



# Partnerships for African Vaccine Manufacturing

*Meeting: Enhancing the sustainability of Investment for vaccine manufacturing in Africa*

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# There are clear social and economic benefits in investing in African health products and technologies



Improve **health security** and capacity for emergency response

**Reducing reliance on imports** to enable greater responsiveness to endemic and pandemic diseases, as well as **addressing Africa-specific disease burden and context** (such as Ebola virus, HIV/AIDS, Tuberculosis)



Improve **regulatory harmonization** between countries to **facilitate trade**

**Developing regional congruency and collaboration by relying on key bodies** (such as the Africa Regulatory Taskforce (ART) which will accelerate ongoing regional harmonization initiatives, and elevating the maturity levels of National Regulatory Authorities (NRAs)



Elevate **technological expertise and capabilities**

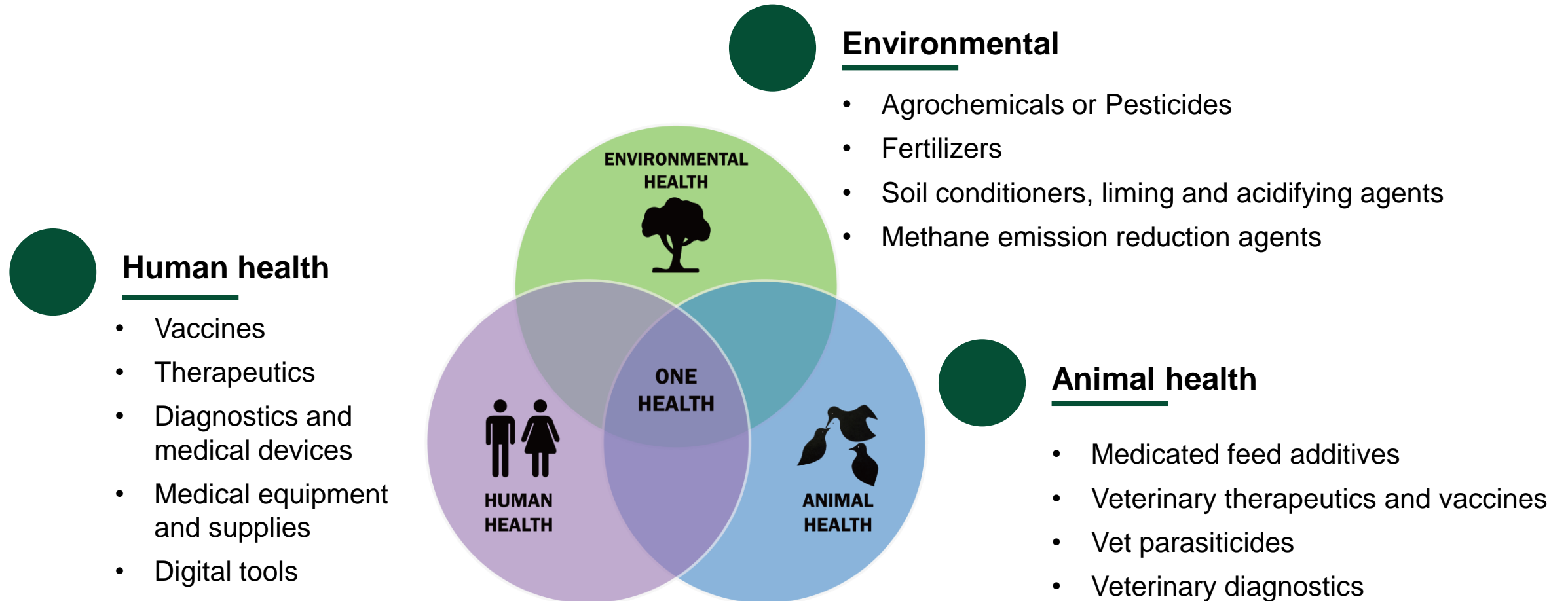
**Stimulating investment in R&D** (currently <2% of global R&D projects in Africa), **technological development and upskilling NRAs** as well as promoting scientific research and demand for high-quality technical jobs



**Facilitate economic growth**

**Increasing manufacturing market in Africa** which will generate substantial economic impact through job creation, increasing investments and intracontinental trade

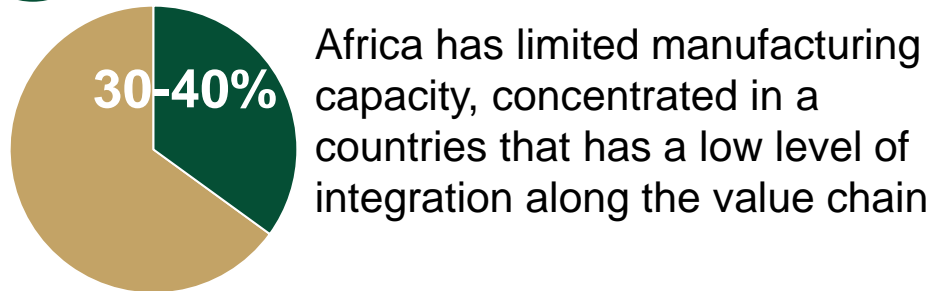
# Local manufacturing as an enabler of both health and food security



