufacturers Association (WAPMA)
m. Pharmaceutical Society of Nigeria
n. United States Agency for International Development (USAID)
o. National Institute for Medical Research (NIMR)
p. The World Bank
q. World Health Organization (WHO), Nigeria Country Office.

The questionnaire was administered to 75 identified local pharmaceutical manufacturers in Nigeria and responses were received from 73 of them. The respondents were individuals with no less than four years’ experience in pharmaceutical manufacturing in Nigeria. The duration of practice of the respondents is shown in Figure 1.

**Figure 1. Duration of practice of respondents**

![Figure 1](image_url)
2 Overview of the ecosystem for local pharmaceutical and vaccine manufacturing, including mRNA vaccine manufacturing

2.1 Policies relating to local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccines

Intervention through industry-specific policies plays a vital role in the progress and survival of any industry. Any intervention or government policy that augments the business environment or changes the structure of economic activity toward sectors, technologies or tasks is expected to offer better prospects for economic growth or societal welfare than would occur in the absence of the intervention.²

Despite the commendable progress made over the years, nearly 2 billion people worldwide have no access to essential medicines. Global health initiatives rely on international collaboration but the extreme inequity in access to COVID-19 vaccines across countries demonstrates that governments and industry alone cannot be relied upon to make strategic choices for global benefit.¹⁷ Vaccine inequity is an increasingly important matter in public health and foreign policy debates for both moral and rational reasons – more especially because access to essential medicines and vaccines are prerequisites for the fundamental human right to health for all.

While COVID-19 Vaccines Global Access (COVAX), a global initiative to ensure fair access to COVID-19 vaccines worldwide, had sent out country allocations of 910 million doses delivered as of 30 December 2021 to all 190 COVAX countries, at the current vaccination rate it would take 5 years to cover 75% of the world’s population.¹⁸

High-income countries have, however, allegedly been subverting the organized purchase and equitable distribution of COVID-19 vaccines through non-transparent pharmaceutical deals, production delays and vaccine export restrictions. It is reported that as of 1 November 2021, fewer than 35 million of over 7 billion COVID-19 vaccine doses had been administered in low-income countries – equivalent to 0.2% of the population – compared to 16.7% in middle-income countries and 48.7% in high-income ones.¹⁸ The high- and middle-income countries continue to protect their populations by the purchase of large quantities of the vaccines ahead of production, leaving LMICs especially in Africa exposed to serious delays and shortages of vaccines, leading to insufficient doses to continue the vaccination.¹⁸ This is despite the WHO’s plea to pause the administration of booster doses of vaccines by high- and middle-income countries to give low-income countries a chance to vaccinate their most vulnerable populations.

The COVID-19 pandemic revealed Africa’s vulnerability due to its reliance on imports for most vaccines, medicines, and other health product needs and therefore the urgency of strengthening local pharmaceutical manufacturing in Africa as a key pillar for achieving universal health coverage (UHC) cannot be over-emphasized.

The Federal Ministry of Health in Nigeria is concerned with the formulation and implementation of the country’s policies related to health. Several implementing agencies and parastatal bodies set up by the government carry out activities aimed at achieving the goals of the policies. Several policies have been promulgated over the years to develop, promote, strengthen and sustain the country’s health system in order to achieve access to required health services by citizens and ensure positive health outcomes. Some of those policies are highlighted below.
National Health Policy 2016
The 2016 edition of the National Health Policy is the third edition of this policy with the first and second editions published in 1988 and 2004 respectively. This current edition of the policy provides direction for improving the performance of the health system. It also lays emphasis on strengthening primary health care as the bedrock of the national health system to ensure delivery of effective, efficient, equitable, accessible, affordable, acceptable and comprehensive health-care services and to provide financial risk protection to all Nigerians, particularly the poor and most vulnerable groups. (19)

One of the 10 areas of the policy is Medicines, Vaccines, and other Health Technologies with the objective of building and maintaining an integrated and effective system at all levels that ensures the availability of good-quality medicines, vaccines, health commodities and other technologies always in accordance with international standards.

Part of the strategies for implementing this thrust include the following:

a. Revise, update, and implement the National Drug Policy, the National Essential Medicines List, the Nigeria Supply Chain Policy for Pharmaceuticals and other Healthcare Products, and the National Quality Assurance Policy for Medicines and other Health Products.

b. Promote the local production of high-quality medicines, vaccines, therapeutic foods, commodities, and other health technologies.

c. Facilitate public–private partnerships in the production of medicines and vaccines.

d. Support local drug manufacturers to attain WHO prequalification (PQ) status.

e. Strengthen existing systems for effective monitoring, surveillance and evaluation in the whole logistics channel for health-care delivery.

f. Strengthen relevant regulatory bodies (NAFDAC and Standards Organization of Nigeria) to reduce the supply of fake and substandard medicines, vaccines, commodities and other technologies for health-care delivery.

g. Strengthen a unified supply management system for medicines, vaccines, commodities and other technologies with a functional logistics management information system and leverage the benefits of pooled procurement and economies of scale.

h. Facilitate adequate expansion/upgrading of all medical stores and cold chain storage facilities at all levels for the purpose of effective storage and proper distribution of drugs, vaccines and commodities.

These strategies are being implemented across several government agencies with responsibilities spelt out in the policy document and also support the promulgation of other policies that are intended to enable the achievement of the goals of the National Health Policy.

National Drug Policy 2021 (3rd edition)
In line with the strategies for implementing the thrust of the National Health Policy 2016, the National Drug Policy was revised in 2021 with some of the objectives being to ensure equitable access to safe, efficacious, quality and affordable drugs at all levels of health-care delivery, to promote the local production of drugs and pharmaceutical raw materials through favourable policies and advocacy for local manufacturing, and to promote the export of locally-manufactured medicines as well as promoting pharmaceutical research and development in support of the National Drug Policy. (5) The National Drug Policy has, as one of its targets, a 70% increase in local production capacity for medicines as well as 80% adherence to the Essential Medicines List in the selection and procurement of medicines at all levels of health care by the end of 2025.

The policy proposes that, in order to achieve self-sufficiency in local production of medicines, the government should intensify efforts to improve basic infrastructure and facilities, provide an efficient regulatory environment, and provide favourable interest rates, tax and duty structures for locally manufactured medicines and imported pharmaceutical raw materials and packaging materials. The government is also expected to strengthen the petrochemical and other essential industries (e.g.
plastics, glass and aluminium foil) for the development of pharmaceutical raw materials and packaging materials, as well as encouraging research and development of pharmaceutical raw materials and also patronizing locally manufactured products in government procurement of medicines.\(^{(5)}\)

The policy mandates National Regulatory Authorities to establish effective mechanisms for inspection of all drug manufacturing, storage, and distribution establishments for compliance with applicable good practices, as well as registration of medicines to ensure quality, safety and efficacy. The policy also aims at promoting and supporting ethical, scientific, and operational research in the pharmaceutical sector to enable development of new medicines and to improve existing ones that will be safe and efficacious for use.

**Nigeria Vaccine Policy 2021 (1\(^{st}\) edition)**

The policy was developed with the objective of establishing appropriate and sustainable structures to achieve local production and uptake of vaccines that meet all global quality standards and ensure vaccine security in line with the requirements of the Sustainable Development Goals and Universal Health Coverage. It is also aimed at engendering sustainable access to funding for local vaccine production and for research and development of existing and new vaccines using innovative technologies while also taking ownership of all vaccine supply chain management. The policy also aims to strengthen bilateral/multilateral cooperation and to encourage public–private partnerships for the local production of vaccines and for vaccine research and development.\(^{(16)}\)

The Policy has a Monitoring and Evaluation (M&E) framework to assess its level of implementation, with responsibilities assigned to relevant organizations and institutions. Some of the targets of the policy which have been achieved within the set timelines include the establishment of the Inter-Ministerial Vaccine Steering Committee and the Technical Working Group for Local Vaccine Production. Considering ongoing global efforts to develop vaccines for COVID-19, proper implementation of the Nigeria Vaccine Policy will provide the strategic direction needed for the country to participate in these global efforts as the policy applies to all vaccine types, including mRNA vaccines.

**Policy implementation in the pharmaceutical sector**

Over the years, several policies, some of which are highlighted above, have been promulgated for achievement of strategic goals and objectives in the pharmaceutical sector. The Nigeria Vaccine Policy is a new policy, established in 2021, for which implementation is just commencing; however, an evaluation of implementation of previous policies will give good insight into possibilities for proper implementation of the Vaccine Policy and will enable previous areas of concern to be addressed.

Most stakeholders in the pharmaceutical ecosystem agree that the available policies are adequate to promote local manufacturing of pharmaceuticals, including vaccines, if implemented as promulgated. Assessment of implementation of these policies, however, indicates limited levels of implementation and therefore a lack of achievement of goals and objectives. This, among other reasons, has contributed to the observed levels of achievement of health goals and the rating of health indices in the country.

In the preface of the National Drug Policy 2021, it is stated that the first two editions of the policy did not achieve the intended objectives of improving drug availability, distribution, and rational use partly because the earlier editions lacked an M&E plan to assess implementation and effectiveness of the policy and achievement of the objectives. This lack of implementation was alluded to by some stakeholders, and several reasons were judged to be responsible.

Table 1 (also represented in Figure 2) below supports this claim.
Table 1. Reasons for the level of policy implementation for local pharmaceutical manufacturing

<table>
<thead>
<tr>
<th>Reason</th>
<th>Response (Agree)</th>
<th>Response (Strongly agree)</th>
<th>Response (Disagree)</th>
<th>Response (Strongly disagree)</th>
<th>Response (Not sure)</th>
</tr>
</thead>
<tbody>
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<td>21</td>
<td>35</td>
<td>58.3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Poor allocation of resources</td>
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<td>32.3</td>
<td>56.9</td>
<td>4</td>
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<tr>
<td>Limited local competence</td>
<td>14</td>
<td>21.5</td>
<td>13.8</td>
<td>22</td>
<td>3</td>
</tr>
<tr>
<td>Competing interests</td>
<td>20</td>
<td>30.8</td>
<td>50.8</td>
<td>4</td>
<td>8</td>
</tr>
</tbody>
</table>

Note: Freq = frequency.

Figure 2. Reasons for level of policy implementation for local pharmaceutical manufacturing
Some of the reasons said to be chiefly responsible for lack of implementation of local pharmaceutical manufacturing policies, as seen from perspective of respondents to the questionnaire, include lack of political will on the part of government (58.3%), poor allocation of required resources (56.9%) and competing interests in the execution of policies (50.8%). Most respondents (59.9%) disagreed that unavailability of local competence was responsible for poor implementation of policies relating to pharmaceutical manufacturing in Nigeria as the country is blessed with the required intellectual competence to achieve the aims of established policies.

As regards the availability of policies for local vaccine manufacturing, the responses to the questionnaire indicate that most manufacturers are not aware of the existence of the Nigeria Vaccine Policy as 53 out of 73 respondents (representing 72.6%) said there were no established policies for local vaccine manufacturing while the remaining 20 (representing 27.4%) were aware that the government had established policies to support local manufacturing of vaccines and other biologicals in Nigeria, as represented in Figure 3.

**Figure 3. Awareness of availability of policies for local vaccine manufacturing**

Information gathered from respondents regarding the level of implementation of policies on local manufacturing of vaccines indicates that manufacturers expect these policies to progress similarly to those for pharmaceutical manufacturing which had been in existence earlier. This is because most respondents believe there is no evidence of implementation and therefore the policies were not implemented as proposed. The respondents suggested similar reasons for lack of implementation of policies on local vaccine manufacturing as those for local pharmaceutical manufacturing as shown in Table 2 and Figure 4 below.

Lack of political will on the part of government to implement policies (54.8%), poor allocation of required resources (49.2%) and competing interests in the execution of policies (40.6%) were the reasons that respondents strongly agreed were responsible for lack of implementation of policies relating to local vaccines manufacturing.

Respondents may conclude that similar reasons are responsible for lack of implementation of policies on local vaccine manufacturing as for local pharmaceutical manufacturing because policies such as the National Health Policy and National Drug Policy, which have been in existence before the recent Nigeria Vaccine Policy, are overarching policies which also apply to local vaccine manufacturing and so the reasons for poor implementation of those policies will also be relevant to vaccine manufacturing.
Table 2. Reasons for the lack of policy implementation for local vaccine manufacturing

<table>
<thead>
<tr>
<th>Reason</th>
<th>Freq.</th>
<th>%</th>
<th>Freq.</th>
<th>%</th>
<th>Freq.</th>
<th>%</th>
<th>Freq.</th>
<th>%</th>
<th>Freq.</th>
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<td>54.8</td>
<td>4</td>
<td>6.5</td>
<td>1</td>
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<tr>
<td>Poor allocation of resources</td>
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<td>4.8</td>
<td>1</td>
<td>1.6</td>
<td>5</td>
<td>7.9</td>
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<tr>
<td>Limited local competence</td>
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<td>3.1</td>
<td>9</td>
<td>14.1</td>
</tr>
</tbody>
</table>

Note: Freq = frequency.

Figure 4. Reasons for the lack of policy implementation for local vaccine manufacturing

Some of the stakeholders interviewed believed a major reason for lack of implementation of policies was lack of government commitment and political will which worsens when there is a change in government or leadership of the ministry or implementing agencies. They stressed that leadership buy-in is critical to commitment to any policy. Leadership commitment is also critical for allocation of
resources for implementation of policies as leaders will provide resources for causes to which they are committed.

Some stakeholders also emphasized the need for objectivity and an unbiased outlook of the leadership of the policy-making body. They observed that, over time, bias in the professional affiliation of the leadership of government institutions may also hinder implementation of policies relating to the pharmaceutical sector. Some respondents “strongly agreed” that competing interests of the policy implementers could be a hindrance to the implementation of policies.

Stakeholders are of the opinion that, for most subjects, policies are often drawn up by different organs of government, but these policies are not harmonized and properly coordinated, and a lot of duplication is observed. It was noted that, while in a rush to take the lead on a particular subject, some policies end up conflicting with others, leading to a lack of policy consistency and congruence. This disconnect therefore leads to conflicts and lack of depth in implementation.

Some stakeholders also highlighted that lack of proper contextualization of public health problems before developing appropriate policies to address them hampers policy implementation. Other stakeholders suggested that the solution to the recurrent problem of not deriving the expected benefits from policies is to implement as planned and conduct post-implementation impact analyses to assess progress made and continue to improve while possibly amending the policy and the implementation plan where necessary.

2.2 Incentives to promote and sustain local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccine production

The pharmaceutical manufacturing industry is a key sector in ensuring effective health-care delivery. A thriving pharmaceutical manufacturing industry contributes significantly to GDP, provides employment opportunities for citizens, and instils confidence in, and reliance on, health-care products. It is therefore important for governments to create an enabling environment and provide incentives to attract investment into the pharmaceutical manufacturing industry.

In the opinion of Nigerian pharmaceutical manufacturers, an enabling environment starts from establishing and implementing policies that will enable the industry to survive and thrive. They feel that such policies must indicate a clear bias for local manufacturing of pharmaceuticals and vaccines as the medicines security of a nation cannot be achieved through importation. To this end, implementation of policies that prioritize the local pharmaceutical industry is a key incentive that will drive investment and sustain local manufacturing of pharmaceuticals and vaccines. The example of prioritization of the agricultural sector by the Federal Government of Nigeria was cited, where this sector received more support from the Central Bank of Nigeria (CBN) than any other sector of the economy in terms of grants, soft loans, and provision of inputs at low cost. The support from the government started with a program for local manufacturing of rice enhanced by the highlighted support system followed by a ban on importation of rice into the country. Where such government policies are implemented, industry players can recalibrate their return on investment and return on effort and are therefore motivated to invest in the industry.

Governments of some countries such as India have been known to provide financial incentives to promote domestic manufacturing of critical key pharmaceutical starting materials, drug intermediates, APIs and finished pharmaceutical products (FPPs), especially for new projects. Other support provided to the pharmaceutical manufacturing industry includes assistance to strengthen the
capacity of existing pharmaceutical clusters for sustained growth by creating common facilities for the industry. (20)

In Nigeria, the government has several incentives in place to promote pharmaceutical manufacturing and it is expected that these incentives will also apply to local vaccine manufacturing, including mRNA vaccines, as there are currently no incentives specifically established for local vaccine (including mRNA vaccine) manufacturing. Some of the available government incentives include the Executive Order No. 003 of 2017 which provides support for local content in public procurement such that “Made-in-Nigeria” products shall be given preference in the procurement of items including pharmaceuticals, and at least 40% of the procurement expenditure on these items in government ministries, departments and agencies shall be locally-manufactured goods or local service providers. (21) This Executive Order also aligns with the Public Procurement Act 2007 which provides for a margin of preference in the evaluation of tenders, when comparing tenders from domestic bidders with those from foreign bidders or when comparing tenders from domestic suppliers offering goods manufactured locally with those offering goods manufactured abroad. (22)

Another incentive of government to support local manufacturing of pharmaceuticals is the exemption of pharmaceutical raw materials from Value Added Tax (VAT). The 2022 fiscal policy measures include an approved list of critical medical supplies (such as pharmaceutical manufacturing machinery) which are exempted from some import duty. This exemption is, however, subject to receiving a letter of support from the Federal Ministry of Health and an Import Duty Exemption Certificate from the Federal Ministry of Finance Budget and National Planning. (23)

All these government incentives are documented but effective implementation and timeliness is said to be the challenge. It was noted by industry respondents that the process required to get the waivers are long and increase the length of the production cycle. For instance, the VAT Modification Order of 2021 (“MO 21”) which amended the list of goods and services exempted from VAT and eligible as zero-rated goods and services to include pharmaceutical raw materials among other products was commended by the industry; however, the process for obtaining the waiver is said to be tedious and time-consuming. (24) Similarly, obtaining the Import Duty Exemption Certificate for pharmaceutical raw materials and equipment is also time-consuming as the process is initiated by the applicant on the National Single Window for Trade portal but it passes through Federal Ministry of Health, the Federal Ministry of Finance Budget and National Planning, the Nigeria Customs Service and NAFDAC, and goes back to the Federal Ministry of Finance Budget and National Planning before the exemption certificate can be issued.

