

# Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action



2022 (Version 1)

Confidential and proprietary. Any use of this material without permission of the PAVM Secretariat is strictly prohibited

# Foreword

It gives me great pleasure to present the Framework for Action (FFA) that the Partnerships for African Vaccine Manufacturing (PAVM) has prepared under the supervision of the African Centers for Disease Control and Prevention (Africa CDC). The Framework for Action sets forth the key diagnostic findings on the current vaccine manufacturing environment in Africa and recommends eight bold programs to unlock Africa's potential to grow and scale vaccine development and manufacturing over the next two decades.

The African Centers for Disease Control and Prevention and the African Union together have called for a New Public Health Order which will safeguard the health and economic security of the continent as it strives to meet the aspirations of the Agenda 2063. A key pillar of this mandate seeks to expand the local manufacture of vaccines, diagnostics, and therapeutics. Presently, less than one percent of vaccines administered on the continent are manufactured locally. This places a great burden on the health systems of African countries and reduces their ability to respond to pandemics and other health crises.

The Framework for Action answers the call made by the African Union Commission and the African Centers for Disease Control and Prevention at a summit in April 2021 to develop a framework that will enable Africa to manufacture 60 percent of its vaccine needs locally by 2040. The bold programs it outlines will see Africa become more self-reliant as it addresses its vaccination needs.

These programs advocate for implementing an African vaccines procurement pooling mechanism to provide certainty for African manufacturers; strengthening National Regulatory Authorities and Regional Centres of Regulatory Excellence to build vaccine regulatory excellence; establishing a Vaccine Manufacturing Deal Preparation Facility to help manufacturers build compelling business plans for investors and to support project financing for vaccine ecosystem enablers; establishing a Vaccine Technology Transfer & Intellectual Property Brokering Service to link technology providers and recipients to an ecosystem of support for tech transfers; forming vaccine research and development centres and a research and development coordinating unit to manage research conducted on the continent; establishing Regional Capability and Capacity Centres to enhance human capital; and supporting enabling trade policies for vaccines – all guided by a continental strategy with a delivery and oversight mechanism.

The implementation of these bold programs will be Africa-led, with support from the global system, and will demand that key stakeholders and implementation partners including governments, manufacturers, national regulatory authorities, donors, and funders, work in a coordinated manner. A coordinated approach will enable Africa to achieve its ambitions faster and will foster collaboration between countries and regions. The Framework for Action will complement and build on efforts already begun by certain countries across the continent to expand vaccine manufacturing. This coordinated approach seeks to augment and expand these efforts.

The ambitions of the Framework for Action require governments to commit to its objectives and align with them. The Framework for Action calls for governments to provide increased financial resources, to shift national health priorities where required, and to advocate for enabling policies, all with the goal of making vaccine manufacturing and trade easier within the continent.

The Partnerships for African Vaccine Manufacturing will aim to coordinate and enable partnerships within and between countries and with the global community of supporters, acting as an intermediary and enabler where required.

We recognise that the vaccine manufacturing ecosystem is a dynamic one, and we therefore view the Framework for Action as a "living document" that will be updated on an ongoing basis by the Partnerships for African Vaccine Manufacturing to account for any significant changes that impact the vaccine ecosystem.

The bold programs that make up this framework were designed by a Task Force composed of volunteer experts and industry leaders from across the continent. These committed individuals met regularly between July and November 2021 to identify the key problems affecting Africa's vaccine manufacturing ecosystem and worked to develop programs to address them. We appreciate the time and effort the Task Force invested, and we thank the organisations that allowed them to dedicate time to the project. For their own contributions towards drafting the Framework for Action, we also thank the advisory committee, the scientific peer review group, and all our partners who attended workshops and other engagement forums over the past months and those who funded some of the complex analyses underpinning the framework.

We are embarking on an ambitious and exciting journey that will strengthen African health systems and secure the future of health responses across the continent. This is a time to work together and to support each other as we build a more resilient Africa for current and future generations. We call on all stakeholders to embrace this journey ahead of us and to play their part in bringing us to 'the Africa we wish to see'.

Dr John Nkengasong

Director of the African Centres for Disease Control and Prevention

# Contents

<b>Executive summary</b>	<b>8</b>
<b>What it will take to meet the continent’s vaccine needs through African manufacturing</b>	<b>8</b>
An integrated ecosystem approach is required to realize the vision	9
The prize: health security and economic development	11
Mobilizing the investment required: \$30 billion over the next 20 years	12
<b>The Framework for Action: Building the African ecosystem required to scale vaccine manufacturing</b>	<b>13</b>
Program 1: Creating an African vaccines procurement pooling mechanism	14
Program 2: Establishing a vaccine manufacturing deal preparation facility and fundraising for ecosystem enablers	15
Program 3: Strengthening National Regulatory Agencies and Regional Centres of Regulatory Excellence to build vaccine regulatory excellence	16
Program 4: Support the transfer of vaccine technologies and intellectual property through an enablement unit	16
Program 5: Creating Regional Capability and Capacity Centres	17
Program 6: Putting in place vaccine research and development centres and a research and development coordinating platform	18
Program 7: Undertaking advocacy for enabling trade policies for vaccines	19
Program 8: Ensuring an effective continental strategy for delivery and oversight	19
<b>Looking forward</b>	<b>20</b>
The FFA’s implementation roadmap—and the approach to measuring progress	20
Getting started: quick-win actions can be taken in 2022	20
Monitoring progress: Key Performance Indicators	22
Further measures are needed to future-proof the Framework for Action	22
<b>I. Introduction</b>	<b>24</b>
<b>II. African vaccine market environment</b>	<b>25</b>
<b>Demand for vaccines is set to grow at a rapid pace</b>	<b>25</b>
<b>Supply remains uneven and unreliable</b>	<b>26</b>
<b>The investment required</b>	<b>27</b>

<b>Threats &amp; Challenges</b>	<b>28</b>
<b>III. The case for PAVM</b>	<b>30</b>
<b>Context</b>	<b>30</b>
<b>PAVM structure and organization</b>	<b>31</b>
<b>PAVM mandate</b>	<b>31</b>
<b>PAVM target outcomes</b>	<b>32</b>
<b>IV. What it will take to meet the continent’s vaccine needs through African manufacturing</b>	<b>33</b>
Rationale for increased African manufacturing capacity	34
The prize: health security and economic development	34
Inspiration from other markets	36
Methodology and key angles	37
An integrated ecosystem approach is required to realize the vision	37
Insights on potential focus areas	38
Mobilizing the investment required: \$30 billion over the next 20 years	44
High-level implementation plan	45
<b>V. The Framework for Action: Building the ecosystem required to scale vaccine manufacturing in Africa</b>	<b>47</b>
<b>Program 1: Creating an African vaccines procurement pooling mechanism</b>	<b>47</b>
Context and challenge	48
Overview	48
Market design and demand-related challenges of the current system in Africa	48
Recent developments in African procurement mechanisms	51
Africa vaccine demand forecast	52
Strategic directions	55
Objectives for the future state pooled procurement architecture	55
Design of a future state pooled procurement architecture	56
Potential risks and mitigating factors	59
Looking forward	60
High-level implementation plan	60

<b>Program 2: Establishing a vaccine manufacturing deal preparation facility and fundraising for ecosystem enablers</b>	<b>61</b>
Context and challenge	61
Demand	62
Supply	62
Enablers	62
Strategic directions	63
Demand	63
Supply	64
Enablers	64
Recommendation	64
Looking forward	65
Scope and mandate	65
Design principles	66
High-level implementation plan	67
<b>Program 3: Strengthening National Regulatory Agencies and Regional Centres of Regulatory Excellence to build vaccine regulatory excellence</b>	<b>67</b>
Context and challenge	67
Strategic directions	69
Looking forward	71
High-level implementation plan	72
<b>Program 4: Support the transfer of vaccine technologies and intellectual property through an enablement unit</b>	<b>74</b>
Context and challenge	74
Strategic directions	77
Looking forward	78
High-level implementation plan	80
<b>Program 5: Creating regional Capability and Capacity Centres</b>	<b>81</b>
Context and challenge	81
Strategic directions	83
Looking forward	85

High-level implementation plan	87
<b>Program 6: Putting in place vaccine research and development centres and a research and development coordinating platform</b>	<b>88</b>
Context and challenge	88
Strategic directions	90
Looking forward	92
High-level implementation plan	92
<b>Program 7: Undertaking advocacy for enabling trade policies for vaccines</b>	<b>93</b>
Context and challenge	93
Strategic directions	95
Looking forward	101
<b>Program 8: Ensuring an effective continental strategy for delivery and oversight</b>	<b>101</b>
Implementing the FFA	103
Future-proofing the FFA	108
<b>VI. Conclusion</b>	<b>109</b>
<b>VII. Appendices</b>	<b>110</b>
<b>VIII. Abbreviations</b>	<b>111</b>
<b>IX. Exhibits and tables</b>	<b>113</b>

# Executive summary

The Partnerships for African Vaccine Manufacturing (PAVM) was established by the African Union (AU) in 2021 to deliver a bold goal: enabling the African vaccine manufacturing industry to develop, produce, and supply over 60 percent of the total vaccine doses required on the continent by 2040, up from less than 1 percent today (with interim goals of 10 percent by 2025 and 30 percent by 2030).

African leaders gathered in April 2021 to map out a path to achieve this ambition.<sup>1</sup> They agreed on the need for a robust continental strategy adapted to regional specifics—a Framework for Action (FFA). Since then, the Africa Centres for Disease Control and Prevention has worked with stakeholders across the continent to shape a detailed FFA that lays out the key interventions required to enable the development of a sustainable vaccine manufacturing industry in Africa.

This document summarizes the FFA and the steps required to implement it. The document also considers what it will take to meet the continent’s vaccine needs through African manufacturing, current state challenges and opportunities, and the benefits that will result from realizing this vision. It then presents the eight bold programs that make up the FFA and concludes with an overview of the approaches needed to drive those programs successfully in the short-, medium-, and long-term, which include close coordination across the continent and quick wins in the next year.

The FFA should be considered a living and dynamic strategy. Any additional insights and recommendations from these analyses, as well as other updates that may emerge because of the dynamic nature of the industry, will continue to be syndicated, incorporated into the FFA, and adopted for implementation. The FFA will not seek to limit innovation and entrepreneurship within the defined pathway; rather, it will act as a flexible guide to building a sustainable African vaccine manufacturing industry.

## What it will take to meet the continent’s vaccine needs through African manufacturing

Achieving the PAVM vision—which will mean developing the manufacturing capacity to produce at least 1.5 billion vaccine doses per year by 2040—will be a massive and complex undertaking. The need is clear; while the supply of routine vaccines has been stable, the supply of outbreak vaccines remains uneven and unreliable, as evidenced by the COVID-19 pandemic.

However, while vaccine manufacturing in Africa is currently nascent, demand is set to more than double in volume over the next decade from ~1 billion doses today to over 2.7 billion doses in 2040. By value, excluding future demand for COVID-19 vaccines and most other new vaccines yet to be developed, the public market for vaccines in Africa is expected to reach an estimated \$3 billion to \$6 billion by 2040<sup>2</sup>, with a potential upside of \$10 billion to \$17 billion if there is sustained demand for COVID-19 vaccines.<sup>3</sup>

Already, self-financing countries represent a market of \$419 million, or one-third of the African vaccine market. The share of self-procuring countries is expected to grow in the next decade as more countries transition from Global Alliance for Vaccines and Immunization (Gavi) support. Currently, Gavi-supported countries account for about 90 percent of total vaccine production volumes and spend as little as one-third of the price per dose compared to self-financing countries.<sup>4</sup>

1 African Union and Africa Centres for Disease Control and Prevention, “Conference Paper: Expanding Africa’s Vaccine Manufacturing,” Africa CDC, April 2021, [africacdc.org](http://africacdc.org).

2 [UNECA report](#)

3 Data from [Linksbridge.com](http://linksbridge.com); World Health Organization, [who.int](http://who.int); United Nations, [un.org](http://un.org); The World Bank, [worldbank.org](http://worldbank.org); and expert interviews.

4 Gavi Alliance, [WHO MI4A database](#)



Currently, local African manufacturing supplies ~1 percent of the total continental demand and manufacturers are consolidated across just five countries (South Africa, Morocco, Tunisia, Egypt, and Senegal). Remaining supply is dependent on global providers, including established suppliers in India who provided 70 percent of Gavi supply and up to 40 percent for self-procuring countries. Remaining supply is provided by large multinational corporations (MNCs) (Merck, Sanofi, Pfizer, and GSK) or large, incumbent developing countries vaccine manufacturers (DCVMs).

### **An integrated ecosystem approach is required to realize the vision**

The FFA is built on the premise that Africa can and should adopt a fully integrated ecosystem to generate investment in all steps of the vaccine manufacturing supply chain—including research and development (R&D), drug substance (DS), and fill and finish (F&F). The FFA calls for increasing R&D activities to include pre-clinical and clinical trials, particularly for diseases with high impact on the continent. The FFA further recommends greater investment in DS manufacturing for vaccines critical for the continent.

Growth in the vaccine industry will also need to be accompanied by growth in supporting industries to provide raw materials and inputs, including active ingredients for the different types of vaccines, inactive ingredients (including acids, concentrates, and other excipients), and consumables (including vials, sterile bottles, syringes, and rubber stoppers). This will be critical to unlocking key benefits such as self-reliance and health security. Developing these industries, as well as supporting manufacturers to achieve scale by developing the enabling landscape, will increase the sustainability of vaccine production on the continent, and also reduce production costs.

With this integrated ecosystem approach in mind, the FFA prioritizes the manufacturing of vaccines for 22 diseases identified as critical. These comprise vaccines for ten legacy diseases (including tuberculosis, hepatitis B, and measles), which are typically high-volume and can offer economies of scale; six expanding diseases that typically do not yet have commoditized vaccines or have relatively higher-priced vaccines (including key pandemic and endemic diseases for which vaccines are needed such as HIV, malaria, and COVID-19); and six outbreak diseases (including Ebola and Disease X).<sup>5,6</sup> A focus on these diseases would address the continent’s pressing patient needs through vaccines that would be feasible and attractive to manufacture. Some of the prioritized diseases have vaccines that have already been developed, and so the need is for local production and access. Others have vaccines still under development, which could be brought to fruition and subsequently produced on the continent.

The FFA also prioritizes seven vaccine manufacturing technologies to provide sufficient flexibility to produce these vaccines. These include traditional technologies such as live attenuated virus technologies, which will be critical in manufacturing vaccines with high demand, and novel technologies such as mRNA, which are likely to grow in scale as the science and investment supporting the technologies advance.

Manufacturing the vaccines for prioritized diseases, as well as achieving the targeted technology mix, will be done by expanding and diversifying existing vaccine manufacturing plants, as well as by setting up new ones, particularly for DS production. Overall, it is expected that about 23 manufacturing plants will be required to achieve this ambition, as well approximately 12 integrated DS and F&F plants, and around 11 F&F-only plants (inclusive of existing and planned capacity).

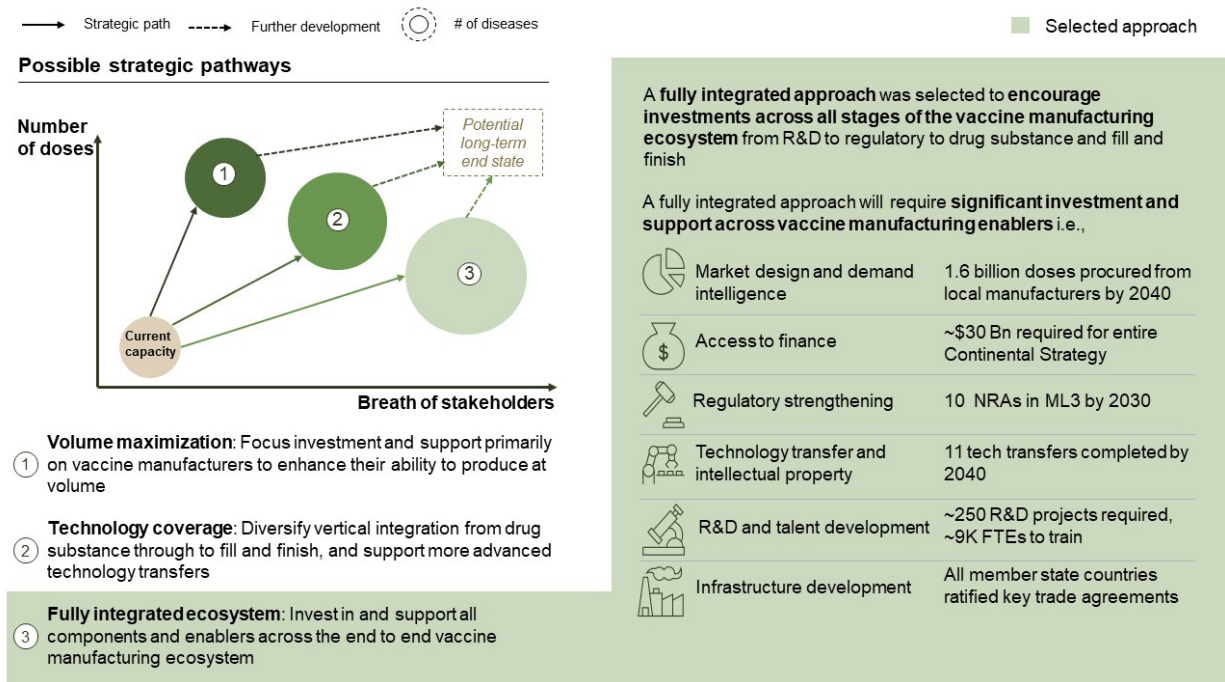
To support the establishment of these plants, the vaccine manufacturing ecosystem will be accelerated through multiple ecosystem enablers, as shown in Exhibit 1.

---

5 Legacy diseases refer to diseases with high coverage vaccines, primarily produced by Indian players at high volumes with low unit prices; expanding diseases refer to diseases that do not yet have commoditized vaccines, where vaccines are sold at relatively higher prices with some products still in development and not yet licensed; and outbreak diseases refer to diseases that are characterized by having emerging vaccines with unpredictable demand driven by outbreaks, often with higher prices due to lower scale and urgent need.

6 Disease X refers to a hypothetical, unknown pathogen that could emerge and result in an epidemic

Exhibit 1: Possible strategic pathways for delivering the FFA



### The prize: health security and economic development

Successful implementation of the FFA will deliver multiple benefits to the continent and its people, including:

- Sovereign health security:** Reduced reliance on imports will enable greater responsiveness to current and future endemic and pandemic diseases and accelerated access to vaccines with high global demand which could save thousands of lives and reduce disease burden. A coordinated African approach will also help address vaccine nationalism, particularly in times of critical need.
- Regional regulatory and trade policy harmonization:** Localization of manufacturing with support from the World Health Organization (WHO), the Africa Centres for Disease Control and Prevention (Africa CDC), and the Africa Regulatory Taskforce (ART) will accelerate ongoing regional harmonization initiatives such as the Africa Medicines Agency (AMA), ratification of the African Continental Free Trade Area (AfCFTA), and elevation of the maturity levels of National Regulatory Authorities (NRAs).
- Technological expertise:** Indirect technological spill-over benefits will flow to regions establishing themselves as Capacity and Capability Centres (CCCs) and will contribute to strengthening the ecosystem for future investment. In addition, investment into R&D and technological development could build capacity for the manufacture of more complex molecules, including Monoclonal Antibodies (MABs), to tackle other diseases that are on the rise in Africa, such as cancers.
- Economic impact:** Localizing vaccine manufacturing could also reduce reliance on foreign aid and supply, mitigate risks of supply chain disruption and priority vaccine access, and generate substantial economic impact through job creation, increased investments, and increased intracontinental trade. This could result in an incremental GDP of \$4 million to \$6 billion, and the creation of ~7 thousand additional manufacturing jobs and ~5.5 thousand additional R&D jobs resulting in a total of ~12.5 thousand vaccine related roles in 2040 (up from ~3 thousand currently). This could also drive the creation of ~33 thousand indirect jobs<sup>7</sup> from suppliers across the sector.

<sup>7</sup> Indirect jobs sized using pharmaceutical (biological product) multipliers derived from GTAP, ILO, Oxford Economics, and MGI Economics Analytics Calculations

## Mobilizing the investment required: \$30 billion over the next 20 years

Approximately \$30 billion will be required to implement the FFA, of which around \$5 billion is needed to fund capex and other one-off costs (primarily the set-up of the required vaccine manufacturing plants, the related cold-chain infrastructure, and the operationalization of key FFA programs). The remaining \$25 billion is required to fund recurring costs over 20 years, including investments into priority R&D diseases as well as R&D into continual process improvement for vaccine manufacturing, royalties paid out for technology transfers, and additional spend on increased vaccine procurement on the continent.

Exhibit 2: Cost of delivering the FFA

PRELIMINARY- NUMBERS STILL BEING REFINED

■ CAPEX ■ Other one-off ■ Total recurring costs over 20 years<sup>2</sup>

	Continental strategy costs, USD Bn	Components included
Market design & demand intelligence	~1	Set-up and running costs for expanded pooled procurement mechanism and short-term subsidy (over next 5 years) for additional Vx procurement
Access to finance	<1	Set-up and running costs for the vaccine manufacturing deal preparation and financing facility
Regulatory strengthening	<1	Improvement of front-runner country NRA maturity levels and operationalization of AMA
Technology transfer and IP	~5	Set-up and running costs for Tech Transfer and IP Enablement Unit, and annual royalty fees paid for tech transfers
Talent development	<1	Set-up and running costs for CCC coordinating body, cost of upskilling manufacturing plant FTEs and subsidization of CCC programs
R&D	~20	Vx development (~\$7Bn), improvement of Vx manufacturing (~\$12Bn), Capex for R&D pilot plant (<\$1Bn), set-up and running of R&D coordinating platform, (<\$1Bn)
Infrastructure development	~5	Capex and project development costs for set-up of manufacturing plants and cold chain infrastructure
Agenda-setting	<1	TA support for operationalization of FFA programs, and PAVM running costs
<b>Total</b>	<b>~30<sup>1</sup></b>	

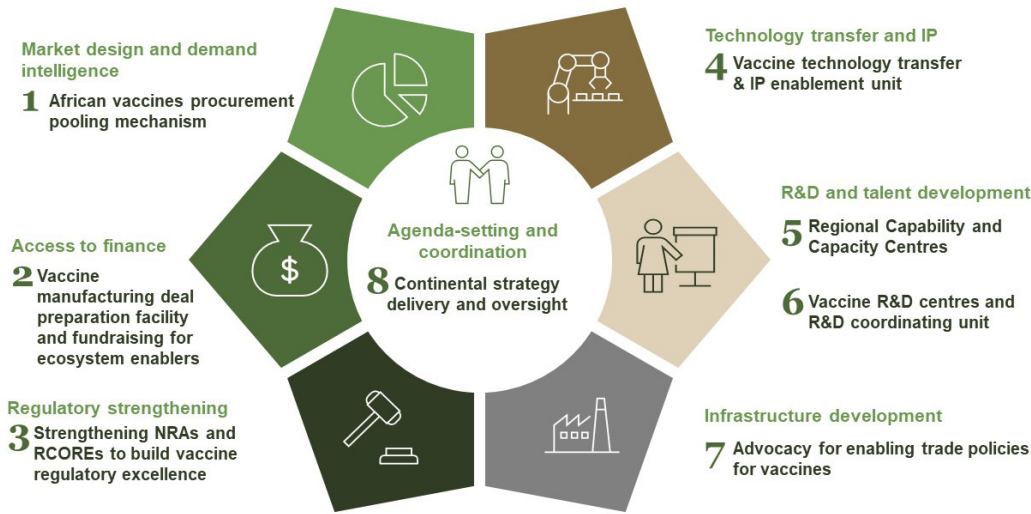
1. By comparison, other funds dedicated to vaccine manufacturing have been sized at \$1.6 Bn (European Commission), \$2 Bn (CEPI), \$10 Bn (COVAX), and \$24 Bn (the White House), though all are for a period of <10 years
2. Manufacturing plant & R&D centre Opex costs (such as salaries, material costs, and overheads) are not included in this analysis

## The Framework for Action: Building the African ecosystem required to scale vaccine manufacturing

The Framework for Action recommends that the African vaccine manufacturing ecosystem focus on strengthening eight enablers, which will require it to roll out eight bold programs (Exhibit 3). To start with, an ambitious pooled-procurement mechanism will drive sustainable and reliable volumes through economies of scale, and a deal preparation facility will mobilize the considerable investment needed. Efforts in technology transfers, regulation, R&D, and infrastructure will strengthen the enabling environment required for success. Regional Capability and Capacity Centres (CCCs) will be established to enhance human capital in the ecosystem, ensuring adequate skilling along all key enablers. Overall, a strong focus on continent-wide strategy delivery and oversight will ensure that all programs are implemented effectively and in harmony with one another.

Exhibit 3: Eight bold FFA programs

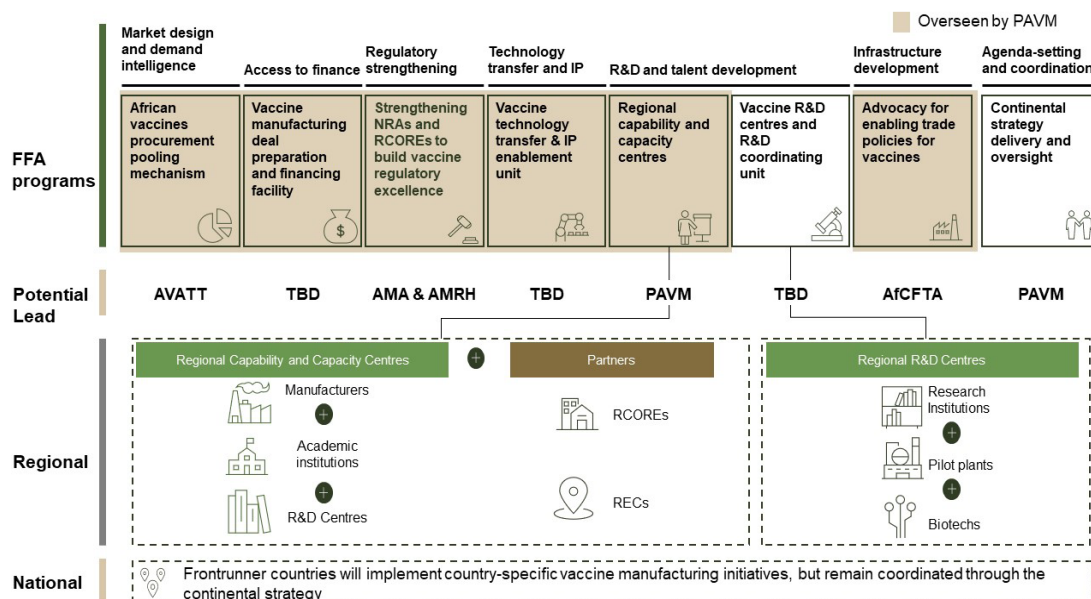
FFA Programs



Multiple stakeholders will need to work in unison to deliver on the ambition of localizing African vaccine manufacturing by 2040. This cooperation involves AU member state governments, local vaccine manufacturers (existing and potential entrepreneurs), various AU agencies, Regional Economic Communities (RECs), NRAs, African Development Finance Institutions (DFIs), and African Research Institutions (ARIs). It also includes global stakeholders, including donors, multinational vaccine manufacturers, and research organizations. It will be essential to engage with and coordinate these stakeholders across the vaccine ecosystem at all levels—global, regional, and local.

PAVM will play various roles across each bold program including roles such as convener, catalyst, facilitator, and coordination. PAVM will use its operating model and governance structure to bring together the stakeholders across the ecosystem and ensure collaboration, while maintaining the sovereignty of member states to develop a resilient and sustainable vaccine manufacturing ecosystem (Exhibit 4)

Exhibit 4: Stakeholders involved in delivering the FFA



## Program 1: Creating an African Vaccines Procurement Pooling Mechanism

A prerequisite for expanding African vaccine manufacturing is achieving sustainable and reliable volumes with economies of scale. Mechanisms that pool procurement of vaccines can create greater certainty of demand and volumes for African manufacturers and support them in accessing the financing required to invest in expanding capacity. Such mechanisms can also facilitate country procurement and enable greater demand for vaccines across the continent.

The emerging consensus is that a pooled-procurement mechanism can be used to procure routine vaccines for all AU countries by 2040. This mechanism would expand an existing entity (the African COVID-19 Vaccine Acquisition Task Team— AVATT) and leverage existing expertise in organizations such as Africa Medical Supplies Platform (AMSP), Afreximbank, and UNICEF.

A primary design decision involves how AVATT may scale up to additional products beyond COVID-19 vaccines over time (with the ultimate ambition of being the predominant pooling mechanism for all vaccines for all member states). Given their lack of access to a pooled-procurement mechanism today, countries not supported by Gavi (and those transitioning from Gavi support) may be especially incentivized to procure routine vaccines through AVATT. AVATT may initially start its scale-up with these countries and a subset of products, subject to the speed of its organisational and operational scale-up. Over time, Gavi-supported countries may also procure routine vaccines through AVATT, potentially starting with vaccines produced in Africa.

## Program 2: Establishing a vaccine manufacturing Deal Preparation Facility and supporting fundraising for ecosystem enablers

The development of Africa’s vaccine industry will require sustained investment into manufacturing capacities and the broader enabling ecosystem. To mobilize the investment required, stakeholders will need to overcome several long-standing challenges that have held back the vaccine manufacturing industry. These include limited numbers of truly bankable projects and an environment that has generally not been conducive to investment. Since most of the machinery and equipment need to be imported (particularly equipment that is compliant with current good manufacturing practice— cGMP), the cost of setting up facilities is high and the revenue horizon long. The return on investment for vaccine research is lower than other biopharmaceutical opportunities, and the long production cycle, coupled with heavy regulatory and quality requirements which require significant amounts of time to be spent on quality controls, assessments, and remediations, make operations costly and accurate forecasting essential. However, even if associated costs are high, the vaccine industry can bring long-term economic growth to the continent. Africa has the potential to be a vaccine hub exporting vaccines internationally. The development of the vaccine industry on the continent will also increase capacity for emergency response and ensure better health security for the continent.

The establishment of a vaccine manufacturing deal preparation and financing facility would be an important step in tackling these challenges. The facility would use a one-stop-shop approach to provide support across all critical project phases and enhance deal bankability. This would be done by providing technical support to manufacturers in the idea phase to clearly define project feasibility through support on business case and feasibility studies, as well as by building credible business cases by relying on precise industry intelligence to convince investors. It would also work to advocate for de-risking incentives such as land giveaways and tax breaks to mitigate in-country risk for investors and enhance the value proposition of African manufacturers. All this would create a meaningful pipeline of viable projects of different risk profiles, with deal preparation such that that the facility could then play a coordinating role in connecting to a broad range of financiers (public, private and donor) with a broad set of financing tools. The facility would enable these connections through marketplace forums to matchmake manufacturers and financiers, as well as by advocating for the use of innovative partnerships and financial tools.

Fundraising initiatives to support the vaccine ecosystem enablers, which could be done through the PAVM, would complement such a facility. These fundraising initiatives would support enablers such as capacity development and R&D, ensuring that the ecosystem develops in a coherent and holistic manner.

Of the total cost of implementing the FFA, about \$5 billion of project financing is estimated to be needed for vaccine manufacturing capex costs and associated cold-chain infrastructure set-up, which could be unlocked through the matchmaking offered by the deal preparation and financing facility. An additional \$10 billion could be raised to support capacity building (for manufacturing plants, R&D institution FTEs, and regulatory bodies) as well as R&D activities (pre-clinical and clinical trials for priority diseases) through the PAVM’s fundraising activities.

### **Program 3: Strengthening National Regulatory Agencies and Regional Centres of Regulatory Excellence to build vaccine regulatory excellence**

The development of best-in-class National Regulatory Authorities (NRAs) is a critical requirement for the development of a sustainable vaccine manufacturing industry. NRAs need to be strengthened to enable African manufacturers to achieve World Health Organization prequalification (WHO PQ), a prerequisite for a vaccine manufacturer to export its products to almost all self-financing countries and countries supported by Gavi. To obtain WHO PQ for vaccine products, vaccine manufacturers need their NRAs to achieve at least WHO maturity level three (ML3) status. Today, however, 81 percent of the African NRAs are still at ML1 or ML2, with none of them reaching ML3 for vaccine production. Only Ghana and Tanzania have reached ML3 (not for vaccine manufacturing) at the time of this report.

PAVM will work through the AMA and the Africa Medicines Regulatory Harmonization Program (AMRH) to strengthen the regulatory system for vaccines and develop a harmonized African ecosystem in five key ways:

- By creating a suitable legal environment for NRAs to review vaccine regulatory frameworks and advocate for the implementation of best practices for vaccine manufacturing.
- By harmonizing NRAs’ operating models in vaccine manufacturing through greater cross-border collaboration and support to implement continental harmonization initiatives (such as vaccine pre-market authorization).
- By developing vaccine manufacturing knowledge- and expertise-sharing mechanisms between NRAs through multiple South-South partnerships.
- By improving regulation capabilities through upskilling leadership, creating sustainable financing mechanisms, and launching capability-building programs via the development of Regional Centers for Regulatory Excellence (RCOREs) dedicated to vaccine manufacturing regulatory activities.
- By facilitating early NRA engagement to accelerate the rollout of technology transfers.

