



# Coalition for Dialogue on Africa (CoDA)

## HIGH LEVEL POLICY DIALOGUE

ON VACCINE DEVELOPMENT AND EQUITABLE,  
UNIVERSAL ACCESS TO ESSENTIAL VACCINES  
AND VACCINATION IN AFRICA

## CONCEPT NOTE

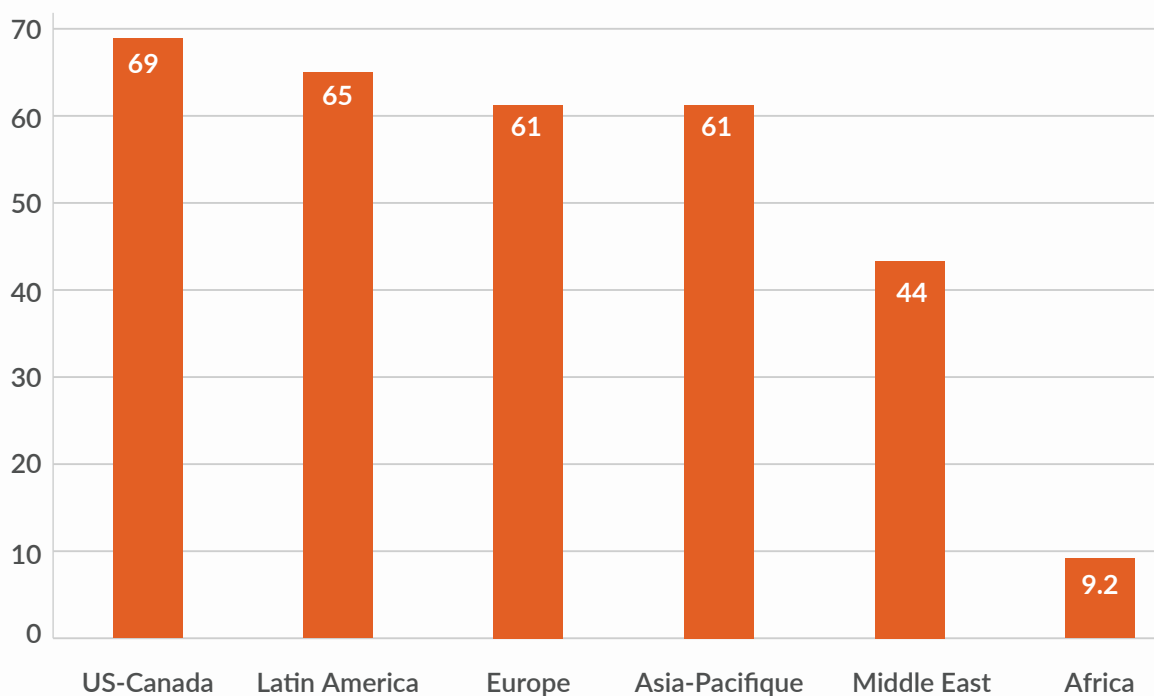
Abeokuta, Nigeria | 25–26 November 2021



### I Background and Context

The COVID-19 pandemic has brought to light the vulnerabilities faced by Africa’s health systems. Moreover, the pandemic has exposed the stark disparities in vaccines access in Africa as compared to other regions of the world. As the continent continues to grapple with a devastating third wave of coronavirus infections, it is also being left behind in the global COVID-19 vaccine competition. According to the Africa CDC, as of 12 November 2021, only 6.06% of Africa’s population have been fully vaccinated, while 9.20% have been partially vaccinated. The New York Times reports that worldwide 75% of COVID-19 shots that have been administered occurred in high- and upper-middle-income countries, with only 0.7% of doses administered in low-income countries. Figure 1 shows the dramatic divide between regions of the world regarding Covid-19 vaccination. Africa holds the last position among the world regions in the share population having received at least one dose of COVID-19 vaccines, as of 12 November 2021.

## Share of Population Having Received At Least One Dose of COVID-19 Vaccine By Region



**Source:** NYTimes/Covid Vaccinations Tracker, November 12, 2021

Africa's need for vaccines and vaccination is not limited to the COVID-19 pandemic. Indeed, vaccine preventable diseases such as measles, diphtheria, and tetanus, coupled with emerging and re-emerging infectious pathogens such as Ebola Viral Disease, HIV/AIDS, TB, and malaria continue to ravage fragile health systems and negatively impact mortality rates and economic development. Up to now, the continent has relied on vaccine imports to fulfil its needs in this area. Indeed, it is estimated that 99% of the vaccine doses required to respond to Africa's needs are imported.