During the COVID-19 pandemic, the Federal Government, through the Central Bank of Nigeria (CBN), earmarked one hundred billion Naira credit support intervention for the health-care industry as part of measures to cushion the effects of the pandemic on the economy. This intervention aimed to strengthen the sector’s capacity to meet potential increase in demand for health-care products and services by providing long-term credit to indigenous pharmaceutical companies and other health-care value chain companies that were intending to build or expand capacity. The objectives of the intervention included provision of long-term, low-cost finance for health-care infrastructure development that would lead to establishment of world-class health-care facilities in the country and improve access to affordable credit by indigenous pharmaceutical companies to expand their operations and comply with relevant applicable standards. (25)

According to pharmaceutical manufacturers who were interviewed, only about 5% of the industry was able to access this facility due to the stringent conditions applied. The loan was provided in Naira and these companies had to source foreign exchange (USD) from the parallel market at exorbitant exchange rates to execute the intended projects as most inputs needed for upgrade and construction
of new manufacturing facilities were imported, thereby diminishing the value of the loan. It is the opinion of the industry that this type of intervention should not be one-off as was the case during the COVID-19 pandemic; rather, for more impact, similar interventions should be instituted and tied to a specific range of product needs and other products of public health importance.

It was noted that there is no robust mechanism for monitoring the implementation of these incentives to determine how many companies benefitted from them. Also, the implementation of these incentives should be tracked over time to determine areas of use to stimulate innovation.

A key support partner of the local pharmaceutical manufacturing industry was of the opinion that it is not enough to have documented incentives; instead, the government needs to be seen to incentivize the local pharmaceutical industry in order to avoid inadvertently suppressing local manufacturing activities due to over-regulation and under-utilization in the area of procurement as the government rarely procures from local manufacturers despite policies requiring this to be the case. It was also said that the government needs to guarantee security of the supply chain to attract investment in the industry.

NAFDAC, as the NMRA in Nigeria, instituted a policy for migration to local production of registered imported drug products for which there is in-country manufacturing capacity. The policy, called “the Five Plus Five-Year Validity Policy”, is instituted to ensure local manufacturing of essential medicines by mandating foreign manufacturers to either form partnerships with Nigerian companies or set up local manufacturing plants for the previously registered imported FPPs. This policy allows the initial registration of an imported drug product valid for five years and one registration renewal cycle of another five years by which time the Marketing Authorization Holder should have concluded arrangements for migration of the products to a local manufacturing facility, either established by the manufacturer or through contract manufacturing arrangements with an existing local manufacturer. This policy is expected to boost local manufacturing of medicines, ensure engagement of idle manufacturing capacity available in existing local manufacturing companies through contract manufacturing arrangements as well as engendering the transfer of technology for manufacturing of previously imported products to the local manufacturing companies. This policy is beginning to gain traction as several companies, including multinational companies, have concluded arrangements for contract manufacturing and transfer of technology of previously imported products to some local manufacturers. The knowledge gained in execution of the transfer of technology is good for capacity-building of the relevant companies, making it easier for them to be involved in subsequent projects. It was noted, however, that some local manufacturers approached for contract manufacturing arrangements for local manufacturing of imported products treated the contract givers as competitors rather than customers which discouraged the importers and therefore undermined the aim of the policy which is to boost local manufacturing of pharmaceuticals and enable utilization of vacant capacity in the local industry.

Another means of incentivizing the industry, as suggested by stakeholders, is for the political will of the government to keep supporting the industry despite challenges that may be encountered. This political will is a collective direction of the country as regards the sector, such that the case made for ensuring quality by the government matches the business case of the investor, thereby encouraging those involved to keep investing their profits and to continue improving their operations and performance despite initial challenges.
2.3 Financing conditions and mechanisms for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccine production

Throughout the pharmaceutical sector, as well as the health-care system in general, financing plays a central role and financing choices have a major impact on system performance.\(^{(27)}\) The pharmaceutical industry is highly capital-intensive and requires significant investments in construction of new plants and facilities. Between 2018 and 2019, the Nigerian NMRA – NAFDAC – in collaboration with USP-PQM+ conducted a nationwide assessment of local pharmaceutical manufacturers for compliance with GMP requirements. The outcome of the inspections revealed that most pharmaceutical manufacturing companies in Nigeria need to invest significant sums of money to attain the requisite GMP compliance status. The adequacy of the current mechanisms and financial instruments being offered by the Nigerian Government and finance institutions to meet the need of local pharmaceutical manufacturers appropriately can, however, be argued. This position can be inferred from the results obtained from respondents to the questionnaire which indicated very close figures in the assessment of the adequacy of available financing mechanisms for local manufacturing of pharmaceuticals, vaccines and other biologicals, as seen in Table 3 and Figure 5.

Table 3. Adequacy of financing mechanisms

<table>
<thead>
<tr>
<th>Reason</th>
<th>Adequate available financing</th>
<th>Easy access to finance</th>
<th>Favorable interest rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Response</td>
<td>Response (Agree)</td>
<td>Response (Strongly agree)</td>
<td>Response (Disagree)</td>
</tr>
<tr>
<td>Freq.</td>
<td>%</td>
<td>Freq.</td>
<td>%</td>
</tr>
<tr>
<td>Adequate available financing</td>
<td>20 28.6 4 5.7 19 27.1 18 25.7 9 12.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Easy access to finance</td>
<td>5 7.1 3 4.3 30 42.9 25 35.7 7 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Favorable interest rates</td>
<td>2 2.9 7 10 20 28.6 34 48.6 7 10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Freq = frequency.
Some 28.6% of respondents agreed and 5.7% strongly agreed that there are financing mechanisms available to support local manufacturing of pharmaceuticals, vaccines and biologicals in Nigeria, while 27.1% and 25.7% disagreed and strongly disagreed respectively. Most of the respondents, 42.9% and 35.7% disagreed and strongly disagreed respectively, that the available financing mechanisms and associated processes were easily accessible to local manufacturers just as 48.6% and 28.6% strongly disagreed and disagreed respectively, that interest rates on financing instruments promote local investment into manufacture of pharmaceuticals, vaccines and other biologicals in Nigeria.

Discussions with some stakeholders in pharmaceutical manufacturing in Nigeria aligned with the above results from the questionnaire respondents as they also agreed that access to finance instruments was difficult because conditions attached to these instruments were difficult to meet and interest rates from commercial and development banks were also said to be prohibitive. The example of the Hundred Billion Naira Credit Support provided by the CBN for the health-care sector to cushion the effects of the COVID-19 pandemic was cited, whereby only about 5% of local pharmaceutical manufacturers were able to access the loan due to stringent conditions.

Access to foreign exchange at official exchange rates by genuine investors in local pharmaceutical manufacturing is said to be very difficult, as seen in Figure 6. This emanated from the exchange rate policy that resulted in a scarcity of foreign exchange, so that manufacturers obtained only 5–10% of their foreign exchange needs from the CBN at the Nigeria Autonomous Foreign Exchange (NAFEX) rate but getting 90–95% through the parallel market or their own proceeds. This support to a large extent dissuaded meaningful investment in capital-intensive pharmaceutical manufacturing and, by extension, the vaccine manufacturing industry,(28) including mRNA vaccine manufacturing.
The prevailing environment for financing local manufacturing in Nigeria has prompted some pharmaceutical manufacturing companies to begin discussions with foreign partners for investment opportunities while others are discussing with international organizations. The PMG-MAN is also in discussions with the Nigerian Sovereign Investment Authority on possible financing opportunities for the industry.

Currently, there are no financing mechanisms specifically for the manufacture of mRNA vaccines in Nigeria.

The Federal Government and the pharmaceutical company in Nigeria, May & Baker Nig. Plc. (MBN), incorporated Biovaccines Nigeria Limited (BVNL) in 2005 as a joint venture to serve as the “Special Purpose Vehicle” to revive vaccines production activity in the country. Some 51% of the company is owned by MBN while 49% is owned by the Federal Government. However, the company is yet to commence operations due to paucity of funds, among other reasons.

With the advent of the COVID-19 pandemic and the attendant restrictions and supply chain disruptions, as well as the realization for the need for self-sufficiency in medicines and vaccines, there was a reawakening which led to some significant financial investment in vaccine manufacturing in Nigeria by the government. The Federal Government took the lead by appropriating the sum of 10 billion Naira (US$ 26 315 789) in 2020 to support local vaccine manufacturing efforts of the BVNL. This was before the pronouncement of Nigeria as one of the countries to receive the mRNA vaccine production technology from the technology transfer hub in South Africa. The BVNL is now expected to receive the technology on behalf of the country. However, it is unclear whether the BVNL will invest the said funds in mRNA vaccine production upon receipt of the technology since discussions on the funds had been ongoing for the manufacture of routine immunization vaccines before establishment of the technology transfer hub and selection of Nigeria as a recipient.

While all of this is commendable, stakeholder engagement during this survey revealed that the appropriated fund is yet to be released to BVNL and the reality on ground by far requires much more
than the provided budget. This is because funding required for vaccine manufacturing is huge. A study by WHO and the United Nations Industrial Development Organization (UNIDO) published in 2017 indicated that the cost of building a vaccine manufacturing plant ranges from US$ 30 million to US$ 225 million, depending on the volume of manufacturing and whether the facility is fully integrated or will be for “fill and finish” (i.e. filling of vials) only.(29) The BVNL has therefore been in discussion with several international funding organizations to seek additional funding to meet the required financial needs to launch the local vaccine manufacturing project.

One key stakeholder in vaccine manufacturing in Nigeria expressed the opinion that some international organizations and development partners may have the wherewithal to provide such huge financial support to manufacturers in LMICs. One such organization – Development Finance (Dfi) – is an organization with human and social impact as its key objectives. Dfi is an arm of the World Bank which engages in strategic resource mobilization, playing an intermediary role to help align the needs of recipients, institutional priorities of the World Bank Group and the priorities of funding partners through a variety of funding instruments.(30)

Another organization that can support local manufacturing of vaccines in Nigeria is the International Finance Corporation (IFC), a sister organization of the World Bank and a member of the World Bank Group. IFC is the largest global development institution focused exclusively on the private sector in developing countries.(31) Potential vaccine manufacturers may be able to obtain the required funds from the IFC and set up their manufacturing facilities to commence commercial production of vaccines in the next 2–3 years, introducing some competition into the erstwhile monopoly of Gavi, the Vaccines Alliance, which is the sole procurer of vaccines from UNICEF for the Nigerian government under a procurement agreement between the two parties which lasts until 2028.

Some stakeholders note that funding from the above-mentioned organizations may not be accessible to intending manufacturers in the near future because Dfi and IFC may not be disposed to release funds for an organization that may be perceived to be in competition with Gavi which is also funded by the World Bank.

Some companies interested in local vaccine manufacturing in Nigeria are discussing with other funding partners such as Nigerian Sovereign Investment Authority and international donors for funding of investments in the vaccine manufacturing sector. These companies are, however, wary of securing these loans without commitment of offtake by the government since the government is the major procurer of vaccines. The government on the other hand also has concerns with committing to all the companies that show interest due to the possibilities of litigation if the government is unable to take up the manufactured products.

One stakeholder suggested that the United States Trade and Development Agency (USTDA) could be approached for funding of local manufacturing since the agency is willing to support manufacturing in Africa and can provide some grants as well as lead interested companies to sources of cheap financing in the United States.

2.4 Regulatory system for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccine production

NAFDAC – The National Medicines Regulatory Authority in Nigeria
An optimally resourced and effective NMRA is essential for the existence and sustainability of a vibrant pharmaceutical industry capable of ensuring the safety, quality and efficacy of all medicines used in the country. The NMRA should have the capacity continually to assess the safety, efficacy, and quality
of all marketed medicines – whether locally-manufactured or imported – through dossier evaluations, manufacturing facility inspections and post-marketing surveillance, and by ensuring that all involved comply with acceptable standards.\(^{(32)}\)

The National Agency for Food and Drug Administration and Control (NAFDAC) is the NMRA in Nigeria. The agency was established by Decree No. 15 of 1993 as amended by Decree No. 19 of 1999, now cited as the NAFDAC Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004. The Act mandates the agency to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, medical devices, packaged water, chemicals and detergents (collectively known as regulated products). The agency has the following activities within its functions:

- conduct appropriate tests and ensure compliance with standard specifications for the effective control of the quality of regulated products;
- undertake appropriate investigations into, and inspection of, the production premises and raw materials of regulated products, including certification of the production sites.
- undertake the registration of regulated products;
- establish and maintain relevant laboratories or other institutions in strategic areas of Nigeria and pronounce on the quality and safety of regulated products; and
- determine the suitability or otherwise of regulated products for human and animal use.\(^{(33)}\)

NAFDAC has 18 directorates, seven of which have responsibilities relating to regulation of drugs and vaccines. These directorates, along with an overview of their activities, are highlighted below.

**a. Drug Evaluation and Research (DER) Directorate**

The DER directorate is the pharmaceutical inspectorate of NAFDAC and has the responsibility to conduct Good Manufacturing Practice (GMP) assessments of all domestic and foreign facilities producing pharmaceuticals, vaccines, biologicals, herbal medicines and nutraceuticals as well as cosmetics and medical devices. The directorate also certifies the production sites of regulated products on demonstration of compliance of the sites with the applicable regulations and guidelines and continues to monitor the manufacturing sites for continued compliance with relevant regulations and guidelines through appropriate inspection activities.\(^{(34)}\)

The directorate also houses the Clinical Trial, Vaccines and Biologicals Division which is responsible for review of clinical trial applications for drugs and vaccines; issuance of permits to import investigational medicinal products where applicable; and authorization for the conduct of clinical trials in Nigeria. The directorate uses the NAFDAC Electronic Clinical Trial Application Platform (eCTAP) for processing applications for conducting clinical trials in Nigeria.\(^{(35)}\)

The DER directorate also carries out Good Clinical Practice (GCP) inspections of authorized clinical trial sites for compliance with approved protocols and GCP requirements as well as reviews of clinical data submitted to support product registration applications.\(^{(34)}\)

The division is responsible for carrying out Good Storage Practice (GSP) inspections of cold chain storage facilities for the storage of vaccines and other biologicals.\(^{(34)}\)

The directorate also provides appropriate guidance documents for all its activities, especially GMP and GCP inspections, as well as other clinical trial-related activities.

**b. Drug Registration and Regulatory Affairs (DR&RA) Directorate**

The DR&RA directorate is responsible for the registration of all NAFDAC-regulated products. The directorate has separate divisions that handle the registration of locally manufactured human drugs, imported human drugs and biologicals, vaccines and medical devices.\(^{(36)}\)
The directorate provides relevant guidance documents relating to product registration activities on the NAFDAC website to guide applicants in the process of registration of their products. The directorate implements the use of the common technical document (CTD) format for submission of product dossiers for registration of drugs and vaccines, carries out assessment of the dossiers for adequacy and recommends the products for registration upon fulfilment of other regulatory requirements. The directorate further maintains a database of registered regulated products, including pharmaceuticals and imported vaccines and biologicals.

c. Laboratory Services, Drugs (LS/D) Directorate
The LS/D directorate is the arm of the agency that investigates and pronounces on the quality, safety and efficacy of both imported and locally-manufactured drugs on the basis of compliance with standard specifications and other applicable requirements. The directorate is made up of two laboratories – namely the Central Drug Control Laboratory (CDCL) Yaba and the Area Laboratory, Maiduguri. The CDCL is accredited for 17 testing scopes in compliance with ISO/IEC 17025:2019 standards and is also pursuing WHO PQ of the laboratory.

The agency has two other Laboratory Services directorates (Agulu Laboratory Services and Kaduna Laboratory Services) which are also ISO/IEC 17025:2017 accredited and which also support the LS/D directorate in the analysis of drug products.

d. Vaccines, Biologicals and Medical Devices Laboratory Services Directorate (VBM-LSD)
This is a newly created directorate carved out of the former Laboratory Services, (Drugs and Biologicals) directorate. The directorate houses the National Control Laboratory for Vaccines and Biologicals (NCLVB) which is responsible for the analysis of vaccines and other biologicals as well as medical devices. NCLVB is ISO/IEC 17025:2017 accredited for several scopes for the analysis of vaccines and biologicals.

The National Control Laboratory for Vaccines and Biologicals (NCLVB) is the only NMRA-owned vaccines and biologicals quality control laboratory in western Africa with full capacity for analysis of vaccines and biologicals. It is said that vaccines laboratories of other NMRAs in the region must outsource the conduct of some tests to third parties. The NCLVB carries out lot release of all registered imported vaccines, including those for routine immunization, before they are allowed for distribution and use in Nigeria.

e. Pharmacovigilance and Post-Market Surveillance (PV/PMS) Directorate
The PV/PMS directorate has the responsibility of implementing the National Policy on Pharmacovigilance which includes coordination of pharmacovigilance activities nationwide and provision of science-based advice and information on the safe use of medicines, among other responsibilities. The directorate is also responsible for conducting post-market surveillance (PMS) of all regulated products in collaboration with marketing authorization holders (MAHs) and for carrying out regular surveys relating to the quality and safety of regulated products for required regulatory action. The PMS division of the directorate is also the arm of the agency with responsibility for carrying out the NAFDAC traceability implementation strategy, which aligns with the Nigeria National Pharmaceutical Traceability Strategy, with the aim of having full visibility of all products moving within the pharmaceutical supply chain in Nigeria.
f. **Ports Inspection Directorate (PID)**

PID has the responsibility to regulate the importation of regulated products through screening of import documents and inspection of imported consignments before release of the shipments. The directorate also controls the exportation of regulated products through issuance of quality certification for such regulated products. In order to control drug imports properly, the agency prohibits importation of drugs through land borders and has designated only two seaports and the airports for importation of drugs. The directorate operates an online platform called the Ports Inspection Data Capture and Risk Management System (PIDCARMS) for port clearance operations.

g. **Narcotics and Controlled Substances (NCS) Directorate**

The NCS directorate has the mandate to ensure that Nigeria fulfils its obligations under the International Drug Control Conventions by undertaking measures to ensure that the use of narcotic drugs and psychotropic substances is limited to medical and scientific purposes. This is done through the authorization of import and export of narcotic drugs and psychotropic substances as well as other controlled substances while preventing their diversion to illicit use and abuse.

**Pharmacy Council of Nigeria (PCN)**

The Pharmacy Council of Nigeria (PCN), which replaced the Pharmacists Council of Nigeria, is the government institution responsible for licensing establishments where medicines and poisons are manufactured, imported, exported, distributed, stored, dispensed, or sold in Nigeria on the basis of compliance with Good Pharmacy Practice standards, among other functions.