### **Program 4: Supporting the transfer of vaccine technologies and intellectual property through a TT & IP Enablement Unit**

Successful technology transfers are essential to achieve the PAVM’ vision of localizing African vaccine manufacturing. To achieve the goal of producing between 1.5 billion and 1.7 billion doses of vaccines a year by 2040, local manufacturing will require an estimated minimum of 23 technology transfers in the next 20 years.

This program envisages the establishment of a vaccine technology transfer and intellectual property (IP) enablement unit that will facilitate the transfer of technologies and IP. The enablement unit will accelerate the successful execution of technology transfers on the continent by addressing barriers such as:

- Lack of capacity, capability, and resources required for technology transfers in African companies.
- Lack of clear incentives for technology providers to transfer their technologies to African vaccine manufacturing companies.

- Limited visibility and understanding of different NRAs’ country-specific requirements leading to delays in launch preparations and transfer rollouts.

The enablement unit will provide support to help accelerate technology transfers already in the pipeline (as needed) and create an enabling environment for the additional technology transfers required to achieve the ambition for local manufacturing by 2040. The enablement unit will support local manufacturers to be “transfer ready” and will also facilitate manufacturer-to-manufacturer transfers by sharing best practices and lessons learned. It will further coordinate access to technical expertise, partnerships, funding, talent, research, and manufacturing capacity, and enable regulatory alignment.

In addition, the enablement unit will help to overcome historical limitations to new and alternative vaccine technology development on the continent and, in so doing, will build on the progress in technology development seen during the COVID-19 pandemic. Vaccine manufacturing requires a skilled workforce with experience in a broad range of specialty areas, which may be specific to a particular vaccine.<sup>8</sup> This is especially true for upstream vaccine manufacturing activities such as drug substance production. This know-how is generally learnt in vaccine manufacturing facilities and training is not readily available in most countries, including in African countries. Technology transfers can help bridge this knowledge gap by transferring the technologies and know-how from experienced manufacturers to local manufacturers which would in turn help to drive the African vaccine manufacturing market, including expanding the local drug substance manufacturing capacity.

### **Program 5: Creating Regional Capability and Capacity Centres to support talent and critical skills development**

Scaling vaccine manufacturing and R&D across the continent to meet PAVM’s 2040 ambitions will require quadrupling the vaccine workforce to approximately 12,500 full-time employees (FTEs). This will require training of ~10,500 new FTEs based on ~9,500 new jobs and ~10 percent brain drain.<sup>9</sup>

Currently, there is a scarcity of vaccine development and manufacturing talent in Africa. Today, this talent totals between 2,000 and 3,000 FTEs, of whom many are associated with R&D entities that are not fully vaccine-dedicated. Within this existing talent base, there is a lack of key manufacturing capabilities including drug substance and manufacturing R&D (research activities performed by manufacturers in a dedicated R&D department such as process efficiency improvements). For R&D outside of vaccine manufacturers, around 40 percent of research-centred talent is comprised of students and less than 25 percent is made up of full-time academics.

This program will drive the creation of Capability and Capacity Centers (CCCs) to address identified talent gaps and challenges. These centres will foster partnerships between research institutions, manufacturing companies, and educational institutions to build a much stronger bridge between education and full-time work. In the short to immediate term, they will collaborate with international and global institutions to fill critical talent gaps and support the scaling of local programs. The Centres will create opportunities such as university degree specializations in vaccine fields, early internships for students to embark on vaccine careers, on-the-job development programs for graduates, and experienced hires from adjacent industries and diaspora to provide the hands-on training necessary to succeed in vaccine manufacturing and R&D.

### **Program 6: Putting in place Vaccine Research and Development Centres and a Research and Development Coordinating Platform**

The 2040 ambition for the R&D value chain is to invest in and expand local R&D capabilities to enable four distinct types of end-to-end R&D on the continent: developing new vaccines, improving existing vaccines, improving processes, and creating new vaccine combinations.

<sup>8</sup> WHO article, [Increasing Access to Vaccines Through Technology Transfer](#)

<sup>9</sup> 13 percent brain drain estimate from [AfDB](#) and [AERC Africa](#), reduced to 10 percent assuming that programs can reduce overall brain drain

To meet the 2040 manufacturing target of 60 percent local production, it will also be essential to develop vaccines for five of the prioritized diseases for which no vaccine currently exists—HIV, Chikungunya, Rift Valley fever, Lassa fever, and Disease X (upon emergence).

There are currently several longstanding barriers that African research centres and biotechnology facilities have faced in accessing several important steps of the value chain, such as pre-clinical research and cGMP batch manufacturing for clinical trial. It is currently not possible to move a vaccine concept from research through to clinical trials entirely on the African continent. There is also a lack of required partners, sponsors, investors, and know-how to advance and/or commercialize research projects. Moreover, the expertise that does exist is spread across the continent, with limited connections. The R&D system will address all these challenges.

This program envisages the establishment of a system of regional R&D centres connected by a single continental R&D coordinating platform. R&D centres will consolidate infrastructure, assets, and expertise (virtually or physically) in each region to deliver meaningfully on at least one stage of the R&D value chain. This will include leveraging existing strengths (such as clinical trial capabilities in many countries) and addressing infrastructure gaps (for example, establishing cGMP batch manufacturing for clinical trial and increasing capacity for animal study facilities). The R&D coordinating platform will help set continental R&D priorities, collate funding, and funnel it into R&D centres. It will also connect R&D centres across Africa and coordinate collaboration opportunities with established international or continental organizations.

### **Program 7: Undertaking Advocacy for enabling trade policies for vaccines**

This program will help overcome the challenge that, despite multiple regional trade agreements and favorable national trade policies, overall trade integration remains low across the different regions of the continent. Additionally, the risk of protectionism during outbreaks remains present, as shown by recent trade bans in pandemic periods.

This program will ensure that trade policy within regions and member states enables local vaccine manufacture in four ways:

- By expanding exemptions from import duties, and providing other incentives such as VAT deferments to cover all vaccine and R&D inputs.
- By harmonizing trade and industrial policy to target vaccine manufacturers.
- By helping frontrunner countries ratify and implement key trade agreements like the AfCFTA, prioritizing agreements that support vaccine trade.
- By preventing trade restrictions or bans on vaccines during outbreaks to support regional trade.

Additional advocacy will be required for continuing and accelerating existing infrastructure initiatives by other entities, including advocacy for the pipeline of mega-projects serving frontrunner countries that might indirectly support the vaccine industry, and advocacy for innovative technologies.

### **Program 8: Ensuring an effective Continental Strategy for delivery and oversight**

Implementing this strategy will require several parallel programs and supporting initiatives and pilots. These include the consolidation and oversight of ongoing vaccine manufacturing projects, the creation and maintenance of investment relationships, the streamlining of existing and proposed capability and capacity centres, and advocacy for supportive policies across the ecosystem. In addition, vaccine manufacturing ecosystem enablers such as talent, regulatory environment, and R&D have historically been underfunded because it has been hard to tie them directly to specific manufacturing projects. Fundraising initiatives in line with the FFA strategy can bridge that gap with clear programs aligned with financiers and coordinated by the PAVM Secretariat. About \$10 billion is estimated to be needed over the next 20 years to support capacity building (for talent within manufacturing plants, R&D institutions, and regulatory bodies) as well as R&D activities (pre-clinical and clinical trials for priority diseases), in line with the FFA strategy.



A coordination mechanism is required to set the strategic direction of manufacturing activities on the continent, ensure ambitions between key players are aligned (including financiers), and monitor, track, and report implementation progress. This coordination mechanism could help overcome challenges within the current vaccine manufacturing industry such as fragmentation in the ecosystem, poor coordination of activities, underfunding for ecosystem enablers, disproportionate focus on COVID-19 vaccine manufacturing in the short-term, and insufficient focus on DS manufacturing and R&D overall, among others. PAVM will take on this role by mobilizing the local and global vaccine ecosystem to support delivery of the continental strategy.

## Looking forward

### The FFA’s implementation roadmap and the approach to measuring progress

All eight programs defined in the FFA will be implemented across the continent. This will be accomplished by phasing key activities across the immediate term, short term, medium term, and long term to have full implementation and scale by 2040. In the next year, the focus will be on immediate ‘quick wins’ such as accelerating completion of in-progress projects across the continent (primarily COVID-19 focused) and developing a baseline for the scale-up of other priority vaccines. Each of the bold program implementation bodies will also be set up, and detailed implementation strategies and initiatives will be defined. In the short term, focus will be on piloting key initiatives for each of the eight programs and adapting implementation design based on lessons learned. The medium to long term will focus on scaling up all FFA program initiatives as well as regional manufacturing to achieve the continental strategy by 2040.







### Getting started: quick-win actions can be taken in 2022

Several quick-win activities have been identified which can take place over the next year (2022). These aim to address the urgent need to produce vaccines for the ongoing COVID-19 pandemic, while also building off vaccine- production momentum from COVID-19 vaccine production to establish and operationalize the FFA. Progress in the short term could be monitored against the milestones given in Exhibit 5. Reference source not found.

Exhibit 5: FFA key milestones in 2022

◆ COVID-19 related

Program	Key milestones	2022			
		Q1	Q2	Q3	Q4
 <b>Program 1: Creating an African vaccines procurement pooling mechanism</b>	AVATT mandate extended beyond COVID-19; several countries committed to purchasing first batch of locally produced vaccines		◆		
	Offtake guarantees provided by AVATT for COVID-19 vaccine manufacturers		◆		
 <b>Program 2: Establishing a vaccine manufacturing deal preparation and financing facility</b>	Vaccine manufacturing deal preparation facility design and set-up completed			◆	
	Deal preparation facilities provided to at least 5 vaccine manufacturing deals on the continent				◆

Program	Key milestones	2022			
		Q1	Q2	Q3	Q4
 <b>Program 3: Strengthening NRAs and RCOREs to build vaccine regulatory excellence</b>	Critical processes for vaccine manufacturing harmonized and EUA <sup>10</sup> approval given for outbreak vaccines			▲	
	Countries with COVID-19 vaccine production in 2022 obtaining WHO prequalification emergency use listing which can be achieved through ML3 of NRA or collaborative AMA / AMRH coordinated process of ML3/4 NRAs on the continent			▲	
	Adoption of joint regulatory review for clinical trial approval and joint inspection of manufacturing facilities			▲	
	A control lab network established and lab strengthening done, allowing certified labs to perform analytical tests required for lot release of vaccines produced in Africa			▲	
	At least 1 NRA with vaccine regulatory skills present in each region <sup>11</sup>				▲
 <b>Program 4: Supporting technology transfer through an intellectual property enablement unit</b>	Enablement unit established, with several countries participating			▲	
	Potential tech transfer collaborators identified and introduced to the Enablement Unit <sup>12</sup>			▲	
	Tech transfer facilitated for planned COVID-19 DS production				▲
	At least 3 tech transfers facilitated in total				▲
 <b>Program 5: Creating Regional Capability and Capacity Centres</b>	CCC programs launched, focused on mRNA technologies (incl. COVID-19)			▲	
	~1-3 at-scale international/global partnerships established to support immediate talent needs				▲
	~2 CCC networks set up				▲
 <b>Program 6: Putting in place vaccine R&amp;D centres and an R&amp;D coordinating unit</b>	R&D coordinating platform launched; proposal process defined for identifying R&D centres			▲	
 <b>Program 7: Undertaking advocacy for enabling trade policies for vaccines</b>	Agreement reached on having no trade restrictions for outbreak vaccines (incl. COVID-19)			▲	
	All AU countries signed-on and ratified the AFCFTA				▲
 <b>Program 8: Ensuring effective continental strategy delivery and oversight</b>	PMO fully staffed with required capacity		▲		
	Alignment reached on tech. platforms to prioritize initial vaccine manufacturing		▲		
	Set-up complete of 3-4 announced COVID-19 vaccine plants <sup>13</sup>				▲

10 Emergency Use Authorization

11 Alternatively, an agreement to leverage capacity of another NRA has been reached

12 Recipients should meet the requirements of being “tech-ready”

13 Includes the following plants that have been announced: BioNtech COVID-19 (Rwanda), Vacsera COVID-19 (Egypt), Aspen Pharmacare COVID-19 (SA), Biovac Institute COVID-19 (SA)

## Monitoring progress: Key Performance Indicators

To monitor the progress of the FFA's implementation, 15 Key Performance Indicators (KPIs) have been defined across each of the programs, which will track the overall objective of each (Table 1). These KPIs will be supplemented through a more comprehensive set of indicators provided in the detailed implementation roadmaps.

*Table 1: KPIs to track overall objectives of each FFA program*

Program	KPIs
<b>Program 1: Creating an African vaccines procurement pooling mechanism</b>	<ol style="list-style-type: none"> <li>1. Share of target value of vaccines procured for Africa</li> <li>2. Share of target volume of vaccines procured for Africa</li> <li>3. Percentage of total AVATT vaccine procurement purchased from local manufacturers</li> </ol>
<b>Program 2: Establishing a vaccine manufacturing deal preparation and financing facility</b>	<ol style="list-style-type: none"> <li>4. Percentage of all local vaccine manufacturing projects funded and operationalized</li> </ol>
<b>Program 3: Strengthening NRAs and RCOREs to build vaccine regulatory excellence</b>	<ol style="list-style-type: none"> <li>5. Percentage of vaccine products approved through reliance on and collaborative reviews by an ML3 NRA</li> <li>6. Number of countries able to approve outbreak vaccine within target number of days through an ML3 NRA</li> <li>7. Number of NRAs that have reached ML3 for vaccines</li> </ol>
<b>Program 4: Supporting technology transfer through an intellectual property enablement unit</b>	<ol style="list-style-type: none"> <li>8. Share of target technology transfers (for both DS and F&amp;F) to African manufacturers completed</li> </ol>
<b>Program 5: Creating Regional Capability and Capacity Centres</b>	<ol style="list-style-type: none"> <li>9. Share of target number of graduates from regional CCCs</li> </ol>
<b>Program 6: Putting in place vaccine R&amp;D centres and an R&amp;D coordinating unit</b>	<ol style="list-style-type: none"> <li>10. Percentage of new vaccines developed from target R&amp;D priorities with some local involvement<sup>14</sup></li> <li>11. Total number of pre-clinical and clinical trials publications towards the Continental Strategy target</li> </ol>
<b>Program 7: Undertaking advocacy for enabling trade policies for vaccines</b>	<ol style="list-style-type: none"> <li>12. Share of AU countries that have ratified key trade agreements (e.g., AfCFTA)</li> </ol>
<b>Program 8: Ensuring effective continental strategy delivery and oversight</b>	<ol style="list-style-type: none"> <li>13. Percentage of total vaccine demand in Africa produced on the continent</li> <li>14. Share of priority technology platforms and vaccine products localized on the continent</li> <li>15. Share of total plant target (integrated and F&amp;F only) established on the continent</li> </ol>

Preliminary targets were set across each of these KPIs (Table 2), although these will continue to be refined.<sup>14</sup>

<sup>14</sup> At least one stage of R&D (research, pre-clinical or clinical) took place locally on the continent

Table 2: Preliminary targets for objective-tracking KPIs for FFA programs

Workstream	KPI	KPI targets		
		Short term (2023-25)	Medium term (2026-30)	Long term (2031-40)
<b>Market design and demand intelligence</b>	Share of target value of vaccines procured for Africa achieved	TBD	TBD	TBD
	Share of target volume of vaccines procured for Africa achieved	35%	75%	100%
	Percentage of total AVATT vaccine procurement purchased from local manufacturers	TBD	TBD	TBD
<b>Access to finance</b>	Percentage of vaccine projects funded and operationalized (from idea to operations)	25%	50%	50%
<b>Regulatory strengthening</b>	Percentage of vaccine products approved through reliance on and collaborative reviews by an ML3 NRA	25%	50%	80%
	Number of countries able to approve outbreak vaccine within target number of days through an ML3 NRA <sup>15</sup>	All countries with COVID-19 vaccine producing capabilities	At least 1 in each region, and a total of 17 across the continent	3-5 in each region
	Number of NRAs that have reached ML3 for vaccines	5	10	>10
<b>Technology transfer and IP</b>	Share of target tech transfers (for both DS and F&F) to African manufacturers completed <sup>16</sup>	35%	85%	100%
<b>R&amp;D and talent development</b>	Percentage of new vaccines developed with some local involvement, from target R&D diseases	15% (2 new vaccines total)	38% (5 new vaccines total)	54% (7 new vaccines total)
	Total number of pre-clinical and clinical trials publications towards Continental Strategy target	>60 per year	>80 per year	>100 per year
	Share of target number of graduates from regional CCCs achieved	35% (~4.5K)	90% (~11.5K)	100% (~12.5K)
<b>Infrastructure development</b>	Share of AU countries that have ratified key trade agreements (e.g., AfCFTA)	100%	100%	100%
<b>Agenda setting and coordination</b>	Percentage of total vaccine demand in Africa produced on the continent	10%	30%	60%
	Share of priority technology platforms and vaccine products localized on the continent	60%	90%	100%
	Share of total planned and new plant target (both integrated and F&F only) established on the continent	35%	85%	100%

15 Regular approval is 60 days, expedited approval 30 days, and 15 days for emergency approval (outbreak vaccine)

16 Based on number of additional plants required as per Continental Strategy, considering both acceleration of ongoing tech transfers and support for new tech transfers. Successfully completed indicates that project evaluation has been completed

## Further measures are needed to future-proof the Framework for Action

Additional measures should be considered to future-proof the vaccine industry on the continent, ensuring it remains dynamic and forward-looking. Example measures include:

- **Increasing preparedness for pandemics or outbreaks:** Pandemics and outbreak diseases are inevitable, and have the potential to claim millions of lives and disrupt societies and economies. Increasing financial and technical support for pandemic or outbreak preparedness as well as governance capacity is crucial. Measures to help minimize the adverse impacts could include expanding local manufacturing capabilities, developing trust in local products, developing robust governance mechanisms for pandemic response, and increasing research on emerging and under-researched diseases.
- **Adopting a one-health approach** by increasing coordination between human, animal, and environmental health experts would help adopt the best vaccine solutions for increasingly integrated ecosystems (for instance, by increasing preparedness and response to zoonotic diseases).
- **Rapidly adopting new vaccine products, technologies, and processes,** including for Disease X, which would help ensure the most effective vaccines are being produced efficiently and cost-competitively on the continent.
- **Strengthening vaccine-adjacent industries** (such as diagnostics, adjuvants, and clinical research organizations), which could help improve the effectiveness of vaccine planning and administering.
- **Developing raw material and input suppliers on the continent** to support the expanding DS-manufacturing capacity in a sustainable way, including incentivizing raw material industries in Africa. This could include incentivizing industries producing glass vials, syringes, and other similar products in Africa. This will also be important to ensure the vaccine industry can operate self-sufficiently on the continent.

These measures are an initial perspective on additional dimensions and vaccine adjacencies but can evolve and change much like the Framework for Action.

The COVID-19 pandemic crisis has demonstrated the risk of relying on external suppliers for vaccines. Building a sustainable vaccine manufacturing industry in Africa will increase its independence, drive economic development, and strengthen its health security. However, it will also require complex coordination of multiple stakeholder groups at a continental scale, all aligned towards a single strategic goal: to produce and supply 60 percent of the total vaccine doses required on the continent by 2040.

This is an ambitious vision. It needs the right support to succeed. While several organizations have started building its momentum, African leaders now need to accelerate it. The unified strategy to deliver this vision must be championed by all stakeholders. Private and public sector players need to drive this change together with concrete commitments and tangible support. Achieving large scale vaccine manufacturing on the continent is far from easy, but it is within Africa's reach, as long as the key actors of this industry deliver on promises made and work together to continue to deliver towards 2040.

The work has begun. Let's join the journey to realize this vision together.

# I. Introduction

The Partnerships for African Vaccine Manufacturing (PAVM) was established by the African Union (AU) in 2021 to deliver a bold goal: enabling the African vaccine manufacturing industry to develop, produce, and supply over 60 percent of the total vaccine doses required on the continent by 2040, up from less than 1 percent today.

African leaders gathered in April 2021 to map out a path to achieve this ambition<sup>17</sup>. They agreed on the need for a robust continental strategy adapted to regional specifics—a Framework for Action (FFA). Since then, the Africa Centres for Disease Control and Prevention has worked with stakeholders across the continent to shape a detailed FFA that lays out the key interventions required to enable the development of a sustainable vaccine manufacturing industry in Africa.

This document summarizes the FFA and the steps required to implement it. The document also considers what it will take to meet the continent’s vaccine needs through African manufacturing, and the benefits that will result from realizing this vision. It then presents the eight bold programs that make up the FFA and concludes with an overview of the approaches needed to drive those programs successfully in the short-, medium-, and long-term-, which include close coordination across the continent.

The FFA should be considered a living and dynamic strategy. Any additional insights and recommendations from these analyses, as well as other updates that may emerge because of the dynamic nature of the industry, will continue to be syndicated, incorporated into the FFA, and adopted for implementation. The FFA will not seek to limit innovation and entrepreneurship within the defined pathway; rather, it will act as a flexible guide to building a sustainable African vaccine manufacturing industry.

---

<sup>17</sup> African Union and Africa Centres for Disease Control and Prevention, “Conference Paper: Expanding Africa’s Vaccine Manufacturing,” Africa CDC, April 2021, [africacdc.org](https://africacdc.org).

## II. African vaccine market environment

Developing vaccine manufacturing in Africa is a complex task. Calls to increase vaccine security and self-reliance in response to the COVID-19 pandemic have set the stage to accelerate efforts in that direction.

Currently, only 1 percent of vaccines intended for African countries are manufactured on the African continent. Governments should contrast the current import-based vaccine model with alternative means of accessing vaccines, including local manufacturing at a larger scale.

### Demand for vaccines is set to grow at a rapid pace

Millions of people across the continent are un- or under-immunized, and each year 9.4 million children miss their recommended third and final dose of the diphtheria, tetanus, and pertussis (DTP) vaccine. Compared with other regions, Africa is still expanding its vaccination coverage, and constitutes one of the last unsaturated regions for existing products.

The main variable in market dynamics on the African continent is whether a country is supported by Gavi, the Vaccine Alliance, or is self-financing. Gavi-supported countries, which primarily procure through the UNICEF Supply Division, account for about 90 percent of total vaccine production volumes, and spend as little as one-third of the price per dose compared to self-financing countries.

Today, self-procuring countries represent a market of \$419 million, or one-third of the African market. The share of self-procuring countries is expected to grow in the next decade as more countries transition from Gavi support, including a few of the largest countries on the African continent, like Nigeria.

The vaccine market of the whole African continent is set to more than double in value by 2030, with key drivers being population growth, expanded vaccine coverage and access, a product mix shifting to higher-priced products, and ongoing needs for emerging products.

#### Demographic shifts

Africa's population is expected to grow much faster (2.5 percent annually) than the rest of the world (0.7 percent annually). It is expected to constitute over a quarter of the global population in 2050, from just 17 percent today, with 2.5 billion people by the middle of the century.

#### Access

Demand will be boosted by ongoing efforts to expand vaccine coverage and access (for instance, in under-immunized populations), and the introduction of new, critical products (such as rotavirus, pneumococcal, and HPV vaccines) to countries that have not previously routinely used them.

#### Pricing

Prices for most products are expected to stay the same or decline over time. However, the product mix is expected to shift towards relatively higher-priced products as new products are introduced and some legacy products are possibly phased out.<sup>18</sup> Moreover, several countries may transition from the Gavi system as their per capita income rises. It is unclear how this might impact average prices.

#### New products

Emerging products, such as those for Lassa fever, malaria, and COVID-19, could be needed to meet substantial demand growth in coming years. The market size depends on ongoing needs for products still in development and how soon they are licensed and commercially available.

<sup>18</sup> Andrea Gennari, Tania Holt, Emma Jordi, and Leah Kaplow, Africa needs vaccines. What would it take to make them here? McKinsey, April 14, 2021

Conservative projections put Africa’s public vaccine market at \$2.4 billion by 2030, with the upper end of projections at \$5.6 billion. Actual values will depend on the efficacy of COVID-19 vaccines and disease epidemiology evolution.

## Supply remains uneven and unreliable

The buyer market is highly consolidated: Gavi supports around 90 percent of the market by volume and around two-thirds by value.

It supports countries financially and provides secure, large-scale offtake for manufacturers. Since it maintains low prices and high quality standards, new local manufacturers would need to be competitive in price and quality with large-scale manufacturers.

The COVID crisis has shown that supply is far below demand for outbreak vaccines. As of November 2021, less than 6 percent of the African population was vaccinated against COVID-19. Supply has been boosted slightly by wealthier countries donating directly to African nations or to the global vaccine-sharing scheme, COVAX. However, India halted vaccine exports to tackle its own urgent needs, and manufacturers faced issues ramping up production in a short space of time. This procurement uncertainty was mitigated to some degree by the establishment of the AVATT (Africa Vaccine Acquisition Task Team), a ten-member team drawn from across the continent to ensure that African countries would be able to secure sufficient COVID-19 vaccine doses to achieve herd immunity.

Currently, the African continent is dependent on global supply for its vaccines. Seventy percent of supply procured for Gavi countries, and 40 percent for self-procuring countries, come from a few large, established suppliers in India. The multinational corporations (MNCs) Merck, Sanofi, Pfizer, and GSK provide products (inactivated polio vaccine [IPV], pneumococcal, HPV, and rotavirus) that represent a quarter of volumes but around three-quarters of market value for Gavi and self-financing countries, and that are becoming increasingly routine through country introductions. This may, however, shift over time as Indian companies increase their market share. Large, incumbent developing countries’ vaccine manufacturers (DCVMs) supply around two-thirds of volumes at very large scale, high quality, and low cost.

The African companies actively involved in vaccine production are consolidated in just five countries (South Africa, Morocco, Tunisia, Egypt, and Senegal). Only a few conduct value-adding upstream manufacturing activities. R&D activities on the continent have been limited, with a narrow disease focus. However, activity is increasing in light of recent outbreaks, like Ebola.

There are only ten identified local vaccine value chain players spread across eight countries, in addition to dozens of other companies that import vaccines to distribute but do not provide any value-adding steps. Among the existing players, about 40 percent engage in packaging and labeling, and 40 percent engage in F&F. Five local companies engage in some degree of DS manufacturing, but mostly at a very small scale. There is limited ongoing R&D activity.

## The investment required

Production costs are a major element in the financial viability of African vaccine manufacturing. They are primarily driven by five swing factors that could affect African vaccine manufacturers’ cost competitiveness: technology platform, scale, value chain step, geographic factors, and innovations.

### Technology platform

Each vaccine platform technology has different fixed and variable cost implications. For example, egg-based technologies often have lower capital expenditure (capex) costs compared to bioreactor-



based technologies. mRNA-based processes often have even lower capex and will likely become cheaper as manufacturers find cost efficiencies.

### Scale

Due to economies of scale, larger plants tend to produce vaccines at lower costs than their smaller counterparts, but this varies depending on platform technology. For example, egg-based technologies require smaller volumes to reach economies of scale compared to bioreactor-based technologies, with mRNA technology sitting between the two. However, new production technologies such as modular technologies can offer economy of scale at lower production volumes.

### Value chain steps

Manufacturing a vaccine dose requires several value-adding steps across the value chain, which can take place at different plants. Integrating all steps into one location can reduce costs and lead times. However, this can also increase production complexity. This could, however, be an advantage, as integrating Africa’s plants into the global value chain could see increased trading and exchanging of components with the rest of the world.

### Country-specific structural and productivity factors

African countries vary widely in terms of taxes, tariffs, infrastructure costs, labor costs, and productivity costs. Public and private sector players can focus on transforming areas that impact vaccine manufacturing input costs. Reducing tariffs on raw material imports, improving labor productivity, or introducing incentives for lenders to lower interest rates for vaccine investments can have a major impact on yields and reduce costs.

Taking into account the above cost factors, there may be several combinations of manufacturing set-up, volume, and weighted average cost of capital (WACC) based on today’s market prices to successfully promote vaccine manufacturing in Africa.

## Threats & Challenges

To develop a successful vaccine manufacturing industry, a concerted multi-year effort will be needed to overcome the short and long-term constraints. These include:

### Agenda setting and coordination

Many individual African countries are pursuing parallel and overlapping strategies without oversight or coordination, all currently focused primarily on COVID-19 vaccine manufacturing. Africa needs a continent-wide strategy that defines a framework in which each country can operate. While each country will remain sovereign in its industry-development choices, by setting and enforcing clear priorities in diseases, technologies, and value chain steps on which to focus across different countries, Africa will steer a concerted effort towards a healthy and sustainable market. This will require efforts to ensure continuity of support from sovereign African governments, even in non-pandemic times.

There are also many other important obstacles to local African vaccine production that command attention, all interconnected and co-dependent, outlined below.

### Market demand and intelligence

Vaccine manufacturing requires large-scale, reliable demand. New manufacturers have to sell their products at large enough volumes to achieve economy of scale, which is only possible if countries sourcing vaccines have sufficient economic stability to maintain their ability to purchase them.

## Regulatory strengthening

Many national regulators need more resources and capabilities to build the correct local frameworks for regulation of vaccine manufacturing. Some regions have worked towards harmonized regulation, but significant gaps remain.

## Access to finance

Financing has been limited for local vaccine manufacturing in Africa because the continent is perceived as high risk, and articulation of the business case is somewhat unclear. Both traditional private and foreign direct investment funding require a clear business case, though each has different risk appetites and investment horizons.

## Technology transfer and IP

Manufacturers cite technology transfer as a major enabler to the development of expertise and capacity that is currently lacking. There are, however, too few opportunities to learn from global industry leaders and to train local experts, as vaccine transfers to Africa have historically been limited. Additionally, technology transfers are long and complex processes, with multiple steps and stakeholders, and often take years to complete. IP protection can be a barrier along the vaccine development process and beyond. IP rights in the form of patents, trade secrets, and clinical test data can affect access to inputs or data, and block new formulations, combinations of materials or use of general processes.

## Talent development

Africa has a shortage of pharmaceutical, biotechnological, and industrial talent, which are all critical for vaccine manufacturing. This is due to insufficient local talent development initiatives, a brain drain of existing local talent, and a funding model that does not sustain enough full-time positions, which together lead to a shrinking talent pool.

## R&D

Africa has gaps in the R&D value chain from research through to clinical development. This is caused by insufficient and inappropriate infrastructure (for example, limited pre-clinical capabilities, limited animal studies facilities, and no cGMP manufacturing for batch clinical trial), limited networks and partnerships to connect expertise across the continent, and insufficient funding directed towards Africa.

## Infrastructure development

Some basic infrastructure elements, like power and water at facility level, are insufficient in certain African countries. Transport networks are also inadequate in many areas, with exports slowed by inefficient border-clearance processes.

By creating the correct framework to address those needs, Africa can create the right conditions to expand its local vaccine manufacturing capabilities.

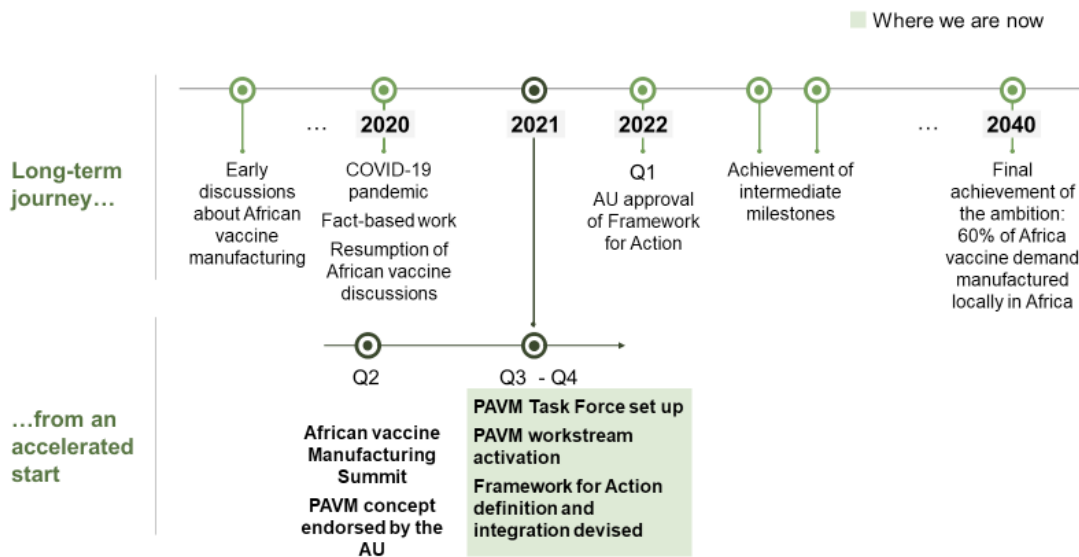
### III. The case for PAVM

PAVM is designed to foster the emergence of a local vaccine manufacturing industry in Africa that can produce 60 percent of routine and outbreak immunization vaccines sustainably and locally, up from less than 1 percent today.

#### Context

In April 2021, the Conference on Expanding Africa’s Vaccine Manufacturing focused on one of four pillars of the New Public Health Order - expanded manufacturing of vaccines, diagnostics and therapeutics - for cross-continental and global collaboration, cooperation, and coordination. It came in the wake of several rounds of discussions on African vaccine manufacturing that aimed to define a framework to enable 60 percent of African vaccine needs to be met by local manufacturing by 2040. This resulted in the creation of PAVM, a task force composed of coordinated working groups tasked with designing this much-needed framework (see Exhibit 6). The AU has endorsed the PAVM concept for immediate implementation.