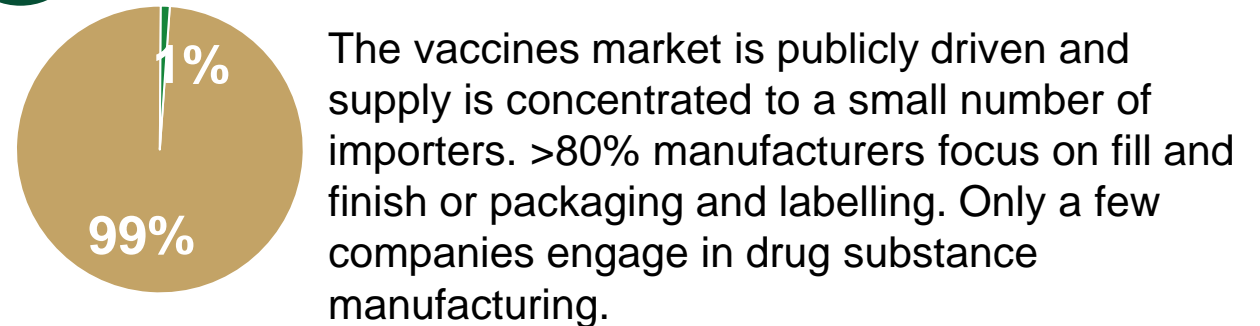
# Situation today: Health product and technology manufacturing in Africa, beyond Vx, is still very nascent

■ Imports ■ Local

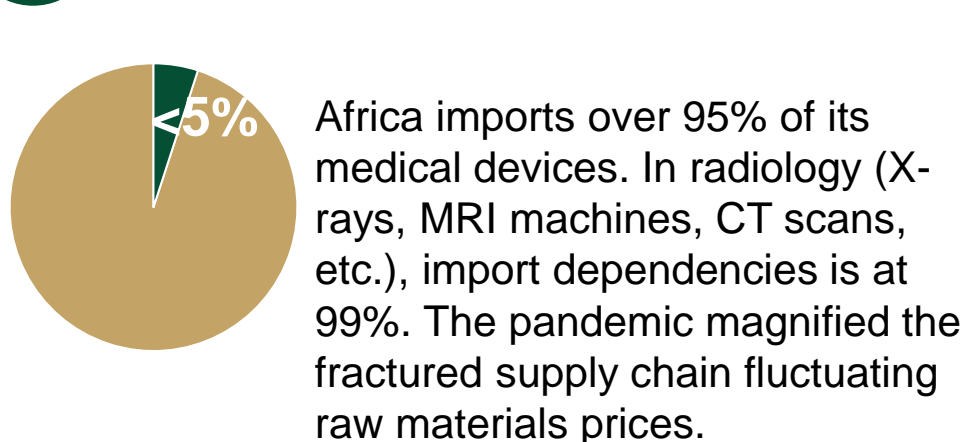
## Therapeutics



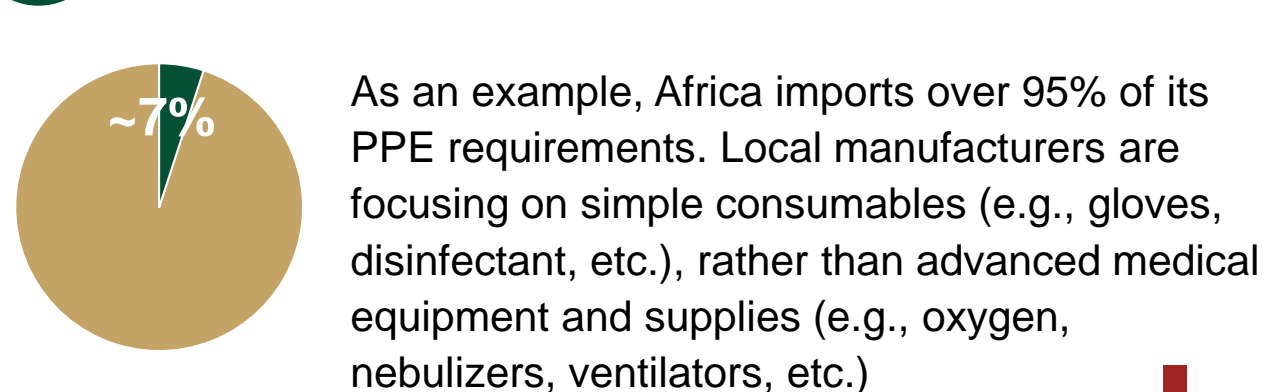
## Vaccines



## Diagnostics and medical devices



## Medical equipment and supplies



# The AU has set a goal for 60% of vaccines administered in Africa to be produced on the continent by 2040 in line with the New Public Health Order