**The national regulatory system in Nigeria**

NAFDAC and PCN are the two organizations that make up the national regulatory system for medicines regulation in Nigeria, as assessed by the WHO Global Benchmarking of Regulatory Systems, and as mandated by the World Health Assembly Resolution WHA67.20 on Regulatory system strengthening for medical products. Of the nine regulatory functions of the WHO Global Benchmarking Tool (WHO-GBT), the Nigerian regulatory system was benchmarked for eight functions, excluding NRA lot release. The PCN was primarily benchmarked for the Licensing Establishments function and partly for the National Regulatory System and Regulatory Inspection functions. NAFDAC, on the other hand, was benchmarked fully for seven functions, namely: National Regulatory System, Registration and Marketing Authorization, Market Surveillance and Control, Vigilance, Regulatory Inspection, Laboratory Testing, and Clinical Trials Oversight. The regulatory system in place in Nigeria for regulation of medicines and imported vaccines (including mRNA vaccines used during the COVID-19 pandemic) was pronounced by WHO to be operating at Global Benchmarking maturity level ML3 in March 2022. This implies that the regulatory system in Nigeria is judged to be stable, well-functioning and integrated for regulation of medicines and imported vaccines. To achieve this, NAFDAC as an organization embarked on strengthening the existing regulatory operational framework of the agency in different ways, some of which are highlighted below:

- management commitment to strengthening of the regulatory system through establishment of the required legal provisions for the regulatory framework through development and approval of relevant regulations; establishment, maintenance and continual improvement of the agency’s Quality Management System (QMS) through development and institutionalization of new – as well as review of existing – guidelines, policies and procedures; improving existing mechanisms to promote transparency, accountability and communication
via establishment of interactive automated processes, improvement of the website and increased stakeholder engagement using media outlets and stakeholder meetings;

- adoption of risk management principles to enable optimization of resources and efficient service delivery, leading to implementation, inter alia, of risk-based sampling of products for laboratory analysis, risk-based testing of products based on defined risk criteria, and risk-based post-market surveillance to monitor substandard and falsified medical products;

- adoption of Good Reliance Practices by reliance on regulatory processes of other NMRAs and advisory bodies for regulatory decision-making (e.g. reliance on reports of GMP inspections conducted by foreign NMRAs for verification of status of foreign manufacturing facilities); and use of WHO Public Inspection Reports and WHO Public Assessment Reports for product registration, especially under the WHO Collaborative Registration Procedure; as well as other reliance activities;

- implementation of Good Regulatory Practices to mitigate the proliferation of substandard and falsified medical products by instilling GMP compliance in the pharmaceutical industry through blacklisting of foreign companies that compromise quality, shutting down non-compliant local manufacturing facilities and deregistration of violative products; procurement and use of detection devices for detection of substandard and falsified products; enforcement and use of information from intelligence gathering; and vigilance in the country of origin for imported products through issuance of Clean Report of Inspection and Analysis (CRIA) upon confirmation of capacity of the CRIA agents;

- deployment of automated processes to promote transparency, accountability and improved efficiency in regulatory service delivery and internal operations – e.g. NAFDAC Automated Product Administration and Monitoring System (NAPAMS) for end-to-end processing of registration applications; Electronic Clinical Trial Application Platform (eCTAP) for processing clinical trial applications and monitoring of trial progress; Medicines Risk Surveillance (MedRS) tool for risk-based selection of products for sampling during post-market surveillance; Ports Inspection Data Capture and Risk Management System (PIDCARMS) for administration of all port clearance activities; and NAFDAC Training Management Application for the planning and archiving of all training activities across regulatory functions; among others;

- improved monitoring of Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs) with deployment and adoption of the NAFDAC MedSafety Application as a reporting platform for ADRs and AEFIs for COVID-19 vaccines and commitment of reports to Vigibase;

- sustained collaboration with external stakeholders and sectoral groups, locally (e.g. PMG-MAN, PCN, National Health Research Ethics Committee and NPHCDA); in the West African sub-region (e.g. West African Medicine Regulatory Harmonization [WA-MRH] and Forum of West African Heads of National Medicine Regulatory Agencies [FOWAHN]); in the African Region (e.g. African Medicine Regulatory Harmonization [AMRH] and African Union-Smart Safety Surveillance [AU-3S]); and internationally (e.g. WHO, European Medicines Agency, International Coalition of Medicine Regulatory Authorities [ICMRA], Health Canada and Global Traceability Steering Committee); and

- establishment and implementation of a policy on engagement of external experts across regulatory functions to provide a platform to select, engage and recruit experts following documented procedures and defined criteria for education, training and experience which led to constitution of the National Drug Safety Advisory Committee (NDSAC) and Clinical Trials Expert Advisory Committee (CTAC), among others.

The foregoing activities give insight to the operations of NAFDAC regarding medicines (local and imported) and imported vaccines regulation and provides facts to support the achievement of the ML3 maturity level conferred by WHO. NAFDAC can therefore be said to have a robust and reliable system for the regulation of pharmaceuticals as the system has evolved over the years since the
inception of the agency in 1993 with continual improvement to the current level. However, the agency still experiences some challenges which were also pointed out by some of the questionnaire respondents and other stakeholders. One of the key challenges of the NMRA is inadequate financial and suboptimal human resources. The agency relies on government subvention for financing of capital projects and procurement of work tools such as the upgrade of facilities, purchase of laboratory equipment and operational vehicles, development of fit-for-purpose automated platforms for regulatory activities, among others. The government’s subsidy is inadequate and the process of securing release of the funds is difficult, and they are therefore not released in a timely manner. The agency is able to receive only some of what is currently obtainable from user fees paid by customers requiring regulatory services; according to information obtained during the stakeholder engagement for this survey, the agency is limited to expending 75% of its internally generated revenue and must remit 25% to the Federal Government. The agency is also mandated to allot 20% of its operating surplus to a General Reserve Fund, while the remaining 80% is to be remitted to government through the Consolidated Revenue Fund (CRF) in line with the Fiscal Responsibility Act.(44) (However, NAFDAC receives annual government budgetary allocations).

This challenge of inadequate resources was also identified from responses received from the questionnaire as a total of 52.8% of respondents (35.7% and 17.1% disagreed and strongly disagreed respectively) believed that the NMRA was not adequately resourced. Several of the interviewed stakeholders felt that NAFDAC is carrying out its responsibilities as well as possible within the limits of the available resources and could do much more if adequate resources were made available to the agency.

Whereas the agency’s activities are increasing with current requirements for regulatory functions, the agency is not able to employ an adequate number of qualified personnel commensurate with the level of operations. This is due to the government embargo on employment into the federal civil service.(45) NAFDAC is able to secure approval only to replace retired and other staff that have left the agency, so that the agency has the same number of staff despite the huge increase in activities. This limited number of staff, which includes a good number of well-trained and competent persons, also have to fulfil the agency’s commitment to subregional and regional harmonization efforts, as well as to other programmes, by participating in the activities aimed at achieving harmonization with other programmes in addition to their primary responsibilities.

Many of the persons interviewed from industry believed the government is not doing enough to support the NAFDAC, especially in the area of funding and staff remuneration, as the agency is experiencing an exodus of some very competent hands due to poor staff welfare conditions compounded by the general economic situation of the country. Some individuals who were offered jobs through the replacement process did not take up the offer as they were disappointed with the remuneration.

### 2.5 Capacity and preparedness of the NMRA for regulation of local manufacturing of vaccines, including mRNA vaccines

The importance of effective and efficient regulatory oversight in ensuring access to safe, efficacious, and quality-assured medicines and vaccines cannot be over-emphasized. A well-functioning and well-resourced regulatory system is critical to the success of efforts being made to boost manufacturing
capacity as the regulatory system ensures that medical products entering the market are safe, effective and produced according to acceptable quality standards.\(^3\)

WHO considered the Nigerian regulatory system to be operating at Global Benchmarking maturity level ML3 for regulation of medicines and imported vaccines as the existing regulatory structure is judged to be sufficiently stable and well-functioning to ensure access to safe, efficacious and quality-assured medicines and imported vaccines in the country. Although Nigeria was not benchmarked for the NRA lot release regulatory function because there is currently no human vaccine manufacturing facility in the country, NAFDAC – through the National Control Laboratory for Vaccines and Biologicals – has been carrying out lot release of imported vaccines since inception of the laboratory. This includes lot release of mRNA vaccines imported during the COVID-19 pandemic and which are still being used for COVID-19 vaccination.

With the lessons learned from the supply chain disruptions experienced during the COVID-19 pandemic, it is obvious that the only way a country can have medicine security and vaccine self-sufficiency is through local manufacturing of medicines and vaccines. Efforts are currently being made to resuscitate local manufacturing of human vaccines which has been suspended in the country since 1991.

Stakeholder responses to the questionnaire revealed varying opinions on the capacity of the NMRA to regulate local manufacturing of vaccines, as seen in Table 4 and Figure 7.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response (Agree)</th>
<th>Response (Strongly agree)</th>
<th>Response (Disagree)</th>
<th>Response (Strongly disagree)</th>
<th>Response (Not sure)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is NMRA adequately resourced?</td>
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<td>3</td>
<td>25</td>
<td>12</td>
<td>14</td>
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<tr>
<td></td>
<td>22.8</td>
<td>4.3</td>
<td>35.7</td>
<td>17.1</td>
<td>20</td>
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<tr>
<td>Are there appropriate pathways?</td>
<td>26</td>
<td>4</td>
<td>12</td>
<td>5</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>37.1</td>
<td>5.7</td>
<td>17.1</td>
<td>7.1</td>
<td>32.8</td>
</tr>
<tr>
<td>Does the NMRA have clearly defined policies, procedures and standards?</td>
<td>28</td>
<td>4</td>
<td>8</td>
<td>4</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>5.7</td>
<td>11.4</td>
<td>5.7</td>
<td>37.1</td>
</tr>
<tr>
<td>Are there regulatory reliance and convergence mechanisms within the NMRA?</td>
<td>21</td>
<td>6</td>
<td>13</td>
<td>3</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>8.5</td>
<td>18.1</td>
<td>4.3</td>
<td>38.6</td>
</tr>
<tr>
<td>Are there platforms within the NMRA that enhance trade?</td>
<td>25</td>
<td>6</td>
<td>14</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>35.7</td>
<td>8.6</td>
<td>20</td>
<td>7.1</td>
<td>28.6</td>
</tr>
</tbody>
</table>
A significant proportion of the questionnaire respondents (42.8%) agreed that the NMRA had appropriate pathways for registration and lot release of vaccines, while 24.2% disagreed with this notion. Some 32.8% of the respondents were, however, not sure of the available pathways for these regulatory functions.

Similar sentiments were expressed in the area of availability of defined policies and procedures in the NMRA for regulation of vaccines and other biologicals, as 40% agreed that the agency had policies and procedures in place while 37.1% were not sure.

While 38.6% of respondents were not sure if there were regulatory reliance and convergence mechanisms within the NMRA targeted at promoting accessibility to quality, safe and efficacious vaccines and other biologicals, including mRNA vaccines, only 30% of respondents agreed that the agency was deploying these Good Regulatory Practices.

These results from the questionnaire give the impression that there is a lack of visibility of the systems in place in the NMRA for vaccine regulation although NAFDAC has done a lot in preparation for the regulation of local vaccine manufacturing, as seen from further information obtained during this survey. The agency therefore needs to create more stakeholder awareness of its activities as they relate to the regulation of vaccine manufacturing.

Leveraging existing regulatory operations, NAFDAC is taking some steps to prepare for regulation of local vaccine manufacturing when it eventually commences. Some of these steps are highlighted below.
2.5.1 Personnel training in preparation for regulation of vaccine manufacturing

One of the important resource gaps identified by many experts in enabling local vaccine manufacturing, especially in LMICs, is the availability of skilled, trained personnel in this highly technologically demanding field. Unless this gap is bridged, achievement of the goal of vaccine self-sufficiency and equity through local vaccine manufacturing will remain a mirage.

NAFDAC is committed to building capacity of relevant staff of the agency in different areas of vaccine regulation which include licensing, inspection, laboratory assessment, post-market surveillance and lot release. The agency makes it mandatory for all pharmaceutical GMP inspectors to participate in available virtual and self-paced online training programmes on vaccine manufacturing – such as the Virtual cGMP Training Marathon for Vaccine Manufacturing organized by WHO in 2021 and the Introduction to GMP Manufacturing and Characterization of Vaccines for Human Use organized by the United States Pharmacopeial Convention (USP) in 2022. These are part of the efforts to prepare the inspectorate for the regulation of locally manufactured vaccines. Most of the inspectors received the certificate of participation which was provided to participants who completed the training programmes and participated in the assessment of participants.

To ensure that all countries build the necessary capacity to produce their own vaccines and other health technologies, WHO in conjunction with the Government of the Republic of Korea established a biomanufacturing workforce training hub (Global Training Hub for Biomanufacturing, GTH-B) at the International Vaccine Institute (IVI) in Seoul. The hub was established to train persons from all interested countries in scientific and clinical research of vaccines, as well as to build production capacity. The hub hosted the first of the planned courses in July 2022 and three staff of NAFDAC from the Pharmaceutical Inspectorate, Vaccines and Biologicals Laboratory and the Vaccines Registration Unit participated in the intensive two-week physical training. The staff are to conduct a step-down of the training to relevant staff of the agency to continue capacity-building efforts in preparation for the regulation of local vaccine manufacturing.

The agency is also making arrangements for relevant staff to attend other upcoming training organized by the GTH-B and other support partners (e.g. the South Africa Biomanufacturing Workshop to be organized by Promoting the Quality of Medicines Plus for staff of NMRAs working in licensing, regulatory inspection and laboratory). The agency expects that, with the commencement of local vaccine manufacturing, there will be an increase in conduct of clinical trials of vaccines. Therefore, training to build capacity of more NAFDAC staff in the area of clinical trials and GCP inspections was organized and conducted over a four-month period in 2022. This training was conducted by internal resource persons from the Clinical Trial Division of the DER directorate. The objective of the training was to increase the pool of staff with capacity in clinical trial regulation to enable proper management of clinical trials for pharmaceuticals, vaccines and other regulated products across the country.

2.5.2 Laboratory capacity for assessment of vaccines and lot release

Prior to the attainment of the WHO Global Benchmarking maturity level ML3 by NAFDAC in March 2022, the agency had already taken a decision to continue strengthening the regulatory framework towards achievement of maturity level ML4, which will further enhance the system to be able to regulate locally-manufactured vaccines and other biologicals and lot release of these products, in addition to effective regulation of medicines.

To this end and to ensure effective discharge of responsibilities, the Vaccines, Biologicals and Medical Devices Laboratory Services Directorate (VBM-LSD) was formed from the former Laboratory Services (Drugs and Biologicals) Directorate. The National Control Laboratory for Vaccines and Biologicals is supervised by this new directorate and the laboratory is currently undergoing a major upgrade with the construction of a world class laboratory facility which will also include a modern animal house.
The agency intends to procure state-of-the-art biomedical equipment required for analysis of vaccines and biologicals, including analysis of mRNA vaccines.

The VBM-LSD is also in the process of developing a regulation for lot release of locally-manufactured vaccines, as well as reviewing the related standard operating procedures. The directorate is also developing a guidance document on chemistry, manufacturing and control of vaccines for intending manufacturers; this document will also serve as a work tool for the relevant regulatory personnel.

2.5.3 Supply chain visibility and traceability of vaccines

Nigeria’s National Pharmaceutical Traceability Strategy was launched in 2020 in support of some of the objectives of the second National Strategic Health Development Plan (NSHDP II) which aims to improve availability and functionality of the health infrastructure required to optimize service delivery at all levels and to ensure that quality medicines, vaccines and other health commodities and technologies are available, affordable and accessible to all Nigerians.\(^{(47)}\) The strategy involves the deployment of GS1 international standards which enable unique identification, accurately capture and automatic sharing of vital information about products.\(^{(48)}\)

As part of the regulatory strengthening efforts and in fulfilment of part of the regulatory goals of establishing a prevention, detection and response mechanism to minimize substandard and falsified medicines and other regulated products, NAFDAC has drawn up a five-year Traceability Implementation Plan in line with the National Strategy in order to achieve supply chain visibility and strengthen its pharmacovigilance activities.

Implementation of the strategy was piloted with tracking of the batches of Covishield\(^{®}\) COVID-19 vaccines received during the pandemic along the supply chain in Nigeria. This was done in conjunction with the National Primary Health Care Development Agency (NPHCDA) and GS1 Nigeria. The report of the pilot study indicated achievement of the objectives – such as proving and assuring stakeholders that traceability is fully implementable in Nigeria for vaccines, medicines and medical devices, providing reliable data on movement of the vaccines through the supply chain to the end-user, supporting the design and validation of a traceability model according to local country requirements and developing a prototype system that can be tested in real time.\(^{(49)}\)

The above activities and other ongoing efforts are part of a bid to build regulatory capacity for effective regulation of local vaccine manufacturing, including mRNA vaccines and lot release by NAFDAC.

2.6 Existing research and development (R&D) capability and in-country capacity for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccine production

2.6.1 Research and development of pharmaceuticals

The pharmaceutical manufacturing industry encompasses manufacturing, testing and distribution activities, all of which depend largely on R&D for the growth of the industry. Efforts in pharmaceutical R&D lead to the creation of new treatments and medicines to treat diseases and to improve people’s quality of life.\(^{(4)}\) Good-quality R&D is crucial to the long-term success of the pharmaceutical industry but acquiring adequate funding for it is often a challenge, particularly at the feasibility or concept stage of R&D.\(^{(50)}\) Governments of some countries have dedicated programmes which provide the required funding to support pharmaceutical R&D such as the United Kingdom’s Biomedical Catalyst programme which provided £ 180 million in 2012 to support small and medium-sized enterprises, academics and universities in that country to accelerate R&D in innovative health-care projects.\(^{(51)}\) Also, pharmaceutical manufacturers, especially in developed countries, devote a lot of their income
Research and development of pharmaceutical products in Nigeria is a sector that would have been more vibrant but is hindered by a lot of challenges. This is seen from the responses received from the questionnaire which indicates a total of 75.4% of respondents agreeing that the pharmaceutical industry is capable of R&D of pharmaceutical products (Figure 7).