Exhibit 6: Key timelines for set-up and operationalization of PAVM and FFA



Since 2020, several countries have begun developing or expanding their national vaccine industries. Egypt, South Africa, and Senegal have each partnered with private sector manufacturers to expand volume capacity, while Ghana is reconfiguring part of its pharmaceutical industry to make vaccines, and Rwanda has drafted plans to start mRNA DS manufacturing from scratch. These countries are forging ahead, signing major agreements, and raising finance. However, some coordination at a continental or even regional level will help ensure long-term sustainability and equitable access to vaccines.

PAVM aims to support the development of a continental strategy that will maintain both scale and cost-competitiveness of local vaccine manufacturing and promote equity and security for all countries involved. This means arranging and enabling partnerships as an intermediary, and when needed, within and between countries, and with the global community of supporters. PAVM will also be a central source of information for African vaccine manufacturing, communicating regular updates and data on local vaccine industry progress.

## PAVM structure and organization

PAVM has been designed by African entities for African manufacturers as an integral part of the Agenda 2063. PAVM is composed of a Task Force that, along with the Secretariat, oversees, steers, and supervises seven workstreams.






















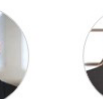


The Task Force is led by the Africa CDC and includes leadership representatives from each of the workstreams. The Secretariat supports the Task Force with coordination and technical support, as well as communication and translation work.

Each of the seven workstreams features a lead person and several members with relevant specialties. Workstreams drive technical analyses and implement the Framework for Action.

More specific details can be found in the Appendix (section 1).

### Exhibit 7: PAVM Advisory Group

#### PAVM Advisory Group

 <b>Ms. Ahunna Eziakonwa</b> UNDP – Chief of Africa	 <b>Dr. Akinwuni Adesina</b> AfDB – President	 <b>Pr. Benedict O. Oramah</b> Afreximbank – President	 <b>Mrs. Eva Kadili</b> UNICEF – Director, Supply Division	 <b>Dr. Francis Collins</b> NIH, USA – Director	 <b>Dr. George F. Gao</b> China CDC – Director General	 <b>Dr. Githinji Gitahi</b> AMREF – CEO	 <b>Ms. Glaudina Loots</b> Health Science Dpt of Science and Innovation – Director	 <b>Dr. John N. Nkengasong</b> AfCDC – Director
 <b>Prof. Kayum Ahmed</b> OSF – Division Director	 <b>Mr. Martin Seychell</b> Team Europe Initiative – Deputy Director General	 <b>Dr. Ngozi Okonjo-Iweala</b> WTO – Director General	 <b>Dr. Olive Shisana</b> South African Presidency – Senior Advisor to the President of South Africa	 <b>Pr. Peter Piot</b> Former Director at London School of Hygiene and Tropical Medicine	 <b>Mrs. Reeta Roy</b> MCF – CEO	 <b>Dr. Richard Hatchett</b> CEPI – CEO	 <b>Mr. Samaila Zubairu</b> AFC – President	
 <b>Dr. Seth Berkley</b> Gavi – CEO	 <b>Dr. Soumya Swaminathan</b> WHO – Chief Scientist	 <b>Mr. Strive Masiyiwa</b> Econet Global – Executive Chairman	 <b>Dr. Trevor Mundel</b> BMGF – President, Global Health	 <b>Dr. Vera Songwe</b> UNECA – Executive Secretary	 <b>Dr. Wade Abel</b> LANAVET – Director General	 <b>Mrs. Winnie Byanyima</b> UNAIDS Executive – Director		

## PAVM mandate

To develop a successful vaccine manufacturing industry, African countries will need to engage in concerted, multi-year agenda setting and coordination. This will allow them to overcome short- and long-term constraints and create an enabling environment through areas including regulatory strengthening, demand certainty, access to finance, talent and know-how, and infrastructure.

PAVM has been endorsed to foster the emergence of a local vaccine manufacturing industry in Africa through the following initiatives:

- Set and coordinate an agenda to:
  - Shape a continental strategy to frame national plans, avoid unhealthy competition, and develop a scalable and sustainable vaccine manufacturing industry by defining priority diseases, platforms, and value chain steps to reach the 60 percent ambition in 20 years.

- Implement initiatives to create a favorable vaccine manufacturing business environment directly, or orchestrate the implementation of these initiatives by others.
- Help countries develop their individual projects locally and support national projects when applicable, in partnership with local and global stakeholders.
- Manage and coordinate global conversations in the vaccine industry as the voice of the continent.
- Create enablers to facilitate this agenda across the continent, organised around:
  - Market design and demand intelligence
  - Regulatory strengthening
  - Technology transfer and intellectual property
  - Access to finance
  - R&D and talent development
  - Infrastructure development

## PAVM target outcomes

PAVM aims to facilitate fast and accurate responses to changes in the vaccine market for its members, to nurture resilience in the face of new outbreaks, and to build a reliable supply pipeline at local country levels.

### Responsiveness

Local manufacturing allows countries to respond faster and in a more targeted fashion to new outbreaks. It also enables countries to develop new vaccines more rapidly, either from existing IP or by developing their own solutions using local facilities and talent. PAVM seeks to enhance this responsiveness by connecting the right stakeholders across and within African countries.

### Resilience

Changes in global vaccine supplies can put pressure on local procurement. If countries can rely on manufacturing near their points of need, it will increase their resilience and supply chain security by making them more resilient to global fluctuations in supply.

Local R&D can also make a significant difference to resilience in African countries where trained talent and adequate facilities are available. PAVM aims to increase such resilience with proper capability-building programs and by channeling investment towards infrastructure developments in African countries.

### Reliability

Achieving sustainable local vaccine manufacturing ensures critical standards are consistently met in quality, quantity, and speed of delivery. While this is essential to deliver African-made alternatives to market-leading vaccines, it also allows African countries to attract foreign investment interested in building additional capacity.

PAVM aims to enable countries to develop such reliability and achieve standalone credibility for both healthcare providers (HCPs) and foreign investors.

## IV. What it will take to meet the continent's vaccine needs through African manufacturing

To meet the 60 percent target set by the Africa CDC, approximately 1.5 billion to 1.7 billion doses must be produced locally in Africa by 2040. As such, there is a need to develop a Continental Framework to build a sustainable vaccine manufacturing industry in Africa.

The strategy must also help interested AU member states to adapt their efforts within their national strategies and ambitions in vaccine manufacturing. While African countries may choose different models for their local vaccine manufacturing expansion, PAVM is designed to serve all its stakeholders equally, regardless of the model used. Some countries may focus on downstream operations like packaging, while others may choose to concentrate on Africa-specific outbreak products or to expand routine products not yet commoditized. The PAVM framework will be adaptable to provide each country with the support it needs to serve its needs effectively.

### Rationale for increased African manufacturing capacity

There are strong motivations for expanding African vaccine manufacturing. Firstly, localizing production will reduce reliance on foreign suppliers and improve public health security. Africa has become reliant on foreign suppliers for vaccines, and this could affect public health security, as it did during the COVID-19 pandemic, as well as decades earlier with delayed access to antiretroviral treatment for HIV/AIDS. Africa could remain last-in-line and face significant procurement challenges in future pandemic outbreaks. In addition, foreign manufacturers and developers may not prioritize development or production of Africa-specific products, leading to potential public health concerns for Africa.

Moreover, having few suppliers based in few geographies creates a tactical risk. If global suppliers consolidate their operations, they could reduce the flexibility of the African supply chain and hurt local vaccine access in the process. Developing local vaccine manufacturing capacity will also be important in covering any potential supply gaps in key areas that may emerge, and supply gaps, particularly for novel products, could open up fairly quickly due to Africa's risk profile. As such, developing a vaccine manufacturing ecosystem is a health security imperative for Africa.

### The prize: health security and economic development

Investing in a local vaccine manufacturing industry in Africa will result in significant long-term benefits, including increased sovereign health security, harmonization of regional regulatory and trade policy, a boost in technological expertise, higher GDP, higher employment, and savings from substituted imports. These long-term benefits are further detailed below.

**Sovereign health security:** First and foremost, improving access to vaccines serves a social purpose. Thousands of lives can be saved if vaccines become readily available at the local level. Thousands more can avoid sickness, reducing the need for foreign aid. These social impacts can bring more stability to the continent and improve prospects for all African countries involved. Relying less on imports and more on local supply and inventory will make African countries more responsive to current and future endemic diseases, and will also ensure accelerated access to vaccines that are in high global demand, particularly in times of critical need, such as the recent COVID-19 pandemic. In addition, a coordinated approach to the local production of vaccines on the continent could help address vaccine nationalism.

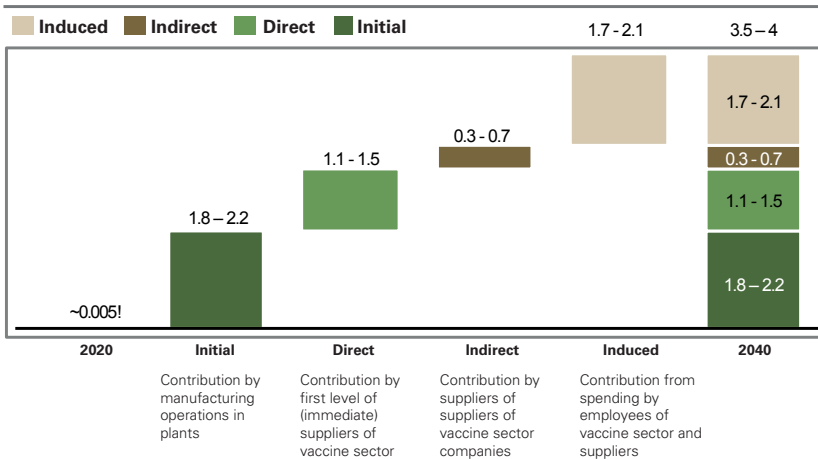
**Regional regulatory and trade policy harmonization:** Ongoing regional harmonization initiatives are expected to accelerate if local vaccine manufacturing scales, including the AMA, ratification of the AfCFTA, and the advancement in maturity levels of NRAs with support from WHO, Africa CDC, and Africa Regulatory Task Force (ARTF).

**Technological expertise:** Local manufacturing of vaccines could lead to indirect technological spill-over benefits, such as information sharing of new patents and IP, and increased collaboration through summits or global partnerships. Such benefits would impact those regions that are establishing themselves as manufacturing and distribution innovation hubs, strengthening their case for future investment. Furthermore, there are benefits for the rest of the world. Africa will increase global vaccine manufacturing capacity and improve the flexibility of the global vaccine supply chain while also contributing new IP from its own R&D efforts. By pursuing R&D priorities identified through the Continental Strategy, there is also potential that the increased R&D and technological development could build capacity for the manufacture of more complex molecules, including Monoclonal Antibodies (MABs). This would create capacity to tackle other diseases that are on the rise in Africa, such as certain cancers.

**GDP growth:** Between direct, indirect, and induced economic contributions to the African economy, a thriving vaccine manufacturing industry would boost GDP—or the value created on the continent from fixed capital investment and raw material transformation—by over \$3 billion annually by 2040 (Exhibit 8, Additional details in Appendix section 9)<sup>19</sup>.

Exhibit 8: GDP impact of increasing continental vaccine manufacturing capacity

**Impact of the local manufacture of vaccines on the African economy  
\$ billion, 2020-2040**



- **\$3.5 - 5.5 billion market value of local production in 2040**
  - Effective revenue multiplier of **0.4 to initial GDP**
  - **Ratio of 1:2.8 initial (in-plant) to total GDP impact on economy**
- Local manufacture could add ~\$3.5 – 4 billion to GDP in 2040**
- Including **~\$1.8 - 2.2 billion GDP contributed by initial operations and ~\$2.6 - 3.8 billion growth in surrounding industries**

In the same way, approximately ~9.5 thousand jobs could be created in manufacturing plants and R&D centers, and a further ~33 thousand throughout the economy over the same timeframe (see Appendix (section 3) for additional detail on FTE estimates). This upskilled vaccine manufacturing and R&D workforce could in turn help benefit other manufacturing or related industries across the continent.

Up to \$3.3 billion in hard currency requirement could be avoided through import substitution. This could both improve the continent’s overall balance of payments and reduce the risk of forex fluctuation, although this impact is not currently quantifiable.

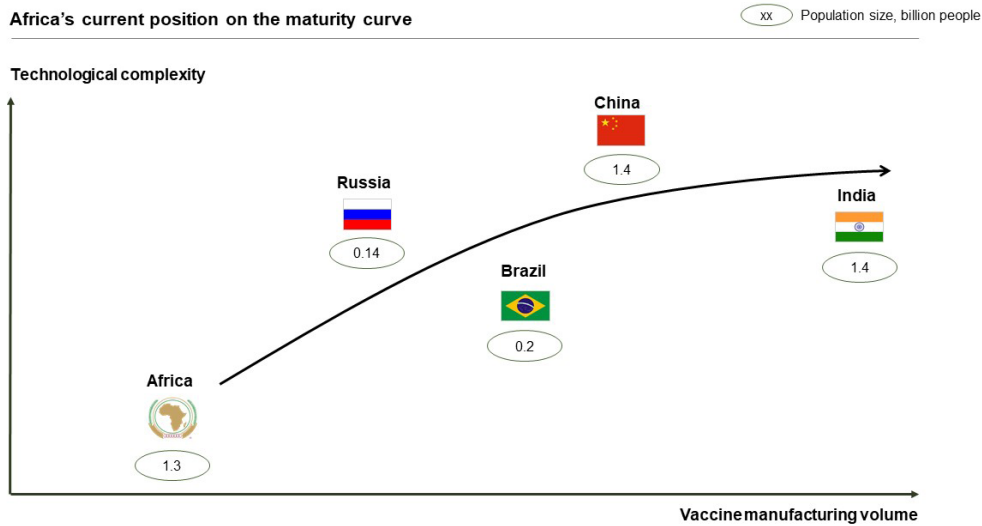
To deliver the benefits outlined above, African countries must expand capability-building programs and design smart subsidy systems to support the health of all African people. This must connect to deep technology and knowledge-transfer programs with properly incentivized mechanisms to drive visibility, predictability, and reliability in the demand for African-made vaccines.

<sup>19</sup> GDP and job multipliers obtained from Global Trade Analysis Project, [grap.edu](http://grap.edu); International Labour Organization, [ilo.org](http://ilo.org); Oxford Economics, [oxfordeconomics.com](http://oxfordeconomics.com); and McKinsey Global Institute economics analytics calculations, [McKinsey.com](http://McKinsey.com).

## Inspiration from other markets

To reach these ambitious goals, African vaccine manufacturers must scale volume and move higher up in the industry value chain. Compared to large countries with comparable industry size or population, Africa is currently far behind (Exhibit 9). However, that gap can be closed.

Exhibit 9: Africa's position in the vaccine maturity curve

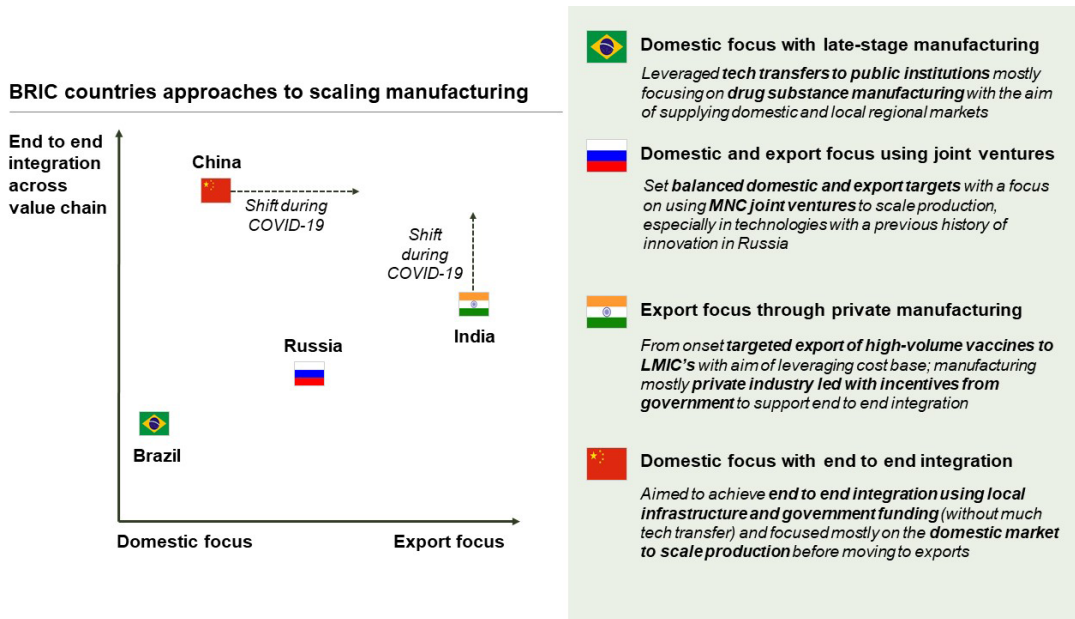


Each territory has a different approach tailored to its needs. The focus is either on domestic demand or on export, depending on population and territory size. Each territory also shows commitments to different stages of manufacturing, from end-to-end integration in China to lower R&D investment in Brazil.

BRIC countries (Brazil, Russia, India, and China) have expanded their capacity through public funding, technology transfers, and regulatory agency modernization. Public funding took the form of grants, direct investments into R&D facilities to facilitate knowledge transfer, or tax breaks to incentivize private companies. Technology transfers occurred through joint ventures, talent repatriation programs, and partnerships with MNCs. Regulatory agencies were upgraded to enable the harmonization of regulations with broader international standards. These measures allowed vaccine manufacturing in these countries to successfully transform and scale (Exhibit 10).



Exhibit 10: BRIC countries approaches to scaling vaccine manufacturing



## Methodology and key angles

We interviewed more than 20 stakeholders to shape the Continental Strategy. These included vaccine manufacturer executives from Africa and elsewhere in the world, epidemiologists with key knowledge of Africa’s infectious-disease landscape, and researchers focused on vaccine research in Africa.

We also consulted over 20 reports published by universities, epidemiologists, and international institutions on the vaccine industry in Africa. We used the results of this research to combine insights with strategic analysis to build the Continental Strategy.

## An integrated ecosystem approach is required to realize the vision

The results of this research and the emergent insights offer different strategic pathways. Ultimately, a fully integrated approach (with investment in all steps of the value chain, including R&D for new vaccines or diseases, as well as DS production) was determined to be most suitable for the continent.

An integrated approach will make it possible to develop produce Africa-specific vaccines independently and sustainably, and will provide more capacity to develop Africa-owned IP. By contrast, a volume-maximization pathway largely focused on F&F production, will lead to continued dependence on external supplies and inputs, and a pathway focused on technology coverage will enable increased DS production on the continent, as well as increased sustainability. However, a gap may still exist when considering under-developed vaccines important for the continent, which will need R&D investments.

A fully integrated approach to vaccine manufacturing on the continent will require more investment. We expect donors to continue to finance vaccines that will be developed by 2040 (such as HIV), and we also expect dedicated mechanisms for dealing with outbreak diseases to be developed (for instance, stockpiling). For countries transitioning from Gavi, most of the required funding will need to come from public sources.

## Insights on potential focus areas

Africa should adopt a fully integrated ecosystem to generate investments in all steps of the vaccine manufacturing supply chain, from R&D to DS to F&F. This offers the possibility to develop and

produce Africa-specific vaccines independently, with greater capacity to develop Africa-owned IP. However, it means that the broader ecosystem must be empowered, from universities to vaccine manufacturers.

To focus the efforts of the Continental Strategy, a subset of diseases was prioritized for regional development through R&D and manufacturing. More than 50 infectious diseases present on the continent were included in this prioritization analysis. Diseases were first assessed quantitatively across three dimensions and seven corresponding metrics:

- **Patient need**, measured by disease burden (prevalence) and unmet need (disability adjusted life years [DALYs])
- **Manufacturing feasibility**, measured by clinical success of the vaccine product (probability of success) and manufacturing maturity (prevalence of DS and F&F manufacturing on the continent)
- **Manufacturing attractiveness**, measured by volume (projected doses in 2040), profitability (based on current vaccine unit price) and competition (number of manufacturers producing vaccine product)

From this **quantitative assessment**, a total of 12 diseases<sup>20</sup> were scored as Tier 1 and were prioritized for the strategy, with the following characteristics:

- **Prevalence:** Disease prevalence was in the highest third of all disease-prevalence values on the continent.<sup>21</sup>
- **Unmet need:** Disability Adjusted Life Years (DALYs) of the disease was in the highest third of all disease DALY values on the continent.<sup>22</sup>
- **Clinical success:** A vaccine already exists.
- **Manufacturing maturity:** There is already F&F and DS manufacturing in Africa.
- **Volume:** More than 50 million doses are expected to be administered annually.<sup>23</sup>
- **Profitability:** The price of the vaccine is higher than \$12.50 per dose.<sup>24</sup>
- **Competition:** There is a minimum of four competitors globally.<sup>25</sup>

Thirty-five diseases were not prioritized as they did not achieve Tier 1 ranking based on the quantitative analysis. Further details on the output of the quantitative analysis across all diseases assessed can be found in Appendix 2.

**A Qualitative assessment** was also conducted which led to ten additional diseases being added to the list of twelve, making 22 in total. These ten diseases include five where there is already strong demand for vaccines (rotavirus, pneumococcal, papillomavirus, COVID-19, and cholera), and another five outbreak diseases (Lassa fever, Rift Valley fever, Chikungunya, Ebola, Disease X), as Africa is subject to regular regional outbreaks.

The resulting group of 22 prioritized diseases further breaks down into:

- **Ten legacy diseases**, which typically have high volumes of vaccines available, primarily produced by Indian players with low unit prices. These vaccines can offer economy of scale if produced on the continent.

<sup>20</sup> Three diseases (hepatitis A, varicella and herpes zoster, and otitis media) that achieved Tier 1 ranking from the quantitative analysis were not included in the priority list because effective treatments are already available, or because their severity is low.

<sup>21</sup> Global Burden of Disease Study 2019 (GBD 2019), University of Washington. [washington.edu](http://www.washington.edu).

<sup>22</sup> Global Burden of Disease Study 2019 (GBD 2019), University of Washington. [washington.edu](http://www.washington.edu).

<sup>23</sup> Information obtained from Linksbridge; Global Burden of Disease Study 2019 (GBD 2019), University of Washington. [washington.edu](http://www.washington.edu); and expert interviews.

<sup>24</sup> Information obtained from Linksbridge, and expert interviews.

<sup>25</sup> Evaluate Pharma database, Evaluate Ltd, [evaluate.com](http://evaluate.com)

- **Six expanding diseases**, which typically do not yet have commoditized vaccines, or have vaccines with relatively higher prices, with some products still in development that are not yet licensed. A number of diseases endemic to Africa (for instance, HIV) are included, and the development of vaccines against these diseases is of high importance for the continent.
- **Six outbreak diseases**, which typically have vaccines with unpredictable demand driven by outbreaks, often with higher prices due to lower scale and urgent need. These diseases are prioritized to quickly meet the required need for vaccines in times of outbreaks.

These 22 diseases are addressed by 18 vaccine products which currently exist or are under development (Exhibit 11). This list will evolve based on new data, innovation, and the changing disease burden over time.

Exhibit 11: 22 diseases prioritized for the FFA

Archetype	Disease	Does a vaccine exist?	African doses volume by 2040 (Mn)	DALYS 2040 (Mn)
Legacy	Hepatitis B, Diphtheria, Tetanus, Whooping Cough	✓	~370	6
	Tuberculosis	✓	~140	12
	Measles	✓	~240	2
	Yellow Fever	✓	~50	<1
	Cholera	✓	~30	1
	Typhoid	✓	~20	1
	Meningococcus <sup>1</sup>	✓	~60	5
Expanding	Human papillomavirus	✓	~30	4
	Pneumococcus	✓	~140	13
	Rotavirus	✓	~120	9
	COVID-19	✓	~710	TBD
	Malaria	✓	~120	20
	HIV	✗	~110	10
	Ebola	✓	~1	9
Outbreak	Influenza <sup>2</sup>	✓	~10	1
	Chikungunya	✗	~1	<1
	Rift Valley fever	✗	~1	<1
	Lassa fever	✗	~1	<1
	Disease X	✗	N/A	N/A
	<b>Total</b>			~2,200

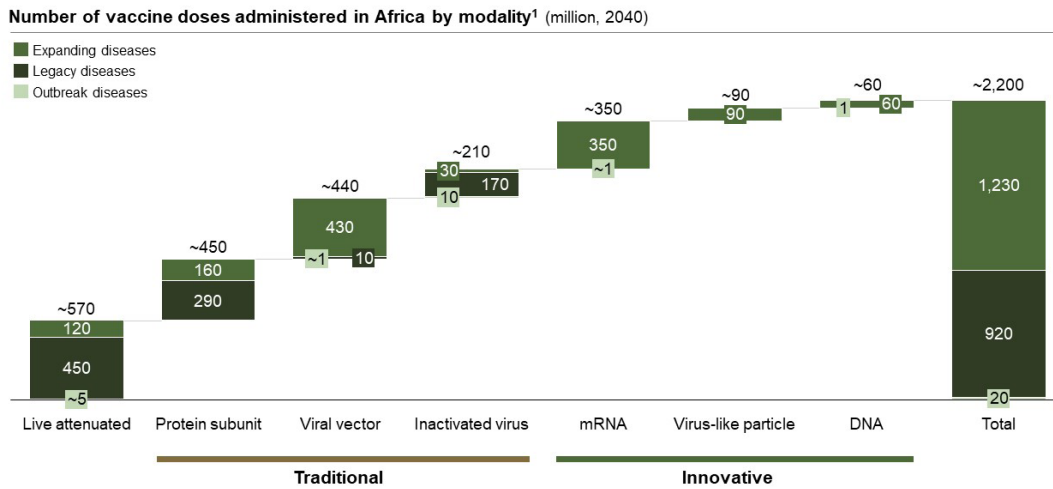
1. Including key serogroups found in Africa (A, C, W and X)  
2. Considering here outbreak influenza

## Vaccine technologies

Vaccines for these prioritized diseases require seven technology platforms to enable production. These technologies include traditional (for example, inactivated virus, live attenuated virus, and protein subunit technologies) and novel technology platforms (such as virus-like-particles [VLPs], viral vectors, mRNA, and DNA).

We mapped the current and future modalities for each prioritized disease, and we estimated volumes per disease and technology platforms to estimate the technology mix required by 2040 (Exhibit 12).

Exhibit 12: Technology mix required by 2040 (by volume) for 22 priority diseases



<sup>1</sup> Data only for the 22 priority Continental Strategy vaccines; assumes that number of doses administered is equal to doses demanded  
 Source: Linkbridge, Evaluate Pharma; expert interviews

Africa will need to increase investments in both traditional and novel technology platforms to manufacture prioritized vaccines. Traditional technologies such as live attenuated virus technologies will be critical to manufacture vaccines with high demand on the continent, such as BCG (for tuberculosis), yellow fever, and MMR (for measles, mumps and rubella). Novel technologies such as mRNA are likely to grow in scale as the science and investment supporting the technology advances.

The growth in the vaccine industry will also need matching growth in supporting industries to provide raw materials, including active ingredients for the different types of vaccines, inactive ingredients (including acids, concentrates and other excipients), and consumables (including vials, sterile bottles, syringes, rubber stoppers). This will be critical to unlocking key benefits such as self-reliance and health security.

### Value chain

All 22 vaccines were prioritized for F&F production, while a subset of the vaccines was prioritized for further value chain integration (DS production and/ or R&D) (Exhibit 13).

Exhibit 13: Value chain focus for each of the 22 priority diseases

Yes     Partially

Archetype	Disease	Does a vaccine exist?	Value chain steps		
			R&D	DS + FF	FF only
Legacy	Hepatitis B, Diphtheria, Tetanus, Whooping Cough	✓	✓	⊗	⊗
	Tuberculosis	✓	✓	⊗	⊗
	Measles	✓		⊗	⊗
	Yellow Fever	✓		✓	
	Cholera	✓			✓
	Typhoid	✓			✓
	Meningococcus	✓			✓
Expanding	Papillomavirus	✓			✓
	Pneumococcus	✓		⊗	⊗
	Rotavirus	✓			✓
	COVID-19	✓		⊗	⊗
	Malaria	✓	✓	✓	
	HIV	✗	✓	✓	
Outbreak		✓	✓	✓	
	Influenza	✓	✓	✓	
	Chikungunya	✗	✓	✓	
	Rift Valley fever	✗	✓	✓	
	Lassa fever	✗	✓	✓	
	Disease X	✗	✓	✓	

1. High volume vaccines were selected for partial DS production, based on whether or not partial production would have sufficient volumes to achieve minimum dosage requirements for economically viable plant set-up

To determine which steps of the value chain to prioritize, we defined high-level principles to select the correct manufacturing steps to focus on for each prioritized disease. This enabled us to design different potential manufacturing models for Africa. We found that there is a real opportunity to expand and accelerate capacity end-to-end, from F&F to R&D.

- **Fill and finish**

Build on existing capabilities and current momentum to scale supply to 1.5 billion - 1.7 billion doses. All prioritized vaccines should have, at the very least, the fill and finish value chain step localized on the continent. This will require the development of a local-input supply industry.

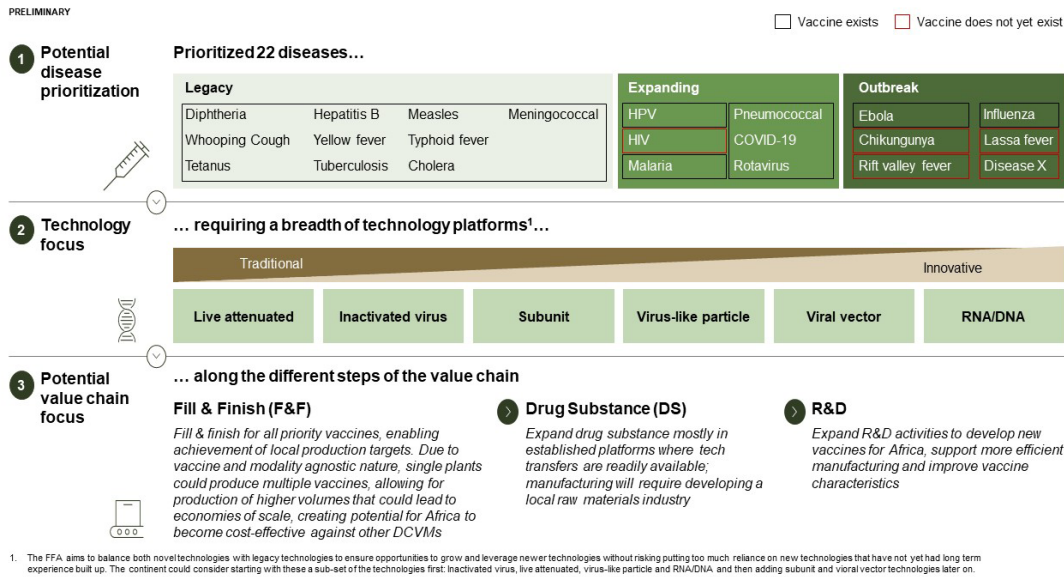
- **DS**

Expand drug substance manufacturing largely in established platforms where tech transfers are readily available, such as for Africa-endemic diseases (Malaria, HIV, outbreak diseases), and high-volume vaccines which could enable production with economies of scale. DS manufacturing will require development of the local raw materials industry.

- **R&D**

Develop regional R&D centres across all five African regions to increase vaccine process efficiency, improve existing vaccines, and conduct dedicated research on new vaccines or diseases relevant to Africa (such as HIV, malaria, tuberculosis, and neglected tropical diseases).

Exhibit 14: Overall summary of the disease, technology, and value chain focus of the continental strategy



## Plants required to deliver the strategy

Producing the prioritized vaccines and adopting the required technology platforms regionally would require manufacturers to invest in the set-up of vaccine manufacturing plants on the continent. It was found that a total of 23 plants would be required to deliver the ambitions of the Continental Strategy, including 12 integrated DS and F&F plants, and 11 F&F-only plants. There are already plans to set up some of these plants on the continent in the near-term future (particularly for COVID-19).

While F&F plants could be used to achieve the ambition to produce 60 percent of demand for vaccines regionally, DS plants are an integral part of the Continental Strategy by increasing the sustainability of production on the continent. For all DS production expected on the continent, plants were assumed to have integrated DS and F&F capabilities, due to the ability of integrated plants to leverage production synergies and reduce input and logistics costs that would be higher for separate DS and F&F plants.

The number of integrated and F&F-only plants required to deliver the continental strategy was based on key assumptions around expected vaccine demand over the next 20 years, minimum plant size required for operational and economic viability, average plant sizes expected of new plants, and vaccine and technology compatibilities in each plant. Details on each of these assumptions can be found in the Appendix (section 4).