This over-dependence on vaccine imports has exposed the continent to vulnerabilities in terms of its preparedness for future vaccine-preventable epidemics and pandemics, while subjecting countries' public health systems to risks – a situation made clear by Africa's current struggle to access COVID-19 vaccines. Furthermore, the uneven global distribution of manufacturing capacity, inequitable access to finance, and poor healthcare infrastructure have led to the absence of equitable and universal access to essential vaccines and vaccination, with African countries largely dependent on external donors and suppliers. This over-reliance on vaccine imports has led to needless loss of lives and livelihoods on the continent due to the unavailability of vaccines, delays and uncertainty in delivery, and inefficient vaccine distribution infrastructure.

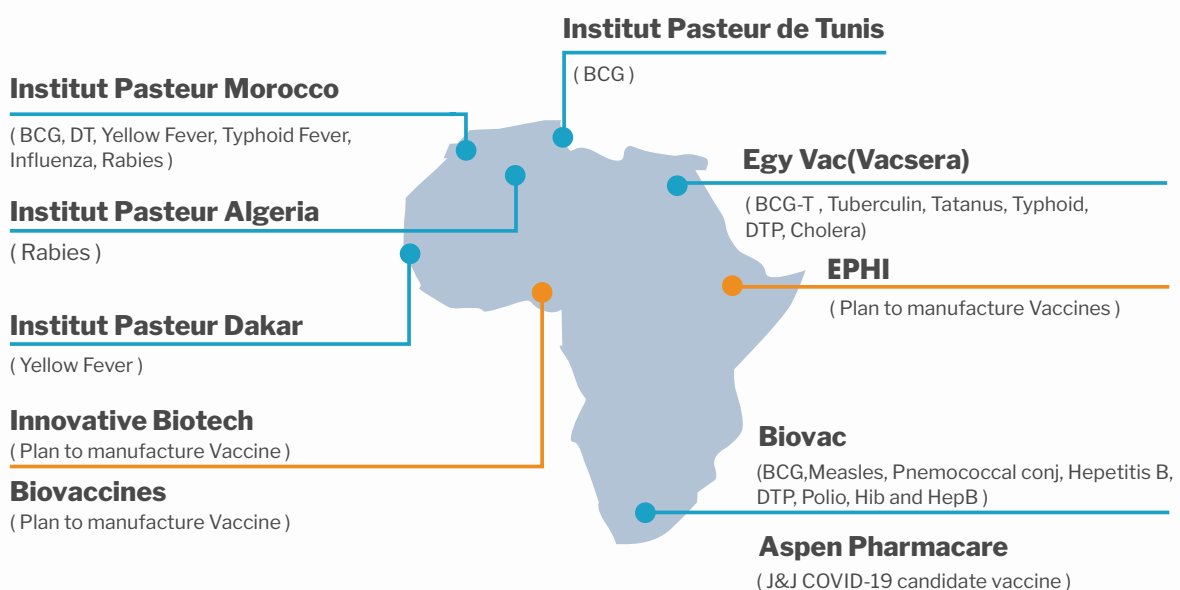
## The Challenges and Opportunities of Vaccine Manufacturing in Africa

The main thrust behind the current initiative is to strengthen the partnerships between African policy-makers, research and academic institutions, civil society, and the private sector with the aim of developing, producing and facilitating access to vaccines in Africa. The public health imperatives for the continent to own its vaccine and vaccination agenda is undisputable. But in addition, Africa also presents a favourable business case for establishing its own vaccine manufacturing industry and vaccination ecosystem. The continent has the fastest growing population globally, and the demand for immunizations in Africa for routine diseases is projected to outstrip current supply by 2030. Specifically, Africa's vaccine market is projected to expand from **USD \$1.3 billion in 2021** to **USD \$2.3- \$5.4 billion by 2030**.