The pharmaceutical R&D sector has, however, experienced some revitalization in the wake of the COVID-19 pandemic. The CBN established the Healthcare Sector Research and Development Intervention Scheme (HSRDIS) to help strengthen the public health-care system with innovative financing of R&D in new and improved medicines, vaccines and diagnostics of infectious diseases in Nigeria. The HSRDIS is designed to trigger intense national R&D activities to develop Nigerian vaccines, drugs and herbal medicines against the spread of COVID-19 and any other communicable or noncommunicable diseases through the provision of grants to biotechnological and pharmaceutical companies, institutions, researchers and research institutes. (52)

The National Institute for Pharmaceutical Research and Development (NIPRD) is an organ of government that has research and development of drugs, biological products including vaccines and pharmaceutical raw materials from indigenous natural resources and by synthesis using appropriate science and technology methodologies as one of its major functions. (53) R&D of pharmaceutical products is being strengthened in NIPRD as the institution conducts R&D of phytomedicines for communicable and noncommunicable diseases (notably HIV, as well as sickle cell disease, diabetes, cancer and peptic ulcer), and antimicrobial agents for tuberculosis, typhoid fever and malaria.

NIPRD has the capacity to carry out collection, identification and extraction of APIs from medicinal plants using high throughput technologies for fractionation and isolation of these substances. The institution is also able to conduct toxicity, preclinical safety, in vitro efficacy and microbiological quality assessments of isolated substances, as well as elemental and proximate synthesis and dosage formulation studies.

NIPRD has developed a number of products, namely: Niprisan, Niprisan-plus and Niclovix (treatment of sickle cell disease), Niprimmune and Niprimmune-plus (immune booster), Nipribol (treatment of Ebola Virus Disease), Niprifan (antifungal agent), Niprimal (treatment of malaria) and Neem products (treatment of malaria). The institute has licensed the rights for Niprisan and Niclovix to May & Baker Nig. Plc. for commercialization of the products.

NIPRD has also contributed some interventions during the recent Ebola Virus Disease epidemic and COVID-19 pandemic by producing repurposed versions of some of their products, specifically Nipribol and Niprimmune, for use in Ebola and COVID-19 respectively. NIPRD is in discussions with some companies for human trials of some of their products that have undergone preclinical studies.

The institute is currently working on the development of pharmaceutical raw materials to ensure self-sufficiency and sustainability and has held several webinars and colloquia with relevant stakeholders to develop the guiding policy. NIPRD has embarked on the development of pharmaceutical-grade starch and has a mini drug manufacturing unit for pilot-scale production of developed research products. It is also being supported by a grant from the African Development Bank to kickstart the process of developing synthetic APIs.

Interviews with key stakeholders in the industry revealed that a lot of research projects with potential to benefit the pharmaceutical industry are ongoing at different universities and research institutes but...
that the lack of funding has opened opportunities for foreign organizations who then fund and publish this research and thus acquire the rights to the eventual discoveries. Some stakeholders are equally of the opinion that rewards for research are not guaranteed in Nigeria and this is compounded by the instability in the university system with disruption due to industrial action.

The role of government in improving pharmaceutical R&D in the country was emphasized by stakeholders as the government’s continued investment in R&D in the wake of the COVID-19 pandemic is a necessity for enhancement of the sector while also being cautious to ensure that government policies are consistent and do not work against R&D in the sector. This was seen in the instance where regulatory approval was given for importation of an innovative product (Amoxycillin Dispersible tablets) in which a local pharmaceutical manufacturer had already invested heavily, leading the manufacturer to suffer huge losses by not being able to compete in the market with the imported brands.

2.6.2 Research and development of vaccines and other biologicals, including mRNA vaccines

Vaccines offer many benefits compared with most other health-care products. Vaccines that are efficacious against infections have an aggregate health impact by reducing the burden of disease through direct protection of those vaccinated and reducing transmission, thereby providing indirect protection to the population. Unfortunately, the vaccine industry was considered one of the most vulnerable and least lucrative segments of the pharmaceutical industry because demand for vaccines usually comes from governments. The companies that have invested massively in R&D of new vaccines are always at risk if governments refuse to pay a fair price for their products. This is an important reason why vaccine manufacturing companies often refuse to sell their products directly to LMICs, thereby leaving the majority of the world population unprotected by vaccines for diseases that are endemic to their regions.\(^{(54)}\)

Nigeria has been identified as one of the six African countries that possess the capability to manufacture vaccines.\(^{(39)}\) This is supported by the responses received from manufacturers, as seen in Table 5 and Figure 8, where 47.8% of respondents agreed that local manufacturers are capable of embarking on vaccine-related R&D activities while 30.4% disagreed. Respondents were, however, not unanimous in their opinion about the availability of established regulations and standards to support product development and provide opportunities for innovations in the local manufacture of vaccines and other biologicals, including mRNA vaccines. A total of 38.6% agreed or strongly agreed with the notion while a total of 32.8% disagreed or strongly disagreed. Some 28.6% of the respondents were unsure of the existence of any such regulations or standards.
Table 5. Capacity for pharmaceutical and vaccine-related R&D activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Response (Agree)</th>
<th>Response (Strongly agree)</th>
<th>Response (Disagree)</th>
<th>Response (Strongly disagree)</th>
<th>Response (Not sure)</th>
</tr>
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<tbody>
<tr>
<td>Capacity for pharmaceutical R&amp;D</td>
<td>Freq.</td>
<td>%</td>
<td>Freq.</td>
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<td>Freq.</td>
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<tr>
<td></td>
<td>36</td>
<td>52.2</td>
<td>16</td>
<td>23.2</td>
<td>10</td>
</tr>
<tr>
<td>Capacity for vaccine (incl. mRNA) R&amp;D</td>
<td>26</td>
<td>37.7</td>
<td>7</td>
<td>10.1</td>
<td>13</td>
</tr>
<tr>
<td>Regulations and standards supporting innovation</td>
<td>21</td>
<td>30</td>
<td>6</td>
<td>8.6</td>
<td>18</td>
</tr>
<tr>
<td>Synergy between industry and academia</td>
<td>10</td>
<td>14.3</td>
<td>1</td>
<td>1.4</td>
<td>33</td>
</tr>
</tbody>
</table>

Note: Freq = frequency.

Figure 8. Capacity for pharmaceutical and vaccine-related R&D activities
Nigeria has several research organizations with specific mandates for research into products that can improve the health of Nigerian citizens, especially in the area of vaccine discovery and development. The activities of some of these organizations are highlighted below.

**National Veterinary Research Institute (NVRI)**
The history of research into vaccine manufacture in Nigeria dates back to the early 20th century following the devastating effects of Rinderpest disease outbreaks in the country leading to the death of millions of cattle which affected the livelihoods of many people. In 1995, the name Federal Department of Veterinary Research was changed to The National Veterinary Research Institute with the mandate to, inter alia, conduct research into all aspects of animal diseases, their treatment and control, and to develop and produce animal vaccines, sera and biologicals.

NVRI has developed and currently produces 22 bacterial and viral veterinary vaccines for prevention of diseases of economic importance to animal health using conventional technologies such as embryonated chicken eggs, cell culture and bacterial culture in the last seven to eight decades. The vaccines produced by the institute are activated and live-attenuated vaccines using whole viruses and bacteria.

Engagement with representatives of NVRI revealed that activities of the institute are said to be 50% research and 50% vaccine production. The institute has a strong background in vaccine production spanning more than seven decades and currently has a lot of research activities in biotechnology, including ongoing work in deoxyribonucleic acid (DNA) and mRNA technology. Although the institute does not currently produce any mRNA vaccines, it has strong human capacity in modern biotechnology as well as some basic biotechnology equipment which will eventually help as a springboard for vaccine production using the mRNA technology.

The existing capacity and vaccine production experience in NVRI is the basis for recent collaboration between NVRI and other research institutions in the Vaccine Development Consortium, providing the institute with the opportunity to upgrade its facilities to accommodate biotechnology-based platforms for vaccine development (i.e. recombinant DNA, protein subunit and engineered viral vectored vaccines) but this does not include the mRNA platform for vaccine development and production. Although the mandate of NVRI is veterinary health products, the institute previously supported the Federal Vaccine Production Laboratory in the production of yellow fever vaccine before the facility was shut down. The institute is hopeful that future partnerships and collaborations with other relevant stakeholders, with support from international organizations and funding agencies, can help to upgrade their capacities and facilities to enable the development and production of mRNA vaccines for diseases of public health importance.

The production pipeline of the institute – e.g. tanks, freeze-driers, filling and capping facilities – are very old and basic. The institute has an uncompleted building that was intended to enable an increase in vaccine production capacity, but this project has been stalled due to lack of funding for both completion of the building and installation of required facilities and equipment to meet current GMP and other regulatory compliance demands. NVRI will also benefit from specialized training for the staff to further build their competence and overall performance.

**National Institute for Pharmaceutical Research and Development (NIPRD)**
Research into vaccines started at NIPRD in 1998 when some work was done to develop a candidate vaccine for HIV. The institution made a lot of progress at the time as the vaccine construct for HIV specific to the species of the pathogens found in Nigerian patients was developed. This project did not receive the required support at the time until recently when vaccine research was reactivated in the institution following receipt of funding from the government’s COVID-19 intervention.
The institution is currently carrying out research studies on COVID-related viruses using animal models. NIPRD is also part of an ongoing clinical trial in collaboration with NAFDAC and NIMR titled *Safety and immunogenicity fractional dosing of COVID-19 vaccines among adults in Nigeria (SIFCoVAN)*. The trial involves fractionation of available COVID-19 vaccines to determine if immune responses can be elicited at lower doses of the vaccines and possibly change the timeline for booster doses.

The institution has human capacity with knowledge in vaccine development with the available research fellows in genetics, virology, pharmacy, laboratory science and medical biology. This knowledge can be built upon with training in mRNA technology platform and other emerging technologies to produce HIV vaccines and other vaccines for use in the country.

**Nigerian Institute of Medical Research (NIMR)**

The Nigerian Institute of Medical Research (NIMR) was established via the Research Institutes (Establishment, Etc.) Order of 1977 with the mandate to carry out basic, applied and operational research for promoting national health and development in Nigeria. The institute has the responsibility of developing viable structures for the dissemination of research findings and providing the enabling environment and facilities for health research and training in collaboration with other stakeholders.\(^{(56)}\)

NIMR has a Centre for Human Virology and Genomics (CHVG) which has been ISO 15189:2012 accredited since 2017 and is a WHO-prequalified laboratory. The centre was officially designated as a WHO National Laboratory for HIV Drug Resistance Testing in 2021 after a rigorous assessment process.\(^{(57)}\) NIMR is gradually progressing in research leading to innovation as the institute is involved in translational research for national health programmes such as the malaria elimination programme and the tuberculosis (TB) and Neglected Tropical Diseases (NTDs) programmes. The institute is also involved in clinical trials such as those on control of onchocerciasis, antimicrobial resistance of Azithromycin and SIFCoVAN. The trial is being conducted in collaboration with NAFDAC and NIPRD.

In the area of vaccine R&D, NIMR used to provide the seed stock for the yellow fever vaccines manufactured by the defunct National Vaccine Production Laboratory, Yaba, Lagos but this stopped some decades ago. NIMR has, however, made progress in vaccine design and development since the COVID-19 pandemic.

NIMR is currently involved in the sequencing of pathogens to provide genetic data for new pathogens in circulation, development of peptide subunit vaccines, viral vector vaccines and nucleotide-based vaccines.

NIMR is interested in the development of vaccines for viral infections because of the realization that most viral infections that are local to the Nigerian environment do not affect the western world which, consequently, will not be interested in investing in development of vaccines for such infections.

The institute has the capacity to carry out genome sequencing to identify genetic patterns of pathogens on four different platforms, namely: the DNA Nanoballs, Oxford Nanopore technology, Genetic Analyzer, and Applied Biosystems Genetic Analyzer. These systems are high-throughput DNA sequencing instruments with state-of-the-art technologies at their core.

The institute has established three tissue culture laboratories for production of pure cell lines for viruses, one for culturing viruses (Center for Human Virology and Genomics) and another for growing malaria parasites with support from the Medical Research Council Unit The Gambia at the London
School of Hygiene and Tropical Medicine. The institute therefore has capacity to make vaccines associated with cell cultures such as the AstraZeneca COVID-19 vaccine which is a non-replicating viral vector vaccine that cannot be produced without tissue culture and sequencing templates.

NIMR has also enhanced its in-house capacity for cloning to express peptide subunits and was supported by the MTN Foundation of Nigeria to establish a DNA synthesis laboratory to make primers and to clone artificial DNA fragments – nucleotides – for different pathogens based on the gene sequence information provided from the sequencing laboratory. NIMR is the only centre in western Africa with capacity to develop artificial DNA fragments and this can speed up the rate of development of DNA vaccines. Despite these achievements, NIMR is yet to progress its research work into the area of mRNA vaccine technology.

The available capacity in NIMR to develop oligonucleotides (short DNA fragments) as well as longer genetic materials is currently being used to develop a candidate vaccine for malaria using the RH5 platform which is the global target for development of malaria vaccine. NIMR has successfully generated population-specific data for the RH5 platform for malaria vaccine based on the institute’s disease surveillance system. This pathogen surveillance is still ongoing in some Nigerian states and the genetic materials from the pathogens are being harvested for further work in the sequencing and cloning laboratories. This project will be improved when additional funding is provided to enable coverage of more states of the federation and the generation of more robust population-specific data.

The institute is also able to carry out protein purification with its recent investment in protein purification equipment to achieve consistent product purity and quality in the development of protein subunit vaccines.

NIMR is part of a vaccine development consortium made up of Usmanu Danfodio University of Sokoto, the University of Jos, NVRI and National Research Institute for Chemical Technology (NARICT). The consortium receives funding from the Tertiary Education Trust Fund (TETFUND) to design and develop subunit vaccines, DNA vaccines and a Newcastle-based non-replicating viral vector vaccine.

However, the institution is facing challenges in developing the biomolecules into actual vaccines due to the lack of a GMP facility for pilot-scale production and quality control testing of the vaccines. Personnel of the institute are receiving GMP training to enable effective operation of the GMP facility when it is available.

NIMR has a surveillance team targeted at viral haemorrhagic fever research which has led to the development of oligonucleotides used for the preparation of diagnostic test kits for Lassa fever and yellow fever. The institute also has ongoing work to produce test kits for monkeypox. Support is needed to build on the success of these kits to lower the cost of diagnostic kits and, where these kits are readily available to the many approved medical laboratories, this will increase surveillance activities and provide information specific to strains of pathogens circulating in Nigeria. The genetic materials of these geographically specific strains can be studied to reproduce the sequences of the materials and can lead to the development of vaccines that will be sensitive to the strains of these Nigeria-specific pathogens. This is important because many of the vaccines developed in other countries for use in Nigeria have been found to contain serotypes that are not sensitive to the strains of the pathogens in circulation in the country.

**National Biotechnology Development Agency (NABDA)**

The National Biotechnology Development Agency (NABDA) was established under the aegis of the Federal Ministry of Science and Technology in 2001 to implement the National Biotechnology Policy which is aimed at promoting, coordinating and setting research and development priorities in
biotechnology for Nigeria. NABDA has, as part of its responsibilities, the conduct of research and development on biotechnology in priority areas of the economy and drawing up programmes and policies for biotechnology utilization in Nigeria. NABDA also promotes the development and application of acceptable and profitable technologies through strategic investments in biotechnology research and development in order to support innovation and economic development and to ensure that Nigeria becomes self-reliant in the development and application of biotechnology-based products and services.

NABDA has a medical biotechnology department which runs a programme with the objective of deploying recombinant technology for relevant application in health-care products and development of candidate vaccines for emerging and re-emerging infectious diseases and pathogens. NABDA is keen to discover and develop vaccines for diseases endemic to Nigeria and has been able to procure some basic equipment for the development of nucleic acid candidate vaccines with a focus on the mRNA platform. This includes equipment for protein purification, electrophoresis, cell culture, biobanking, microscopy, ELISA, spectrophotometry, stability, and vaccine immunology analysis.

The agency is also building personnel capacity in this area with two of its staff currently running PhD programmes on vaccine immunology. The agency also engaged an expert in the area of vector construction to support the vaccine development project. It has streamlined the workflow system and has set up the platform for mRNA candidate vaccine development, especially for current routine immunization vaccines used in the country and vaccines for emerging diseases.

NABDA has a five-year workplan for the vaccine and antibody development project which is currently being executed within the limit of its meagre resources. The programme involves acquiring the technology for homegrown development of nucleic acid and recombinant vaccines; acquiring the technique for development and rapid generation of therapeutic antibodies for intervention in the health sector; and for developing transgenic laboratory animal models for human disease-testing for preclinical and early clinical vaccine trials.

NABDA has also been able to isolate some antibodies for HIV and is currently in the process of determining the antigens that will possibly serve as candidates for protein subunit vaccines for HIV.

NABDA is involved in drug development from medicinal plants and is currently engaged in a project with the International Center for Genetic Engineering and Biotechnology (ICGEB) for transfer of technology for production of insulin and erythropoietin which requires a pilot-scale production facility to demonstrate quality before offtake by a local manufacturer for commercialization. The agency will continue to support any local manufacturer that decides to take up commercialization of the product.

The agency is, however, facing serious funding challenges as government support is grossly inadequate to support equipment procurement, staff training and the engagement of experts. For instance, the subsidy received by the NABDA from the government for 2022 is not enough to send one staff member for training. The lack of funding also makes the environment inconducive for research and encourages knowledge flight as researchers will leave for employment that will enable them to achieve their aims and materialize their ideas.

The lack of funding of NABDA has also hindered progression of some of its discoveries to pilot production level as the agency does not have the facilities for pilot-scale production to demonstrate the effectiveness of the discoveries downstream. A pilot production facility is important, especially in case of another epidemic or pandemic, as the facility will enable immediate progression of the laboratory-scale work to pilot-scale downstream operations which, if found effective, can immediately be taken up by commercial manufacturers for timely response to epidemics or new infections.
The agency also identified the need for synergy between researchers and government agencies to enable harmonization of ongoing research in similar areas in order to avoid duplication of efforts as well as to harmonize policies and programmes. If not resolved, these challenges may hinder progress in the development of vaccines for use in Nigeria.