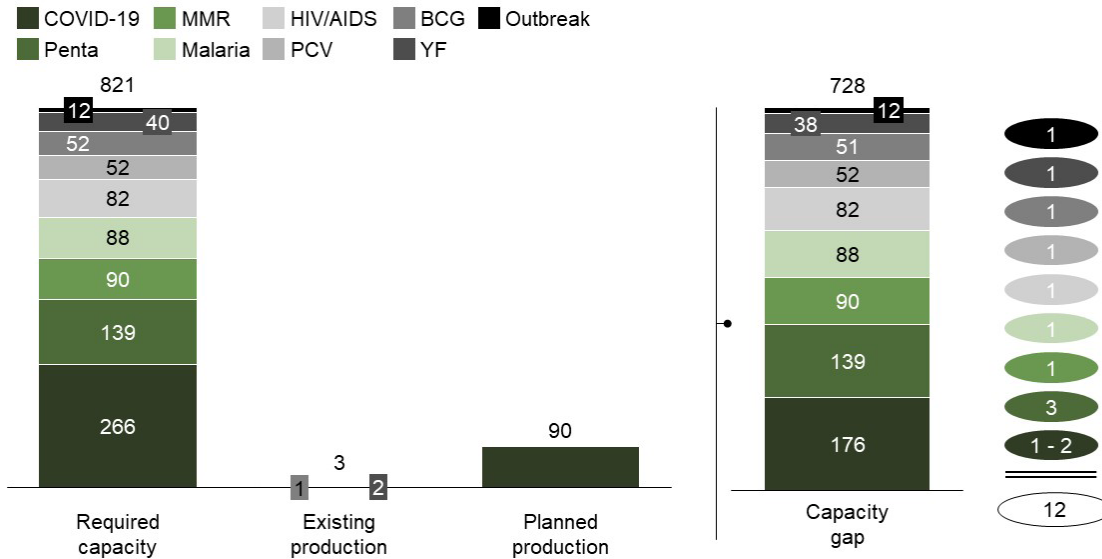
Of the 23 plants required, an analysis was done to determine how much of the required capacity could be met from existing or planned plants, and thus how many new plants would be required to be set up, both for integrated plants and for F&F-only plants.

For DS production, existing and planned production capacity was found to be quite low on the continent (Exhibit 15) and focused primarily on a limited number of vaccine products by volume (primarily COVID-19, yellow fever, and BCG) and a limited number of production technologies (primarily mRNA and live attenuated virus technologies). As such, at least 12 new integrated plants will need to be set up gradually over the next 20 years to meet the DS-production vaccines and volumes outlined in the Continental Strategy.

Exhibit 15: DS capacity required on the continent to achieve the ambition

PRELIMINARY

Required, existing, and planned integrated DS production<sup>1</sup>, Million doses



1. Only considering plants where capacity is known or has been announced  
 2. Manufacturers with existing plants: Institut Pasteur de Dakar (Yellow Fever), Institut Pasteur de Tunis (BCG); manufacturers with planned plants (all COVID): Sidal, Minapharm, Biogeneric, and BioNTech

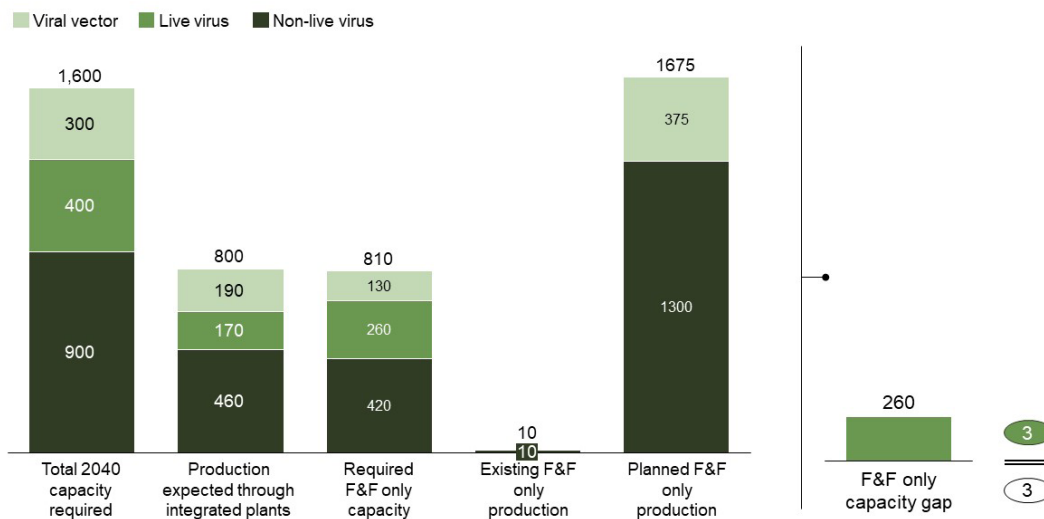
For F&F plants, on the other hand, plans to set them up were accelerated in 2020 and 2021 due to the COVID-19 pandemic. In addition to existing plants, there are plans to set up four non-live virus F&F facilities with a combined expected production capacity of approximately 1.3 billion doses annually, and 12 viral vector F&F facilities with an expected production capacity of around 400 million doses annually.

However, a key gap in F&F production exists for live-virus vaccines (for instance, MMR, BCG, and rotavirus), and three new F&F plants will likely be needed to bridge this gap, each with an assumed capacity of approximately 85 million doses produced annually.

Exhibit 16: F&F capacity required on the continent to achieve the ambition

PRELIMINARY

Required, existing, and planned F&F only production, Million doses



1. Sidal, Vacsera, Sothema, and Biovac Institute  
 2. Aspen Pharmicare

## Mobilizing the investment required: \$30 billion over the next 20 years

Delivering the Continental Strategy will require investment into both the set-up of manufacturing plants required to increase regional production in line with the strategy’s objective, and the enabling environment that will support successful set-up and operation of the manufacturing facilities, primarily through the eight bold programs identified in the FFA. Cost drivers for delivery of the Continental Strategy were identified across each enabler, as detailed in the Appendix (section 5).

The cost of each of driver was sized, to give an overall cost of around \$30 billion for implementation of the entire strategy<sup>26,27</sup> (Exhibit 17).

Exhibit 17: Cost of delivering the FFA

PRELIMINARY: NUMBERS STILL BEING REFINED

■ CAPEX ■ Other one-off ■ Total recurring costs over 20 years<sup>2</sup>

	Continental strategy costs, USD Bn	Components included
Market design & demand intelligence	~1	Set-up and running costs for expanded pooled procurement mechanism and short-term subsidy (over next 5 years) for additional Vx procurement
Access to finance	<1	Set-up and running costs for the vaccine manufacturing deal preparation and financing facility
Regulatory strengthening	<1	Improvement of front-runner country NRA maturity levels and operationalization of AMA
Technology transfer and IP	~5	Set-up and running costs for Tech Transfer and IP Enablement Unit, and annual royalty fees paid for tech transfers
Talent development	<1	Set-up and running costs for CCC coordinating body, cost of upskilling manufacturing plant FTEs and subsidization of CCC programs
R&D	~20	Vx development (~\$7Bn), improvement of Vx manufacturing (~\$12Bn), Capex for R&D pilot plant (<\$1Bn), set-up and running of R&D coordinating platform, (<\$1Bn)
Infrastructure development	~5	Capex and project development costs for set-up of manufacturing plants and cold chain infrastructure
Agenda-setting	<1	TA support for operationalization of FFA programs, and PAVM running costs
<b>Total</b>	<b>~30<sup>1</sup></b>	

1. By comparison, other funds dedicated to vaccine manufacturing have been sized at \$1.6 Bn (European Commission), \$2 Bn (CEPI), \$10 Bn (COVAX), and \$24 Bn (the White House), though all are for a period of <10 years

2. Manufacturing plant & R&D centre Opex costs (such as salaries, material costs, and overheads) are not included in this analysis

Approximately \$30 billion is required for the FFA, of which around \$5 billion is needed to fund capex and other one-off costs (primarily the set-up of the required vaccine manufacturing plants and related cold chain infrastructure, and operationalization of key FFA programs), and around \$25 billion is needed to fund recurring costs over a period of 20 years (R&D investments into priority R&D diseases and continual process improvement for vaccine manufacturing, royalties paid out for technology transfers, and additional spend on increased vaccine procurement on the continent).

## High-level implementation plan

To ensure that delivery of the Continental Strategy is successful and coordinated over the next 20 years, a few key activities could be pursued:

### Over the next year (2022)

Over the next year, staffing of the PAVM should be completed and the eight FFA programs operationalized to ensure that there is sufficient capacity and enabling support for the Continental Strategy’s implementation. In parallel, steps can be taken to begin expansion of vaccine production on the continent by scaling F&F capacity of the ten existing plants on the continent, as well as providing enabling support for the set-up of three to four of the announced COVID-19 F&F and DS plants, for which plans are rapidly advancing.

26 Manufacturing plant & R&D centre operating expenses (such as people’s salaries, material costs, and overheads) are not included in this analysis.

27 Industry expert interviews, company data, [WHO MI4A database](#), Africa CDC



### **In the short term (2023 to 2025)**

Once the PAVM has been set up and FFA programs are running, vaccine production on the continent can be scaled through the set-up of additional F&F plants, particularly to increase diversity of vaccine products produced on the continent. In addition to this, raw material and input industries should be developed to support the scaled F&F production, as well as to prepare for increased DS production on the continent.

### **In the medium term (2026 to 2030)**

The focus of the Continental Strategy's implementation should be on providing the technological and financial support required to introduce any technology platform that hasn't yet been introduced on the continent, with the goal of vaccine production across all seven platforms by 2030. The developed raw material and inputs industries can also support significant scale-up of DS production to ten plants on the continent.

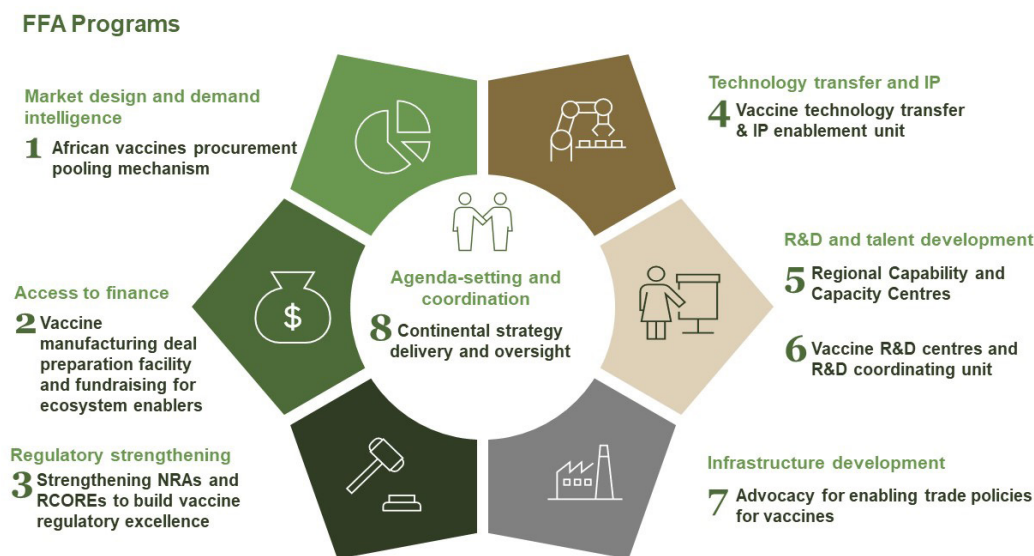
### **In the long term (2031 to 2040)**

Activities should be geared towards expanding F&F production to cover all 22 priority diseases of the Continental Strategy, as well as any additional priorities that may have emerged during the period. Any remaining DS capacity required to meet Continental Strategy DS-production targets should also be set up.

## V. The Framework for Action: Building the ecosystem required to scale vaccine manufacturing in Africa

To achieve the ambition of 60 percent local manufacturing, the FFA identified eight bold programs that will propel the enabling environment of the vaccine ecosystem to scale vaccine development and manufacturing, under the coordination of PAVM (Exhibit 18).

Exhibit 18: Eight bold FFA programs



The eight programs are described in the chapters that follow.

### Program 1: Creating an African vaccines procurement pooling mechanism

This pillar of PAVM sought to understand present challenges in market structures and demand for African vaccines from the perspective of both countries and manufacturers, how demand might evolve over the coming two decades, and what future state could address these challenges as demand evolves.

To achieve this, the pillar working group:

- Catalogued challenges facing both countries and manufacturers specifically linked to vaccine market design and demand (although there may be other vaccine-related challenges, as discussed later in this document),
- Developed demand forecasts for vaccines in Africa across plausible scenarios, and assessed the likelihood that such forecasted demand will be funded, accounting for critical uncertainty, and
- Explored a potential procurement architecture that will capitalize on current Africa-led pooled procurement mechanisms to address market design challenges, given that additional strategies may be used to strengthen the market.

This analysis focused on the African market as a starting point (given the core focus on ensuring African health security through local production), but it recognized that local manufacturers may also consider markets outside of Africa to build their business case.

## Context and challenge

### Overview

Achieving sustainable and reliable volumes to reach economies of scale is one of the most critical enablers to expand African vaccine manufacturing. The current demand profile and vaccine procurement system in Africa can support African manufacturers' volume certainty, as well as country procurement and demand enablement more directly. Only 1 percent of vaccines consumed by African countries are produced on the continent; it is therefore essential to develop the market to support both African manufacturers and countries.

The recent development of an Africa-led pooled procurement mechanism, the Africa Vaccine Acquisition Task Team (AVATT) and the Africa Vaccine Acquisition Trust (AVAT) for COVID-19 vaccines, presents a unique opportunity to meet these needs, as demand for vaccines in Africa is predicted to increase significantly.

### Market design and demand-related challenges of the current system in Africa

#### Challenges faced by African countries

Countries supported by Gavi and UNICEF benefit from substantial funding for vaccine procurement as well as access to professional support across the entire vaccine procurement value chain (from forecasting through to ordering and logistics). However, countries not supported by Gavi, including those transitioning from Gavi, can face several challenges. These include:

- **Challenges in developing procurement strategy and managing procurement process.** For example, some countries have limited reliable information on prices, availability, and financing options, and may struggle to manage negotiations and contracting processes, which can result in arrangements with fewer suppliers and thus lower supply security. In addition, countries may have trouble submitting orders on time, resulting in late supply.
- **Challenges in negotiating beneficial arrangements with suppliers,** given that these countries may sometimes have more limited procurement expertise and lower procurement volumes. This translates into lower and lower-middle income non-Gavi countries facing prices up to 30 percent higher than Gavi-supported countries.<sup>28</sup> This can be especially challenging for products facing supply shortages.
- **Inadequate or at-risk funding for vaccines as demand grows** if countries are unable to allocate sufficient budget line items for vaccine procurement, or if procurement financing is subject to cyclical effects (for example, resource revenue or currency fluctuations). These challenges are worsened if countries do not have access to de-risking financing mechanisms (such as working capital facilities and payment plans) to manage risk and volatility as demand grows over time.

Several other challenges may currently be faced across countries, whether Gavi-supported or not, including:

- **Limited supplier diversification for some routine products,** which result in unstable supply due to over-reliance on a small number of large manufacturers, often geographically concentrated.
- **A lack of global R&D focus on African priorities** (for instance, insufficient prioritization of local diseases or of vaccine product profiles that suit local needs, such as cold chain requirements), which can limit the potential health benefits for countries and complicate delivery and other operations.

28 Gavi Alliance, [WHO MI4A database](#)

- **Vaccine hesitancy** if parts of population distrust particular vaccines, manufacturers, or vaccination in general.<sup>29</sup>
- **Challenges accessing outbreak or pandemic products**, which are more likely to face shortages and suffer from trade restrictions imposed by exporting countries.

### Challenges faced by African vaccine manufacturers and potential manufacturers

Currently there are approximately 40 African countries supported by Gavi that procure vaccines primarily through UNICEF. Manufacturers that are able to sell to Gavi-supported countries can achieve volume certainty at scale.<sup>30</sup> However, new or potential African manufacturers often find it challenging to access Gavi markets because of very competitive pricing that can only be achieved with significant economies of scale over time. Additionally, accessing Gavi markets sometimes involves challenges in obtaining sufficient regulatory approvals (for example, WHO PQ). Only the Institut Pasteur de Dakar has successfully sold vaccines through the Gavi system, and only its yellow fever vaccine, which has limited global supply. As a result, emerging African manufacturers may face challenges around volume certainty and scale, including:

- **Lack of adequate market intelligence and demand forecasting** outside of Gavi or UNICEF, making it hard for companies to predict demand to guide investments.
- **The “Catch-22” of competitive pricing.** Price competitiveness requires achieving economies of scale, which in turn requires sufficient volume to scale up. However, if volume itself requires low pricing, such scale cannot be achieved.
- **Fragmented volume that reduces efficiency.** The need to negotiate and contract with each country individually adds burden to manufacturer operations.
- **Financial and payment risk** when dealing with individual countries instead of pooled mechanisms backed by revenue or market guarantees from larger financial institutions (such as Afreximbank or the World Bank).
- **The “Catch-22” of regulatory standards.** It is challenging (or impossible) to achieve volume without meeting regulatory standards, but it is expensive and risky to invest in achieving acceptable regulatory standards without the certainty of offtake contracts.
- **Procurer preferences.** When countries or other procuring decision-makers may not fully trust the quality of the products produced,<sup>31</sup> and may have pre-existing preferences for, or mention trust in and relationships with, existing non-African suppliers.

These challenges result in weaker business cases and less stable operations, and crowd out potential investors.

A future state model should seek to address and mitigate as many of these challenges as possible.

### Recent developments in African procurement mechanisms

In the wake of COVID-19, two procurement-related initiatives were launched in Africa that have delivered significant upfront benefits in the fight against COVID-19:

- The AMSP platform was launched in April 2020 to pool demand and facilitate the procurement of crucial medical products during the COVID-19 crisis, such as masks, test kits, ventilators, and others. In the first six months of operation, it processed procurement to the value of \$200 million, approximately 35 million items.<sup>32</sup>

<sup>29</sup> Although this can be an important demand-related challenge, it is considered outside the scope of this PAMV pillar, which focuses on more macro-demand dynamics.

<sup>30</sup> Information obtained from Gavi, The Vaccine Alliance, gavi.org.

<sup>31</sup> Note that this report is only considering the promotion and offtake of high-quality vaccines. The Regulatory PAMV workstream covers challenges around improving manufacturer and regulator capacity to ensure high-quality vaccines.

<sup>32</sup> Information obtained from the African Medical Supplies Platform, AMSPafrica.

- AVATT and AVAT were established in November 2020 to complement COVAX and achieve the Africa CDC’s 60 percent-immunization objective by the end of 2022. AVATT/AVAT has thus far secured a contract for up to 400 million doses with Johnson & Johnson, backed by supportive pooled financing mechanisms (for example, Afreximbank’s \$2 billion Advanced Procurement Commitments [APCs]) to provide the necessary guarantees for participating suppliers and to enable contracts to be finalized).<sup>33</sup>

Securing and supplying COVID-19 vaccines and other products has been a unique experience compared to routine products given the context of a global crisis, the need for emergency response, the rapid development of novel products, supply shortages, and the age of key populations. Still, many of the capabilities built by these initiatives and their achievements can be built upon further to create a larger pooled procurement mechanism for an expanded portfolio of vaccines across African countries. With AVATT/AVAT as a point of departure, this section focuses on the potential for an expanded Africa-led pooled procurement mechanism to address many of the challenges noted above.

That said, pooled procurement is not the only potential solution. Other solutions such as shared market intelligence, additional market-shaping initiatives (for example, advanced market commitments), or efforts to address procurer and individual preferences, may be adopted alongside the future pooled procurement mechanism or to complement it (for instance, via a partner).

To understand the needs and potential scope of a future state procurement architecture for vaccines in Africa, it is crucial to develop a quantitative fact base for the size and structure for the future market.

### Africa vaccine demand forecast

In 2019 (pre-COVID-19), the African vaccine market totaled approximately \$1.8 billion, with the top five countries (according to largest public vaccine markets) comprising around 40 percent of market value. African vaccine demand represented 6 percent of global market value and 30 percent of global volume.<sup>34</sup> A major driver of differential market dynamics between African countries is whether a country is supported by Gavi or is self-financing. Gavi-supported countries (including those transitioning from Gavi support), which primarily procure through UNICEF Supply Division (SD), made up about 80 percent of total African volumes and about 60 percent of total value in 2020.

The market for vaccines in Africa is expected to grow substantially over the next two decades. Three forecasting scenarios have been modelled to incorporate uncertainty into major growth drivers in the African vaccine market. These scenarios estimate that the 2040 African vaccine market could be worth between \$3 billion and \$10 billion, with a high scenario of \$17 billion.<sup>35</sup> Growth in the next 20 years is likely to be driven by both volume factors (population growth, increased coverage, and product introductions) as well as price factors<sup>36</sup>. The future of COVID-19 vaccines and the potential introduction of novel vaccines (such as malaria and HIV) drive significant uncertainty that, among other factors, creates the differences between the scenarios seen in Exhibit 19 below. Exhibit 20 shows a regional breakdown of the base case (middle) scenario.

<sup>33</sup> “Africa signs historic agreement with Johnson & Johnson for 400 million doses of COVID-19 vaccines,” Afreximbank, March 29, 2021, [afreximbank.com](https://afreximbank.com).

<sup>34</sup> Information obtained from Linksbridge, [linksbridge.com](https://linksbridge.com); and Gavi; The Vaccine Alliance, [gavi.org](https://gavi.org).

<sup>35</sup> Data from Linksbridge, [linksbridge.com](https://linksbridge.com); World Health Organization, [who.int](https://who.int); United Nations, [un.org](https://un.org); The World Bank, [worldbank.org](https://worldbank.org); and expert interviews.

<sup>36</sup> Note that pricing assumptions do not yet take into account the potential impact of increased pooled procurement on future prices, which could result in decreased price levels and a smaller future market value.

Exhibit 19: Overall model projections (value)

Scenarios estimate that the 2040 African vaccine public market value will reach ~\$3 - 6 billion, excluding COVID-19, with potential upside of ~\$10 – 17 billion with sustained demand for COVID-19 vaccines

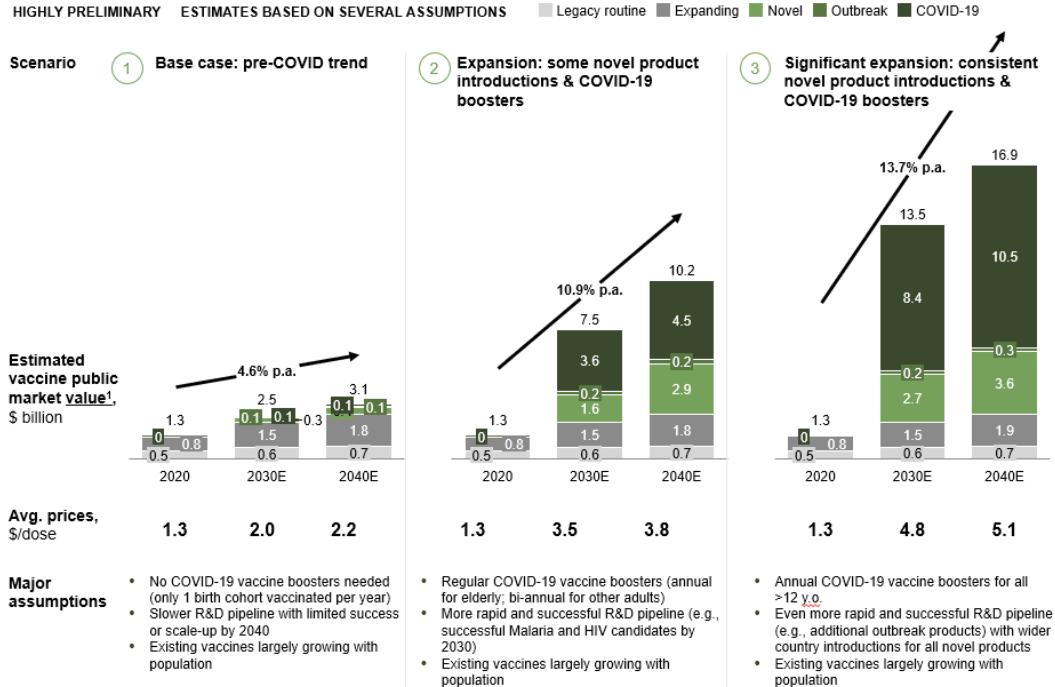


Exhibit 20: Regional projections: East and West Africa could comprise up to ~50 percent of market value on the continent, driven by population size

ESTIMATES BASED ON EXPANSION MARKET GROWTH (SCENARIO 2)  
HIGHLY PRELIMINARY

Regional blocs (number of members)	Population 2040E, Million	Market value by vaccine category in 2040E <sup>2</sup> , \$ Million					Avg. unit prices, \$ 2040E <sup>3</sup>	Regional share of African demand
		Legacy routine	Expanding routine	Novel	COVID-19 <sup>1</sup>	Outbreak		
Central Africa (9)	267	100	135	330	535	Only continental demand modelled	2.9	11%
East Africa (14)	617	160	240	715	1,330		3.0	24%
North Africa (6)	269	185	485	465	760		6.8	19%
South Africa (10)	278	95	640	675	615		5.9	20%
West Africa (15)	643	205	340	715	1,300		2.8	26%
<b>Africa total (54)</b>	<b>2,074</b>	<b>745</b>	<b>1,840</b>	<b>2,885</b>	<b>4,530</b>	<b>245</b>	<b>4.1</b>	<b>100%</b>

1. COVID-19 modelled in base scenario as routine vaccinations for adolescents, with annual boosters for population >50 y.o. and biennial boosters for rest of population >12 y.o.  
2. Please note numbers within the charts may not add up to the total due to rounding. 'E' stands for estimate  
3. Average price differences driven by a number of factors, including share of self-financing countries vs. Gavi-supported countries (based on income levels) and product mix (based on epidemiological factors); 'E' stands for estimate  
Source: WHO, UN, Gavi, World Bank, expert input, Linkbridge (Sep 2021 GVMM 9.2 for existing vaccines through to 2030 only) - detailed methodology and assumptions available in the appendix

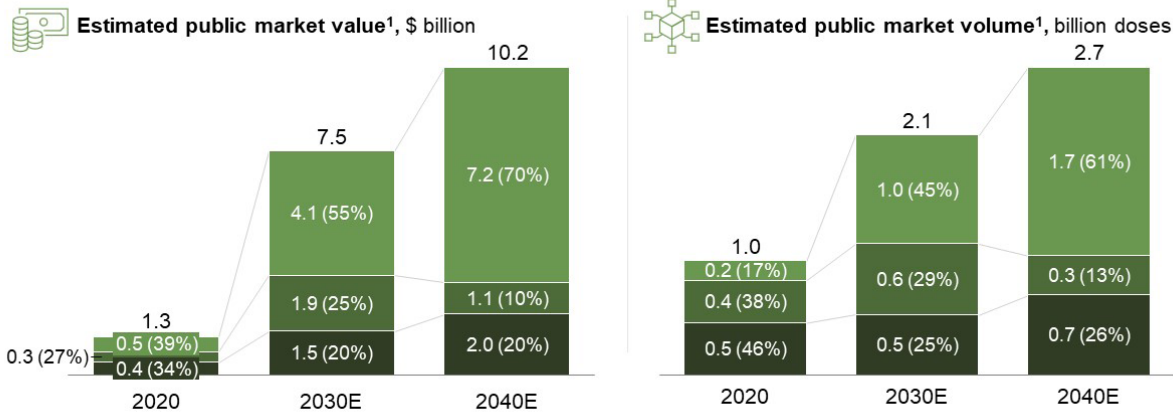
As African countries continue to develop, the proportion of countries eligible for Gavi support is expected to decline significantly over the next 20 years. Countries currently eligible for financial support will slowly be phased out as their Gross National Income (GNI) per capita increases. Gavi-supported or transitioning countries' market share could decrease from approximately 60 percent of

value (more than 80 percent of volume) to an estimated 30 percent of value (40 percent of volume) in the next 20 years.<sup>37</sup> It is therefore urgent to design and implement a pooled procurement solution given the challenges highlighted earlier, particularly for non-Gavi supported countries, and to provide an “offramp” for those transitioning from Gavi. It remains to be seen exactly how the Gavi strategy might evolve in relation to African vaccine manufacturing and pooled procurement ambitions.

Exhibit 21: Estimates of the share of the African market that may be financially supported by Gavi over time

**ESTIMATES BASED ON EXPANSION MARKET GROWTH (SCENARIO 2)**  
**HIGHLY PRELIMINARY**

■ Not Gavi-supported ■ Transitioning ■ Gavi-supported



- Notes**
- ~4x increase in the proportion of total non-Gavi supported country market volumes between 2020 and 2040 (and almost doubling in share of value) is driven by the assumption that 15 countries could fully transition from Gavi support by 2040
  - ~1.5x increase in the proportion of total non-Gavi-supported country value between 2020 and 2040 is driven by the assumption that countries transitioning from Gavi may end up paying higher prices, which are also assumed to grow faster than Gavi prices
  - Assumes that Gavi will cover any novel product introduced in a Gavi-supported country (which, if not true, would mean the above overstates Gavi's share of the forecast)

1. Please note numbers within the charts may not add up to the total due to rounding  
Source: WHO, UN, Gavi, World Bank, Expert input, Linksbridge (Sep 2021 GVMM 9.2 for existing vaccines through to 2030 only) - detailed methodology and assumptions available in the appendix

A critical consideration is to understand whether this forecasted future demand is likely to be funded. Funding can be procured either through domestically mobilized public sector resources or through private sector sources such as loans or donor funds, or a combination thereof.

Given the uncertainty around future market size for COVID-19 vaccines and novel products (for example, HIV), the lower demand and base demand scenarios were used to estimate if there is a potential need for future financing to meet forecasted demand. Based on initial estimates, if growth in country vaccine spend is in line with forecasted GDP growth, the financing of demand for existing vaccines could be met, but future demand for COVID-19 and novel vaccine products (such as HIV and malaria) would not be met unless vaccine expenditures increase beyond GDP trends.

Of course, it is possible that vaccine expenditures grow more slowly than GDP (for instance, in line with historical vaccine or overall health expenditure trends). In this case, it is unlikely that future demand even for existing vaccines would be met. This potential gap is most likely to be driven by non-Gavi supported countries given the relatively higher prices they currently pay for the same vaccines, as well as the expected increase in non-Gavi-supported countries over time as countries transition.

This market-sizing exercise focused on the African market only; if some manufacturers also explore exporting outside of the continent, future sizing efforts could consider these markets as well.

37 Information obtained from Linksbridge's projections on Gavi transition dates, Linksbridge Global Vaccine Market Model 9.1; and details from Exhibit 24.

## Strategic directions

The workstream considered the objectives that the future state architecture should attempt to meet, as well as the critical design dimensions that might best support the architecture to meet these objectives. Furthermore, the workstream has laid out what a potential scale-up could look like and how it might be achieved.

The Demand Intelligence and Market Design workstream has explored the opportunity to expand the scope of AVATT/AVAT as the foundation of the future state pooled procurement architecture. This expansion is set against the backdrop of current challenges that manufacturers and countries face, and also the expectation of significant demand growth that boosts opportunities for manufacturers, but exacerbates some of the existing financing challenges for countries.

This architecture need not include only pooled procurement as a mechanism to support market design. Additional functions such as market transparency, country engagement, and strategic market shaping with other stakeholders can also be considered. Whether these activities fall under the purview of the pool or other systems will be explored over time.

### Objectives for the future state pooled procurement architecture

The new pooled procurement architecture is important for all major stakeholders in the vaccine landscape including populations, manufacturers, and countries. Through numerous interviews, analyses of existing procurement mechanisms, such as the Pan American Health Organization (PAHO) Revolving Fund, and an assessment of the current vaccine procurement systems in Africa, the PAVM Market Design and Demand Intelligence workstream identified ten objectives for the new pooled procurement architecture:

#### Improve access to quality and lower cost vaccines

1. Reduce cost of vaccines, especially for governments not procuring through Gavi/UNICEF.
2. Ensure high-quality standards for vaccines purchased by countries, regardless of where they are produced.
3. Ensure reliability and efficiency of logistics networks and reliable manufacturer supply of vaccines.

#### Ensure sustainability and improve resilience of vaccine supply chain in Africa

4. Incentivize investment in local manufacturing and improve supplier security in emergencies.
5. Increase diversity of supplier mix to improve supply resilience in the steady state and during emergencies, and ensure sustainable cost structures for manufacturers to maintain a healthy market environment.
6. Incentivize Africa-led R&D to develop vaccine products that are more suited to local health priorities and needs (for example, novel vaccines to address Africa-specific diseases, and cold chain requirements).

In addition to these direct objectives, there are economic and political objectives that the future architecture could contribute to indirectly, including:

7. Creating new jobs and improving skills by supporting the growth of the local vaccine ecosystem.
8. Building broader manufacturing capabilities beyond vaccines by incentivizing investment that can spill over into broader manufacturing infrastructure and capabilities.
9. Fostering political collaboration between countries that can build trust and enable further collaboration on similar projects in pharmaceuticals or other sectors.
10. Improving regulatory harmonization between countries to facilitate trade, improve health outcomes, and reduce cost.