The production and distribution of safe and effective vaccines for routine immunizations and future pandemics is admittedly challenging, but necessary. Success requires an integrated, system-wide, end-to-end strategy plus long-term vision and innovation investment from the private sector in Africa to realize anticipated benefits in response to projected exponential demand. Currently however, there is limited manufacturing capacity in Africa. In fact, there are fewer than 10 African manufacturers with vaccine production and are based in eight countries: **Egypt, Morocco, Senegal, South Africa, Algeria, Nigeria, Ethiopia, and Tunisia** (see Figure 2).

More significantly, of these nations, only one – Senegal – exports a WHO pre-qualified vaccine. For the rest, almost all the current vaccine capacity is focused on supplying to internal country markets with very little export taking place, and there is very limited upstream production with most local companies only engaging in packaging and labelling, and occasionally fill and finish steps, according to the WHO (March 2021). Further, WHO also suggests that Africa's current vaccine manufacturing capacities are relatively small (fewer than **100 million doses**) severely vaccine availability in disease emergency situations.

### VACCINE MANUFACTURING SITES IN AFRICA



*Limited vaccine manufacturing capacity*

Figure 2. Vaccine Manufacturing Sites in Africa (Source: Africa CDC)

An important challenge that vaccine manufacturing faces in Africa concerns the existing market size. There is a need for commitment and support to buy vaccine manufactured in Africa. Establishing economies of scale in vaccine production in Africa will require such commitment on the part of all stakeholders, including national governments, regional economic communities, the African Union, civil society, the private sector, and the academic and research community.

## Research and Development and the Vaccine Manufacturing Life Cycle

The vaccine R&D and manufacturing life cycle comprises eight phases, including Research, Product Development, Preclinical Testing, Clinical Testing Phases I, II and III, API Manufacturing, Supply/Distribution, and Marketing, as indicated in **Figure 3**.

The R&D component is comprised of the first four phases, namely: Research, Product Development, Preclinical Testing, and Clinical Testing Phases I, II and III.

The manufacturing component comprises the remaining four phases.

**FIGURE 3: THE R&D AND MANUFACTURING LIFE CYCLE**



Given the complexity and significant cost requirement of a vaccine product development and manufacturing programme, a continent-wide vaccine R&D and manufacturing process is a preferred strategy rather than a narrow nationally-focused approach. By adopting a continental-focused approach, African vaccine researchers and manufacturers can pool their resources and coordinate their efforts to build confidence with respect to Africa-based R&D and manufacturing. Moreover, the continent can further build on and leverage its partnerships in the context of South-South cooperation, and with the Global North, for rapid knowledge and skills acquisition and sharing, to quickly advance Africa-based vaccine R&D and manufacturing programs.

In this respect, growing and expanding Africa's capabilities to carry out vaccine Research and Development will require conducting a mapping and a SWOT analysis of current national-level pharmaceutical and biotechnology R&D capabilities in order to identify best practices, lessons learned and gaps. Based on this analysis, a continental strategy for vaccine R&D must be developed and put in place, for instance through the establishment of Regional R&D Centers of Excellence. These Regional Centers of Excellence (RCEs) must be structured to attract African talent from across continent and the Diaspora. Through the RCEs potential R&D partnerships (national, regional, continental and global) can be identified and leveraged, including forging partnerships with the continent's South-South cooperation partners such as China, India, Brazil, as well as experienced global partners such as Pfizer, Johnson & Johnson, etc... Moreover, the specific roles of the African private sector, academic institutions, research centres and philanthropists in improving access to vaccines and vaccination on the continent must be redefined in light of the continental approach to vaccine R&D manufactured defined above.

This multistakeholder and continental R&D strategy will serve to maximize the chances of the continent to develop and deploy investigation and clinical trials knowledge and skills, and to build national, regional and continental testing capacity, including procuring world class infrastructure, skills, systems and standards for clinical trials for the continent to demonstrate drug safety, efficacy, and side effects. An important component of this strategy will also involve empowering and strengthening Standards Associations across the continent.

With respect to Africa-based vaccine Production and Manufacturing a similar strategic approach must be developed. Specifically, in order to develop Africa's capability and capacity to manufacture vaccines a mapping and SWOT analysis of current national-level pharmaceutical and biotechnology manufacturing capacity must also be conducted to identify best practice, and lessons learned from early starters such as South Africa, Senegal, Morocco, Algeria, Rwanda, Nigeria and Egypt, as well as gaps to be filled. Similarly, potential manufacturing partnerships (national, regional, continental, and global) need to be identified and established, for instance by establishing manufacturing hubs in each of the five regions of Africa.