This sentiment is similar to that shared by the questionnaire respondents (Figure 7) where 47.1% of them disagreed that there was strong synergy or collaboration between the industry and the research institutes/academia that would enable research work by these institutes to progress to commercialization by the industry. This finding also aligns with a study conducted by Ayo-Lawal and colleagues which revealed that there was poor synergy in research between manufacturers and researchers from both universities and research institutes, and weak academia–industry interaction.(61)

Just as the above-mentioned study concluded that the pharmaceutical innovation system in Nigeria requires serious government interventions to create a robust platform to promote productive interactions between all involved. Stakeholders also affirmed the need for a platform for strong collaboration between the pharmaceutical manufacturing industry and the research community to enable exploitation of the benefits of ongoing research into medical products to the advantage of the population.

The Vaccine Development Consortium
As part of the efforts of government to boost the local manufacturing of vaccines, the Federal Government set up a consortium of universities and research institutes in Nigeria to accelerate development of vaccines required for diseases of public health importance. The consortium is made up of Usmanu Danfodio University, Sokoto; Nigeria Institute for Medical Research (NIMR), Yaba; Faculty of Veterinary Medicine, University of Jos; National Research Institute for Chemical Technology (NARICT), Zaria; and National Veterinary Research Institute (NVRI), Vom.

The consortium currently has responsibility for development of recombinant DNA vaccine for the prevention of Lassa fever in Nigeria as well as accelerated development of COVID-19 vaccine using multiple technologies – including the recombinant plasmid DNA vaccine platform, the engineered viral vector vaccine platform, the recombinant peptide subunit vaccine and the nanoparticle delivery system.

The members of the consortium have specific roles in the ongoing vaccine development activities, as follows:

a. Usmanu Danfodio University, Sokoto, has responsibility for molecular construction of recombinant DNA and engineered viral vectored COVID-19 vaccine using a reverse vaccinology approach, while NIMR has the task of cloning and expression of SARS COV-2 spike protein as a potential subunit vaccine candidate against COVID-19.

b. NARICT is to engage in development of chitosan nanoparticles for enhanced delivery of recombinant DNA and subunit COVID-19 vaccine. The preclinical evaluation of the novel COVID-19 vaccine candidates based on recombinant DNA, engineered viral vectored and protein subunit approaches is to be conducted by the Faculty of Veterinary Medicine, University of Jos. Upscale production of the genetically engineered COVID-19 vaccine is to be done by NVRI.

The consortium reported having completed the prediction of immunogenicity and structural modelling of the best vaccine candidates, as well as the molecular cloning and construction of the vaccine candidates, while the nanoparticle synthesis and characterization of the vaccine constructs
was ongoing at the time of this survey. This will be followed by scale-up and preclinical evaluation of the vaccine constructs.\(^{62}\)

The consortium is, however, faced with challenges of inadequacy of research funding for the equipment and consumables needed for vaccine research, in addition to little capacity particularly in mRNA vaccine research and modern vaccine production pipelines because the facilities at NVRI are old conventional production platforms. The consortium requires Biosafety level 4 (BSL-4) laboratories for handling hazardous pathogens as well as upgrade of the BSL-3 laboratories in the various institutions. The consortium is also in need of adequate clinical trial centres as well as a suitable animal house for preclinical vaccine efficacy and safety studies.\(^{58}\)

During discussions, some of the interviewed stakeholders emphasized the need to harmonize available research work in universities and other research institutions in order to support local manufacturing of pharmaceutical products and vaccines.

The Nigerian Immunology and Infection Network (NiiN), which is an initiative of NABDA, has a database for researchers and research institutions – including foreign researchers working with Nigerian scientists and institutions – involved in vaccine- and immunology-related research, with details of the research on the database as well as companies interested in vaccines. The essence of the network is to bring researchers and their studies together on one platform with the manufacturing industry so that, when a disease outbreak or new infection occurs, the platform can be consulted to find out available research on that disease – which can then be leveraged to help find solutions to the emerging health problem. This also serves as a platform for training and mentoring of young researchers in the area of vaccine development. The database can be enhanced by being properly funded to accommodate all research work in the field of vaccine development and immunology studies so that available funding from support partners can be targeted to enable the harmonized studies to progress from the laboratories to the manufacturing facilities.

Other research stakeholders identified the importance of gathering surveillance data to determine the need for specific vaccines by carrying out detection and quantification exercises and building capacity for local manufacturing and testing of the needed vaccines and related health commodities in order to enable proper responses to outbreaks.

It is also expected that, if government continues to invest in R&D of medical products, including pharmaceuticals and vaccines as in the COVID-19 pandemic, with support from development partners, innovation and discovery of medical products that are fit for Nigerians and for export will be made available. This can be done by putting the available intellectual capacity and facilities in the country to effective use, as is the practice of governments in developed countries.

### 2.7 Patent system for locally-manufactured pharmaceuticals, vaccines and other biologicals, including mRNA vaccines

The National Drug Policy recognizes the need for patent protection, but it emphasizes that such patent rights should not hinder access to essential medicines by Nigerians.\(^{5}\) The policy therefore provides for coordination between the government ministries and agencies responsible for health, justice and trade to ensure that public health concerns are considered in international trade negotiations and agreements in order to ensure access to medicines by Nigerians.\(^{5}\)

Three government organizations are responsible for executing activities relating to intellectual property rights in Nigeria:
a. The National Office for Technology Acquisition and Promotion (NOTAP) is a parastatal body under the Federal Ministry of Science and Technology and is responsible for commercialization of R&D results and inventions and promotion of intellectual property, among other functions. The office also provides guidance to persons wishing to patent their innovations/inventions.\textsuperscript{(63)}

b. The Nigerian Copyright Commission (NCC), which is the government agency responsible for all copyright matters in Nigeria, also has implied mandates in other related intellectual property issues.\textsuperscript{(64)} The NCC deals only with copyright relate mainly to literary and artistic works and is empowered by law to enforce compliance.

c. The Trademarks, Patents and Designs Registry of the Commercial Law Department in the Federal Ministry of Industry, Trade and Investments is responsible for protection of trademarks, patents and designs in Nigeria, using processes that are consistent with global best practices.\textsuperscript{(65)}

Some research stakeholders noted that the existing intellectual property rights system in the country provides for sharing of patent rights in an innovation between the organization on whose platform the innovation was developed and the individual that made the discovery.

In reality, however, Nigeria’s intellectual property (IP) regime can be said to be non-existent since most of the respondents (45.8\%) were not sure if there was any identifiable patent and intellectual property rights protection for novel research and product discovery – particularly for vaccines and other biologicals, including mRNA vaccines. Some 23.7\% and 13.6\% of the respondents disagreed and strongly disagreed respectively that the existing patent and intellectual property rights regime in the country offered any significant patent protection, and this sentiment was also expressed by some other interviewed stakeholders. The questionnaire results are reflected in Figure 9.

\textbf{Figure 9. Existence of effective patent and intellectual property rights protection in Nigeria}

\begin{figure}[h]
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\includegraphics[width=\textwidth]{figure9.png}
\caption{Existence of effective patent and intellectual property rights protection in Nigeria}
\end{figure}
Several of the interviewed stakeholders expressed displeasure at the inadequacies of the patent system in the country which they said does not encourage innovation.

One of the stakeholder organizations was able to develop a COVID-19-related health commodity which was presented to the government agency responsible for patents, but the product was rejected on the basis that no patents were being granted for COVID-19-related products. The industry is of the opinion that this is demotivating and may discourage research and development of new products.

A similar experience was noted in the development of a novel pharmaceutical product or modification of an existing one which should qualify the innovator for pioneer status, leading to incentives such as a tax holiday for a number of years. Two pharmaceutical companies that have been able to develop and manufacture new dosage forms for existing products for the first time in Nigeria were not granted that recognition and did not benefit from the related incentives. It can be argued, however, that such status can be granted only if the companies filed for it with the relevant government agencies. These companies invested large sums of money to set up facilities to manufacture these dosage forms, but the existing policies did not support the innovation and investment because imported brands of these products were allowed to flood the market, which made it impossible for the companies to compete and they therefore suffered high losses on their investments. Such occurrences will discourage other companies from investing in innovative products.

Manufacturers posited that the business environment in the country is not conducive for them as they battle with issues of infrastructure, finance and foreign exchange – among other challenges – and they are therefore struggling to survive, which does not give them room to crystallize ideas that can lead to innovation. Others that have made attempts to manufacture innovative products did not get a return on investment as their efforts were thwarted by the registration of cheaper imported brands.

Some of the interviewed stakeholders argued that the administrators of the IP system in Nigeria are knowledgeable about the laws guiding the patent system but need to be more familiar with the activities of different areas of innovation because investigations of claims made by innovators are not conducted thoroughly. They were also of the view that there is a need for synergy between the relevant agencies and departments that have input into the investigation of claims made by innovators and the granting of patents to ensure the veracity of the claims as this will ensure that evidence-based decisions are made.

Another stakeholder stated that the relevant government agency in collaboration with the Ministry of Industry, Trade and Investment should create more awareness about the opportunities available for exploitation in the recent waiver by the World Trade Organization so that both the research environment and industry can make use of the available information on existing vaccine products for developing vaccines for local needs. The government agencies may also need to seek expert help to guide the policy-making process to address these issues as they may need more knowledge.

2.8 Existing and potential technology transfer activities for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccines

Discovery and development of new products and technologies occur in laboratories at an experimental level, but these discoveries are of no benefit to the needy patient if they are not commercialized and made accessible.
Technology transfer in pharmaceutical manufacturing is the process of transferring information and technologies necessary to manufacture consistently a quality drug product from its inception in a laboratory to the stage of a product fit for commercialization. Technology transfer is a platform that enables an innovator of a product to make a discovery or invention available to a commercial partner for scale-up of the product to a commercial level and hence allows access to the product by patients or other persons in need of the product. It is common knowledge that many new products are discovered and developed in high-income countries while LMICs absorb these products and technologies from the former. In many cases, however, some LMICs are unable to accept these technologies for various reasons — including financial, technical, production and regulatory capacity.

The benefits of technology transfer especially to local manufacturers in developing countries are huge; they include a potential increase in manufacturing capability of the LMIC company which will lead to savings in production costs over time as well as cheaper production and labour costs to the innovators, thereby reducing the cost of drug manufacturing and widening margins. The regulatory environment in some LMICs is also very strict about allowing foreign corporations access to their markets in a bid to protect the local manufacturing industry, so technology transfer to a local manufacturer is a beneficial investment for the foreign company and benefits local industry as well.

Engagement with some local manufacturers during this survey revealed that there are several instances of previous and ongoing contract manufacturing arrangements between multinational companies, such as Sanofi Aventis and GlaxoSmithKline, and the local manufacturers for the manufacture of some frontline pharmaceutical products. This information was also confirmed during engagement with the NMRA as evidence of technology transfer between GSK and the local manufacturer which included facility upgrade to provide dedicated production suites. Transfer of processes and analytical methods were cited and verified for adequacy and compliance with requirements during regulatory inspection of the manufacturer. The manufacturers affirmed that new knowledge gained during the technology transfer activities had also helped them improve their internal operations as the sending unit (Contract Giver) conducted several training sessions for staff of the receiving unit (Contract Acceptor) in both the understanding of the technology transfer process and the actual technical transfer. The transfer included process and method validation, production-scale qualification and process technology, as also highlighted by Dogra and colleagues in their paper on technology transfer in the pharmaceutical industry. The authors reiterated that training between the product developers and the manufacturers is key to the success of the technology transfer project.

PMG-MAN also hinted at ongoing discussions between a local manufacturer and an API manufacturer in India for transfer of technology for the manufacture of Solpadine and Pyrimethamine API which will be the first attempt at API manufacturing in Nigeria. Just as indicated in literature by experts in the field of intellectual property and technology transfer, if this arrangement succeeds it will be a win-win situation for both parties. It is expected that human and operational capacity of the receiving unit will be improved while access to new markets will be guaranteed for the sending unit due to the opportunities for export of the product to neighbouring countries.

Just as elucidated in reviewed literature, progress with technology transfer activities in the Nigerian pharmaceutical manufacturing industry can increase the consistency of drug supply and decrease the dependence on imports. It will also improve the competence of the local workforce and reverse “brain drain” from the country by increasing employment opportunities in local companies operating new-generation technologies.
These opportunities for technology transfer could also be attributed to the Five-plus-Five-Year Validity Policy by NAFDAC for the migration of previously imported FPPs to local manufacturing although the policy is applicable only to products that local manufacturers have the capacity to produce or cases when partnership with the foreign corporation would enhance the local capacity to manufacture. The knowledge gained in execution of the transfer of technology is good for capacity-building for the relevant companies and this will make implementation of subsequent projects easy for such companies.

In the area of vaccine manufacturing, and especially mRNA vaccines, Nigeria was chosen as one of the six Spoke countries to receive the technology for mRNA vaccine production from the technology transfer hub in South Africa. Biovaccines Nigeria Limited (BVNL), a joint venture company of the Federal Government of Nigeria represented by the Federal Ministry of Health and May & Baker Nig. Plc., is expected to receive the technology on behalf of the country. BVNL is reported to have had series of meetings with Afrigen Biologicals, the operators of the Technology Transfer Hub in South Africa, and other partners, to develop an integrated workplan that will guide the activities for obtaining and adapting the mRNA technology for pandemic preparedness and to support universal health coverage in Nigeria.(70)

The BVNL intends to manufacture the vaccines used for routine immunization in the country with plans to adapt the mRNA technology for developing novel vaccines for other vaccine-preventable diseases such as Lassa fever.(69) Unfortunately, the company has not been able to kickstart the setting-up of their manufacturing facility due to financial and other constraints. However, the company is engaging in capacity-building of relevant personnel and other activities in preparation for the manufacturing operations.

Interviews of R&D stakeholders also revealed that there are some ongoing technology transfer discussions for some pharmaceuticals, vaccines and biologicals – such as the collaboration between NIPRD and Oxford University for transfer of the technology used in developing the Lassa Fever vaccine. This collaboration is a platform to be exploited to access the western Africa subregion (where Lassa fever is endemic) for further research and development work. Knowledge of the technology and other new learning will be leveraged by NIPRD for the development of other vaccine products.

NABDA is also involved in a project with the ICGB for transfer of the technology for production of insulin and erythropoietin. This project also requires the pilot-scale production facility to demonstrate quality before uptake of the intended product by a local manufacturer for commercialization.

On the basis of the existing and potential technology transfer activities and capabilities in the local pharmaceutical manufacturing and research space in Nigeria, it can be argued that – given the right conditions and availability of the needed support in terms of infrastructure, regulatory and financing mechanisms among other areas – there is great potential for uptake of transfer of technology for mRNA vaccines in Nigeria.

This sentiment is supported by the responses received from the questionnaire respondents, as seen in Figure 10 below and as stated by interviewed stakeholders. Almost half (47.2%) of the respondents (32.9% agreed and 14.3% strongly agreed) were confident in the ability of the industry to accept mRNA technology and progress it to commercialization. Some 28.5% disagreed with this position while 24.3% were not sure about the capacity of the industry for the uptake of mRNA technology.
Some stakeholders suggested the establishment of mega-companies through mergers and acquisitions as this would attract investors, R&D and technology transfer opportunities to such companies. It was pointed out, however, that the Nigerian cultural orientation towards business ownership hinders mergers and acquisitions that can lead to the creation of functional companies and facilities.

### 2.9 Challenges for local manufacturing of pharmaceuticals, vaccines and other biologicals, including mRNA vaccine production

Although Nigeria has about 170 local pharmaceutical manufacturing facilities, the industry is faced with many challenges. Some of these challenges include inadequate utilities and infrastructure with consequent high cost of production operations; high cost of funds for importation of raw materials and other inputs; lack of policy harmonization at the government level; unreliable market data and poor demand leading to low utilization of capacity; and tough competition from imported medicines. Scarcity of some required skills – such as those for product formulation – were discussed in earlier sections of this report and are reiterated in the responses received from the questionnaire (as shown in Table 6, Table 7, Figure 11 and Figure 12) for local manufacturing of pharmaceuticals, vaccines, and biologicals, including mRNA vaccines. The challenges and barriers hindering local manufacturing are highlighted in this section to give focus and visibility to the challenges as they apply generally or specifically to certain organizations within the ecosystem.
Table 6. Major barriers to local production of pharmaceuticals in Nigeria

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Response (Agree)</th>
<th>Response (Strongly agree)</th>
<th>Response (Disagree)</th>
<th>Response (Strongly disagree)</th>
<th>Response (Not sure)</th>
</tr>
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<td>Freq.</td>
<td>%</td>
<td>Freq.</td>
<td>%</td>
<td>Freq.</td>
</tr>
<tr>
<td>Inadequate financing mechanisms</td>
<td>23</td>
<td>33.3</td>
<td>28</td>
<td>40.6</td>
<td>16</td>
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<tr>
<td>Lack of political will</td>
<td>29</td>
<td>42.6</td>
<td>32</td>
<td>47.1</td>
<td>5</td>
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<tr>
<td>Limited local competence</td>
<td>16</td>
<td>22.9</td>
<td>10</td>
<td>14.3</td>
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<tr>
<td>Lack of infrastructure</td>
<td>19</td>
<td>27.1</td>
<td>45</td>
<td>64.3</td>
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<tr>
<td>Inconducive business environment</td>
<td>22</td>
<td>31.4</td>
<td>43</td>
<td>61.4</td>
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Note: Freq = frequency.

Figure 11. Major barriers to local production of pharmaceuticals
Table 7. Potential impediments to local vaccine production, including production of mRNA vaccines, in Nigeria

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Response (Agree)</th>
<th>Response (Strongly agree)</th>
<th>Response (Disagree)</th>
<th>Response (Strongly disagree)</th>
<th>Response (Not sure)</th>
</tr>
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<td>%</td>
<td>Freq.</td>
<td>%</td>
<td>Freq.</td>
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<tr>
<td>Local competencies</td>
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<td>Regulatory bottlenecks</td>
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<td>22</td>
<td>31.4</td>
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<tr>
<td>Lack of political will</td>
<td>21</td>
<td>30.4</td>
<td>41</td>
<td>59.4</td>
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<tr>
<td>Lack of intellectual property</td>
<td>28</td>
<td>40</td>
<td>15</td>
<td>21.4</td>
<td>15</td>
</tr>
</tbody>
</table>

Note: Freq = frequency.

Figure 12. Potential impediments to local vaccine production, including production of mRNA vaccines
Inadequate financing mechanisms to support local manufacturing of pharmaceuticals and vaccines, including mRNA vaccines
Available financing mechanisms for local manufacturing of pharmaceuticals were considered grossly inadequate by an overwhelming 73.9% of respondents to the questionnaire (33.3% agreed, 40.6% strongly agreed) just as 92.9% of respondents agreed (22.9% agreed, 70% strongly agreed) that inadequate financing mechanisms were impediments to local manufacturing of vaccines.