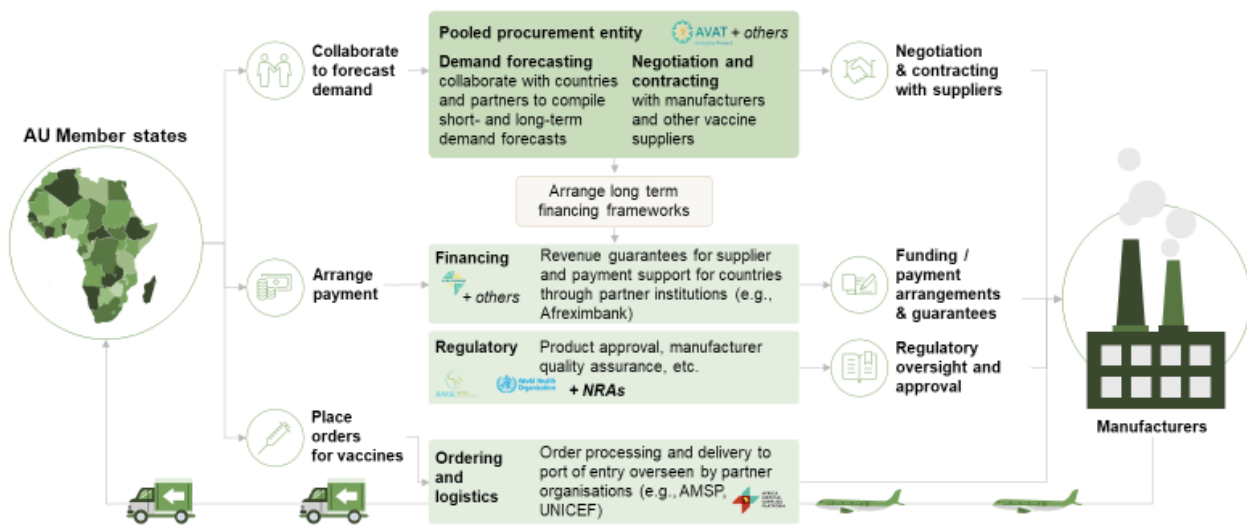


## Design of a future state pooled procurement architecture

The above objectives were used as a guide to understand the key design dimensions for a pooled procurement architecture. A robust framework for such an architecture was analyzed across design dimensions and articulated below. For each of these dimensions, multiple options were considered, and through broad stakeholder engagement and learnings from existing pooled procurement cases, an emerging consensus for the future vision was developed (Exhibit 22).

Exhibit 22: Overview of pooled procurement mechanism

### High level overview of emerging consensus



The expansion of products beyond COVID-19 vaccines changes the dynamics that AVATT would be working through, as routine immunisation products often require longer-term contracts with assurance of regular payments and financing mechanisms to support it, reliable methods for estimating and consolidating demand across multiple products, and overall very different supply and demand dynamics (e.g., as most products are often not in short supply).

As shown above, there is an emerging consensus around the future state across the following design dimensions:

**Governance:** Institutionalizing and expanding AVATT/AVAT to become the main pooled procurement mechanism for routine and outbreak vaccines in Africa.

**Procurement scope:** The scaled-up mechanism will focus on critical elements of pooled procurement (such as negotiation and contracting) while benefitting from the Africa Medical Supplies Platform's (AMSP) capabilities in order processing and, over time, logistics. It will also collaborate with existing international agencies (for example, UNICEF's supply division) for other functions as needed to ensure access to the best available expertise.

**Supplier strategy:** The scaled-up mechanism will focus on purchasing from African manufacturers and take an active role in promoting them as they scale up, such as by providing supportive terms to enable local players to compete.<sup>38</sup> As this will take time, and because supplier diversity is critical to de-risk procurement, the pool will necessarily also procure from a mix of suppliers across geographies as well.

<sup>38</sup> Technical design work is still required precisely to determine the nature of support or preference for African manufacturers, so that it encourages investment without creating market distortions or breaching international obligations (such as WTO rules). For example, new manufacturers may require a price premium as they scale up, or an underwriting of risk (as done by the US government in the case of Operation Warp Speed for COVID-19 vaccines).

Contracting terms would need to balance supplier needs and preferences with benefits for purchasing parties, which impacts contract length, terms, and volatility (i.e., how much contracts turn on and off for particular suppliers).

Furthermore, specific market-shaping mechanisms may also be considered (for example, Advanced Market Commitments or volume guarantees) directly to incentivize the development of specific products that meet African needs or specific manufacturer market entry, scale-up, and/or pricing reduction. As these mechanisms can lead to significant volatility in the short-term, the pool might consider working with or through partners who can deploy these instruments (for instance, by collaboratively identifying market-shaping needs that partners might deploy) and consider direct provision of such tools over time if appropriate.

**Products included:** The mechanism will continue procuring COVID-19 products and eventually include all relevant routine and outbreak vaccines and allow countries to choose between different brands where there are meaningful differences (such as dose schedule or storage requirements).

**Country participation:** AVATT/AVAT already serves all AU member states with COVID-19 vaccine procurement. The ultimate ambition is to expand over time to offer all vaccine products to all member states.

**Regulatory standards:** Regulatory standards will be WHO PQ for now. Once the AMA has finally scaled-up, reached international quality standards, and has become an equally trusted approval body, responsibility for standards and regulatory oversight can shift to AMA if the right conditions are met, with support from regional regulatory bodies and NRAs.

**Procurement-related financing:** A pooled financing mechanism, supported by a financing partner (such as Afreximbank) or a set of partners, can underpin the architecture by providing procurement guarantees to manufacturers (for instance, by way of Advanced Purchase Commitments). Furthermore, the pool (through its partners) can facilitate country payments, potentially including a mix of financing solutions (such as a working capital facility that enables country payment plans).

Ideally, countries otherwise eligible for donor support will be able to maintain that support when procuring through the pool. This chapter does not consider financing that is not related to procurement (but could have an impact on product pricing), for instance, capex support for manufacturers—such topics are covered in the Access to Finance chapter of the FFA.

**Pricing:** Pricing may be tiered by income levels and other factors (for example, immunization rates and disease prevalence) to support accessibility for all countries.

Achieving this vision is an ambitious and complicated project, which will likely require a phased approach, ongoing political and financial support, and significant capability-building effort over time. To achieve this vision, it is essential that:


- Existing organizations have or can develop the bandwidth and capabilities required to scale the procurement entity to more products as well as much larger order volumes and values over time.
- Countries recognize a clear health and economic incentive to participate, and donors continue to finance the procurement of those countries eligible for support.
- Manufacturers (both African and non-African) can benefit from the increased demand and financial certainty associated with the pooled procurement architecture, despite their potentially lower bargaining power in negotiations.

## Potential risks and mitigating factors

There are several risks associated with the future state as articulated in the previous sections. At a high level, there are three categories of risk: political, operational, and financial (Exhibit 23).

Exhibit 23: Potential risks and mitigating factors

**DRAFT FOR DISCUSSION – HIGHLY PRELIMINARY AND NON-EXHAUSTIVE**

	Potential risks	Potential mitigating factors
 <b>Political</b>	<p>Potential lack of sufficient political support (at a leadership and technical level) in the short and/or long term</p> <p>Governance structure may be liable to political influences</p> <p>Potential competition between countries or regions could reduce the collaboration required for successful pooling</p>	<p>Leverage the success of AVATT for COVID-19 and existing initiatives to support manufacturing in Africa and highlight the potential benefit of pooled procurement</p> <p>Conduct deep engagement with countries and other critical decision-makers</p> <p>Work to minimize concerns and risks countries face, where appropriate</p> <p>Identify “first mover” countries whose endorsement will be most critical</p> <p>Identify appropriate ways to engage countries in the future state model</p>
 <b>Operational</b>	<p>Delay in ramp up due to complexity of setup negotiations</p> <p>Inadequate information sharing between countries</p> <p>Difficulty in recruiting necessary talent</p> <p>The transition to a new architecture might cause disruptions in the procurement process or supply chain</p> <p>Complicated interface between AVATT/AVAT and other existing procurement mechanisms</p>	<p>Maintain independence of AVATT and leverage its current momentum and political support to kick-start the institutionalisation and expansion strategies</p> <p>Collaborate closely with countries and existing procurement mechanisms to ensure a gradual transition which is continually improved over time</p> <p>Leverage existing expertise to support a smooth scale up of AVATT/AVAT</p> <p>Set up capability-building programmes with existing organisations</p>
 <b>Financial</b>	<p>Pooled procurement might not lower prices as expected</p> <p>Lack of adequate offtake certainty for manufacturers</p> <p>Lack of long-term sustainable financing and a potential reduction in donor funding</p> <p>Concentrated buyer power could negatively impact manufacturers</p>	<p>Engage early on with manufacturers and countries to understand their needs and identify the most suitable financial and legal instruments to underpin architecture (e.g., preferential loans, AMCs, volume guarantees)</p> <p>Engage with potential donors early on to understand their priorities</p> <p>Build overall procurement and market shaping strategy with clear objectives to support both countries and manufacturers</p>

Many of these risks can be managed and mitigated with early preparation and engagement with the relevant stakeholders.

## Looking forward

A primary design decision involves how AVATT/AVAT may scale up to additional products beyond COVID-19 vaccines over time (with the ultimate ambition of being the predominant pooling mechanism for all vaccines for all member states).

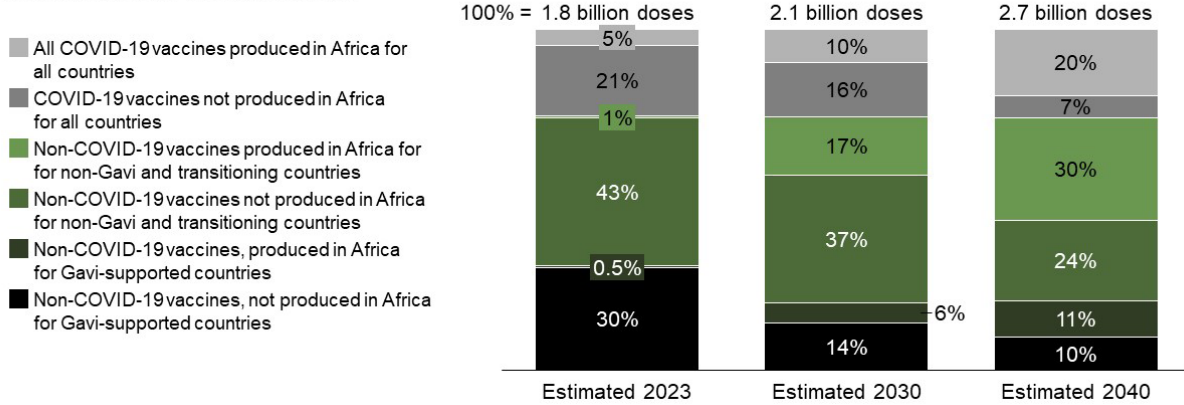
AVATT/AVAT currently procures COVID-19 vaccines across member states and will continue to do so. When moving beyond COVID-19 vaccines, given their lack of access to a pooled procurement mechanism at the moment, countries not supported by Gavi (and those transitioning from Gavi support) may be especially incentivized to procure routine vaccines through AVATT/AVAT. AVATT/AVAT may initially start scale-up with these countries and a subset of products, subject to its organizational and operational scale-up speed. Over time, Gavi-supported countries may also procure routine vaccines through AVATT/AVAT, potentially starting with vaccines produced in Africa, as shown in Exhibit 24.

Exhibit 24: Scaling of AVATT/AVAT will leverage a tailored approach based on country and product strategy

ESTIMATES BASED ON EXPANSION MARKET GROWTH (TOTAL DOSE FORECASTS VARY BY MODELING SCENARIO<sup>1</sup>, SCENARIO SHOWN IS MIDDLE CASE)

**Estimated market share by vaccine and country combination**

% of total African market volumes



Notes: 2023 used instead of 2020 to provide a more "stable" COVID-19 demand figure to compare with later years. If COVID was not included, the non-Gavi and transitioning share would appear even higher (going from ~60 to ~75%). African-produced vaccine estimates provided by the PAVM secretariate, which assumes ~60% of doses procured in Africa by 2040 and ~38% of the following products at least filled & finished in Africa by 2030: yellow fever, malaria, HIV, influenza, Ebola, chikungunya, Rift Valley fever, Lassa fever, meningitis, TCF, HPV, rotavirus, OCF, Penta, MMR, BCG, COVID-19, and PCV

1. Modeling scenario highly dependent on COVID-19 assumptions

Source: Linksbridge (Sep 2021 GVM 9.2 for existing vaccines through to 2030 only), UNICEF, WHO

Overall, the role of Gavi in a self-sustaining African continent with regard to vaccines remains to be explored as AVATT/AVAT refines its scale up strategy. To achieve this vision, a strategic expansion of AVATT/AVAT programmes and partnerships will be required.

**High-level implementation plan**

In order to operationalize and leverage the pooled procurement mechanism, a few key activities could be pursued:

**Over the next year (2022)**

Over the next year, the primary focus should be on expanding the existing pooled procurement mechanism beyond COVID-19 vaccines to include some routine vaccines, starting with a pilot involving a subset of countries and products. More specifically, this would involve:

- Developing a compelling health and economic impact rationale for countries to participate in the expanded architecture.
- Determining which countries could be part of a potential expansion pilot and negotiating a preliminary participation agreement.
- Determining which products beyond COVID-19 could be part of the architecture at the outset and engaging potential suppliers to negotiate procurement agreements.

**In the short term (2023 to 2025)**

In the short term, expansion of the pooled procurement mechanism to include additional routine vaccines and other countries could be realized. Priority activities could include:

- Refining the health and economic rationale based on the emerging context and country feedback.
- Determining how quickly to ramp up to additional products and countries based on the outcome of the pilot phase, administrative feasibility given the evolving strength and bandwidth of the procurement mechanism, and considerations of equity and contextual reality.

## In the medium to long term (2026 to 2040)

In the medium to long term, the pooled vaccine-procurement mechanism should be opened to all AU member states for all vaccines (routine and outbreak). It will be important to continue measuring the potential impact of pooled procurement on health and economic indicators for countries.

## Program 2: Establishing a vaccine manufacturing deal preparation facility and fundraising for ecosystem enablers

### Context and challenge

Historically, and particularly in emerging markets, the vaccine manufacturing industry is supported by public and donor funds. To develop a local vaccine manufacturing industry, African countries will need to invest in manufacturing capacities along with the broader enabling ecosystem.

The financial terms of such investments are not immediately attractive. Since most machinery and equipment will need to be imported into Africa (particularly equipment that is compliant with cGMP), the cost of setting up facilities is high and the revenue horizon long. However, new technology such as mRNA-based vaccines is changing this. Beyond manufacturing facilities, dedicated funding is required to strengthen broader enablers, such as talent for manufacturing plants and research institutions, regulatory frameworks for vaccine approval, and R&D, particularly for development of new vaccines (covered under program 8).

For manufacturing projects, financing is needed across all phases of project development, from one-off costs like asset capex and related technical assistance, to more regular funding needs like operating expenses, R&D, and technology-transfer costs. To support these projects, financing is also needed for the enabling environment. Overall, three aspects of the financing landscape for vaccine manufacturing currently present challenges.

### Demand

Capital demand is limited by three main factors, namely:

- **Quality of deals**, due to limited experience in project preparation (feasibility assessments and business case development) and unclear exit options or breakeven points for investors.
- **Limited pipeline of bankable deals** in drug substance manufacturing, as governments and development financial institutions (DFIs) focus more on the growth of other parts of the pharmaceutical industry.
- **Externalities** negatively impacting returns on vaccine manufacturing investment (for example, global downward pressure on price, limited talent and expertise on the continent, and low visibility on guaranteed volume).

### Supply

For financiers, there are two main bottlenecks to increasing capital supply in the vaccine manufacturing industry:

- **Lack of interest or knowledge** about industry economics and the specific needs of vaccine manufacturing, combined with limited efforts from the industry itself to share such information.
- **Inadequacy** between available financing tools and the needs of the industry, with key financing stakeholders (such as private equity funds and commercial banks) not actively involved.

## Enablers

Beyond capital, an enabling environment is essential to healthy industry financing. This includes a healthy and skilled talent pool, a supportive regulatory environment, visibility over demand volumes, and reliable infrastructure.





There is currently limited investment and financing from stakeholders into these enabling instruments. This lack of investment has negative ripple effects on the broader local vaccine industry.

## Strategic directions

There are several types of financial tools and mechanisms that can improve the financing landscape for vaccine manufacturing in Africa. Some are already used on the continent while others are not yet in place.

Similarly, governments can consider a range of incentives to encourage local vaccine manufacturing. While some will boost operations, others will create financial options for stakeholders (Exhibit 25).

*Exhibit 25: Examples of financial tools and mechanisms*

	Improve financials		Improve operations	
				
	<b>Access to capital</b>	<b>Preferential pricing, payment terms, and taxes</b>	<b>Restricted international competition</b>	<b>Demand guarantee</b>
<b>Examples</b>	Subsidies and loans on Capex Land giveaway	Price de-boxing for localized products Custom duty exemptions on raw materials VAT and other tax exemptions Upfront payment on orders	Closed bid tenders where local manufacturers are bidding Significant import taxes on select goods, and tax incentives for exports Faster market access authorization process for local products	Long term contracts Special contracts, such as guaranteed offtake in volume and prices
<b>Potential benefits</b>	Assists in addressing high upfront costs required	Assists in addressing the challenge that local manufacturing is likely to produce vaccines at higher cost per dose in initial years	With Africa currently importing 99% of vaccines it consumes, the export market in this sector is extensive and highly competitive. Reducing competition gives local manufacturers room to incubate	Securing stable long term demand strengthens the business case and attractiveness of the deal More critical as governments are the dominant off-takers for vaccines prioritised for local manufacturing by the PAVM

Given these available tools, there are different ways to address each of the challenges identified:

### Demand

Increase the attractiveness of vaccine manufacturing deals through:

- Deal bankability**  
 Mobilize donors and DFIs to provide heavy support for deal preparation, including project guidelines for manufacturers, shareable business case models featuring financial indicators (for instance, net present value [NPV] or return on investment [ROI]), risk assessment, and ring-fenced funds for technical assistance.
- Project de-risking**  
 Create incentives to de-risk vaccine manufacturing projects (for example, land giveaways, tax breaks, import-duty reduction, and offtake or special pricing) to lower costs and ensure product competitiveness.

## Supply

Improve the match between financing supply and funding needs so financiers can support vaccine manufacturing projects through:

- **Innovative partnerships**  
Implement innovative and balanced financing structures between stakeholders (such as DFIs, governments, and manufacturers). This can include public-private partnerships to split risk and joint ventures to enable robust technology transfers.
- **Innovative financing**  
Develop and implement innovative financing products that match the industry's return horizon and upfront capital commitment needs.

## Enablers

Ensure key stakeholders (such as DFIs, governments, and manufacturers) are properly incentivized to invest in ecosystem enablers that support vaccine manufacturing.

## Recommendation

To support both industry and enablers, two complementary programs should be put in place:

1. A vaccine manufacturing deal preparation facility

This facility will serve as a one-stop-shop that provides support across all critical project phases and ensures deal bankability. It will de-risk manufacturing deals and host marketplace forums to connect manufacturers and financiers. It is important that interaction between the deal preparation and financing facility and the Technology Transfer and IP Enablement Unit takes place to provide visibility across both programs of ongoing activities and emerging opportunities for support.

2. Fundraising initiatives for ecosystem enablers

This effort will focus on raising funds for talent development through R&D centers and Capacity and Capability Centres (CCCs), including regulatory capability building, and for clinical and pre-clinical trials for R&D. It will also support fundraising efforts for biotech start-ups, as well as for RCOREs and NRAs.

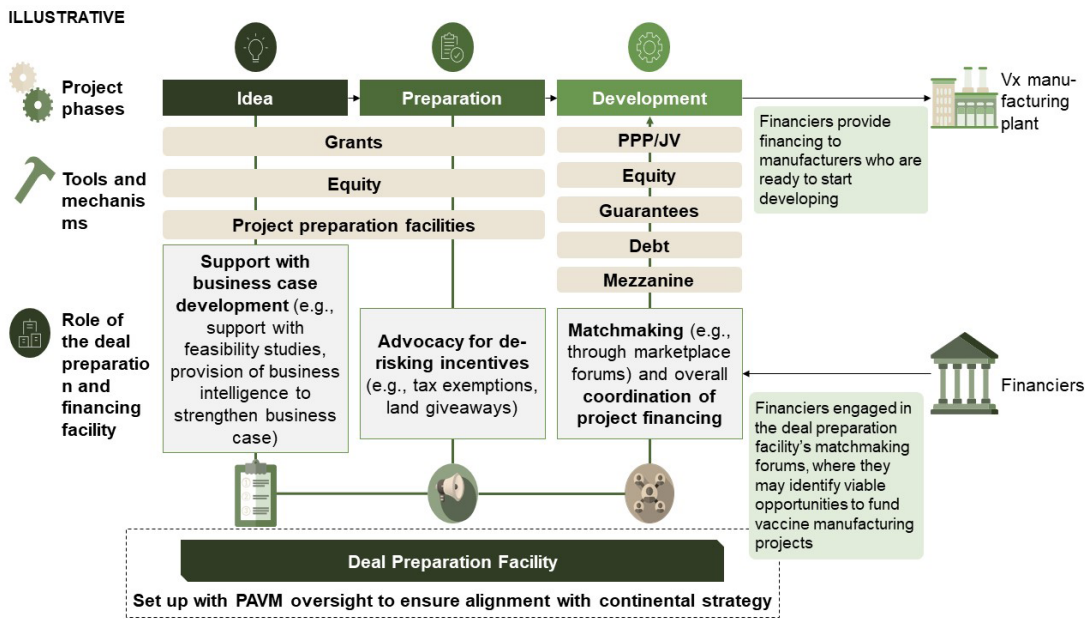
The PAVM Secretariat will have oversight of both solutions and will coordinate fundraising for ecosystem enablers, as detailed under program 8 (ensuring an effective continental strategy delivery and oversight).

## Looking forward

### Scope and mandate

The deal preparation facility will be aimed primarily at manufacturers seeking to get financing from investors. Financiers ready to invest in manufacturing facilities in Africa have identified project viability and clear business cases as key missing ingredients in existing business projects. As such, this facility will address current shortcomings on the continent in preparing solid business plans and will provide support from project feasibility studies and market data, all the way to raising funds. To further boost the attractiveness of African vaccine manufacturing projects, this structure could also have several measures in place to reduce the in-country risks down to the local business environment level. This deal preparation facility will accelerate deal bankability and will increase chances for local manufacturers to attract funding as they seek to expand their facilities.

Exhibit 26: Design features of the vaccine manufacturing deal preparation and financing facility



By providing matchmaking on existing and future deals, advocating different kinds of partnership and financial solutions, and offering investment guarantees, the facility can help source funding for manufacturing projects across Africa that are in the development phase. Beyond matchmaking, the facility could play a critical role in providing coordination for financing of vaccine manufacturing projects on the continent, which often require multiple financiers to be engaged for each project. This would involve assessing the end-to-end financing needs for supported manufacturing deals and ensuring that, during matchmaking, all the various required financiers are pulled in when and as needed.

The facility will ultimately create a meaningful pipeline of viable projects of different risk profiles, with adequate deal preparation that the facility could then connect to a broad range of financiers (public, private, and donor), with a broad set of financing tools.

### Design principles

Prior to implementing the facility, some key design decisions will need to be made, first of which is where the facility will be set up. For this, two options could be considered: the deal preparation and financing facility could either be set up as a new entity, or integrated into an existing platform. A new facility would be more focused on vaccine manufacturing and designed specifically to serve the industry over the long term, but would be more costly and complex to implement since it would be built from scratch. Integrating the facility into an existing platform would be faster and could tap into synergies from existing resources, but there are only a limited number of such relevant platforms, and integrating any of them would make prioritizing vaccine manufacturing difficult over the existing platform's current mandate. Nevertheless, each of these configurations can lead to an effective structure.

Once a decision is made on the set-up of the facility, several operational aspects of the deal preparation facility will need to be decided on, including whether the facility should fundraise and disburse funds for deal preparation, whether the multiple solutions that the facility provides should be implemented gradually or simultaneously, where financing for the facility's operationalization will be sourced, and how the facility should be governed and staffed to operationalize the facility within the next 12 months. These important elements should be addressed before launching market initiatives.



## High-level implementation plan

A high-level implementation plan was defined to enable the set-up of the vaccine manufacturing deal preparation and financing solution.

### Over the next year (2022)

Over the coming year, financiers and vaccine manufacturers could be linked by leveraging existing initiatives or platforms (for example, the African Investment Forum) to ensure support for vaccine production on the continent.

In parallel, a decision should be made as to whether the facility should be set up as a new entity or integrated into an existing platform. Thereafter, the facility could be launched to begin deal preparation support, along with a marketplace forum.

### In the medium to long term (2026 to 2040)

In the medium to long term, relevant market data can be progressively collected to benefit business intelligence tools provided to manufacturers and deal makers. This would be complemented by the development of a robust deal pipeline database, which would give a clearer picture of the manufacturing industry's support needs at the continent level. These activities would enable the facility to scale up, bringing multiple deals to maturity while developing additional tools to support projects across multiple deal stages.

With the right initiatives to find funding for the ecosystem enablers half of all vaccine projects on the continent could be operationalized within a decade. Dozens of deals could be supported through deal preparation, and dozens more could be funded in the post-development phase.

## Program 3: Strengthening National Regulatory Agencies and Regional Centres of Regulatory Excellence to build vaccine regulatory excellence

### Context and challenge

Regulatory systems play an essential role in assuring the quality, safety, and effectiveness of medical products. Effective regulatory systems are critical to national health systems and contribute to desired public health outcomes and innovation.

The WHO uses a Global Benchmarking Tool (GBT) to evaluate regulatory systems as objectively as possible. This GBT enables the WHO to identify strengths and areas for improvement for regulatory systems, and helps subsequently to develop an institutional development plan (IDP) to build on these strengths, address gaps, prioritize interventions, and monitor progress and achievements.

The WHO defines four Maturity Levels (MLs), for NRAs. The first two levels indicate a nascent but incomplete NRA effort that may be considered functional if it relies on other regulators for specific functions. ML3 is the mark of a stable, well-functioning, and integrated regulatory system. ML4 is applied to NRAs that are advanced and that show momentum for continuous improvement.

To develop a sustainable vaccine manufacturing industry on the continent, African NRAs must reach ML3. Only then can they provide the required vaccine approvals and ongoing oversight for continued regulatory compliance that are pre-requisites for local vaccine manufacturers to submit applications to the WHO for WHO Pre-Qualification (PQ). WHO PQ is a global standard to ensure vaccines are safe and properly made. Manufacturers require a WHO PQ to export vaccine products to most self-financing countries and to UNICEF.

Multiple benefits of a capable NRA for manufacturers exist. They can:

- efficiently process applications from manufacturers
- adequately govern quality, safety, and efficacy of medical products without needing external input (which often slows down the process)
- provide efficiencies with technical standards and support for manufacturers
- detect and adequately sanction illegal manufacturing and trade

NRA's able to perform all these functions effectively and reliably can be awarded ML3 status by WHO.

A stronger NRA will then have direct impact on manufacturers, providing:

- broader access to national procurement and Gavi/UNICEF markets
- quicker access to markets due to efficiency of process
- development of stronger manufacturing processes with the assistance of WHO
- better pharmacovigilance
- limited illegal competition, allowing margins to be protected

To be able to provide the required approvals for vaccine manufacturers to submit applications to the WHO for WHO PQ for vaccine products, NRAs must demonstrate at least ML3 status along nine regulatory functions (as benchmarked against the WHO GBT):

- National regulatory system
- Registration and marketing authorization
- Licensing of premises
- Market surveillance and control
- Vigilance
- Regulatory inspections
- Clinical trials oversight
- Laboratory access and testing
- NRA lot release

Presently, 92 percent of the African NRAs that have conducted the WHO GBT benchmarking are still at ML1, and only 2 percent have attained ML2. Most importantly, while Ghana and Tanzania are the only countries to have reached ML3, neither of them produces vaccines.






However, over the past year, African NRAs have actively worked towards improving their level of maturity, but they face obstacles across all maturity levels, including limited expertise, insufficient financial and human resources, and policy constraints. Many remain over-dependent on government funding and lack any kind of sustainable self-funding mechanisms. Training is not adequate for the few staff they have, and it can be hard to hire more qualified people locally. Political instability also contributes to the uncertainty NRAs face, which makes planning difficult and progress slow.

However, progress achieved so far suggests that more NRAs will be able to reach ML3 status within the next four years.

## Strategic directions

Different initiatives are currently ongoing on the continent to support NRAs in their regulatory responsibilities, including the harmonization of regulations across Africa. However, even taken together, these initiatives don't address all the bottlenecks identified. More support is needed to improve alignment among stakeholders, enhance frameworks for clinical trials, and improve coordination between governments, funders, and regulatory bodies (Exhibit 27).

*Exhibit 27: Additional support required for key challenges*

Challenges	Additional support required
Autonomy, legislation, and regulatory 	Advocacy to align government and stakeholder priorities in favor of <b>harmonization of vaccine manufacturing regulatory activities</b> (AU Model Law on Medical Products Regulation)
Processes and documentation 	<b>Guidelines and tools</b> (e.g., Quality management system) on vaccine manufacturing related regulatory functions. <b>Current support focused on clinical trials for medicines</b>
Efficiency and effectiveness 	<b>Guidelines and tools</b> (e.g., Quality management system) on vaccine manufacturing-related regulatory functions. Current support <b>focused on Clinical trials for medicines</b>
Leadership commitment, financial, and HR 	<b>Designation of new RCORES that focus on critical functions for vaccine manufacture</b> (e.g., laboratory testing, inspection, lot release)  <b>Coordinated funding from donors and governments</b> to help priority NRAs to reach ML3
Support for the ecosystem 	<b>Strengthen capabilities and know-how for R&amp;D and Tech Transfer regulatory oversight</b> (capability building for NRAs staff & communication plan for manufacturers)

Three initiatives are focused on regulatory strengthening: AVAREF, AMRH, and AMA. These actors work together towards the harmonization of regulatory legislation across the continent (Exhibit 28).

*Exhibit 28: Key initiatives focused on regulatory strengthening*

 <p>AVAREF is the first pan-African network for the regulation of medical products and was first established in 2006</p>	<p>AVAREF contributed to the vision, mission and goal of the AMRH initiative and serves as a Technical Committee of the AMRH. It supports countries to issue marketing authorisations for products</p>	 <p>Started in 2009 and is implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA). AMRH played a central role in accelerating regulatory harmonization and process streamlining within RECs. It also worked through RECs to conduct regulatory benchmarking exercises, leveraging tools such as the WHO GBT. AMRH initiative contains 3 important sub-projects:</p> <ul style="list-style-type: none"> <li>• Regional Centres of Regulatory Excellence (RCORES)</li> <li>• AU Model Law on Medical Products Regulation</li> <li>• AU smart safety surveillance (AU-35) Project</li> </ul>	<p>AVAREF may be incorporated into the future African Medicines Agency as a Technical Committee</p> <p>2015, AU Executive Council decision 2015 EX.CL/Dec.857 (XXVI) recognises AMRH as a foundation for establishment of the African Medicines Agency (AMA)</p>	 <p>AMA was adopted by the AU Assembly in February 2019, and has since reached the ratification threshold with 15 countries signing, allowing the AMA to come into force in November, 2021. It is seen as the progressive next step towards harmonization of legislation across the continent. Part of its role will be to consolidate RECs initiatives</p>
--	--	---	--	---

AMA and PAVM have common goals for Africa and should work together to share expertise, initiate capability-building programs and talent exchanges, and create new regulation. AMA can contribute in several important ways to Africa's vaccine regulatory ecosystem:

- **Transformational initiative**

AMA can enable more pan-African initiatives to transform African regulatory systems and improve the business environment for local manufacturers.

- **Continent-level impact**

AMA can have a similar impact in Africa as EMA had in Europe on public and economic health.

- **Regulatory excellence**

AMA can improve the regional harmonization of regulatory processes by helping to build capabilities and develop expertise.

- **Collaboration of the ecosystem**

AMA can help integrate RECs and NRAs to collaborate more effectively with regulatory stakeholders.

- **Focus on R&D**

AMA can help build regulatory capabilities in strategic R&D processes required for vaccine manufacturing.