Again, such Regional Manufacturing Hubs, will serve to attract African experts from across the continent and the Diaspora and will become the pillars of manufacturing partnerships with the continent's South-South cooperation partners and global partners. To better establish the credibility of Africa's vaccine manufacturing efforts within the global context, an overview of trade-related issues, patents concerns, and TRIPS with respect to vaccines, within the context of the WTO framework and the AfCFTA, must be thoroughly conducted. For Africa, it is vital that the vaccine production and manufacturing strategy put a particular focus on fully identifying and understanding the challenges and opportunities involved with respect to IPR so as to protect its own intellectual property rights, requiring thereby strengthening and deepening independent African national and regional IPR Agencies across the continent.

## Cost Drivers of Vaccine Production and Manufacturing

According to the WHO, vaccine manufacturing is characterized by high upfront costs, and significant ongoing operational and maintenance expenditures. But more particularly for the case of Africa, the cost of vaccine manufacturing may depend on the quality of existing support infrastructures and the difficulties to reach and maintain Good Manufacturing Practice (GMP) and international quality requirements. Vaccine manufacturing must integrate the fact that it is a complex and highly regulated process, with high manufacturing costs due to: a. the complexities of types of manufacturing; b. High risk of failure; c. Complex logistics, cold chain, internal warehouse processes; and d. Stringent quality management system.

As indicated in Table 1, the main drivers of the cost of production and manufacturing of vaccines include: Capital expenditure (CAPEX), Investment Costs, Direct Operating Expenditures (Direct OPEX), and Indirect OPEX. The WHO has estimated the cost of building a vaccine manufacturing facility (20 million doses) to be between **USD60 million** and **USD130 million**, depending on vaccine technology and formulation (UNIDO/WHO, avmi-africa.org, 2017). Of this, the capital.

**Table 1: Cost Drivers of Vaccine Production and Manufacturing**

<b>Capital Expenditure (CAPEX)</b>	Funds used by a company to acquire or upgrade physical assets such as property or equipment. Also include downstream R&D activities, preclinical and clinical trials, associated with bringing the product to commercial production.
<b>Investment Costs</b>	Estimated at 60% of total manufacturing cost, and form the highest cost barrier. Include buildings for API manufacturing, formulation-fill-finish, storage, equipment, quality control facilities, and support structures such as pilot facilities and animal houses.
<b>Direct Operating Expenditures (OPEX)</b>	OPEX in vaccine manufacturing can be divided into fixed and variable costs associated with production. Typically, the variable costs will rise as the volume increases, while the fixed costs decrease as in the CAPEX case.
<b>Fixed Costs</b>	Labor costs, predominantly highly specialized and qualified scientists, are treated as fixed due to the high level of expertise needed.
<b>Variable Costs</b>	Main drivers are volume, presentation, formulation, packaging, and quality control activities.
<b>Indirect OPEX</b>	The indirect costs are related to administrative and manufacturing overheads as well as to maintenance, commercial production costs and quality management

**Source:** <https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf>

expenditures constitute 60%, but that can be reduced through economies of scale and scope, and technology. A 2017 WHO/UNIDO AVMI study also indicates that a highly-specialized workforce is a key contributor to the operating costs; and in Africa lack of existing support infrastructure can increase indirect costs such as maintenance, as can importing of spare parts and material via taxes and transportation. Finally, the study has underlined the fact that quality management systems and international standards are important cost drivers to maintain GMP and quality requirements and achieve access to market (UNIDO, WHO, avmi-africa.org, 2017).

## Sources of Funding and the Need for Public-Private Partnerships and Innovative Financing

In view of the high start-up and operating costs of vaccine manufacturing, and considering that vaccines are first and foremost a public good and a public health instrument to respond to current and emerging public health crises, Governments' support for vaccine manufacturing in Africa is critical and vital. Specifically, Governments will be encouraged to provide incentives and subsidies to vaccine development and manufacturing to reduce costs of production and attract more private sector involvement. Such public investment strategies will prove instrumental to the private sector's ability to achieve the necessary economies of scale and scope for successful and sufficient vaccine manufacturing in Africa. Additionally, building and fostering public-private partnerships (PPP) for financing vaccine manufacturing in Africa will prove effective and beneficial not just for African Governments but also for the continent's African and global private sector partners in this endeavor.