These opinions were supported by those of interviewed stakeholders who expressed the view that the cost of finance available to manufacturers in Nigeria is both high and prohibitive because commercial bank lending rates are not affordable and therefore increase cost of production – making it difficult for the locally-manufactured product to compete with imported products in the market. They stated that specialized investment financing through the Bank of Industry is limited and that funds from other sources – such as commercial banks – although available, provide no attractive incentives for access by potential borrowers, especially considering the propensity for high inflationary trends and the unstable monetary policy of the Nigerian financial sector. With deposit money banks’ lending rate ranging from 18% to 35% as of 26 August 2022,(71) the cost of funds represents a huge challenge for the pharmaceutical manufacturing industry. This is compounded by the challenge of the cost of importing all APIs, pharmaceutical excipients and manufacturing equipment as access to foreign exchange at the official rates is herculean and limited, and most manufacturers resort to purchasing foreign exchange from the parallel market. The exchange rate policy has resulted in a scarcity of foreign exchange with the result that manufacturers receive only 5–10% of their dollar needs from the Central Bank of Nigeria (CBN) or at the Nigeria Autonomous Foreign Exchange (NAFEX) rate but get 90–95% of their needs through the parallel market or their own proceeds.28 One of the interviewed stakeholders also noted that, when bidding for foreign exchange from CBN/NAFEX, companies are required to tie down the Naira value of the amount they are bidding for on the bidding portal for six weeks without assurance of receiving the amount they are requesting. These are funds that could have been put to better use by the company with the possibility of some returns during the time they are blocked on the CBN portal.

Generally there is no long-tenured finance option for development areas such as pharmaceutical and vaccine manufacture, while the pooled manufacturing investment fund is not only skewed but scarce. Stakeholders strongly believe that, for the manufacturing sector to grow in Nigeria, a mix of long-tenured financing options and grants must be readily available to operators.

Poor implementation of policies
The role played by industry-specific policies in the progress and survival of any industry cannot be over-emphasized as, when properly implemented as planned, policies give strategic direction to the structure of economic activity relating to the specific sector, thereby offering better prospects for economic growth or societal welfare.

A review of available policies relating to local manufacturing of pharmaceuticals, vaccines and biologicals in Nigeria revealed that these policies are oftentimes adequate to address the intentions for their development. However, it has been noted that the hitherto laudable objectives of these policies are hardly achieved due to several reasons, including lack of government commitment and political will which is worsened with change in government or leadership of the ministry or implementing agencies. It is important to have leadership buy-in and commitment to any policy.

Lack of political will to implement policies has been noted as a major barrier to local manufacturing of pharmaceuticals and, by extension, an impediment to local vaccine manufacturing. This is confirmed with the results obtained from the survey where a vast majority of respondents agreed that lack of
political will to implement policies was a major hindrance to local manufacturing of pharmaceuticals (89.7%) and vaccines (89.8%).

The reasons proposed as being responsible for this lack of political will include limited leadership commitment to a policy which affects allocation of resources for implementation of such policies since leaders will provide resources only for courses to which they are committed. Leadership commitment to policy implementation is also affected by objectivity and unbiased outlook of the leadership of the policy-making body; it has been observed over time that bias in the professional affiliation of the leadership of some government institutions may hinder implementation of policies relating to the pharmaceutical sector. This can be seen in the results obtained from respondents, as shown in Figure 4 above, who strongly agreed that competing interests of the policy implementers was a hindrance to the implementation of policies.

Duplication and multiplication of policies were mentioned by some interviewed stakeholders as a reason for poor implementation of policies as it was noted that policies are drawn up by different organs of government for the same or similar subjects without harmonization and proper coordination, thus implying a silo approach to governance. This lack of congruence leads to policies working at cross-purposes. The disconnect therefore leads to conflicts in implementation and lack of depth of activities which have a negative impact on the citizens at the receiving end.

Some stakeholders also mentioned that proper contextualization of the problem that led to the need for policies is hardly comprehensive, and this lack of context usually makes policy implementation difficult. It was suggested that post-implementation impact analyses – to assess progress made with a possibility to amend policy and implementation plans where necessary – will help resolve the recurrent problem of not deriving expected benefits from policies.

**Lack of supporting infrastructure for local manufacturing of pharmaceuticals and vaccines**

Nyanzi et al. stated in their journal publication that infrastructure development is key to a thriving manufacturing industry as, while infrastructure development may be expensive, it affects manufacturing output positively in the long term. (72) Manufacturers are particularly reliant on infrastructure to receive their raw materials and distribute their goods in a timely manner. Infrastructural inadequacies, especially in transportation and energy, reduce manufacturers’ productivity and create delays, thereby driving up production costs. (72)

The foregoing information from the available literature confirm the importance of functional infrastructure to manufacturing. Hence an industry that is plagued with inadequate infrastructure is definitely seriously challenged. This can be said to be the situation with the Nigerian pharmaceutical manufacturing industry which, if not addressed in a timely manner, will also besiege the vaccine manufacturing sector when it eventually commences. The responses from questionnaire respondents and interviewed practitioners in the industry indicate an obvious and gross lack of required infrastructure to support local pharmaceutical and vaccine manufacturing in Nigeria. A whopping 91.4% of questionnaire respondents agreed (27.1% agreed, 64.3% strongly agreed) that lack of infrastructure was a huge hindrance to local manufacturing of pharmaceuticals just as 94.3% (38.6% agreed, 55.7% strongly agreed) of respondents also see the current situation of lack of infrastructure as a potential obstacle to the success of the vaccine manufacturing industry in Nigeria.

Local pharmaceutical manufacturers currently battle with energy costs as high as 40% of their production overhead costs for an input which should cost less than 7% of total overheads. These companies also need to transport both their raw materials and other inputs, as well as finished goods, along bad roads at high cost across the country. If it is agreed that the manufacturing sector is key to
the economic growth of the country, addressing the factors constraining this sector such as infrastructural development should be of prime importance.

**Inconducive business environment**

The business environment affects the success and profitability of a company. However, a conducive business environment assures the success and growth of companies operating in that environment. Results obtained from the survey indicates that the local pharmaceutical manufacturing industry in Nigeria is not operating within a conducive business environment. This is because an overwhelming 92.8% of respondents (31.4% agreed, 61.4 strongly agreed) are of the opinion that the business environment for local pharmaceutical manufacturing in Nigeria does not support the growth and profitability of the companies. This may be attributable to the fact that government policies, plans and actions which are supposed to create the enabling environment for businesses to survive and thrive have not achieved this objective, as shown by previous discussions on the subject. The problem of poor implementation of policies and lack of policy congruence, as well as the lack of infrastructure and unsupportive financing policies and mechanisms, are some of the factors contributing to the inconducive business environment.

Lack of incentives to attract investment in the pharmaceutical and vaccine manufacturing industry was also pointed out as a factor contributing to the inconducive business environment in Nigeria. Although the government has put in place a number of incentives supposedly to attract investment into the pharmaceutical manufacturing sector, ineffective implementation of these incentives and cumbersome processes for accessing the incentives which lead to prolonged production cycle times have been described as the bane of these incentives which defeat the aim of the incentives – part of which is to reduce production costs.

**Non-availability of required workforce competence to support local manufacturing of pharmaceuticals and vaccines, including mRNA vaccines**

The importance of competent human resources in any endeavour cannot be over-emphasized and it is no different with manufacturing of pharmaceuticals and vaccines. The absence of skilled and trained personnel is one of the main limitations identified by experts in enabling local vaccine manufacturing, especially in LMICs, because of the high level of technological know-how and know-why required in this field. Engagement with stakeholders and responses received from the questionnaire revealed varying opinions as regards availability of local competence to support local manufacturing of pharmaceuticals and vaccines, including mRNA vaccines.

This can be seen from the responses to the questionnaire where some 37% agreed that there was limited local competence in-country for local manufacturing of pharmaceuticals while 60% disagreed with this position. For local vaccine manufacturing, 47% of respondents believe that there is a lack of competence to support vaccine manufacturing in the country while 50% disagreed with this position. Veracity of the two opinions can in fact be argued as some stakeholders believe that there is a lack of some specialized competencies that are required to support both the pharmaceutical and vaccine manufacturing sectors – which include skills such as product formulation; heating, ventilation and air-conditioning (HVAC) system validation; and calibration services – as well as engineering companies that can manufacture equipment and change/maintain parts of the equipment. However, other stakeholders believe that, if exposed to the knowledge and technologies through training and experiential learning, the industry workforce including the R&D sector have more than basic knowledge that can be leveraged to catch up on the new technologies required for modern day product development and manufacturing of pharmaceuticals and vaccines.
Unguaranteed government patronage for vaccines Another major challenge identified by many stakeholders is the uncertainty surrounding government uptake of locally manufactured vaccines. Currently, the Federal Government of Nigeria is responsible for procurement and distribution of vaccines for routine immunization as well as for use in disease outbreaks such as COVID-19. The vaccines administered across the country are procured by government internationally through the support of international development partners such as Gavi and UNICEF. The government, as the sole scalable buyer of vaccines, has a contractual procurement commitment with Gavi and UNICEF. This commitment was recently reviewed and extended until 2028. This makes it difficult for investors to sink their funds into manufacturing vaccines that the main procurer is not ready to buy. This consideration is key for investors because of the experience of pharmaceutical manufacturers that invested hugely to upgrade their facilities in the quest for WHO PQ of their products and succeeded in achieving WHO GMP certification at the time. These manufacturers did not get government support in terms of patronage and payment for supplies, which led to many of the companies running out of business and being taken over by new entities.

The government, on the other hand, also has some concerns about committing to as many companies as show interest in local manufacturing of vaccines because of the possibility of litigation if the government is unable to take up the manufactured products. The government is also of the view that investors into the vaccines space need to show concrete commitment in order to provide motivation and impetus for discussing vaccine uptake guarantees.

Inadequate support for the R&D sector to boost development and local manufacturing of pharmaceuticals and vaccines

The research sector, as currently operating in Nigeria, is not sufficiently encouraging as there are extremely limited incentives for researchers in addition to existing demotivating factors such as poor remuneration structure, inadequate resources to support research, lack of rewards for innovation and lack of comprehensive health insurance. This is currently leading to a brain drain and knowledge flight in the sector as researchers with a lot of potential to help develop the industry are leaving the country in droves, thereby depleting available capacity for research and development.

The vast knowledge of and research into herbal medicinal products available in institutions like NIPRD which has led to standardization of many herbal medicinal plants has not been exploited to contribute to available pharmaceutical products for health-care provision. This is because there is no buy-in for the products by the citizens and health-care practitioners. Unlike in some countries such as China and India where traditional medicines are accepted alongside the orthodox medicines, there is no such acceptance of herbal medicines in the mainstream health-care system in Nigeria. Consequently, the manufacturing industry is not convinced that investing in large-scale manufacturing of herbal medicines is worthwhile. It is therefore difficult for a standardized herbal medicine for malaria, for instance, to compete in the market with an orthodox antimalarial drug whereas, if the opposite were the case, the standardized herbal medicinal product would increase access to safe and efficacious essential medicines in the country.

2.10 National Strategy for Strengthening Local Production of Pharmaceuticals, Vaccines and other Biologicals

The Nigerian government has put in place a number of strategies in collaboration with key stakeholders to strengthen local manufacturing of pharmaceuticals and vaccines with some focus on mRNA vaccines, especially since the announcement of Nigeria as a Spoke for mRNA vaccine manufacturing in Africa. Some of these strategies are highlighted below.
Implementation of the National Drug Policy
Further to the lessons learned by all countries during the COVID-19 pandemic, critical of which are the risks inherent in reliance on imports for essential health commodities such as medicines and vaccines, the need to chart a course for medicines security, self-sufficiency and sustainability has come to the fore in discussions at the top echelon of the health sector in Nigeria. Key to this is implementation of the 3rd edition of the National Drug Policy for which a framework for the monitoring and evaluation plan in the policy is to be drawn. This will involve teasing out the activities and sub-activities relating to the strategic objectives on local production of drugs and pharmaceutical raw materials, as well as promotion of pharmaceutical research and development to enable a phased implementation of the policy.

This strategy is to include an enumeration of local pharmaceutical manufacturers vis-a-vis the proportion of the products on the Essential Medicines List (EML) that are manufactured locally following the revision of the Nigeria EML for Adults in 2020 and publication of the first edition of the Nigeria Essential Medicines List for Children also in 2020. The enumeration of local manufacturers will include determination of areas of weakness and strengths of the manufacturers with necessary stakeholder engagement to address the findings.

Nigerian Pharmaceutical Manufacturing Sector Strategic Plan
The Federal Government through the Federal Ministry of Health is collaborating with the Promoting the Quality of Medicines Program Plus (PQM+) funded by USAID and the United States Pharmacopeial Convention (USP) and other stakeholders to work on a Nigerian Pharmaceutical Manufacturing Sector Strategic Plan (NPSSP) with several objectives, including: mapping out strategies with implementation timelines and a monitoring and evaluation framework for building required human capacity in the pharmaceutical sector; proposing effective implementation plans for pharmaceutical sector-related policies; proposal of innovative strategies for accessing affordable financing; and regulatory system strengthening, harmonization and exploitation of the benefits of the African Continental Free Trade Area (AfCFTA). (73) This strategy is still at the level of consideration but it proposes the establishment of technical working groups made up of both government and nongovernmental actors for each thematic area. It is hoped that, upon finalization, the strategy will provide actionable plans that will be effectively implemented to position the pharmaceutical manufacturing sector for sustainable self-sufficiency.

Local manufacturing of active pharmaceutical ingredients
There are ongoing discussions at the level of the government on strategies for local manufacturing of APIs. According to information obtained during engagement with the Federal Ministry of Health, a mapping study to determine APIs that can be manufactured locally was completed and the NIPRD is carrying out a pilot project on the production of some process APIs. The intention is that a successful outcome of the pilot should lead to transfer of the technology by NIPRD to a willing local manufacturer. As at the time of this survey, only one local manufacturer, Emzor Pharmaceuticals Ltd. was reported to have expressed interest in local manufacture of APIs.

Reactivation of local vaccine manufacturing
In the area of vaccine production, the Federal Government of Nigeria, represented by the Federal Ministry of Health, signed a memorandum of understanding (MoU) with May & Baker Nigeria Plc (MBN) in 2005, which culminated in the Joint Venture Agreement that resulted in the incorporated company Biovaccines Nigeria Limited (BVNL) to serve as the special purpose vehicle to revive vaccine production in Nigeria. Some 51% of the company is owned by MBN while 49% is owned by the Federal Government of Nigeria. The MoU between the two parties was re-ratified in 2017. According to the MoU, the project is expected to build local capacity in vaccine production as well as develop a centre of excellence for research and development of vaccine technology and other biologicals. The project
is also expected to enable the country to respond effectively to public health emergencies such as disease outbreaks and endemic diseases, and to generate internal revenue and increase the GDP of Nigeria.\textsuperscript{66} The company has not commenced manufacturing operations for several reasons but there has been some reawakening of activities with the advent of the COVID-19 pandemic, the attendant restrictions and supply chain disruptions experienced, as well as the realization of the need for self-sufficiency in medicines and vaccines which can only be resolved through local vaccine manufacturing.

The Federal Government appropriated the sum of 10 billion Naira (US$ 26 315 789) in 2020 to support the vaccine manufacturing efforts of the BVNL. This was before the pronouncement of Nigeria as one of the countries to receive the technology for mRNA vaccine production from the technology transfer hub in South Africa for which BVNL is now the representative recipient of the technology on behalf of the country. The company is, however, in discussion with several international organizations to access funding for establishment of the facility and commencement of operations as the funds from government are yet to be released and the project requires far more than the amount provided by the government.

In order to guarantee patronage, return on investment and return on effort, BVNL has secured government commitment for the uptake of eight of the 15 routine immunization vaccines when manufacturing commences. The company has also been given approval to supply 15% of the routine immunization vaccines that are currently fully-funded by the Nigerian Government in the co-financing arrangement with Gavi. This is to enable the company to gain bite-portions access to the Nigerian market and earn some revenue which will then be ploughed back into establishing the manufacturing facility.

A few other private-sector companies have also expressed interest in investing in local vaccine manufacturing. One of such companies is Innovative Biotech which recently signed a deal with a German biotech firm for local production of vaccines in Nigeria. It is reported that, on completion of its facilities, the company intends to engage in end-to-end vaccine development and manufacturing which will enable Nigeria to handle future epidemics/pandemics as well as to export vaccines to other African countries to reduce reliance on imported vaccines and thereby strengthen health security in the continent.\textsuperscript{66}

The Nigeria Integrated Biopharmaceuticals Industries Consortium, made up of European biotechnology companies Merck, Unizima, Rommelag and Fredlab in collaboration with the Nigerian start-up company PIA BioPharma, has also had engagement with the government. The consortium intends to establish a world-class Bio-Pharma industrial complex for the manufacture of vaccines and essential therapeutics in Nigeria.

However, some hesitancy is observed in companies that have shown interest in local vaccine manufacturing due to government inertia to grant uptake guarantees of the manufactured vaccine products.

**The Nigeria Vaccine Policy 2021**

Further to the efforts to reactivate vaccine manufacturing in the country, the Federal Government of Nigeria through the federal Ministry of Health launched the first edition of the Nigeria Vaccine Policy (NVP) in September 2021 with the goal of achieving vaccines availability and self-sufficiency in Nigeria through local manufacturing of vaccines and ownership of the vaccines supply chain management in the country.\textsuperscript{16}

Implementation of the NVP has commenced with the inauguration of the Inter-Ministerial Steering Committee and the Technical Working Group (TWG) for local vaccine production. The first meeting of
the TWG was held in August 2022 with the development by the group of a workplan to achieve the thrusts of the policy. Approval of the workplan by the Inter-Ministerial Steering Committee is being awaited to enable its deployment.

The Vaccine Development Consortium
The critical role of research and development (R&D) in the long-term success of the pharmaceutical as well as vaccine manufacturing industry cannot be over-emphasized. Vaccine R&D leads to discovery and development of vaccines that help to address vaccine-preventable diseases as well as to enable timely response in public health emergencies. This has been confirmed by the prompt development of COVID-19 vaccines because of ongoing research work on similar diseases and manufacturing platforms which was leveraged to produce the vaccines that rescued the whole world during the pandemic.