## Looking forward

As some gaps still exist between the ongoing initiatives and the challenges identified, five main solutions have been identified to create a mature regulatory ecosystem on the continent:

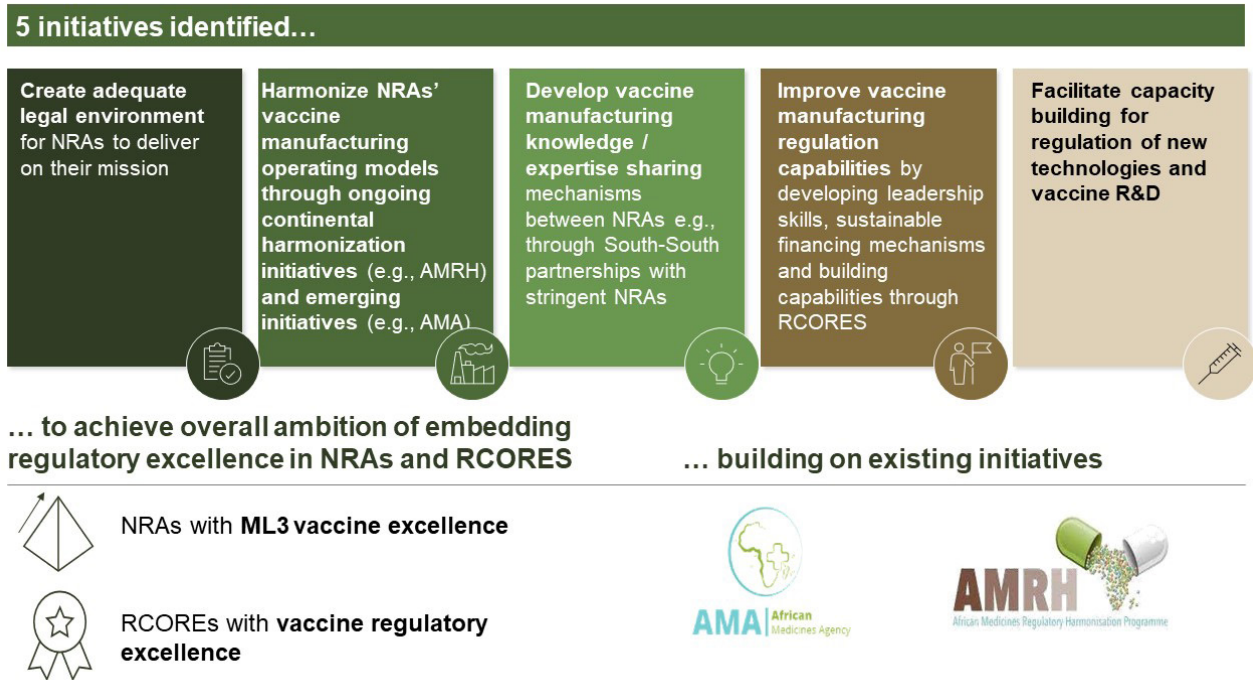
- **Maturity level solutions**

1. Create a suitable legal environment for NRAs to deliver on their missions, mainly by supporting the operationalization of AMA.
2. Harmonize NRA-operating models through standardized processes, tools, and documentation.
3. Develop knowledge- and expertise-sharing mechanisms between NRAs by leveraging RCOEs.
4. Improve regulatory capabilities by developing committed leaders, appropriate financial resources, and capability-building programs.

- **Broader NRA role in the ecosystem**

5. Build technology transfer and R&D capabilities through capability building and by sharing best practices among the ecosystem stakeholders (Exhibit 29).

Exhibit 29: Programs and initiatives to strengthen regulatory capacity



PAVM will work closely with existing institutions, extend its outreach to AMRH and AVAREF as AMA becomes operational, and build on lessons learned from these institutions.

Through AMA and AMRH, PAVM will support the harmonization of NRA operating models with standardized processes (for example, by creating an emergency regulatory approval process for outbreak vaccines), as well as tools and documentation that will improve collaboration, patient safety, and health outcomes. AMA could also advocate for an adequate legal environment and financing for NRAs to deliver on their mission.

RCORES will play a critical role in regional harmonization and standardization of regulatory science curricula. Through the RCORES, PAVM could strengthen human and institutional capacity and expertise to regulate vaccines at the regional level (including R&D regulation and technology transfer regulatory oversight).

**High-level implementation plan**

A few key activities could support AMA and ongoing initiatives (AMRH) to build vaccine regulatory excellency over the next 20 years:

**Over the next year (2022)**

Over the next year, it would be important to place a focus on:

- Advocating for the implementation of an AU guidance document for outbreak vaccine (including COVID-19) regulatory approvals.
- Ensuring that countries with COVID-19 vaccine production in 2022 are able to obtain WHO prequalification emergency use listing which can be achieved through ML3 of NRA or collaborative AMA /AMRH coordinated process of ML3/4 NRAs on the continent. This will require simultaneously strengthening NRAs on the continent, strengthening RCORES in inspection and lot release, supporting labs for testing, clearly outlining the collective support, and ensuring that WHO would accept it.

- Advocating for regulatory best practices and expertise sharing (such as good reliance practice, and an mRNA guiding document).
- Assessing the implementation of AMA and ongoing harmonization initiatives (for example, AU model law).
- Identifying existing RCORES to be strengthened as regional vaccine manufacturing RCORES.
- Affiliating regional vaccine RCORES to CCCs to enable capability building.
- Building capabilities for regional RCORES on vaccine topics (for instance, R&D).

### In the short term (2023 to 2025)

In the short term, it would be important to:

- Support the strengthening of AMA vaccine regulatory capabilities, and build on lessons learned from past initiatives (such as, AMRH).
- Finalize implementation of all ongoing regulatory initiatives (for example, AU model law).
- Develop a new regulatory framework based on vaccine manufacturing industry needs.
- Continue to put effort into bringing all countries' NRAs up to ML3, and some countries' to ML4, by creating knowledge-sharing initiatives (for example, forums) hosted by RCORES where African and stringent NRAs share expertise, and by developing a platform for external partnerships for RCORES and NRAs to access regulatory capabilities (such as experts and laboratories).
- Developing laboratory networks that allow countries to share lab testing resources, providing efficiencies and aiming to ensure that quality control testing for every vaccine produced and used on the continent is available in to any African country regardless of their national capacity.

### In the medium to long term (2026 to 2040)

Beyond 2025, new regulatory frameworks should be developed continuously, based on vaccine manufacturing industry needs, and best practices should continuously be shared for sustainable financial operating models for all RCORES and NRAs.

## Program 4: Support the transfer of vaccine technologies and intellectual property through an enablement unit

### Context and challenge

To achieve 60 percent locally-manufactured vaccines in Africa by 2040, between 1.5 billion and 1.7 billion doses must be produced on the continent each year. This will require significant investment in new and existing vaccine technologies and production processes.

Development of new vaccine technologies on the continent has historically been limited compared to other regions. While vaccine IP activity has accelerated in the last ten years, African countries have generated only a limited number of IP rights concerning vaccines; less than 1 percent of global vaccine patent filings have come from Africa.<sup>39</sup> Africa is still largely dependent on existing IP and technology licenses from other regions for vaccine development and manufacturing across the value chain.

There is varying complexity in the patent landscape. While there are limited patent barriers for legacy vaccines, there is a more complex landscape for expanding and outbreak vaccines. Different aspects of these latter vaccines are covered by multiple patents, creating a narrower scope to invent around these patents. IP protection can block the vaccine development process and beyond. IP rights (IPRs) such as patents, trade secrets, and clinical test data can hinder access to inputs or data, block new

39 World Intellectual Property Organization, wipo.int

formulations or combinations of materials, or usage of general processes.<sup>40</sup>

Several IP issues need to be addressed to increase patenting and licensing of vaccine technologies on the continent:

- **Access to and use of IP information**

- Lack of quantitative and qualitative data transparency around patenting of vaccine technologies and production processes.
- Limited or no use of technological information from patent applications and scientific publications.

- **IP and technology licensing capabilities**

- Limited patent-examination capacity (so far, only the Egyptian patent office is recognized as an international search and preliminary examination authority in Africa).
- Limited local manufacturer experience in IP and technology licensing and formation of international partnerships.

- **IP policy**

- Underdeveloped patent policy (for example, on disclosure of inventions), patentability, parallel importance, and regulatory use.
- Insufficient development of IP policy in government-funded research and industry-university collaboration.

During the past 20 years, technology transfers to developing countries have been essential in developing DCVMs (for example, in India, China, Brazil, and Indonesia) and increasing local vaccine supply. Since new and alternative vaccine development has been limited in Africa, successful technology transfers will be critical to reach the 2040 ambition.

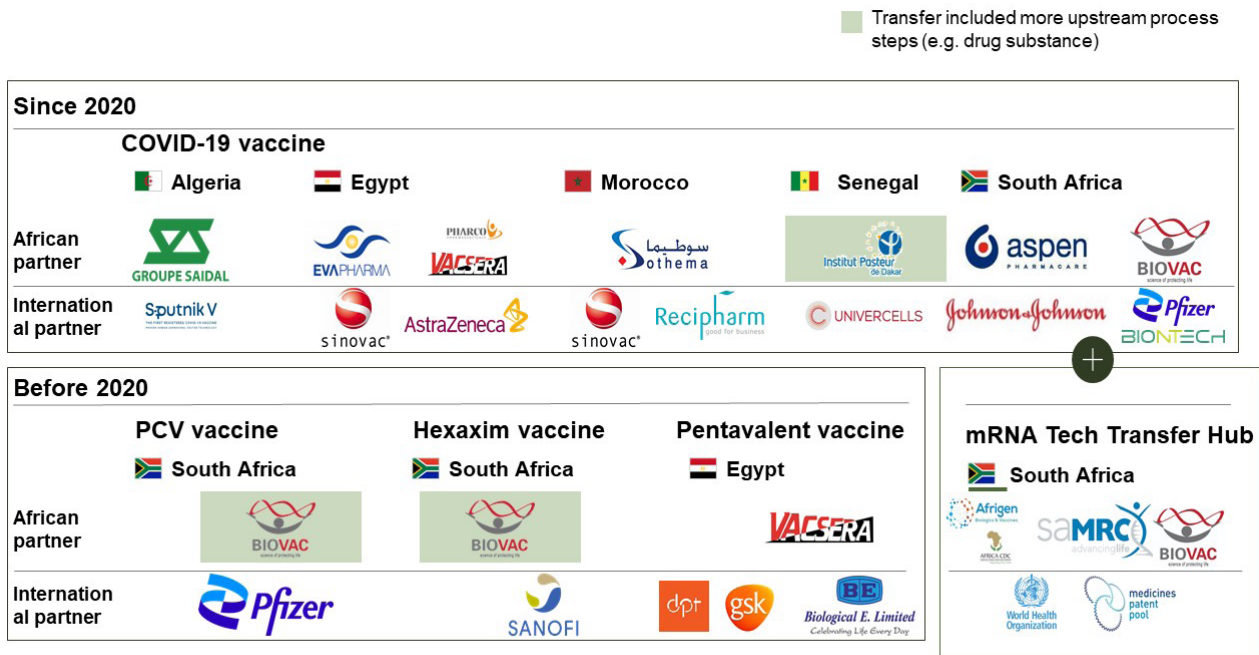
Technology transfers are long and complex processes with multiple steps and stakeholders, often taking years to complete. For example, the Sanofi technology transfer of the trivalent influenza vaccine to the Butantan Institute took nearly ten years to complete, while the technology transfer of the Hib vaccine from GSK to Bio-Manguinhos took nearly eight years. Further, technology transfers will require strong Chemistry, Manufacturing, and Control expertise, which is globally limited.

However, the COVID-19 pandemic has accelerated technology transfers and created new opportunities, with more than eight technology transfers announced in the past 18 months to ensure adequate supplies of vaccines (Exhibit 30).

---

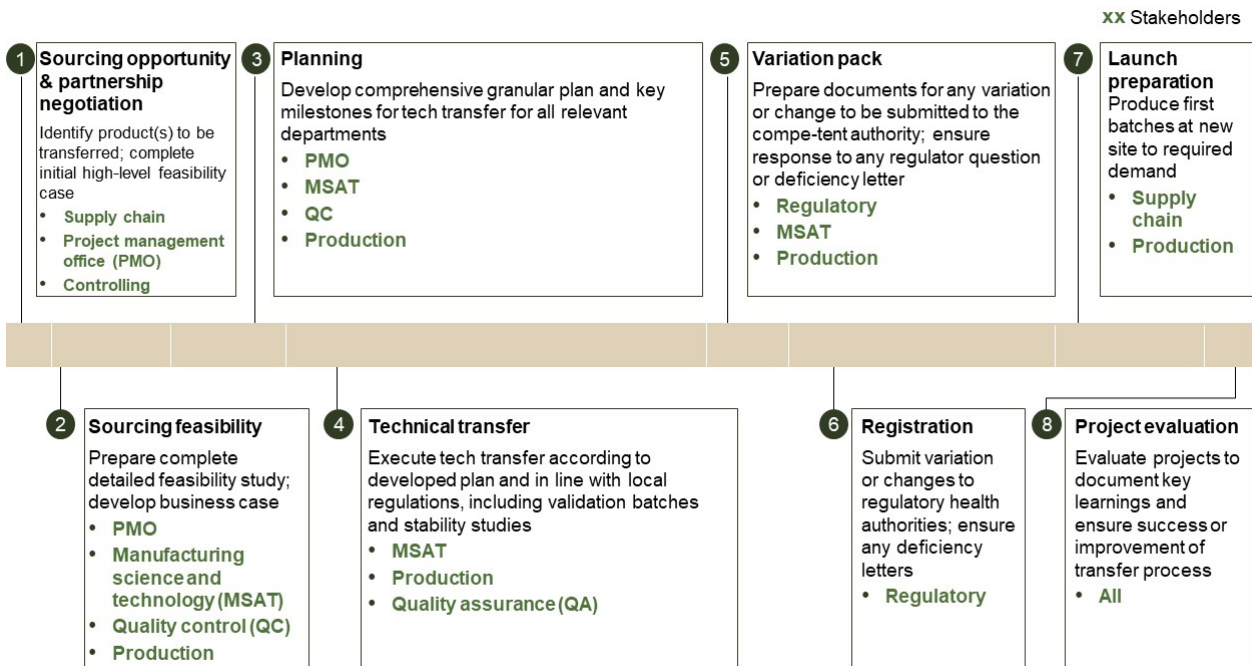
<sup>40</sup> Médecins sans frontières (MSF), A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines, September 2017

Exhibit 30: Technology transfers initiated on the continent before and after 2020



Technology transfers are structured around eight main steps. Each step contains 20 to 30 separate activities for which technology providers and recipients must account.<sup>41</sup> They also require the involvement and coordination of a large number of stakeholders.

Exhibit 31: Typical steps and stakeholders for each transfer step activity



Source: McKinsey article: Why tech transfer may be critical to beating COVID-19

41 Cormac O'Sullivan, Paul Rutten, and Caspar Schatz, "Why tech transfer may be critical to beating COVID-19," July 23, 2020, McKinsey.com.



To meet the required capacity needs and reach the target level of production by 2040, a minimum of 23 technology transfers will be required:

- 12 technology transfers across seven modalities (mRNA, inactivated virus, live attenuated virus, viral vector, virus-like-particles, DNA, and protein subunit) will be required to enable DS production of the 13 vaccines<sup>42</sup> prioritized for DS focus.
- Another 11 technology transfers will be required to enable F&F production across 11 F&F facilities – six non-live virus, three live virus and two viral vector facilities.

See the Appendix for more details on how the minimum number of technology transfers required was estimated.

Several key pain points should be addressed to accelerate technology transfers on the continent. These include:

- **Technology recipient side**  
African companies often lack awareness of technologies and available partners and are put off by the high investments in staff development and facility enhancement that technology transfers require.
- **Technology-providing side**  
Technology-providing companies lack incentives to transfer their technology to African vaccine manufacturing companies. They are also concerned about political and regulatory conditions in recipient countries. Providers are also concerned about the lack of requisite quality management systems, expertise, and experience in vaccine manufacturing on the recipient side.
- **Regulatory side**  
Country-specific NRA requirements are not fully transparent which leads to delays in launch preparations and transfer rollouts.<sup>43</sup>

## Strategic directions

- To address the key pain points of technology and IP transfers and enable the expansion of vaccine manufacturing on the continent, a vaccine technology transfer & IP enablement unit should be created to link technology providers and technology recipients to an ecosystem of supporting stakeholders along the technology transfer journey to facilitate the transfer of technologies to the continent and support the licensing of existing and new technologies.

In parallel, three key initiatives could help promote technology transfers, increase transparency, and strengthen capabilities around patenting and licensing of vaccine technologies.

1. Develop an **incentive framework** to promote technology transfers with African manufacturers that will include:
  - a. Providing local market access and demand guarantees—the ‘market design and demand intelligence’ pillar of PAVM.
  - b. Offering competitive financial incentives (for example, preferential pricing and favorable payment terms)—the ‘access to finance’ pillar of the PAVM
2. Create a **continental capability-building program for NRA technical staff** focused on vaccine development, manufacturing and technology-transfer regulatory processes, and the development of an early engagement framework between NRAs and local manufacturers—the ‘regulatory strengthening’ pillar of the PAVM

<sup>42</sup> Includes COVID-19, Pentavalent, MMR, malaria, HIV, PCV, BCG, YF, influenza, Rift Valley fever, chikungunya, Lassa fever, and Ebola.

<sup>43</sup> Based on technology-transfer case studies and manufacturer interviews

3. Launch a **coordinated R&D effort** to enable development of alternative vaccine technologies or processes to produce vaccines around licenses not obtained from IPR holders—the ‘R&D’ pillar of the PAVM

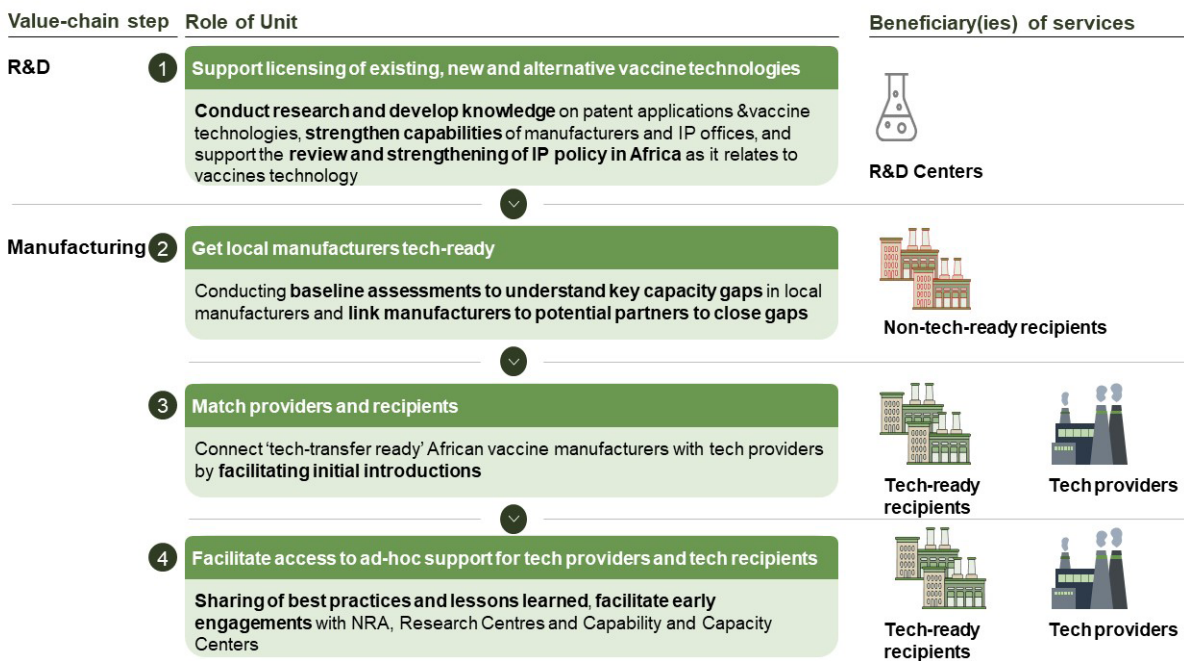
Other PAVM pillars will have the responsibility to consolidate these solutions, with further details presented in the relevant sub-chapters.

## Looking forward

The **Vaccine Technology Transfer & IP Enablement Unit** can accelerate vaccine manufacturing on the continent by **linking technology providers and technology recipients to an enabling ecosystem of support along the technology-transfer journey** and by **supporting the licensing of existing and new technologies** (Exhibit 32).

Exhibit 32: Four primary roles of the Vaccine Technology Transfer & IP Enablement Unit

NOTE: UNIT WILL NOT ACT AS A GO-BETWEEN BUT INSTEAD A FACILITATOR; ACTIVITIES WILL BE EXECUTED WITHIN THE LEGAL FRAMEWORK OF AU/AFRICA CDC



This enablement unit would support three groups of local manufacturers along the technology-transfer journey:

- Manufacturers already engaged in vaccine manufacturing.
- Manufacturers or pharmaceutical companies that have not manufactured vaccines before but could repurpose their facilities.
- Biotechnology or early-stage startups that are building capacity for vaccine manufacturing.

The enablement unit would serve four primary roles:

- **Capacity building** — supporting local manufacturers in getting ‘technology-transfer ready’ in line with key conditions required by technology providers.<sup>44</sup>

44 This will include, as identified by the IFPMAs “Technology Transfer: A Collaborative Approach to Improve Global Health,” 1: A viable and accessible local market ; 2: Political stability and transparent economic governance; 3: Appropriate capital markets; 4: Innovation-friendly environment with sound intellectual property rights; 5: Proper access to information; 6: Adherence to high regulatory standards; 7: Skilled workforce; 8: Clear economic development priorities

- **Match-making** — connecting ‘technology-transfer ready’ local vaccine manufacturers with technology providers interested in transferring their technologies to Africa.
- **Roll out support** — facilitating the provision of ongoing support for technology transfers by sharing best practices and lessons learned; facilitating access to technical expertise, partnerships, funding, talent, research capacity; and enabling regulatory alignment.
- **Vaccine technology and IP information support** — providing central management of IP information and technology support services to enable vaccine technology development on the continent in the long term. This would be delivered through a Regional Vaccines Technology and IP Support Service - a single unit located within the enablement unit. The Support Service would focus on four key activities:
  - i. Researching and developing knowledge on patent applications, vaccine technologies, and emerging trends and technologies
  - ii. Strengthening capabilities of IP offices on patent examination, and of manufacturers on IP and technology licensing and partnerships
  - iii. Fostering collaboration between local manufacturers (i.e., pooled licensing) and with international partners and public research organizations
  - iv. Supporting the review and strengthening of IP policy in Africa as it relates to vaccines technology

The activities of the Regional Vaccines’ Technology and IP Support Service would be executed through mutually beneficial collaborations and partnerships with organizations such as the Medicines Patent Pool (MPP).

## High-level implementation plan

The regional vaccines’ technology and IP support service could be set up and scaled through the following key activities:

### Over the next year (2022)

- **Set-up of the Vaccine Technology Transfer & IP Enablement Unit:** An anchor organization could be identified and onboarded, and its key objectives and activities aligned with the anchor organization (for example, through a memorandum of understanding). The unit could then be set up, which would include securing funding to staff the unit. Match-making and vaccine technology and IP support functions will require business development/commercialization experts, while capacity building and roll-out support functions will require technical with technical expertise.
- **Introductions facilitated between high potential African-vaccine manufacturers and technology providers:** The established unit could then work to develop target product profiles in line with the Continental Strategy by identifying the required technology transfers needed and developing a list of technology providers with which to engage. Information sessions could be hosted to introduce the identified technology providers and interested local manufacturers to the enablement unit, and finally, fact packs could be collated to help ‘technology-transfer ready’ manufacturers adequately position their capabilities.
- **Local manufacturers supported in getting ‘technology-transfer ready:** Guidelines should be developed for local vaccine manufacturers on key conditions required by technology providers. To support this, a technology-transfer protocol or plan document could be developed and disseminated to local manufacturers ready for technology transfer. In parallel, a playbook could be collated and shared with pharmaceutical and biotechnology companies on how to get ‘technology-transfer’ ready.

- **Provision of ongoing support for technology transfers:** During the initial year of set-up, it would be important to identify and engage, and develop a registry of, potential supporting stakeholders including public health organizations and other donors, NRAs, and vaccine manufacturing and technology-transfer experts. It will also be important to agree on a support model and engagement framework with identified stakeholders using MoUs.
- **Regional vaccines technology and IP support service:** Potential partners (for example, MPP) could be engaged, and a collaboration model agreed upon. Through such collaborations, capability-building programs could be developed and implemented for Africa IP offices on patent examination.

### In the medium to long term (2023 to 2040)

In the medium to long term, it would be important to:

- Continue to facilitate initial introductions between the technology providers and local manufacturers ready for technology transfer.
- Check in regularly with PAVM to assess progress and to help address key blockers.
- Conduct baseline assessments to understand key gaps among manufacturers interested in engaging in technology transfers, and link manufacturers to potential partners and resources to plug identified capacity gaps.
- Facilitate access to support on an ad-hoc basis for technology providers and technology recipients including funding, partnerships, talent, research capacity, manufacturing and logistics capacity, and NRA engagement..
- Support the review and strengthening of IP policy in Africa as it relates to vaccine technology by developing and implementing capability-building programs for African manufacturers on IP and technology licensing, and by the formation of international partnerships.
- Initiate pooled vaccines patent licensing for sub-licensing in collaboration with international partners.
- Facilitate collaboration with public research organizations with relevant vaccines patent portfolio or R&D pipeline.
- Assist manufacturers and R&D organizations in understanding IP systems and filing patent applications.

## Program 5: Creating regional Capability and Capacity Centres

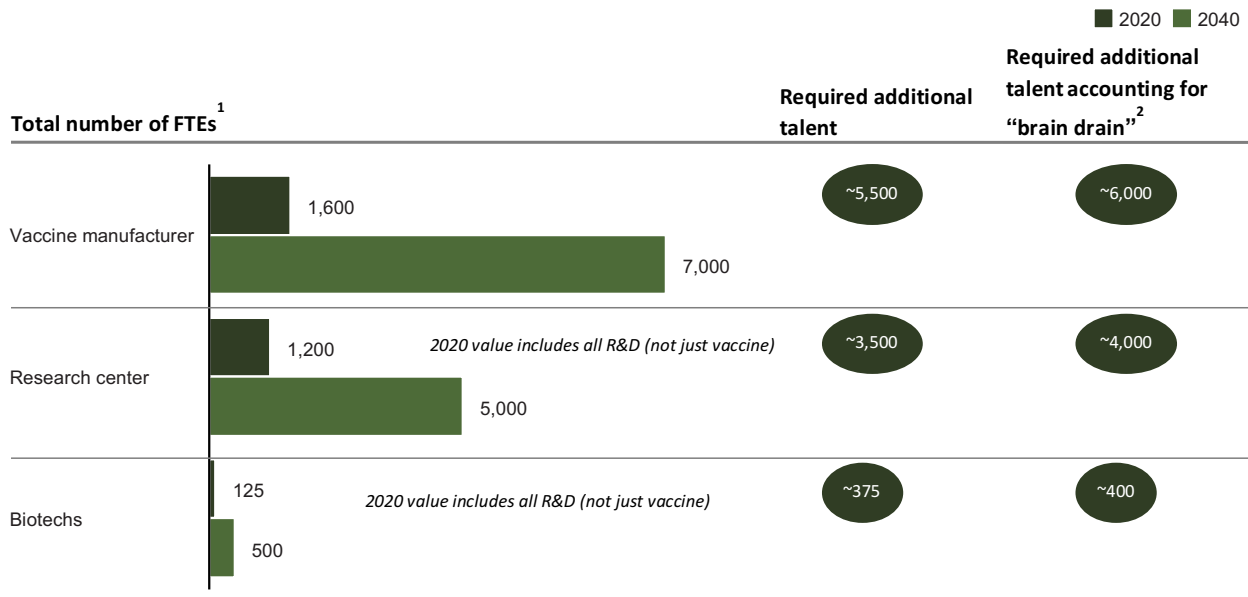
### Context and challenge

Africa’s ambition will require vaccine production to scale up to 1.5 billion - 1.7 billion doses locally and to ramp up R&D capacity. This means scaling total vaccine manufacturing and R&D full time equivalents (FTEs) up to 12,500 by 2040.

Currently, there are an estimated ~3,000 FTEs in R&D and manufacturing positions, of which ~1,325 are in R&D (including FTEs not focused solely on vaccine development) and ~1,600 in manufacturing.<sup>45</sup> See Appendix (section 3) for additional details on FTE sizing.

45 Example organizational charts from companies across Africa

Exhibit 33: Research and manufacturing talent required to support the 2040 vaccine ambition



1. Leverages the higher number of the estimated FTE range  
 2. Assumes ~10% increase required to offset brain drain based on statistics from AFDB.org (13%)  
 Source: Expert inputs and surveys, 12 plants from 3 countries (China, India, Korea) were assessed to derive average plant capacity per modality and average FTEs per

On average, vaccine manufacturing companies in Africa employ 85 percent of the total workforce in operations and only 6 percent in R&D (compared to 28 percent in R&D for an MNC). Additionally, research centres often have a large portion of the workforce occupied by students (about 40 percent for pre-clinical centres) or support staff (about 35 percent for clinical centres).<sup>46</sup>

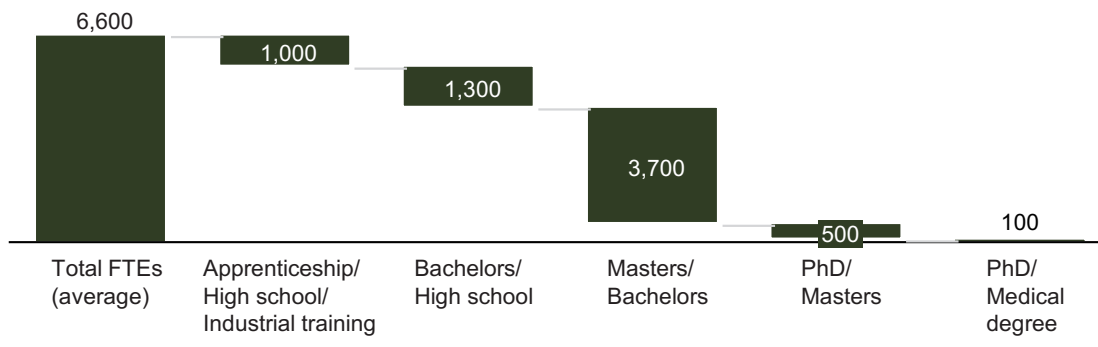
To meet future talent needs, R&D FTEs will need expertise in specialized areas such as molecular biology, pathology, biochemistry, and immunology as well as other areas such as regulatory expertise. The exact mix of expertise will vary based on the organization (for example, research centers will require backgrounds in science, while Clinical Research Organizations will require backgrounds in regulatory expertise). Manufacturing FTEs will also require specialized expertise in areas such as pharmaceutical engineering, chemical engineering, biotechnology, and process engineering, as well as more traditional business disciplines such as accounting and communication., resulting in a wide range of potential educational paths for vaccine industry candidates.

Education levels will also vary across the workforce, with R&D centers requiring a large number of PhD or MD candidates (~15-20 percent based on lab type), with a majority of individuals possessing a bachelors or masters degree. In manufacturing plants, ~60 percent of the workforce may require a bachelors or masters degree and ~35 percent only a high school degree, vocational school, or similar degree (Exhibit 34).

46 Based on example organization charts from 8 manufacturers, 3 pre-clinical research centers, 2 clinical research centers and 8 biotechnology companies across Africa.

Exhibit 34: Degree breakdown for required vaccine manufacturing talent

Number of FTEs by degree based on average of high and low headcount estimates



Education categories determined based on expected roles within each department (e.g., technician/operator roles)

Where two education levels are grouped (e.g., Masters/Bachelors), the candidate could have either degree for the required role

Source: Biovac, Tony Blair Institute, WHO, UNIDO, Expert input

There are three main challenges hindering talent availability and scale across vaccine manufacturing and R&D:

- **Scarcity of local talent-development initiatives**

There are too few degree programs relevant to vaccine manufacturing, and the programs that do exist focus on clinical training; as a result, even graduates with relevant degrees are not always equipped with adequate industry know-how and technical skills required on the job. **Lack of funding** Local research centres do not have the means to create more full-time positions and cannot keep the talent they develop.

- **Brain drain of local talent**

Local manufacturers and university research labs on the continent find that graduates of training programs often leave for opportunities in higher-income regions due to lack of open and well-paid posts in their home countries.

## Strategic directions

Talent challenges can be addressed using four key solutions:

- **Degree specializations** in vaccine topics which can include accelerated programs or even combined programs where relevant
- **Internships** to promote vaccine career exposure
- **On-the-job development programs** (including apprenticeships and programs targeted at experienced hires from diaspora or adjacent industries).
- **A playbook to enhance industry employee value propositions** to ensure candidates are attracted to vaccine industry roles (in both manufacturing and R&D)
- **Pipeline development** to ensure sufficient early awareness of vaccine career opportunities in youth through to sustainable full time career opportunities

Existing STEM-degree programs need to create specializations tailored to vaccine expertise by involving industry experts as additional lecturers and incorporating industry-specific nuances into

course curricula. These could also include accelerated program options that move students through to industry more quickly or combined programs (for example, bachelors and masters) as needed to meet vaccine industry role requirements. STEM program specializations will increase both local talent development of vaccine-specific expertise and student awareness of the industry.

To raise awareness of vaccine career opportunities further and give students exposure to industry mentorship during their studies, internships can be deployed across the continent. Internships will help students convert from degree programs to vaccine careers, potentially reducing brain drain.

Additionally, industry players must set up on-the-job development programs or apprenticeships that provide recent graduates (of all education levels) and experienced hires with a mix of hands-on job training and additional vaccine-specific classroom training over multiple years. On-the-job development programs should be tailored to relevant candidates. For example, programs could include apprenticeship programs for vaccine plant operators, longer programs for masters/PhD graduates and lighter touch programs for experienced hires, such as diaspora or adjacent industry hires. Programs like these can help provide specific vaccine-related training on a given product, disease, or process to develop a stronger local talent base.