Depending on the prevailing conditions, funding vaccine manufacturing in Africa may be made possible through innovative financing methods and sources such as:

- ✓ Social Impact, Development, and Private Funds
- ✓ Corporate Social Responsibility (CSR)
- ✓ International Finance Facility for Immunization (IFFIs)
- ✓ Domestic health bond type structures in Africa
- ✓ A combination of the above and/or other innovative funding methods

The important insight is that with the right combination of supportive public policy and public investment, and through national, continental and global partnerships, funding vaccine manufacturing in Africa can be accomplished. In short, finance should not be an obstacle to vaccine development and manufacturing in Africa.

## II

# Objectives of the High-Level Policy Dialogue

The preceding sections have presented the issues, challenges, and opportunities characterizing vaccine production and manufacturing in Africa. The current COVID-19 crisis has not only exposed the vulnerabilities of the health systems in Africa, but also the precarity of the vaccine and vaccination policy in Africa, where despite the fact that demand for vaccines in Africa is booming due to a growing population, accompanied by constant need for immunization coverage and increased vaccine expenditure, vaccine supply in Africa is 99% depending on external sources and its funding highly influenced by global partners' decisions, policies, and interests.

This is an urgent situation that is unsustainable and demands focused and immediate attention from all stakeholders. It is in this context that the Coalition for Dialogue on Africa (CoDA), under the auspices and guidance of its Board Chairman, His Excellency President Olusegun Obasanjo, has organized this *'High-Level Policy Dialogue on Vaccine Development and Equitable, Universal Access to Essential Vaccines and Vaccination in Africa.'*

Key objectives of this High-Level Policy Dialogue include:

1. Identify global vaccine and vaccination policy best practices, and adapt to African needs, conditions, and aspirations
2. Agreement on a strategy for how to grow and expand Africa's capabilities to carry out vaccine Research and Development, including mechanisms to protect African IPRs
3. Agreement on the best strategy for how to develop Africa's capability and capacity to manufacture vaccines on a scale and scope that will sufficiently meet its growing demand
4. Identify the roles of the African private sector, academic institutions, and research centers, civil society, and philanthropists in improving access to vaccines and vaccination on the continent in partnership with the public sector.
5. Discussion of the types of regulatory reforms, enabling legislation, and continent-level policy harmonization mechanisms needed to expand private sector participation in vaccine development and manufacturing in Africa
6. Establish a continental strategy on how African governments can enhance partnerships, including with the private sector, the international community and South-South cooperation around vaccine development and manufacturing in Africa
7. Agreement on funding mechanisms and strategies for financing the expansion of vaccine development and manufacturing in Africa
8. Identify mechanisms to achieve equitable access to vaccines and vaccination across Africa

### III

## Dates, Format, and Expected Participants

The High-Level Policy Dialogue on Vaccine Development and Equitable, Universal Access to Essential Vaccines and Vaccination in Africa will be of a hybrid nature, hosted by HE President Olusegun Obasanjo on 25 – 26 November 2021, and will include participants physically present at the selected venue in the historical and beautiful city of Abeokuta, Nigeria, as well as participants who will join by Zoom videoconference link.

Invited participants will include:

- ✓ Selected African Ministers Health and other High-Level Continental Policy Makers
- ✓ High-Level Representatives of Regional Economic Communities
- ✓ Vice Chancellors of African private and public universities
- ✓ Heads of African-based Research Institutions and networks
- ✓ Heads of African Manufacturing Associations and networks
- ✓ Leaders of African finance and banking sectors
- ✓ Civil Society and Philanthropy partners
- ✓ South-South Cooperation and Global Community Partners

### IV

## Partnerships

The High-Level Policy Dialogue on Vaccine Development and Equitable, Universal Access to Essential Vaccines and Vaccination in Africa is organized by the Coalition for Dialogue on Africa (CoDA), in partnership with the African Union Commission (AUC), the African Development Bank (AfDB), African Export-Import Bank (AFREXIMBANK), the Igbinedion University Teaching Hospital (IUTH), the African Research Universities Alliance (ARUA), Manufacturers Association of Nigeria (MAN), and the Pan-African Manufacturers Association (PAMA).