This realization also led to the coming together of some government institutions to form the Nigeria Vaccine Development Consortium with federal government funding from the Tertiary Education Trust Fund (TETFUND). The consortium of universities and research institutes has the responsibility to accelerate development of vaccines required for diseases of public health importance and further build in-country capacity to enable public health emergency preparedness and response.

The consortium is currently working on the development of vaccines for Lassa fever and COVID-19 using current technologies such as a recombinant DNA platform for Lassa fever vaccine and multiple technologies including: the recombinant plasmid DNA vaccine platform, engineered viral vector vaccine platform, recombinant peptide subunit vaccine and the nanoparticle delivery system for COVID-19 vaccine.

The consortium is reported to have completed the prediction of immunogenicity and structural modelling of the best vaccine candidates as well as the molecular cloning and construction of the vaccine candidates. The nanoparticle synthesis and characterization of the vaccine constructs was ongoing at the time of this survey. This will be followed by scaling up and preclinical evaluation of the vaccine constructs. (58)

2.11 Initiatives to strengthen local production of pharmaceuticals, vaccines and biologicals, including mRNA vaccines, by support partners

Over the years, Nigeria has benefitted, and is still benefitting, from assistance from several support partners in different areas of the health-care system. This support has been in different forms, including funding, technical assistance, donation of equipment and facilities, advocacy, development of strategies and action plans and much more. A number of partners are supporting the country in areas such as policy development and reviews, distribution and supply chain of health commodities, health financing, health information systems and others. Some of the previous and ongoing support received from partners specifically to strengthen local manufacturing of pharmaceuticals and vaccines including mRNA vaccines is highlighted below:

World Health Organization
As the foremost global health body, WHO through its convening mandate has rallied support for local manufacturing of pharmaceuticals and vaccines for Nigeria via the following mechanisms:

- WHO conducted a scoping mission to Lagos (the industrial base of Nigeria) in 2016 which resulted in a report that highlighted the challenges of local manufacturing. The report led to revisiting the ban on importation of 17 medicines for which there was evidence that the local manufacturing
industry in Nigeria had the capacity to meet local needs and even produce for export. The ban on importation of these medicines was meant to encourage local manufacturing of the medicines.

- The WHO Country Office supported the Federal Government to review the Nigeria Drug Policy 2005 leading to the publication of the 3rd edition of the Policy in 2021. The revised policy focused on local manufacturing and procurement of locally-manufactured pharmaceuticals and APIs in Nigeria.

- The WHO Country Office led other development partners to support the country in the development of the maiden edition of the Nigeria Vaccine Policy 2021. The Policy again focused on self-sufficiency of vaccines through local manufacturing and supply chain management of vaccines within the country. The WHO Country Office is supporting the Federal Ministry of Health to implement activities and sub-activities for achievement of the goals and objectives of the Policy as well as monitor progress in the implementation of the policy.

**United States Agency for International Development (USAID), United States Pharmacopoeia Convention – Promoting the Quality of Medicines (USP-PQM) & United States Pharmacopoeia Convention – Promoting the Quality of Medicines Plus (USP-PQM+)**

USAID has been supporting the local pharmaceutical manufacturing sector of Nigeria for about a decade through the PQM program and now the PQM+ program implemented by USP by providing technical assistance to the Nigerian pharmaceutical sector since 2012. PQM has been supporting and strengthening the capacity of Nigerian pharmaceutical manufacturers to produce quality-assured medicines for the Nigeria populace.

In order to make Nigerian pharmaceutical manufacturing companies more competitive globally and increase the supply of priority medicines in-country and for export, a national plan to achieve a minimum “quality system” for all manufacturers was needed. This plan was implemented in conjunction with the NMRA and NAFDAC in the Nigeria Pharmaceutical GMP Roadmap project of 2018–2019. The roadmap was intended to enable appropriate risk categorization of local pharmaceutical manufacturers based on their risk rating as this will facilitate the development of an action plan by the manufacturer to migrate to a minimum quality system level within a given timeframe.

USAID through USP provided technical assistance to several local manufacturers in different thematic areas e.g. Drugfield Pharmaceuticals Ltd. was supported to achieve manufacturing of Chlorhexidine Gel, one of the United Nations Life-Saving Commodities used for neonatal umbilical care, which is now registered in some African countries. Swiss Pharma, May & Baker Nig. Plc. and Juhel Nig. Ltd. were provided technical assistance in various areas including dossier preparation and GMP compliance of their facilities in their quest for WHO PQ of their products.

The partners have also supported several government agencies in the health sector to strengthen their operations especially the regulatory systems and pharmaceutical product development. The USP-PQM (and PQM+) supported NAFDAC in achievement of ISO 17025:2017 accreditation of four laboratories for Quality Control testing of medicines and vaccines, conduct of biannual post-market surveillance activities for priority medicines, implementation of the pharmaceutical traceability strategy as well as implementation of some of the institutional development plans (IDPs) recommended for achievement of the maturity level ML3 status by the WHO Global Benchmarking of NRAs.

The Pharmacy Council of Nigeria was also supported to improve on their activities to have verifiable systems and procedures in place for regulation of pharmacy practice which includes manufacturing.
NIPRD was also supported by PQM in achieving ISO 17025:2017 accreditation of its laboratory for testing of critical quality parameters of pharmaceutical products.

As mentioned above, USP is working actively with the relevant government agencies on development of a Pharmaceutical Manufacturing Sector Strategy. Although it has been noted that biotechnology products and medical devices are rated as medical products, the strategy initially covered only medicines, but the Minister of Health granted approval to expand the scope of the strategic plan to now include medical devices. The consultant and key stakeholders are currently engaging with key actors in the industry, especially the chief executive officers of manufacturing companies, to chart a course for the sector.

**The World Bank**

Engagement with the World Bank during this survey revealed that the World Bank Group (WBG) has two arms, namely:

i. The World Bank (WB) which engages with governments of countries with potential to support the governments in the areas of capacity-building, regulatory systems strengthening and reforms; and

ii. The International Finance Corporation (IFC) which works with the private sector for mobilization of capital to support the sector.

The WBG – in collaboration with Federal Ministry of Health, Ministry of Industry, Trade and Investment and Nigeria Export Processing Zones Authority – is supporting the country to establish Medical Special Economic Zones (MSEZs) in designated locations or within the existing Special Economic Zones. The World Bank supported the country through the ministries and agencies mentioned above to develop the legal framework for the MSEZs which has been approved by the government. The first of these MSEZs is to be established in the Lagos Free Trade Zone in Lekki, Lagos. These MSEZs are to be established as world class “plug and play” technically driven zones providing an enabling business environment for companies interested in pharmaceutical and possibly vaccine manufacturing. All required infrastructure will be provided as the companies only need to set up their facilities within the zone for operation. All imported manufacturing inputs in the MSEZs are duty-free and this helps the processes of the manufacturing companies and makes the country competitive to attract foreign direct investment.

The World Bank also supports the fiscal space for government to procure needed vaccines after appropriate quantification using the Gavi accountability framework to ensure funds are always available to purchase the vaccines.

IFC equally conducted scoping of potential companies that can be supported to engage in vaccine manufacturing as most foreign vaccine manufacturers have agreements with the World Bank which can be leveraged by IFC by introducing these local companies to the foreign manufacturers for technology transfer and other contract manufacturing arrangements. IFC makes funds available for such projects either as equity share or by bringing local or international finance institutions on board. This was the initial arrangement with BVNL before the issues relating to conflict of interest in the governance structure of BVNL halted the arrangements.

**Bloom Public Health**

Bloom Public Health is a private sector organization with the mission to achieve better health care in Africa. The organization focuses on public health supply chain, pharmaceutical quality systems and policy for public health. The organization has embarked on a project to establish a Pharmaceutical Park called Pharmacity, which provides infrastructural support and mentoring for companies intending to go into pharmaceutical manufacturing. The Park is to help pharmaceutical manufacturers...
produce affordable, accessible and quality-assured products with reduced production costs to make them more competitive both locally and for export in a more resilient supply chain that has reduced vulnerabilities.\(^{(74)}\)

Pharmacity is said to be a compact modern-day pharmaceutical industrial estate that will bring together pharmaceutical companies of various sizes, service providers and companies providing support services to co-locate and share infrastructure. It will serve as a means to increase Nigeria’s medicine and health product manufacturing capacity and enable her to reach her full potential while ensuring strict adherence to international standards.\(^{(75)}\)

Bloom Public Health is also participating in the Impact Project to support malaria treatment and immunization and is agitating for local procurement of medicines for the project which will boost local manufacturing of the required medicines.

2.12 Objectives and Expectations of being a Spoke of the mRNA Technology Transfer Hub

The Hub and Spoke model is a business model that enables the distribution of goods or services from a centralized hub to the different delivery points which are the spokes. The Hub and Spoke model enables more efficient use of scarce resources thereby reducing overhead costs. It ensures faster delivery of goods, increases workforce productivity, optimizes work planning, reduces logistical costs and enables consistent pricing.\(^{(76)}\)

All these benefits of the Hub and Spoke model applies to the deployment of the model for transfer of the mRNA technology from the Hub to the Spokes. Nigeria, as one of the Spokes that will receive the mRNA technology from the Hub in South Africa, expects that the transfer of technology will enable capacity-building of staff in the manufacturing processes for mRNA vaccines such that the knowledge may be deployed for manufacture of other vaccines in addition to those for COVID-19, as this will be more beneficial to the country since the COVID-19 pandemic is effectively tackled.

BVNL expects that being a Spoke of the mRNA Technology Transfer Hub will enable more efficient use of scarce resources, thereby reducing overhead costs and saving substantially on product development costs as these costs would have been borne by the Hub, thus making the final products from the Spoke more competitive in the market and thereby easing market entry.

Stakeholders believe that since the Spokes will be engaging only in the fill & finish operations of the vaccine manufacturing process, this will ensure faster delivery of the vaccines and enable access to the vaccines by the citizens of Nigeria and beyond. It is also expected that the Hub and Spoke model for mRNA technology transfer will enable increased workforce productivity as the workforce and the management of the organizations will be focused on specific operations, thus reducing the incidence of operational issues stemming from different activities.

The efficient use of resources, optimized work planning and reduced overhead and logistical costs attendant to being a Spoke will enable consistent pricing of the final vaccine product, making the Spoke company competitive in the market. Nigeria has high hopes of getting all the expected benefits of being a Spoke country, as listed above, and more – especially contributing to the country’s GDP and reduction in the need for foreign exchange for procurement of imported vaccines.

2.13 Nigeria’s next steps towards local manufacturing of vaccines, including mRNA vaccines and areas of support from WHO
In the words of the Honourable Minister of Health in the foreword of the Nigeria Vaccine Policy, “the driving force of the Nigeria Vaccine Policy is to encourage local production of vaccines and to ensure self-sufficiency in vaccines availability”. The minister reiterated the government’s commitment and political will in making Nigeria a hub for the production of quality, safe, affordable and efficacious vaccines. To lend action to these words, the government and other key actors are taking steps necessary to achieve this objective. However, the country may not have the capacity to carry out all activities needed and, if so, will need support from development partners like WHO. Some of the next steps to be taken by the government and specific organizations as well as areas of support are highlighted below:

Federal Government of Nigeria
The Government of Nigeria can facilitate the efforts of the BVNL to begin construction of the manufacturing facility to receive the technology for mRNA vaccine production by ensuring the release of the 10 billion Naira appropriated since 2020. The Federal Government, through the Federal Ministry of Health, realized the expediency of identifying other available capacities to support and sustain local manufacturing of vaccines, including mRNA vaccines. Hence the offer from WHO to provide technical support for a situational analysis, ecosystem mapping, business plan and vaccine development roadmap for the country. This is being pursued rigorously. The Federal Government of Nigeria is also to engage in advocacy to support partners for assistance in addressing the myriad of challenges being experienced and envisaged in the local manufacturing of vaccines. One advocacy effort wooed Mr Holm Keller, Executive Chairman of the KENUP Foundation, to establish a partnership with Nigerian vaccine researchers and to support Nigeria’s efforts towards local vaccine manufacturing. Support of WHO will be required for finalization of the workplan of the TWG for local vaccine manufacturing and for implementation of the activities and sub-activities in the plan.

National Institute for Pharmaceutical Research and Development (NIPRD)
In order to progress ongoing research into potential antigens for vaccine development, the NIPRD needs support to upgrade its laboratory facilities to acceptable standards, especially in the vaccine development laboratory which requires Biosafety Level three (BSL3) standards with a supporting P3 containment system for the safe handling of pathogens.

The NIPRD is also in need of standard Laboratory Information Management System software for proper management of laboratory operations and records relating to all research being carried out in the organization.

Nigerian Institute of Medical Research (NIMR)
Further to the existing facilities and ongoing research into candidate vaccines, the NIMR needs WHO support to establish a modular GMP facility and supporting quality control testing system for pilot-scale production of developed vaccines in order to enable progression of the studies to clinical trials since the vaccines cannot be tested in humans unless they are manufactured under GMP conditions.

There is a need for WHO to support the country in conducting advocacy programmes to bring together relevant government agencies to review and harmonize their mandates and activities in order to clearly define roles and responsibilities, thereby preventing overlap and duplication of efforts and fostering cooperation and collaboration. This collaboration and cooperation will also enhance information-sharing within the research space and the pharmaceutical industry in the country. WHO’s support is also needed for establishment and maintenance of QMS in research institutions and for building the skills and capacity of personnel of these institutions to manage the QMS effectively.

The country needs a lot of support in terms of motivating factors for the research sector to reduce the brain drain in the sector as researchers with huge potential for development of the industry are leaving
Nigeria in droves, thereby depleting available capacity for research and development. NIMR has only one laboratory that is ISO 15189:2012-accredited and requires support to extend this accreditation to other laboratories in the Institute.

National Veterinary Research Institute (NVRI)
Regarding the role to be played by NVRI in the Vaccine Development Consortium and considering government’s desire to commence local manufacturing of human vaccines in earnest, NVRI is in dire need of support to upgrade its manufacturing facilities as the available facilities and equipment are old and the technologies employed have been overtaken by new methods and systems.

WHO support will be needed to complete and equip the uncompleted building intended for expansion of manufacturing capacity of the institute to enable compliance with current trends and requirements for vaccine manufacturing which can be escalated for human vaccines.

National Biotechnology Development Agency (NABDA)
As discussed earlier in this report, the subvention received by NABDA from the federal government is grossly inadequate. As such, the agency needs funding to set up a GMP-compliant pilot production facility to enable progression of laboratory discoveries to pilot scale downstream operations.

NABDA also requires funding to meet the commitment of counterpart funding of the insulin and erythropoietin project with the International Center for Genetic Engineering and Biotechnology (ICGEB). The agency is also undertaking the establishment of standard animal house facilities to enable effective conduct of preclinical trials, and this requires a lot of funds for the establishment and maintenance of the facilities. NABDA will therefore appreciate WHO’s support in this regard.

There is a lot of individual and institutional research work going on in the universities and research institutions which needs to be harnessed to enable the country to benefit from the knowledge and to translate this to improvement of the health of the citizens. A platform to serve as a repository to bring together the different studies in a particular area will therefore be beneficial to the system. There is also the need to establish a platform for strong collaboration between the pharmaceutical manufacturing industry and the researchers to enable exploitation of the benefits of ongoing research into medical products to the advantage of the citizens. The support of WHO in establishing such platforms will be appreciated.

Vaccine Development Consortium
The role of the consortium in vaccine R&D in Nigeria cannot be over-emphasized. Effective execution of this role requires substantial investment in vaccine research, development and provision of new-generation vaccine production pipelines.

The consortium also requires the support of WHO to establish a Biosafety level-4 facility for handling dangerous pathogens such as Lassa fever and Ebola viruses, as well as upgrading the BSL-3 laboratories in the various institutions in the consortium and across the country. A state-of-the-art animal research centre for preclinical studies of vaccines is an essential need for which WHO’s support is solicited in addition to the establishment of more clinical trial centres in various parts of the country to generate reliable clinical trial data on the Nigerian population which can then be extrapolated to similar populations in Africa and beyond.
3 Manufacturers and market information

3.1 mRNA vaccine manufacturers
Nigeria is plagued with a high burden of disease and an infant mortality rate of 56.22 deaths per 1000 live births in 2022.\textsuperscript{(77)} There are fewer than 10 vaccine manufacturers in Africa and they are based in five countries: Egypt, Morocco, Senegal, South Africa and Tunisia. None of these manufacturers produce mRNA vaccines except for Afrigen Biologicals in South Africa which was recently able to replicate the Moderna COVID-19 vaccine on the basis of publicly available information.

It is a cause for concern that with the large Nigerian population and the existence of a vibrant pharmaceutical manufacturing industry, there are no human vaccine manufacturers, including mRNA vaccine. Nigeria therefore needs to take urgent critical steps to commence vaccine manufacturing and to ensure supply security, control over production scheduling and sustainability, control of costs, socioeconomic development and rapid response to local epidemics and other emerging diseases. Local manufacturing of vaccines, including mRNA vaccines, will increase the country’s GDP, create jobs and attract foreign direct investment among other benefits.

3.2 Manufacturers of other vaccines and biologicals
As mentioned in 3.2 above, there are no manufacturers of vaccines or any other biological products in Nigeria.

3.3 Locally manufactured vaccines and other biologicals procured by international procurement agencies
There are no locally manufactured human vaccines or biologicals in Nigeria as all human vaccines and biologicals used in the country are imported. Vaccines for routine immunization and for supplemental immunization activities (SIAs) are procured by Gavi in collaboration with UNICEF through a co-financing arrangement with the Nigerian government.

3.4 Market conditions for vaccines
In Nigeria, the government is the main procurer of vaccines as out-of-pocket expenditure for vaccines is very minimal. This makes the vaccine market quite limited as any manufacturer or importer of vaccines at scale needs to secure government commitment for offtake to assure a return on investment.

Nigeria has over the years received support from donors and other partners for the procurement of vaccines and maintenance of the systems required for management of the immunization programme. Gavi has supported Nigeria for the last two decades with procurement of vaccines and cold chain equipment, technical assistance, conduct of immunization campaigns, and general health systems strengthening.