In the immediate term, while programs are being set up and scaled at local African institutions, efforts can be made to leverage international expertise and talent by recruiting expatriates or leveraging international capabilities to speed up program set-up. Additionally, there could be an opportunity to prioritize set-up of programs targeted for experienced hires (whether local individuals or diaspora), as talent could be recruited more rapidly from adjacent industries where a foundational skill base already exists.

To combat brain drain, a playbook can be developed to help organizations define and establish a robust employee value proposition to keep talent on the continent. Organizations can boost aspects such as employee sense of purpose or ability for employees to connect with colleagues in addition to traditional value drivers such as salary or benefits rewards.

Finally, there is a need to develop a robust end-to-end pipeline to attract youth into vaccine related careers and ensure sufficient full time sustainable industry positions. From an early age, young people need to be made aware of vaccine career opportunities and relevant education paths. This can include awareness or recruiting campaigns that bring speakers from industry into local schools, government support or sponsorship of vaccine career paths (such as via scholarships) or other programs to inform youth.

It will be important to consider all relevant labor policies, educational policies, or other relevant policies when setting up training or talent development programs across the continent.

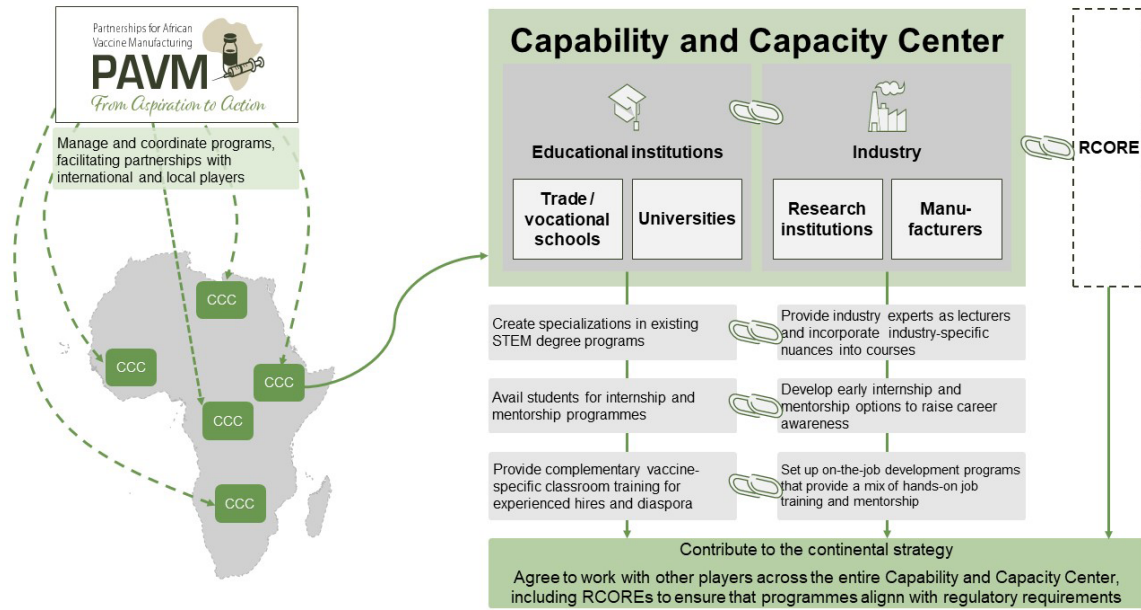
As these initiatives are ramped up on the continent, there is a need to consider immediate solutions for talent gaps. In particular, there is an opportunity to leverage international expertise or talent to fill gaps and train workers in the immediate term (e.g., Clinical Research Organizations, MNCs). In the long term, these international partnerships can continue to support talent development where no local training programs exist (for example, talent exchange programs and knowledge transfers).

## Looking forward

PAVM will play a critical role in the Capability and Capacity Centers by coordinating across the regional centers. Each center will be composed of educational institutions and industry players. The regional centers would each be affiliated with an RCOE and leverage virtual connections to ensure collaboration with regional R&D centers, the Technology and IP Enablement Unit, and so on. PAVM would manage CCC program requirements, coordinate funding, support matching talent with capability gaps, and serve as a networking and communication platform.

To participate in a regional CCC, players will need to demonstrate a clear commitment to contribute to the broader Continental Strategy (Exhibit 35).

Exhibit 35: Overview of Regional Capability and Capacity Centres



1. Includes industries such as other pharmaceuticals, cosmetics, medical diagnostics, etc.

The CCCs will connect educational institutions with industry to enhance educational programs and create internships and on-the-job development programs. Educational institution participants could include both universities as well as other post-high school options such as vocational schools or trade schools (where relevant). Industry players will include both manufacturing facilities and R&D institutions.

To participate, educational institutions and manufacturing facilities will need to meet certain criteria. For example, educational institutions will be expected to help customize existing courses and degree programs to increase industry relevance. They will also help by providing access to relevant talent pools for industry players as well as providing supplemental classroom instruction for industry training programs like apprenticeships.

Industry players will provide support by providing expertise to integrate into degree program coursework and industry experts as occasional lecturers. Industry players will also host shorter internships programs and longer on the job development programs. These programs will change based on industry and role (e.g., post-doc programs for PhD students entering research institutions vs. apprenticeships for vaccine plant operator roles). These programs can be hosted in-person or virtually based on the training required (e.g., likely in-person programs required for many plant roles as well as lab roles).

Both educational institutions and industry players will need to contribute to pipeline development activities such as campaigns to raise awareness for vaccine-related careers with youth and strong pathways from high school through to full time roles. Industry players should help ensure candidates entering training programs have sustainable, long terms roles to move into. This can include ensuring strong diversity, equity, and inclusion across the end to end talent development pipeline when recruiting and advocating for vaccine-related programs and roles<sup>47</sup>.

Finally, the CCCs can support the establishment of international and global partnerships. These partnerships can help fill short term and immediate talent needs with expatriate talent or diaspora. They can also support longer term talent exchange programs or other training programs that complement local programs, such as specialized areas not offered locally.

47 PAVM and the CCCs can help launch campaigns and programs targeted at vaccine career awareness and track the progress and impact of each program



Centres can help tailor development programs to different roles and education levels. For example, PhD candidates could access longer on-the-job programs with reduced classroom training while shorter apprenticeships with a larger classroom component would be better suited to manufacturing operator roles (Exhibit 36, additional detail in appendix).

*Exhibit 36: Potential talent development programs*

Potential programs (for R&D or manufacturing)	Description	Candidates
Internships	Short-term (3 – 12 months) with job exposure (e.g., mentorship, light hands-on work, etc.)	Current students (bachelors+)
<b>On the job development</b> - apprenticeship (limited post-secondary education)	~2-year program, ~50/50 classroom learning with hands-on job training	High school graduates, vocational or trade school graduates or bachelors graduates (not students)
<b>On the job development</b> (post-secondary education) or post-doctoral fellowships	Longer term (3+ years) with ~10/90 split between classroom learning & mentorship/job training	Bachelors+ graduates (not students); For R&D roles this would be post-doctoral fellowships programs
<b>On the job development</b> (re-skilling of experienced hires)	Longer term (3+ years) with ~20/80 split between classroom learning & mentorship/job training	Diaspora or locals with experience in vaccines or related industries (such as pharma or cosmetics)
<b>STEM degree specialization</b>	100% classroom instruction in educational institutions	Current students (likely in pre-existing STEM programs)
<b>Note that implementation of programs will require consideration of local labor, education, and other relevant policies</b>		

The CCCs can help vaccine-related organizations build a differentiated employee value proposition to increase talent and reduce brain drain.

A successful CCC will require key enablers including:

- Clear understanding of existing talent and talent needs, such as robust data collection and management.
- Robust marketing campaigns to raise awareness and engage students sooner than the final year of education
- Robust value proposition for all program participants including students, educational institutions, and industry
- Sustainable funding year over year
- Program champions at participating institutions to ensure buy-in and support
- Standardization of program experiences (potentially including salary and benefits)

## High-level implementation plan

A few key activities could support operationalization of the CCCs over the next 20 years:

### Over the next year (2022)

Over the next year, programs for the CCCs should be defined, and requirements established for all CCC participants (educational institutions and industry). Two CCC networks could then be set up in areas with existing industry, research, and educational institution presence. Through these CCC networks, pilot internships and on-the-job development programs could be launched for COVID-19 manufacturing and mRNA technologies, which constitute the immediate need.

Building off the pilot experience, a model with CCC participants could be defined for broader internship, on-the-job development, and degree-specialization programs.

In addition to setting up and launching the first Capability and Capacity Centers, partnerships should be set up with global and international organizations for immediate talent training. These organizations can support the training of talent and providing expertise while local programs scale. Additionally, the CCCs should launch recruiting campaigns targeted at the diaspora to begin to raise awareness of future career opportunities that can bring talent back onto the continent.

### In the medium term (2023 to 2025)

In the medium term, internship, on-the-job development, and degree programs could be launched and scaled for the two established CCC networks, and the three remaining CCC networks could be set up. Processes should have been set up to onboard additional participants to each regional CCC at this point, and a playbook developed to support industry players in retaining talent as it exits CCC programs. Finally, recruiting of members of the diaspora and other experienced hires can be ramped up across the continent and globally.

### In the medium to long term (2026 to 2040)

In the medium to long term, mechanisms should have been put in place to track program success and refine playbooks and requirements for internships, apprentices, and degree specializations. Additional CCC members should also have been onboarded to each regional network.

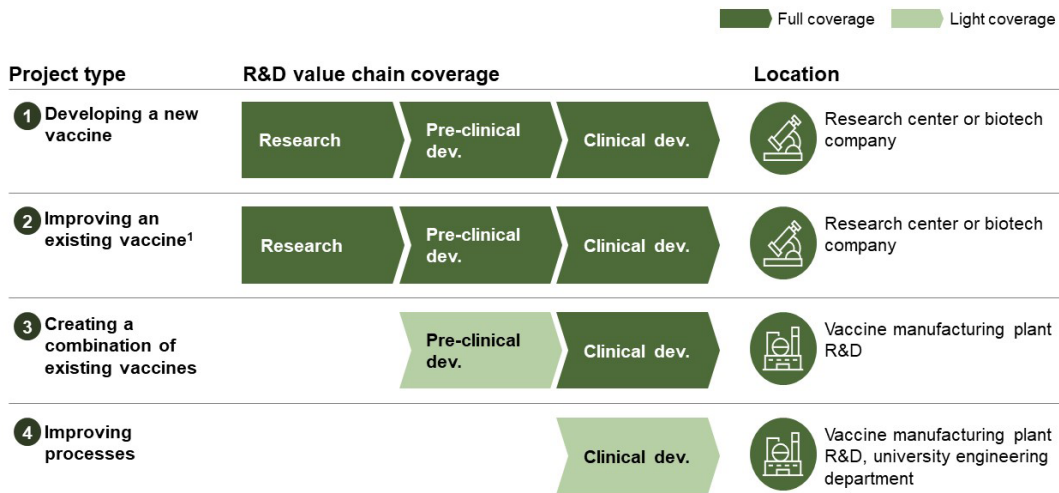
## Program 6: Putting in place vaccine research and development centres and a research and development coordinating platform

### Context and challenge

To expand R&D across the continent by 2040, capacity needs to increase across research, pre-clinical development, and clinical development. This will enable the improvement of existing vaccines, the development of new vaccines, the creation of new combinations of vaccines, and process improvement.

Not all types of vaccine R&D will be conducted in research centres or biotechnology centres. Activities like process improvement could take place at vaccine manufacturing facilities. Additionally, private sector organizations like Clinical Research Organizations (CROs) can support critical R&D activities such as regulatory documentation or compliance. Different R&D projects require different capabilities and leverage different stages of the R&D value chain, as explained below (Exhibit 37).

Exhibit 37: Overview of R&D project categories



1. Defined as improving a vaccine where the same technology will be used; If a new technology will be used, it is categorized as developing a new vaccine

As R&D scales, research priorities for the continent will be based on five key principles:

- To pay attention to both routine vaccines and future emergency vaccines.
- To focus R&D activities on under-developed vaccines presenting substantial potential for the African continent.
- To account for disease priority as indicated by other leading health organizations (such as the WHO or the Coalition for Epidemic Preparedness Innovations [CEPI]).
- Where possible, to tap into existing technology expertise across the continent.
- To consider prioritizing some technologies for focus across diseases.

R&D priorities can include the improvement of existing vaccines prioritized for manufacturing (tuberculosis vaccines, for example), the development of new vaccines prioritized for manufacturing (HIV vaccines, for instance), as well as other potential Africa-specific priorities (such as respiratory syncytial virus [RSV]). With regards to manufacturing, R&D will be required for at least five diseases targeted for 2040 manufacturing, as no vaccines currently exist. In addition to these target activities, R&D on the continent should also aim to bridge studies of special populations such as pregnant women, dose fractionation studies, real-world effectiveness studies, and phase IV post-licensing adverse event monitoring studies, among others.

Exhibit 38: Potential R&D priority diseases – subject to change

**PRELIMINARY SET OF PRIORITY DISEASES - SUBJECT TO CHANGE** ■ Required to meet manufacturing goal as no vaccine exists ✓ Yes ✗ No

Archetype	Potential R&D diseases	Prioritized for 2040 manufacturing	Does a vaccine exist?	R&D need
Legacy	Hepatitis B, Diphtheria, Tetanus, Whooping Cough	✓	✓	Create a new combination
	Tuberculosis	✓	✓	Develop a new vaccine
Expanding	Malaria	✓	✓	Develop a new vaccine
	HIV	✓	✗	Develop a new vaccine
Outbreak	Ebola	✓	✓	Monitor/improve an existing vaccine
	Influenza	✓	✓	Develop a new vaccine
	Chikungunya	✓	✗	Develop a new vaccine
	Rift Valley fever	✓	✗	Develop a new vaccine
	Lassa fever	✓	✗	Develop a new vaccine
	Disease X	✓	✗	Develop a new vaccine
Next generation <sup>1</sup>	RSV	✗	✗	Develop a new vaccine
	GBS	✗	✗	Develop a new vaccine
	Multi-drug antibiotic resistant bacteria	✗	✗	Develop a new vaccine

1. Currently not part of the prioritized list of 22 vaccines for manufacturing

Currently, capacity and appropriate infrastructure are limited at several stages of the R&D process (such as the lack of cGMP batch manufacturing for clinical trials or limited pre-clinical capacity). There are three main challenges hindering Africa’s R&D efforts to transition to a fully-integrated R&D value chain:

- **Funding model is not directed to Africa**—local research centres can’t access funds going to more developed regions or attract local funding.
- **Lack of sufficient and appropriate R&D infrastructure**—research centres and biotechnology companies don’t have the infrastructure to advance and/or commercialize projects.
- **Lack of existing networks and expertise**—expertise is spread across the continent, so research players lack partnerships or know-how to advance projects.

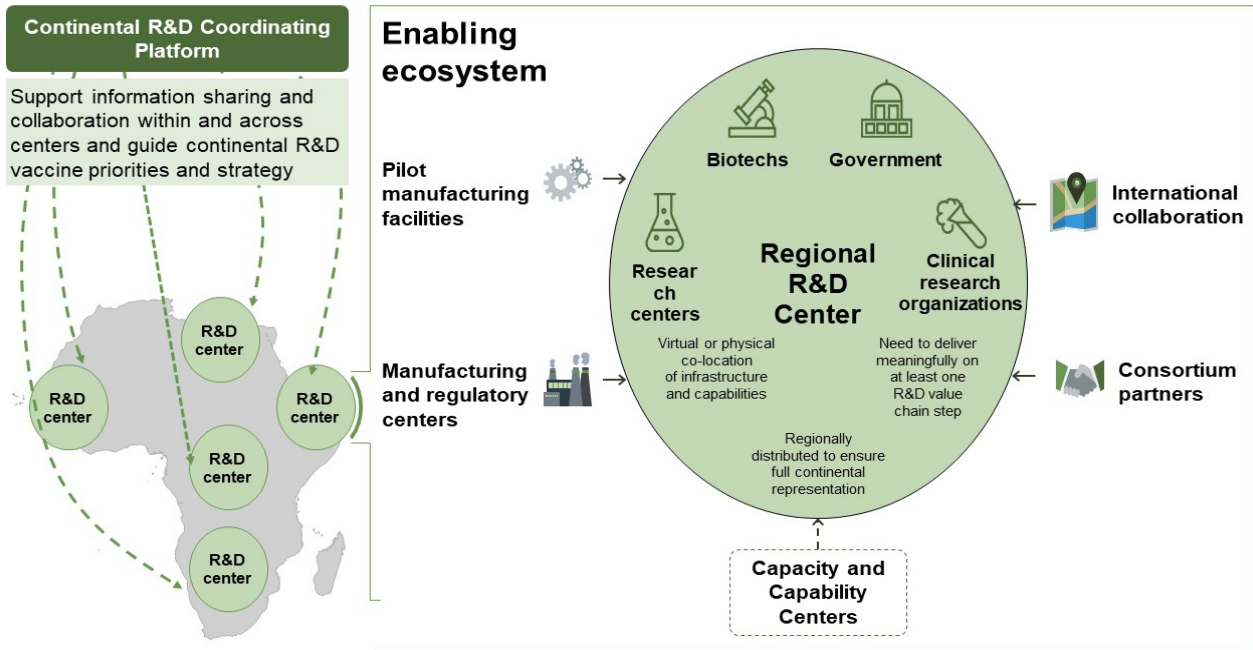
## Strategic directions

R&D capacity challenges can be addressed by launching three key initiatives:

- Setting up regional R&D centres.
- Developing an R&D coordinating platform across the continent.
- Establishing pilot cGMP batch manufacturing facilities.

R&D centres will consolidate regional infrastructure, capacity, and expertise across a given segment (for example, pre-clinical versus. clinical) of the R&D value chain. These centres will include research institutes, biotechnology companies, government organizations and Clinical Research Organizations (CROs). Consolidation can be accomplished via virtual networks across countries in a given region (without full physical co-location); see Exhibit 39.

Exhibit 39: Overview of structure of R&D coordinating platform and R&D centres



R&D centres will be established based on key criteria including talent access such as nearby universities and international talent exchange potential, existing R&D infrastructure (whether co-located in one center or available via partnerships with neighboring countries), conducive NRA and government environment including buy-in and government financial support and existing value chain network including access to up-stream and down-stream value chain providers. For efficacy trials, clinical sites will need to be located where a disease is present, but this is not a driving criterion for overall R&D center location. These centres will foster the strengthening of R&D assets and infrastructure across the continent, such as by building up research institutes within academic organizations and strengthening review and approval boards.

In addition to R&D centres, a continental R&D coordinating platform can be set up to orchestrate R&D across the continent. The platform will help to:

- Guide continental R&D vaccine priorities and strategy
- Support information sharing and collaboration across regions and countries including developing crucial support services for scientists (e.g., training in submitting competitive funding applications)
- Develop partnerships with both local and international organizations and connect knowledge enablers across the continent
- Bring together scientists and expertise across the continent to share progress and learning regularly (for example, via regular continental conferences)
- Promote the scale-up of critical infrastructure and networks including local animal study facilities and CROs

Finally, to connect pre-clinical research through to clinical trials, at least one cGMP- batch-manufacturing pilot facility should be implemented on the continent. Pilot facilities should be set up according to continental need for clinical trial batch-production capabilities.

## Looking forward

Regional R&D centres and cGMP-manufacturing pilot facilities will be connected in a continental network orchestrated by the R&D coordinating platform:

- Responsibilities and critical priorities can flow from a continental level down to individual regional centres to ensure sufficient hub autonomy while maintaining the ability to deliver on the Continental Strategy.
- The platform can be a pathway for collaboration between researchers, centres, and experts to move vaccine products rapidly through the R&D pipeline.
- The R&D platform could attract and funnel funding to regional centres according to continental priorities.
- Representatives from each regional R&D center will participate in and contribute to the continental R&D platform.

Establishing a continental coordinating body will unlock key benefits including enhanced ease of setting and maintaining a continental strategy, increased opportunity for collaboration across the continent, increased access to funding channels for individual research bodies and a stronger value proposition for external organization collaboration due to continental scale of R&D infrastructure.

To build a successful center and attract investors, an ecosystem with strong performance across key enablers, including funding, access to infrastructure, a relevant talent pool, and a network of stakeholders and expertise, is required.

In addition to R&D centres and the continental coordinating platform, there are key interdependencies across other workstreams, including the need for a R&D funding forum, supported by PAVM fundraising.

## High-level implementation plan

A few key activities could support operationalization of the R&D centres over the next 20 years:

### Over the next year (2022)

Over the next year, top R&D center candidates could be identified in each region, in collaboration with Regional Economic Communities and country governments. From identified candidates, top pre-clinical R&D centres could then be funded and implementation launched. While local R&D capabilities scale, there may be opportunity to encourage international CROs to set up African subsidiaries to support research on the continent. To support set-up of the centres, the R&D coordinating platform should be established, and an implementation plan developed for cGMP-batch-manufacturing pilot plants (for instance, plant size, potential locations, consideration of existing plans for plants, and required technology transfers). Finally, a continental R&D conference could be hosted within the year, to aggregate key players on the continent to share an update on scientific achievements taking place on the continent and ongoing efforts towards boosting R&D with a global audience.

### In the medium term (2023 to 2025)

In the medium term, R&D pre-clinical centres can be scaled up and can progress towards Good Laboratory Practice compliance. R&D clinical centres will be funded and implemented. International partners or industry partners can be identifying for clinical centres to leverage while pre-clinical centres continue to scale. In parallel, pilot manufacturing facilities can be implemented to support ongoing R&D activities. Finally, the R&D coordinating platform should be scaled to include full R&D center representation and additional stakeholders, with mechanisms set up to establish, evaluate and monitor R&D priorities.

### In the medium to long term (2026 to 2040)

















In the medium to long term, pilot manufacturing facilities for R&D should be operating at full capacity, and clinical R&D centres scaled so that the majority of clinical trials on the continent are conducted on vaccines where pre-clinical development was performed regionally.

## Program 7: Undertaking advocacy for enabling trade policies for vaccines

### Context and challenge

To localize vaccine manufacturing, both physical and intangible infrastructure must be improved. The upstream (prior to manufacturing), manufacturing itself, and downstream (post-manufacturing) steps (detailed in Exhibit 40) of the value chain need to be upgraded.

Exhibit 40: Value chain infrastructure requirements

	Value chain requirement	Components
 <b>Physical infrastructure</b>	<b>Upstream utility inputs to the industry</b>	<ul style="list-style-type: none"> <li> Stable electricity supply</li> <li> Stable clean water supply</li> <li> Sewage and effluents treatment capacity</li> </ul>
	<b>Downstream transport and storage of finished goods</b>	<ul style="list-style-type: none"> <li> Reliable basic logistics capacity (road, rail, port, airport)</li> <li> Cold chain equipment for storage between production site and port-of-entry of buyer country, or network for stockpiling and redistribution</li> <li> ICT infrastructure to enable distribution, including temperature recording, vaccine track and trace, and equipment monitoring and communication.</li> </ul>
 <b>Manufacturing infrastructure</b>	<b>Additional production facilities required to meet future demand</b>	<ul style="list-style-type: none"> <li> Facilities, including land and buildings</li> <li> Availability of general and specialized equipment</li> <li> Specialized utility needs, including purified water, pharma waste treatment, compressed air, and steam</li> </ul>
 <b>Intangible infrastructure and enablers</b>	<b>Upstream trade and industrial policy to support imports</b>	<ul style="list-style-type: none"> <li> Favorable trade policy to enable import of raw material and inputs (API, glassware, solvents, etc.) and specialized equipment</li> </ul>
	<b>Downstream trade policy to enable intra-continental distribution, storage, and exports</b>	<ul style="list-style-type: none"> <li> Favorable trade policy to encourage manufacture and export of vaccine products</li> <li> Ratified regional and continental trade agreements to enable free movement of finished products</li> <li> Clear trade rules to avoid trade bans and nationalism regarding health goods</li> </ul>

Despite some variation between frontrunner countries, upstream and downstream infrastructure is generally unreliable, existing manufacturing infrastructure is limited, and cross-country trade enablement is also weak. A high-level view of this is illustrated in Exhibit 41.












Exhibit 41: Assessment of infrastructure in regions

			Region: West South East North Central				
			Frontrunners: Ghana, Nigeria, Senegal, Cote d'Ivoire, Angola, Botswana, South Africa, Ethiopia, Kenya, Rwanda, Tanzania, Uganda, Algeria, Egypt, Morocco, Tunisia, Cameroon				
	Requirement from the industry	Challenges					
Physical infrastructure upstream and downstream	Upstream: Sufficient and reliable utilities including electricity, water and sewage treatment	Despite some outliers, supply and electricity costs lag aspirational and emerging benchmarks	●	●	●	●	●
		Water supply reliability scores are low compared to vaccine manufacturing benchmark countries	●	●	●	●	●
	Downstream: Cost-competitive, effective and cold-chain capable logistic networks	Most countries face challenges in infrastructure for at least one mode of transport	●	●	●	●	●
		Intra-African exports are limited by low internal transport capacities and high cost of transport	●	●	●	●	●
		Limited integrated monitoring of national cold-chain logistic infrastructure capacity and readiness	●	●	●	●	●
	ICT access in most countries on par with global benchmark averages with some exceptions	●	●	●	●	●	
Manufacturing infrastructure	Additional production facilities required to meet future demand	Limited number of vaccine manufacturing companies in Africa, most are focused on downstream value-chain steps	●	●	●	●	●
Intangible infrastructure and enablers	Upstream: Favorable industrial policy to support and encourage imports of raw material / equipment	A vast majority of African countries exempt Vx products from import tariffs but taxation policy is not targeted at Vx manufacture or related pharma and R&D inputs	●	●	●	●	●
			●	●	●	●	●
	Downstream: Trade policy to enable intra-continental distribution, storage and exports	Countries have promoted export through favourable industrial policy, indirectly supporting local production of Vx	●	●	●	●	●
		Despite multiple regional and continental free-trade agreements, trade integration remains limited	●	●	●	●	●
	Risk remains of local protectionist measures hampering regional outbreak response	●	●	●	●	●	

- Trade incentive policy varies significantly across regions and the risk of trade restrictions during outbreaks remains.
- Despite multiple free-trade agreements, Africa remains very fragmented, as trade integration is low across the continent. The reliability of water and electricity supply lags behind aspirational and emerging country benchmarks, particularly in East, West and Central Africa; many countries operate with the dual challenge of expensive and unreliable electricity.
- Intra-African exports are limited by low internal transport capacities and the high cost of transport.
  - Most frontrunner countries lag behind in air, land and sea logistics indexes.
  - Cold chain monitoring and readiness is low. High level details of cold chain requirements are included in the Appendix.
- Existing manufacturing operations are limited to six countries and predominantly focus on F&F.
  - A range of existing and emerging projects form the basis for future manufacturing operations, displayed in Exhibit 42



Exhibit 42: Existing and emerging manufacturing operations

Manufacturing maturity level	Country	Current value chain	Vaccine product	Planned and potential vaccine manufacturing
<b>Existing</b> Member states with existing DS or F&F <sup>1</sup> capacity and in the process of enhancing it	<b>Tunisia</b> 	Drug substance	BCG	Potential production of COVID-19 in cooperation with Chinese and Russian Pharmacos announced after clinical trials
	<b>Senegal</b> 	Drug substance	Yellow Fever	Plans initiated to expand capacity through development of a new plant (~30 million doses p.a.) with some interest in expanding to other products
	<b>South Africa</b> 	Fill and finish	BCG, Measles, Pneumococcus, Hexavalent, DTP, Polio, Hib and HepB	Biovac partnership with Pfizer for Fill and Finish of COVID-19 vaccine Aspen partnership with J&J for Fill and Finish of COVID-19 vaccine
	<b>Egypt</b> 	Fill and finish, packaging	Various	Announced manufacturing of coronavirus vaccine in cooperation with the Chinese government
	<b>Ethiopia</b> 	Packaging, import	Some production of Rabies vaccine (legacy Fermi tech)	Nascent plans to produce other vaccines but portfolio is not yet announced
<b>Engaged</b> Have engaged in talks with international partners to establish DS or F&F capacity	<b>Morocco</b> 	Import for distribution	Various	PPP incl. China National Biotec Group (CNBG) for COVID-19 vaccine at Sothema By 2023, agreement with Recipharm for production of multiple vaccines at new facility Beyond 2025, establishment of biopharma hub
	<b>Algeria</b> 	Import for distribution	Various	Announced planned production of Sinovac and Sputnik V COVID-19 vaccines
	<b>Ghana</b> 	N/A	Potential for COVID-19	Announced preliminary plans to produce COVID-19 vaccines in potential partnership with Merck NRA is ML3 certified
	<b>Nigeria</b> 	N/A	Potential for COVID-19, EPI, routine vaccines	Plans to produce a range of EPI products Bio vaccines recently signed an MOU to manufacture COVID-19 vaccines Some MNC/DCVM partnerships discussed for routine products
	<b>Uganda</b> 	N/A	Potential for COVID-19 mRNA	Announced planned mRNA facility
	<b>Rwanda</b> 	N/A	Potential for COVID-19 mRNA	Announced association with BioNTech for potential mRNA facility

Source: M4A, Linksbridge GVMM, World Bank, BMI, expert interviews, press search

## Strategic directions

PAVM will adopt the role of advocate, focusing primarily on enabling trade policies for vaccine manufacturing and trade through ACFTA. In addition to this, PAVM will support partners' advocacy efforts related to infrastructure and manufacturing technology initiatives.

Advocacy efforts to improve trade policies will involve steering conversations to ensure trade policy within regions and member states enables local vaccine manufacture in four ways:

- While most countries exempt raw inputs of vaccine manufacture from import duties, there is potential to expand exemptions to cover all pharmaceutical and R&D inputs.
- Trade and industrial policy benefitting exporters should be harmonized and targeted at vaccine manufacturers.
  - Coordinating terms between pharma parks, industrial parks, or special economic zones (SEZs) would further harmonize policy at the continental level. The differences in terms across countries is illustrated in Exhibit 43.

Exhibit 43: Summary of trade and industrial policies

### Summary of trade and industrial policies

Harmonization potential ■ Significant ■ Moderate

NOT EXHAUSTIVE, CURRENT AS OF NOVEMBER 2020

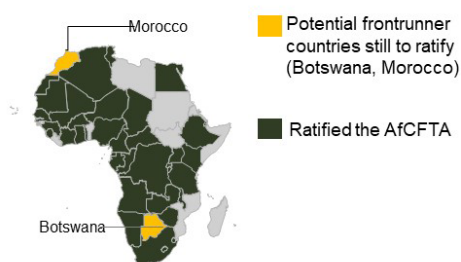
Region	Country	General corporate income tax rate, %	SEZ, Industrial Parks, or Free Trade zones?	Tax holiday <sup>1</sup> (years)
North	Algeria	23	✓	5
	Egypt	22.5	✓	Varies
	Tunisia	25	✗	10
	Morocco	31	✓	5
East	Kenya	30	✓	10
	Ethiopia	30	✓	10-15
	Rwanda	30	✓	Indefinite
	Uganda	35	✓	10
West	Senegal	25	✓	Partial
	Nigeria	30	✓	Partial
	Ghana	25	✓	10
South	South Africa	28	✓	Partial
Central	Cameroon	33	✓	10

1. Tax holidays for qualifying manufacture

Source: KPMG Africa Incentive Survey 2016, 2019; ITC Market Access Map; Oxford Business Group, PWC "Navigating Taxation" country-specific reports (2019), Deloitte 2020 tax highlights reports

- All potential frontrunner countries will need to ratify and implement key trade agreements like the AfCFTA to facilitate intra-continental vaccine distribution. Exhibit 44 shows that many have already done so, in whole or in part, but more need to follow to create the right free trade framework that will open the door to efficient country-to-country distribution.

Exhibit 44: Status of AfCFTA agreement



#### AfCFTA<sup>1</sup> Background

Brings together all 55 member states of the African Union, covering a market of more than 1.3 billion people and potentially creating the largest Free Trade Area in the world

Entered into force on 30 May 2019

41 countries have both signed and ratified the AfCFTA Agreement

38 countries that had deposited their instruments of ratification<sup>2</sup>

Agreement began on 1 January 2021

1. Agreement Establishing the African Continental Free Trade Area  
2. As at 10 September 2021

Source: World Bank, Press search

#### Objectives

Create a single continental market for goods and services, with free movement of business persons and investments

Enhance the competitiveness of the economies of State Parties within the continent and the global market

Promote industrial development through diversification and regional value chain development

Accelerate the establishment of the Continental Customs Union

Harmonize and coordinate trade liberalization and facilitation and instruments across the RECs

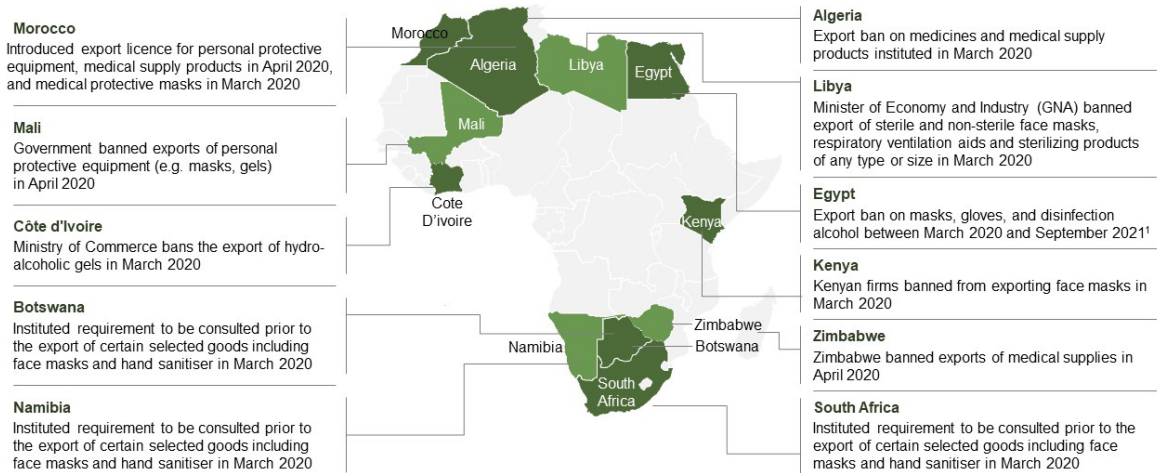
- Additional measures will be required to prevent trade restrictions during outbreaks (examples of which are detailed in Exhibit 45), while balancing the ability of member states to prioritize sovereign health security.

Exhibit 45: Temporary restrictions enforced during the COVID-19 pandemic

### Countries that enforced temporary trade restrictions during the COVID-19 pandemic

March 2020 – September 2021

■ Frontrunner country imposing restriction ■ Country imposing restriction



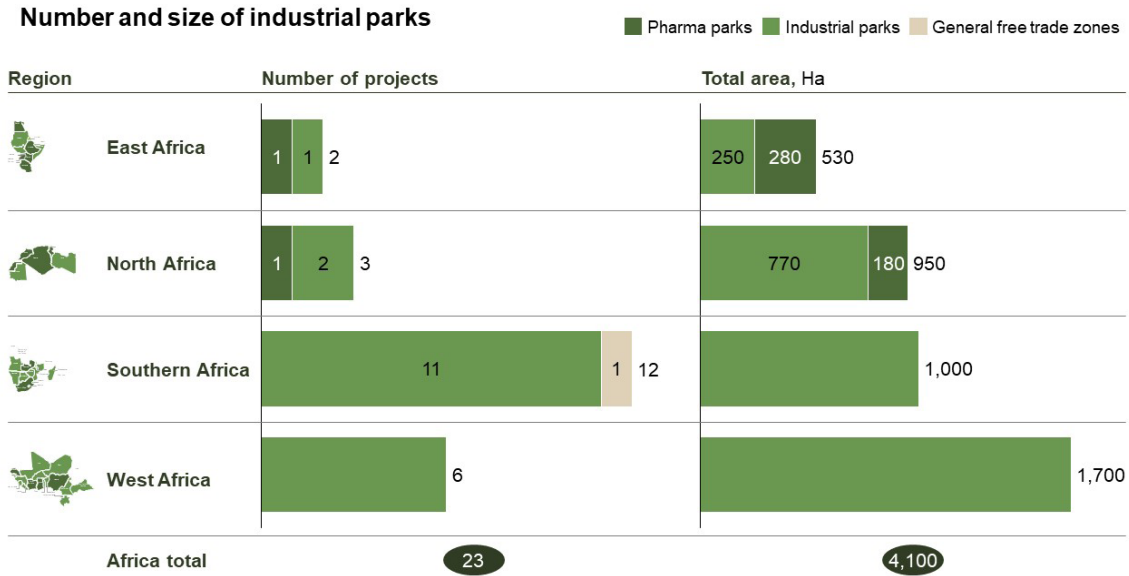
1. While announcing trade restrictions on exports, Egypt donated PPE equipment to various African countries during this period  
Source: ITC Market Access MAP – Covid-19 Temporary Trade Measures (as at August 2021)

PAVM will also advocate for the acceleration of existing infrastructure initiatives by other entities, including the pipeline of mega-projects serving frontrunner countries that might indirectly support the vaccine industry:

- Approximately 20 key industrial and pharma-park projects with high-quality, dedicated public supply of utilities (water, electricity, and waste management), dedicated distribution networks and ports, and favorable trade incentives directly targeted at vaccine manufacture.<sup>48</sup>
  - Though all regions contain industrial parks, only East and North Africa contain pharma-specific parks with dedicated utilities and distribution infrastructure.
  - While most parks surveyed (shown in Exhibit 46) provide independent utility infrastructure, capacity rarely exceeded basic backup requirements.

48 Information obtained from "Programme for infrastructure development in Africa," African World Development Bank, <https://www.afdb.org/en/topics-and-sectors/initiatives-partnerships/programme-for-infrastructure-development-in-africa-pida>; Infrastructure Projects Analytics Tool, IPAT

Exhibit 46: Status of industrial parks



Source: PIDA, IPAT - Infrastructure Projects Analytics Tool, Expert interviews, Press search

- Approximately 120 logistics infrastructure projects (summarized in Exhibit 47) aimed at improving rail, air, and road networks.<sup>49</sup>

Most logistics projects by number and value involve improving rail logistics, though frontrunners lagged behind benchmark countries across all modes of transport.

However, air transport is expected to be critical to vaccine distribution and investment is comparatively low.

Exhibit 47: Status of mega-projects

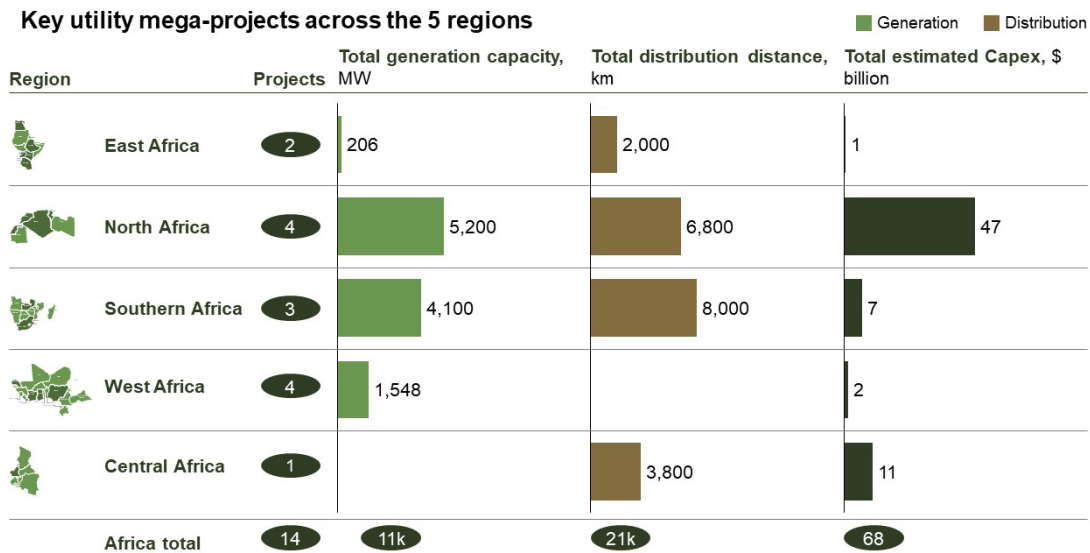


Source: PIDA, IPAT - Infrastructure Projects Analytics Tool, Expert interviews, Press search

49 Information from Programme for Infrastructure Development in Africa, <https://www.afdb.org/en/topics-and-sectors/initiatives-partnerships/programme-for-infrastructure-development-in-africa-pida>;

- Approximately ten electricity utility projects (summarized in Exhibit 48) aimed at creating an estimated 11 GW of generation capacity and covering 17,000 km of distribution.<sup>50</sup>
  - All regions are investing significantly in key infrastructure improvement projects.
  - However, most energy-improvement initiatives are focused in North and Southern Africa, regions which were also the most mature compared to benchmarks (Exhibit 48).

Exhibit 48: Key utility mega projects










Source: PIDA, IPAT - Infrastructure Projects Analytics Tool, Expert interviews, Press search

Furthermore, PAVM will advocate for the consideration of technologies that have the potential to accelerate the expansion of manufacturing and distribution capacity, examples of which are shown in Exhibit 49:

- Micro-facilities using modular cleanroom technology could reduce costs and facility footprints.
  - Many innovative companies have already made an impact and continue to show potential across the vaccine value chain.
  - With the right infrastructure, Africa too could host some innovative companies pushing the boundaries of vaccine research.

50 Information obtained from PIDA; IPAT: expert interviews; and press search.

Exhibit 49: Example innovations

Example innovation	High-level overview of innovative tech	Cleanroom technology	Relevant vaccine technology	Potential impact (self-reported, may not be independently verified)
 Univercells/ Omnivax	Modular 1000sqm micro-facility aimed to be deployed locally, quickly, and inexpensively for viral vaccine production	 BATAVIA  Omnivax cleanroom	Inactivated polio vaccine (sIPV) – 40 million doses	<ul style="list-style-type: none"> <li>• 20 – 36 times higher-yield bioreactor vs microcarriers</li> <li>• 3 - 4 times smaller footprint facility</li> <li>• Targeted 80% reduction in Capex over traditional technologies</li> </ul>
 Just Evotec Bio- therapeutics	Modular micro-facility using continuous manufacturing and modular clean-rooms to reduce costs and accelerate antibody production	 G-CON Pod	COVID-19 antibodies	<ul style="list-style-type: none"> <li>• 10 – 30 times reduction in cost of antibody production (target \$10/g)</li> <li>• 19 month construction compared to 4+ years for conventional plant</li> </ul>
 Cytiva FlexFactory	Custom designed biomanufacturing platform for general biological applications	 Cytiva KuBio3	Monoclonal Antibodies, mRNA	<ul style="list-style-type: none"> <li>• 30% reduced footprint</li> <li>• 48% less Capex than stainless steel</li> <li>• 2 day changeover between mAbs</li> </ul>
<b>BioNTech Marburg mRNA</b>	Compact plant in Marburg utilizing mRNA technology platform		mRNA	<ul style="list-style-type: none"> <li>• Compact 1,8k sqm vs. ~90k sqm for traditional facilities</li> <li>• Accelerated set-up time (~10-12 weeks, not ~12 months) and reduced capital costs</li> </ul>
<b>Single-use technologies</b>	Processing using disposable materials (e.g. bags, filters)		Various	<ul style="list-style-type: none"> <li>• Filling time reduced 30-50%</li> <li>• Less than six months to commission equipment</li> </ul>

End-to-end bulk manufacturing technologies address multiple processing steps of DS manufacturing with continuous processes, and complete redesign of process and new platforms address complete vaccine platform

Source: BMGF study on disruptive technologies, Expert interviews, company websites, scientific literature Pardi, N., Hogan, M. J., Porter, F. W., & Weissman, D. (2018). mRNA vaccines—a new era in vaccinology. *Nature reviews Drug discovery*, 17(4), 261.

- Innovative cold-chain solutions, focusing on different value chain steps and vaccine archetypes, could expand capacity and capabilities.
  - Different vaccine archetypes determine the correct cold-chain capacity approaches to use.
  - Capacity in chilled and frozen distribution, along with incremental deep-frozen storage, can expand with the right combination of physical infrastructure.

## Looking forward

Several essential infrastructure elements need to move forward in parallel to support the expansion of African vaccine manufacturing.

Furthermore, investments in both upstream and downstream infrastructure must not only continue but also accelerate. As these tasks are addressed hand-in-hand, regional facilities can progressively begin to operate and provide reliable and sustainable vaccine supply to the continent.

## Program 8: Ensuring an effective continental strategy for delivery and oversight









Implementing this strategy will require several parallel programs and supporting initiatives. These include the consolidation and oversight of ongoing vaccine manufacturing projects, the creation and maintenance of investment relationships, fundraising initiatives towards vaccine ecosystem enablers, the streamlining of existing and proposed capability and capacity centres, and advocacy for supportive policies across the ecosystem.

A coordination mechanism is required to set the strategic direction of manufacturing activities on the continent, ensure ambitions between key players are aligned, and monitor, track, and report implementation progress. This coordination mechanism could help overcome challenges within the current vaccine manufacturing industry such as fragmentation in the ecosystem, poor coordination of activities, and disproportionate focus on COVID-19 vaccine manufacture in the short-term and insufficient focus on DS manufacturing and R&D overall, among others. PAVM will take on this role by mobilizing the local and global vaccine ecosystem to support delivery of the continental strategy.

In addition, vaccine manufacturing ecosystem enablers have historically been underfunded because it has been hard to tie them directly to specific manufacturing projects. Fundraising initiatives in line with the FFA strategy can bridge that gap with clear programs aligned with financiers and coordinated by the PAVM Secretariat. As shown in Exhibit 50 below, funding could be focused around two key areas: capacity building through CCCs for manufacturers, academic institutions, R&D centres, RCOREs and NRAs and R&D for pre-clinical and clinical trials. The total funding required for these enablers would be approximately \$10 billion over the next 20 years.

Exhibit 50: Fundraising needs for ecosystem enablers

**PRELIMINARY**

Fundraising focus	Beneficiaries	Funding needs	Likely funders	
<b>Capacity building through CCCs</b>	 Manufacturers	Reskilling and upskilling FTEs for manufacturing plants	↑ Donors DFIs Governments Philanthropists Manufacturers ↓	Vaccine manufacturing ecosystem enablers have historically been <b>under-funded</b> , largely because these enablers <b>cannot be directly tied to a specific manufacturing project</b>
	 Academic institutions	Set-up of vaccine capacity building programs in institutions		
	 R&D Centres	Reskilling and upskilling FTEs for R&D Institutions		
	 RCOREs	Capacity building for regulators		
	 NRAs	Capacity building for regulators		
<b>Research and development</b>	<b>Regional R&amp;D centres</b>			PAVM will play a <b>coordinating role</b> ensuring financing enablers through programs structured in alignment with financiers
	 Research Institutions	Funding for pre-clinical and clinical R&D trials	Governments Donors	
	 Pilot plants	Funding for set-up of pilot plants needed for R&D testing	Governments Manufacturers	
	 Biotechs	Funding for pre-clinical and clinical R&D trials	Donors DFIs	

Prior to implementation, some key design decisions will need to be made, firstly around the fundraising model to be used, and secondly on how funds will be disbursed.

Fundraising initiatives can either take the form of a database of financiers that PAVM builds, maintains, and shares with potential beneficiaries; vetting of beneficiaries by PAVM to identify funding-ready projects for financiers to consider; or annual fundraising goals set by PAVM to operationalize FFA programs in R&D and capacity building by actively approaching financiers.

Disbursement of funds can then occur either directly from financiers to beneficiaries or can be channeled to PAVM and redistributed thereafter. Several configurations are available for PAVM’s involvement, all leading to constructive solutions.

### Implementing the FFA

All eight programs defined in the FFA will be implemented across the continent. This will be accomplished via phasing key activities across the immediate term, short term, medium term and long term to have full implementation and scale by 2040. In the next year, the focus will be on immediate ‘quick wins’ such as accelerating completion of in-progress projects across the continent (primarily COVID-19 focused) and developing a baseline for scale-up of other priority vaccines. Each of the bold program implementation bodies will also be set up and detailed implementation strategies and initiatives defined. In the short term, focus will be on piloting key initiatives for each of the 8 programs and adapting implementation design based on lessons learned. The medium to long term will focus on scaling up all FFA program initiatives as well as regional manufacturing to achieve the continental strategy by 2040.

A number of quick-win activities over the next year (2022) were identified that aim to address the urgent need to produce vaccines for the ongoing COVID-19 pandemic, while also building off vaccine production momentum from COVID-19 production to establish and operationalize the FFA. Progress in the short term could be monitored against the milestones given in Exhibit 51.

Exhibit 51: Short term milestones

◆ COVID-19 related

Program	Key milestones Q1	2022			
		Q1	Q2	Q3	Q4
<b>Program 1: Creating an African vaccines procurement pooling mechanism</b>	AVATT mandate extended beyond COVID-19; several countries committed to purchasing first batch of locally produced vaccines		◆		
	Offtake guarantees provided by AVATT for COVID-19 vaccine manufacturers		◆		
<b>Program 2: Establishing a vaccine manufacturing deal preparation and financing facility</b>	Vaccine manufacturing deal preparation facility design and set-up completed			◆	
	Deal preparation facilities provided to at least 5 vaccine manufacturing deals on the continent				◆
<b>Program 3: Strengthening NRAs and RCOEs to build vaccine regulatory excellence</b>	Critical processes for vaccine manufacturing harmonized and EUA <sup>51</sup> approval given for outbreak vaccines			◆	
	Countries with COVID-19 vaccine production in 2022 obtaining WHO prequalification emergency use listing which can be achieved through ML3 of NRA or collaborative AMA / AMRH coordinated process of ML3/4 NRAs on the continent			◆	
	Adoption of joint regulatory review for clinical trial approval and joint inspection of manufacturing facilities			◆	
	A control lab network established and lab strengthening done, allowing certified labs to perform analytical tests required for lot release of vaccines produced in Africa			◆	
	At least 1 NRA with vaccine regulatory skills present in each region <sup>52</sup>				◆
<b>Program 4: Supporting technology transfer through an intellectual property enablement unit</b>	Enablement unit established, with several countries participating			◆	
	Potential tech transfer collaborators identified and introduced to the Enablement Unit <sup>53</sup>			◆	
	Tech transfer facilitated for planned COVID-19 DS production				◆
	At least 3 tech transfers facilitated in total				◆

51 Emergency Use Authorization

52 Alternatively, an agreement to leverage capacity of another NRA has been reached

53 Recipients should meet the requirements of being “tech-ready”



Program	Key milestones Q1	2022			
		Q1	Q2	Q3	Q4
<b>Program 5: Creating Regional Capability and Capacity Centres</b>	CCC programs launched, focused on mRNA technologies (incl. COVID-19)			▲	
	~1-3 at-scale international/global partnerships established to support immediate talent needs				▲
	~2 CCC networks set up				▲
<b>Program 6: Putting in place vaccine R&amp;D centres and an R&amp;D coordinating unit</b>	R&D coordinating platform launched; proposal process defined for identifying R&D centres			▲	
<b>Program 7: Undertaking advocacy for enabling trade policies for vaccines</b>	Agreement reached on having no trade restrictions for outbreak vaccines (incl. COVID-19)			▲	
	All AU countries signed-on and ratified the AFCFTA				▲
<b>Program 8: Ensuring effective continental strategy delivery and oversight</b>	PMO fully staffed with required capacity		▲		
	Alignment reached on tech. platforms to prioritize initial vaccine manufacturing		▲		
	Set-up complete of 3-4 announced COVID-19 vaccine plants <sup>54</sup>				▲

To monitor progress of the end to end FFA implementation in both the short and long term, 15 Key Performance Indicators (KPIs) were defined across each of the programs, which will track the overall objective of each of the programs (Table 3).

Table 3: Program KPIs

Program	KPIs
<b>Program 1: Creating an African vaccines procurement pooling mechanism</b>	<ol style="list-style-type: none"> <li>1. Share of target value of vaccines procured for Africa</li> <li>2. Share of target volume of vaccines procured for Africa</li> <li>3. Percentage of total AVATT vaccine procurement purchased from local manufacturers</li> </ol>
<b>Program 2: Establishing a vaccine manufacturing deal preparation and financing facility</b>	<ol style="list-style-type: none"> <li>4. Percentage of all local vaccine manufacturing projects funded and operationalized</li> </ol>
<b>Program 3: Strengthening NRAs and RCOREs to build vaccine regulatory excellence</b>	<ol style="list-style-type: none"> <li>5. Percentage of vaccine products approved through reliance on and collaborative reviews by an ML3 NRA</li> <li>6. Number of countries able to approve outbreak vaccine within target number of days through an ML3 NRA</li> <li>7. Number of NRAs that have reached ML3 for vaccines</li> </ol>
<b>Program 4: Supporting technology transfer through an intellectual property enablement unit</b>	<ol style="list-style-type: none"> <li>8. Share of target technology transfers (for both DS and F&amp;F) to African manufacturers completed</li> </ol>
<b>Program 5: Creating Regional Capability and Capacity Centres</b>	<ol style="list-style-type: none"> <li>9. Share of target number of graduates from regional CCCs</li> </ol>

<sup>54</sup> Includes the following plants that have been announced: BioNtech COVID-19 (Rwanda), Vacsera COVID-19 (Egypt), Aspen Pharmacare COVID-19 (SA), Biovac Institute COVID-19 (SA)

<b>Program 6: Putting in place vaccine R&amp;D centres and an R&amp;D coordinating unit</b>	10. Percentage of new vaccines developed from target R&D priorities with some local involvement <sup>55</sup> 11. Total number of pre-clinical and clinical trials publications towards the Continental Strategy target
<b>Program 7: Undertaking advocacy for enabling trade policies for vaccines</b>	12. Share of AU countries that have ratified key trade agreements (e.g., AfCFTA)
<b>Program 8: Ensuring effective continental strategy delivery and oversight</b>	13. Percentage of total vaccine demand in Africa produced on the continent 14. Share of priority technology platforms and vaccine products localized on the continent 15. Share of total plant target (integrated and F&F only) established on the continent

Preliminary targets were set across each of these KPIs (Trade 4), though these will continue to be refined.

Table 4: Preliminary targets for objective-tracking KPIs for FFA programs

Workstream	KPI	KPI targets		
		Short term (2023-25)	Medium term (2026-30)	Long term (2031-40)
Market design and demand intelligence	Share of target value of vaccines procured for Africa achieved	TBD	TBD	TBD
	Share of target volume of vaccines procured for Africa achieved	35%	75%	100%
	Percentage of total AVATT vaccine procurement purchased from local manufacturers	TBD	TBD	TBD
Access to finance	Percentage of vaccine projects funded and operationalized (from idea to operations)	25%	50%	50%
Regulatory strengthening	Percentage of vaccine products approved through reliance on and collaborative reviews by an ML3 NRA	25%	50%	80%
	Number of countries able to approve outbreak vaccine within target number of days through an ML3 NRA <sup>56</sup>	All countries with COVID-19 vaccine producing capabilities	At least 1 in each region, and a total of 17 across the continent	3-5 in each region
	Number of NRAs that have reached ML3 for vaccines	5	10	>10
Technology transfer and IP	Share of target tech transfers (for both DS and F&F) to African manufacturers completed <sup>57</sup>	35%	85%	100%

55 At least one stage of R&D (research, pre-clinical or clinical) took place locally on the continent

56 Regular approval is 60 days, expedited approval 30 days, and 15 days for emergency approval (outbreak vaccine)

57 Based on number of additional plants required as per Continental Strategy, considering both acceleration of ongoing tech transfers and support for new tech transfers. Successfully completed indicates that project evaluation has been completed

Workstream	KPI	KPI targets		
		Short term (2023-25)	Medium term (2026-30)	Long term (2031-40)
<b>R&amp;D and talent development</b>	Percentage of new vaccines developed with some local involvement, from target R&D diseases	15% (2 new vaccines total)	38% (5 new vaccines total)	54% (7 new vaccines total)
	Total number of pre-clinical and clinical trials publications towards Continental Strategy target	>60 per year	>80 per year	>100 per year
	Share of target number of graduates from regional CCCs achieved	35% (~4.5K)	90% (~11.5K)	100% (~12.5K)
<b>Infrastructure development</b>	Share of AU countries that have ratified key trade agreements (e.g., AfCFTA)	100%	100%	100%
<b>Agenda setting and coordination</b>	Percentage of total vaccine demand in Africa produced on the continent	10%	30%	60%
	Share of priority technology platforms and vaccine products localized on the continent	60%	90%	100%
	Share of total planned and new plant target (both integrated and F&F only) established on the continent	35%	85%	100%

While these KPIs will track progress against key objectives of each program, they will be supplemented by a more robust set of input, output and outcome indicators, which are detailed in the Appendix (section 8) for each of the FFA programs.

**These milestones and KPIs will serve as an initial high-level guide but significant work is still required to develop a detailed implementation plan. Moving into implementation of the Framework for Action will require first ensuring alignment and agreement on the strategic direction and then launching a second phase of detailed implementation planning.**

## Future-proofing the FFA

Beyond these immediate initiatives to put in place, further analysis will be needed, and initiatives adopted, to future-proof the vaccine industry on the continent, ensuring it remains dynamic and forward-looking. Examples include:

- **Increasing preparedness for pandemics and outbreaks.** Pandemics and outbreak diseases are inevitable, and have the potential to claim millions of lives, disrupt societies, and economies. Increasing financial and technical support towards pandemic or outbreak preparedness (for example, by expanding local manufacturing capabilities, and increasing research on emerging and under-developed diseases) could help minimize the adverse impacts of these.
- **Adopting a one-health approach** by increasing coordination between human, animal, and environmental health experts would help adopt the best vaccine solutions for increasingly integrated ecosystems (for instance, by increasing preparedness and response to zoonotic diseases).
- **Rapidly adopting new vaccine products, technologies, and processes,** which would help ensure the most effective vaccines are being produced efficiently and cost-competitively on the continent.
- **Strengthening vaccine-adjacent industries** (such as diagnostics and adjuvants), which could help improve the effectiveness of vaccine planning and administering. This analysis will also

expose what opportunities exist for countries not directly involved in manufacturing but that stand to benefit from adjacencies, such as supporting industries that provide raw materials, including active ingredients for the different types of vaccines, inactive ingredients (like acids, concentrates and other excipients), and consumables (including vials, sterile bottles, syringes, rubber stoppers).

- **Developing raw material and input suppliers on the continent** to support the expanding DS-manufacturing capacity in a sustainable way.
- **Enhancing intra-continental vaccine distribution capabilities** (e.g., lyophilization capabilities in manufacturers) to ensure sufficient downstream distribution and storage capabilities across the continent

In addition, the case for public investment and subsidy will benefit from further study of the positive socio-economic impact of a local vaccine manufacturing industry in Africa, particularly with regards to changes in individual purchasing power, employment levels, education uptakes, and opportunities for women, for example.

The FFA should be considered a living and dynamic document, and any additional insights and recommendations from these analyses, as well as other updates that may emerge because of the dynamic nature of the industry, will continue to be syndicated, incorporated into the FFA and adopted for implementation.

## VI. Conclusion

The pandemic crisis has demonstrated the risk of relying on external suppliers for vaccines. Building a sustainable vaccine manufacturing industry in Africa will increase its independence, drive economic development, and strengthen its health security. However, it will also require complex coordination of multiple stakeholder groups at a continental scale, all aligned towards a single strategic goal: to produce and supply 60 percent of the total vaccine doses required by the continent by 2040.

This is an ambitious vision. It needs the right support to succeed. Although program has gained momentum thanks to multi-lateral bodies , African leaders now need to accelerate it. The unified strategy to deliver this vision must be championed by all stakeholders. Private and public sector players need to drive this change with concrete commitments and tangible support. Achieving large scale vaccine manufacturing on the continent is far from easy, but it is within reach, as long as the key actors of this industry deliver on promises made and work together to continue to deliver towards 2040.

**The work has begun, but there is still significant work ahead of us.** Let's join in this journey to realise this vision together.

## VII. Appendices

Appendices provided in a separate document

1. PAVM workstreams and governance
2. Demand sizing methodology
3. FTE sizing methodology
4. Plant sizing methodology
5. Cost estimation methodology
6. Technology transfer sizing methodology
7. Disease selection methodology
8. KPIs to track implementation
9. GDP benefit methodology
10. Talent development programs
11. Cold chain considerations
12. Sources and contributors

## VIII. Abbreviations

ADR	Adverse drug reaction
AfCFTA	African Continental Free Trade Area
Africa CDC	African Centres for Disease Control and Prevention
AMA	Africa Medicines Agency
AMRH	Africa Medicines Regulatory Harmonization Program
AMSP	Africa Medical Supply Platform
APC	Advance Procurement commitments
AU	African Union
AUC	African Union Commission
AVAREF	Africa Vaccines Regulatory Form
AVAT	African Vaccine Acquisition Trust
AVATT	African Vaccine Acquisition Task Team
CCC	Capability and Capacity Center
CEPI	Coalition for Epidemic Preparedness Innovation
cGMP	Current good manufacturing practice
CT	Clinical trial
DCVM	Developing Countries Vaccine Manufacturer
DFID	UK Department for International Development
DS	Drug substance
FFA	Framework for Action
FTE	Full-time equivalent
F&F	Fill and finish
Gavi	Global Alliance for Vaccines and Immunization
GBT	Global Benchmarking Tool
GNI	Gross National Income
HCPs	Healthcare providers
ICSR	Individual case safety report
IDP	Institutional Development Plan
IP	Intellectual property
IPR	Intellectual property right
LR	Lot release

LT	Laboratory testing
ML	Maturity Level
MNC	Multinational corporation
MPP	Medicines patent pool
MS	Market surveillance and control
MSAT	Manufacturing science and technology
NRA	National Regulatory Authority
PAVM	Partnerships for African Vaccine Manufacturing
PAHO	Pan American Health Organization
PAP	Pan-African Parliament
PEPFAR	President’s Emergency Plan for AIDS Relief
PMO	Project management office
PMPA	Pharmaceutical Manufacturing Plan for Africa
PPB	Pharmacy and Poisons Board
PQ	Prequalification
PV	Pharmacovigilance
QA	Quality assurance
QC	Quality control
RCORE	Regional Centres of Regulatory Excellence
REC	Regional Economic Communities
RSV	Respiratory syncytial virus
R&D	Research and development
Vx	Vaccine
VLP	Virus-like-particles
WACC	Weighted Average Cost Capital
WB	World Bank
WHO PQ	World Health Organization prequalification



## IX. Exhibits and tables

Exhibit 1: Possible strategic pathways for delivering the FFA.....	11
Exhibit 2: Cost of delivering the FFA.....	12
Exhibit 3: Eight bold FFA programs.....	13
Exhibit 4: Stakeholders involved in delivering the FFA.....	14
Exhibit 5: FFA key milestones in 2022.....	21
Exhibit 6: Key timelines for set-up and operationalization of PAVM and FFA.....	30
Exhibit 7: PAVM Advisory Group .....	31
Exhibit 8: GDP impact of increasing continental vaccine manufacturing capacity.....	35
Exhibit 9: Africa’s position in the vaccine maturity curve.....	36
Exhibit 10: BRIC countries approaches to scaling vaccine manufacturing.....	37
Exhibit 11: 22 diseases prioritized for the FFA .....	40
Exhibit 12: Technology mix required by 2040 (by volume) for 22 priority diseases .....	40
Exhibit 13: Value chain focus for each of the 22 priority diseases .....	41
Exhibit 14: Overall summary of the disease, technology, and value chain focus of the continental strategy.....	42
Exhibit 15: DS capacity required on the continent to achieve the ambition.....	43
Exhibit 16: F&F capacity required on the continent to achieve the ambition.....	44
Exhibit 17: Cost of delivering the FFA.....	45
Exhibit 18: Eight bold FFA programs.....	47
Exhibit 19: Overall model projections (value).....	53
Exhibit 20: Regional projections: East and West Africa could comprise up to ~50 percent of market value on the continent, driven by population size.....	53
Exhibit 21: Estimates of the share of the African market that may be financially supported by Gavi over time .....	54
Exhibit 22: Overview of pooled procurement mechanism .....	57
Exhibit 23: Potential risks and mitigating factors .....	59
Exhibit 24: Scaling of AVATT/AVAT will leverage a tailored approach based on country and product strategy.....	60
Exhibit 25: Examples of financial tools and mechanisms .....	63
Exhibit 26: Design features of the vaccine manufacturing deal preparation and financing facility.....	66
Exhibit 27: Additional support required for key challenges .....	70
Exhibit 28: Key initiatives focused on regulatory strengthening .....	70
Exhibit 29: Programs and initiatives to strengthen regulatory capacity.....	72

Exhibit 30: Technology transfers initiated on the continent before and after 2020 .....	75
Exhibit 31: Typical steps and stakeholders for each transfer step activity .....	76
Exhibit 32: Four primary roles of the Vaccine Technology Transfer & IP Enablement Unit .....	78
Exhibit 33: Research and manufacturing talent required to support the 2040 vaccine ambition ..	82
Exhibit 34: Degree breakdown for required vaccine manufacturing talent .....	83
Exhibit 35: Overview of Regional Capability and Capacity Centres .....	85
Exhibit 36: Potential talent development programs .....	87
Exhibit 37: Overview of R&D project categories .....	89
Exhibit 38: Potential R&D priority diseases – subject to change .....	90
Exhibit 39: Overview of structure of R&D coordinating platform and R&D centres .....	91
Exhibit 40: Value chain infrastructure requirements .....	93
Exhibit 41: Assessment of infrastructure in regions .....	94
Exhibit 42: Existing and emerging manufacturing operations .....	95
Exhibit 43: Summary of trade and industrial policies .....	96
Exhibit 44: Status of AfCFTA agreement .....	96
Exhibit 45: Temporary restrictions enforced during the COVID-19 pandemic .....	97
Exhibit 46: Status of industrial parks .....	98
Exhibit 47: Status of mega-projects .....	99
Exhibit 48: Key utility mega projects .....	100
Exhibit 49: Example innovations .....	101
Exhibit 50: Fundraising needs for ecosystem enablers .....	102
Exhibit 51: Short term milestones .....	103
Table 1: KPIs to track overall objectives of each FFA program .....	22
Table 2: Preliminary targets for objective-tracking KPIs for FFA programs .....	22
Table 3: Program KPIs .....	105
Table 4: Preliminary targets for objective-tracking KPIs for FFA programs .....	106



[www.au.int](http://www.au.int)