The arrangement with Gavi is for co-financing the procurement of vaccines in a tapered manner whereby Gavi support is decreased with an increase in the country’s Gross National Income. Consequently, some vaccines for routine immunization are currently fully funded by the Nigerian government. A time will come when the country has to self-finance vaccine procurement fully without any further support. This arrangement led to the development of the Nigeria Strategy for Immunization and Primary Healthcare System Strengthening (NSIPSS) which is a 10-year strategy document that defines the country’s plan to transition from Gavi support. This plan, which was developed in collaboration with partners, highlights the financial and programmatic decisions that
Nigeria will need to make to attain at least 84% equitable and sustained national immunization coverage for all antigens by 2028. The transition plan initially started as a 5-year strategic plan (2017–2021) but eventually became a 10-year plan following negotiations with Gavi.\(^{(78)}\)

An Accountability Framework was developed to guide the implementation of the NSIPSS. The most salient aspect of the Accountability Framework is that the Federal Government of Nigeria must provide incremental funds from budgetary sources every year culminating in 100% funding for vaccine procurement by 2028.\(^{(19)}\) The implication of this arrangement is that no investment in the vaccines sector, and especially local manufacturing of vaccines, can have market access until expiry of the Gavi agreement in 2028.

Stakeholders pointed out that another likely challenge is the issue of competitive pricing. Gavi has been able to negotiate very low prices for vaccines from foreign manufacturers because of the large volumes procured and therefore the Nigerian government has been buying vaccines at very low prices. If the Nigerian government does not commit to buying locally manufactured vaccines at prices that will enable the manufacturers to achieve return on investment, the local manufacturers will run at a loss. Offtake of the manufactured vaccines by the Nigerian government will give assurance and will encourage other countries to procure the made-in-Nigeria vaccines.

### 3.5 WHO prequalification/emergency use listing of pharmaceuticals, vaccines/biologicals

The WHO medicines PQ programme was established to guide agencies of the United Nations and other international organizations in the procurement of quality-assured medicines to achieve universal health coverage by improving the access of low-income countries to these priority medicines.\(^{(79)}\) This programme was initiated in response to the challenges in access to antiretroviral drugs and the scope has been expanded to other therapeutic classes and medical products, including vaccines.

The WHO medicines PQ program has enabled populations of low-income countries to access treatment for priority diseases and has thereby improved public health outcomes. The programme has also improved the capacity of manufacturers of pharmaceutical products to manufacture products in accordance with international standards, thereby increasing their market access and acceptability.\(^{(80)}\)

Several pharmaceutical manufacturing companies in Nigeria have at different times expressed interest in WHO PQ of their products. In 2014, four companies – Swiss Pharma Nig. Ltd., May & Baker Nig. Plc., Evans Medical Nig. Ltd and Chi Pharm. Ltd – were certified as operating in compliance with WHO’s GMP standards. Unfortunately, only two of these companies (Swiss Pharma Nig. Ltd. and May & Baker Nig. Plc.) are still in the race for products PQ while Juhel Nigeria Ltd. has also joined the race. The applications of these companies are at different stages of the PQ process.

The current efforts by the Federal Government of Nigeria and BVNL to receive the technology for mRNA vaccine production should be pursued vigorously to a logical conclusion. This is because further enquiry from BVNL indicated that the company is interested in WHO PQ, as part of their immediate plan upon completion of their new facility. The company intends to achieve its goal through backward integration by partnering with manufacturers of WHO prequalified routine immunization vaccines for ease of technology transfer and supply of the bulk vaccine for fill & finish operations. This will reduce the costs of production and market entry and will give greater opportunities for procurement and export of the vaccines. However, the company has noted the challenge of limitation of export
opportunities as the possibility of their partner having existing supply arrangements to potential export countries through UNICEF/Gavi procurement cannot be overlooked.

3.6 Targeted markets for locally manufactured mRNA vaccines

The benefits accruing to Nigeria from being positioned as a manufacturing hub and a regional/global supplier of mRNA vaccines which will potentially replace existing vaccine technologies in the long run, can best be imagined. Nigeria’s current pharmaceutical manufacturing landscape is projected to grow to around US$ 3.6 billion by 2026. With the introduction of the local manufacturing and exportation of mRNA vaccines, there will be potential for greater growth of the industry and its consequent contribution to Nigeria’s economic growth and development. In addition, most modern vaccines are targeted towards specific infectious diseases; hence, as more vaccines are routinely used and introduced in a country, the more cost-intensive the country’s vaccination programme (including procurement, cold chain, logistics etc.) will be. This is the case for Nigeria, with about 15 vaccines currently in use for routine immunization and SIAs. Nigeria currently spends US$ 291.77 million annually on the procurement of these vaccines, all of which are imported. Additional amounts are also spent on the storage, nationwide distribution and vaccination schedules for these vaccines. Commencement of local manufacturing of mRNA vaccines in Nigeria will greatly reduce these costs, especially where these vaccines for routine immunization are being manufactured locally.

3.7 Specific training and assistance needed for sustainable production of mRNA vaccines and other vaccines and biologicals

In order to ensure sustainable development and production of mRNA vaccines and other biologicals, relevant persons will need to be trained in the following areas.

Regulation of vaccines

In order to regulate manufacturers of vaccines and other biologicals properly, NAFDAC’s GMP inspectors will need more training on GMP requirements for vaccine manufacturing. Personnel need to participate in coached inspections to provide hands-on, experiential training on conducting GMP inspection of vaccine manufacturing facilities.

Proper regulation of vaccine clinical trials will also be strengthened with training in biostatistics, comparability data assessment, vaccine protocol assessment, review of preclinical studies data and advanced GCP training.

Also, in order to obtain the buy-in of the industry into implementation of the Pharmaceutical Traceability Strategy, training/sensitization programmes are needed for pharmaceutical stakeholders nationwide. Analysis of vaccines and other biologicals will be strengthened by training NCLVB staff in modern biomedical techniques, including sequencing and flow cytometry.

mRNA vaccine development

In order to further ongoing efforts in the R&D of mRNA vaccines, the various research institutions in the pharmaceutical and vaccine area – such as NIPRD, NIMR, NVRI, NABDA and university researchers – need to benefit from training on vaccine development on the mRNA platform as well as mRNA therapeutics.

Manufacturing support

Some services, such as fabrication of equipment parts that meet acceptable standards, are not readily available in Nigeria. There is therefore a need to build capacity in some allied industries (e.g. the steel industry) for capacity in the manufacture of machine parts in collaboration with the Ministry of
Science, Technology and Innovation as well as the National Agency for Science and Engineering Infrastructure (NASENI).

WHO support is also needed to train personnel on HVAC validation to create capacity in these areas since companies have to depend on experts from India for this activity and subsequent maintenance of the system. All these elements will increase production turnaround timelines as well as create the potential risk of manufacturing products under noncompliant conditions.

Additionally, the country needs support to build meteorological services because acceptable calibration services are not readily available.

4 Recommendations and conclusion

This survey was intended to give an overview of the current situation of the different components of the ecosystem for local production of pharmaceutical products, and particularly vaccines, with a focus on mRNA vaccines in Nigeria. Even though a lot of effort was made to ensure that the survey is as comprehensive as possible on the basis of publicly available data sources and information provided by relevant stakeholders, the report cannot be said to be totally exhaustive of all the relevant issues in the ecosystem. The recommendations and conclusions drawn here should therefore be interpreted with an appropriate degree of caution.

Based on the findings of the survey, the following interventions are recommended to address some of the key observations and challenges in enabling improvement of local pharmaceutical manufacturing, as well as commencement and sustainability of local manufacturing of vaccines and other biologicals, including mRNA vaccines, in Nigeria.

4.1 Ownership of the health sector by government

Stakeholders recommend that government should take ownership of their responsibilities in the health sector and reduce reliance on donor agencies and support partners, as this is the only approach to sustainability. This is because Nigeria’s support partners are working with several countries in dire need of their support and these countries procure medical products from the same partners. Stoppage of this support without any concrete system in place by government can have significant negative consequences for the health system. One of the ways to take ownership of the sector is for government to prioritize local pharmaceutical and vaccine manufacturing and distribution by doing all it takes to ensure the sector’s self-sustainability. A Presidential directive on prioritization of local manufacturing of vaccines and other pharmaceuticals will go a long way to achieving this objective. This will ensure the enforcement of policies on procuring and paying for locally made products, and especially vaccines, as no investor will commit borrowed funds when there is no assurance of offtake of the products by government. Government needs to provide the enabling environment for key players to succeed as this has only one outcome, namely boosting performance of the industry leading to medicines security, self-sufficiency, universal health coverage and health equality. Part of the enabling environment is the provision of incentives by government, but these must translate to expected improvements in the industry. Therefore, each incentive provided should be accompanied by a mechanism for monitoring the implementation of the incentives to determine how many companies benefitted, as well as tracking the incentives over time to determine areas of use which will stimulate further innovation.

Another critical aspect of the enabling environment is the availability of affordable and accessible financing opportunities to facilitate investment in the pharmaceutical and vaccine manufacturing
industry. It is recommended that the intervention provided by CBN to manufacturers during the COVID-19 pandemic should not be a one-off activity, but that government should provide a mix of long-tenured financing options and grants for industry operators if industry is to grow as anticipated.

4.2 Improved inter-agency collaboration between organs of government

It has been observed that many government ministries and institutions carry out similar activities without due consultation and harmonization of plans. Due to the lack of synergy between government institutions, similar policies are drawn up by different organs of government without proper contextualization of the problem and without harmonization and coordination, which in some cases have led to lack of policy consistence and congruence. Consequently, this disconnect leads to conflicts in implementation and lack of depth of activities.

It is recommended that organs of government should collaborate more and synergize rather than working in silos. This will enable optimization of resources and more effective outcomes as issues will be addressed more holistically than from the different perspectives.

4.3 Reliance on imports for manufacturing inputs

All manufacturing inputs – including APIs, excipients, equipment and most packaging materials – are imported. In the light of supply chain disruptions experienced during the COVID-19 pandemic, there is a need for local production of critical inputs such as APIs and imported packaging materials.

Venturing into API manufacturing requires, however, a proper mapping of needs to determine which APIs have a comparative advantage for investment. Stakeholders proposed that existing capacity should be targeted, especially in the universities and other research institutions, in order to explore opportunities for scale-up of existing research into the development of APIs. This can be achieved with the required political will through interministerial collaboration between the Ministry of Health; Ministry of Industry, Trade and Investment; and the Ministry of Science, Technology and Innovation using the Ministry of Education through the TETFUND to provide resources to scale up existing research into local manufacturing of APIs.

An unbiased international development partner may be engaged to develop a workplan with the TETFUND for deliverables and an M&E framework to ensure implementation of the plan and alignment of release of funds with achievement of milestones and deliverables.

4.4 Targeted and effective utilization of available local manufacturing capacity

There is a lot of vacant manufacturing capacity in many of the pharmaceutical manufacturing plants that can be used more effectively with targeted plans of interagency collaboration between CBN, NAFDAC, the Ministry of Industry, Trade and Investment and the Federal Ministry of Health to ensure that available capacities are used for the benefit of the nation.

Using the list of local manufacturers in Nigeria and their product lines, as provided by NAFDAC and the EML, the number and volume of products on the EML that are being manufactured locally can be determined and decisions can be taken on which other products can be manufactured locally. An expression of interest to manufacture these products can then be requested from the identified companies with associated incentives such as offtake by the various public health programmes, soft loans and developmental loans but with monitoring of technical compliance over a set timeline.

The relevant policies already provide for the procurement of locally manufactured products by government and this should be efficiently implemented, especially for the various public health
programmes which are both implemented by the government and with support from developmental partners. Companies that meet the requirements of the expression of interest over time can be given these incentives to meet market volume and local needs which should lead to ending importation of the products.

4.5 Considerations for sustainable vaccine manufacturing, including mRNA vaccine manufacturing

Several factors need to be considered when taking the decision to engage in local manufacturing of vaccines, including mRNA vaccines. These factors are important for sustainability of the vaccine manufacturing industry and are issues that need to be addressed beforehand to ensure that the project is not truncated halfway. Some of the questions that require sincere answers before embarking on a local vaccine manufacturing venture include the following:

- What kind of vaccines do we want to produce in Nigeria, and do we intend to manufacture all our routine immunization vaccines or start with a few and increase the scope over time?
- What platforms do we intend to use to manufacture these vaccines? Do we want to use the conventional platforms, or do we want to exploit the advantages of the mRNA platform (short process steps, possibility of using modular facilities etc.) to manufacture the vaccines for routine immunization?
- What level of vaccine manufacturing do we intend to engage in – upstream and downstream operations versus “fill and finish” only?
- What is the volume of vaccine consumption in Nigeria and how many vaccine manufacturers will be needed to meet this demand?
- It is noted that the vaccine procurement agreement with Gavi/UNICEF continues until 2028. Setting up modular manufacturing facilities will take some 18–24 months, followed by time taken to run tests, validate processes and enter the market. A manufacturer commencing establishment of a facility in 2022 should be able to enter the market by 2025. How will this investment be profitable when there is no guarantee of market access by 2025 and considering that the country cannot wait until the expiry of the Gavi/UNICEF agreement before acting for alternative sources?

Sincere answers to these questions and concrete plans of action to address the issues are recommended in order to ensure a sustainable local vaccine manufacturing industry.

There should also be engagement with the industry to determine which vaccines will interest the manufacturers. Intending manufacturers can be assigned to manufacture specific vaccines in order to ensure that needs are met and there is self-sufficiency. A system should be established to monitor performance and service delivery of the manufacturers and to serve as a check for continued compliance.

4.6 Review of the educational curriculum to meet current industry needs

The Ministry of Education, in collaboration with the pharmaceutical industry and the Pharmacy Council of Nigeria, should review the educational curricula in the relevant disciplines (pharmacy, chemistry, microbiology, biotechnology, engineering etc.) to meet current industry needs and to ensure availability of the workforce needed to sustain the industry.
4.7 Local sourcing of critical manufacturing inputs such as equipment and packaging materials

A key finding from the 2018–2019 nationwide GMP assessment of pharmaceutical manufacturing facilities was the absence of a critical utility – the HVAC system – in most facilities. This was mainly due to accessibility problems and the high cost since HVAC systems have to be imported and must be purchased with foreign currency. The HVAC system is critical to pharmaceutical manufacturing and even more critical to vaccine manufacturing as vaccines are manufactured under aseptic environmental conditions which can be achieved only with a functional and well-maintained HVAC system.

It is recommended that government, through the relevant ministries (Federal Ministry of Health, Ministry of Industry, Trade and Investment, Ministry of Science, Technology and Innovation), should collaborate with manufacturers of ventilation systems (e.g. Thermocool Industries) by providing a loan repayable in 10–20 years as an incentive for the company to come up with a plan to manufacture air handling units and other components of the HVAC system locally by the end of five years for procurement by the industry at a cheaper rate rather than the cost of importing these units from India or elsewhere. This will hugely reduce the burden of compliance for local manufacturers, create jobs and ensure sustainability of the industry. Similar arrangements can be made for sourcing other manufacturing equipment and primary packaging materials locally in order to reduce the foreign currency component for sourcing those items.

4.8 Addressing the infrastructural needs of the industry

Reliable electricity supplies are a major challenge for the manufacturing industry in Nigeria as power which should not be more than 7% of production costs now swallows up more than 40% of the overhead costs of companies. Clusters of pharmaceutical manufacturing companies, especially those sited within the same locations, can have independent power projects supplying electricity to these clusters to ensure constant supplies and to drive down overhead costs. Additionally, power cuts during production lead to losses for the company.

4.9 Innovative use of funds from support partners

Government may consider a policy requiring that a fraction of the funds from support partners for the different public health programmes should be invested in existing manufacturing companies that are doing well in the industry – especially those manufacturing products used in these programmes. This will aid technology transfer from the principals of the support partners and will upscale capacity so that these companies can produce medicines for their partners as well as for use in-country. This will also create jobs, reduce poverty and build capacity while accelerating achievement of the set goals of the partners.

4.10 Further strengthening of the NMRA

The NMRA has grown by leaps and bounds over the years and has achieved a lot in the regulation of medicines and vaccines. The agency can, however, be further strengthened to do more by giving it more authority in view of its mandate. Stakeholders recommend that NAFDAC should be moved out of the civil service and upgraded to a presidential commission with improved legislation to enforce its mandate properly. This will also translate into some level of autonomy and better resource provision. The agency is currently limited by a lack of resources to equip facilities due to civil service controls and oversight by other government structures.
4.11 Strengthening of the research and development sector

The contribution of the R&D sector to the development and sustainability of the pharmaceutical, and especially vaccine, manufacturing industry cannot be over-emphasized. There is, however, a need for synergy among researchers to enable harmonization of similar research work as well as synergy between researchers and industry to enable progression of laboratory discoveries to the market. It is therefore recommended that the government should create a platform for these synergies to occur for the benefit of the health-care sector.

It is only with the progression of laboratory discoveries to manufacturing that new medical interventions are obtained, and this can only be achieved where the required resources for R&D are available. It is recommended that government should provide innovative funding mechanisms, as was done during the COVID-19 pandemic, for research into homegrown solutions to our health needs through research into vaccines and other pharmaceutical products that are specific to Nigeria’s disease burden – bearing in mind that the population can be said to be representative of other Africans and therefore such remedies will be useful to other African countries.

4.12 Conclusion

The goal of government for the pharmaceutical sector in Nigeria remains the attainment of self-sufficiency in the supply of quality and affordable medicines and vaccines to the Nigerian people.

Nigeria’s government has developed policies to promote the local production of pharmaceuticals and vaccines and has received a lot of support from development partners in the execution of this project. Critical stakeholders in the various subsectors of the health-care system are carrying out their mandates within the limits of available resources but it has been observed that a lot of factors – including political will and commitment of government, exposure to the required skills and training and provision of the necessary resources – are essential to the overall success of all efforts that are being made to boost local manufacturing of pharmaceuticals and to commence vaccine manufacturing in the country.

Addressing the identified challenges that face local production of pharmaceuticals and vaccines, including mRNA vaccines, will go a long way to achieving medicine and vaccine security, self-sufficiency and sustainability leading to universal health coverage in the country.
References


62. Press release on vaccine development efforts in Nigeria: Breakthrough as tefund sponsored covid-19 vaccine in Nigeria; 2022.
73. Draft concepts note for Nigerian Pharmaceutical Sector Strategic Plan (NPSSP). Promoting the Quality of Medicines Program plus (PQM+), 2022. (not publish, not available to the public).


82. Forecast and projections for 2024 and 2025 vaccines costing MTEF 2023. Lagos: National Primary Healthcare Development Agency; 2022. (not published, not available to the public)
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