## Context



The African Union calls for a New **Public Health Order** aimed at safeguarding the health and economic security of the continent

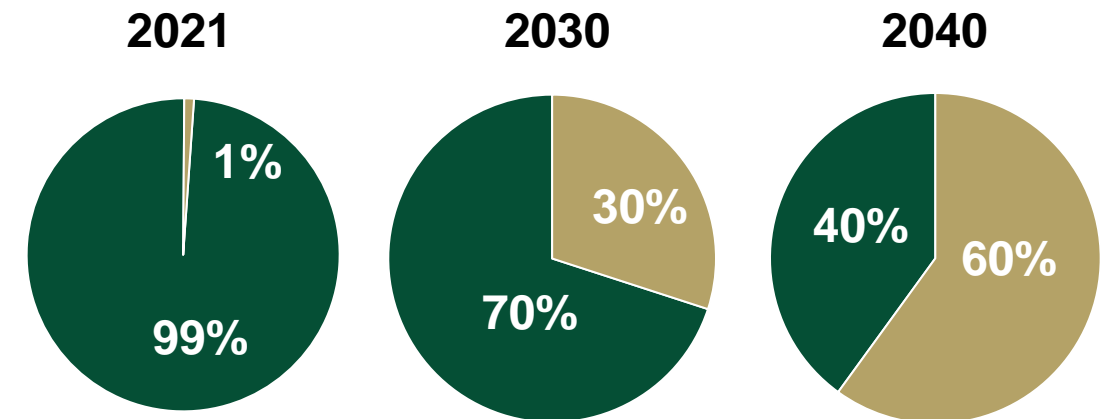
*“Africa’s challenges during the COVID-19 pandemic in securing timely access to tests, therapeutics, and vaccines, have served as a constant reminder that we need to be doing things for ourselves...”*

*H.E. President Paul Kagame,  
Rwanda*

## Ambition



Local Imported



The African Union has set a goal to **increase vaccine manufacturing on the African continent to meet 60% of the demand by 2040** and mandated the Partnerships for African Vaccine Manufacturing (PAVM) to **develop a framework for action to execute this**

# The PAVM was established under the Africa CDC with four objectives



## PAVM's four broad objectives



**Steward a continental strategy** that maintains scale and cost-competitiveness of local manufacturing and promotes equity and security for all



Support partnerships to **create a conducive business environment** that will encourage the emergence of a thriving manufacturing base



Play **intermediary and partner role between Member States and the global community of supporters** on an as-needed basis



Communicate updates and serve as the **central source of information for Africa Vx manufacturing**

# PAVM developed a continental strategy outlining the priority areas for local vaccine manufacturing

## 1 Potential disease prioritization



### Prioritized 22 diseases<sup>1</sup>...

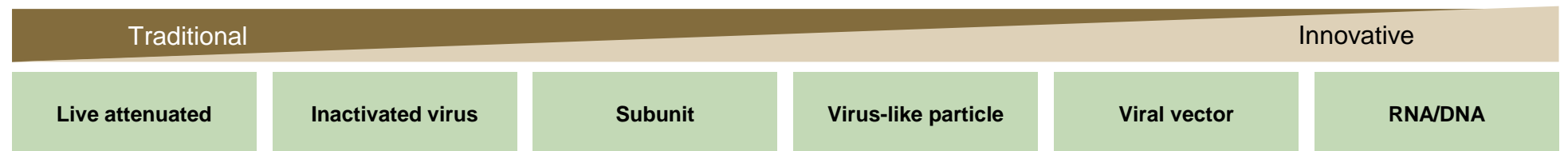
Vaccine exists     Vaccine does not yet exist

Legacy				Expanding		Outbreak	
Diphtheria	Hepatitis B	Measles	Meningococcal	HPV	Pneumococcal	Ebola	Influenza
Whooping Cough	Yellow fever	Typhoid fever		HIV	COVID-19	Chikungunya	Lassa fever
Tetanus	Tuberculosis	Cholera		Malaria	Rotavirus	Rift valley fever	Disease X

## 2 Technology focus



### ... requiring a breadth of technology platforms...



## 3 Potential value chain focus



### ... along the different steps of the value chain

#### Fill & Finish (F&F)

Fill & finish for all priority vaccines, enabling achievement of local production targets. Due to vaccine and modality agnostic nature, single plants could produce multiple vaccines, allowing for production of higher volumes that could lead to economies of scale, creating potential for Africa to become cost-effective against other DCVMs

#### Drug Substance (DS)

Expand drug substance mostly in established platforms where tech transfers are readily available; manufacturing will require developing a local raw materials industry

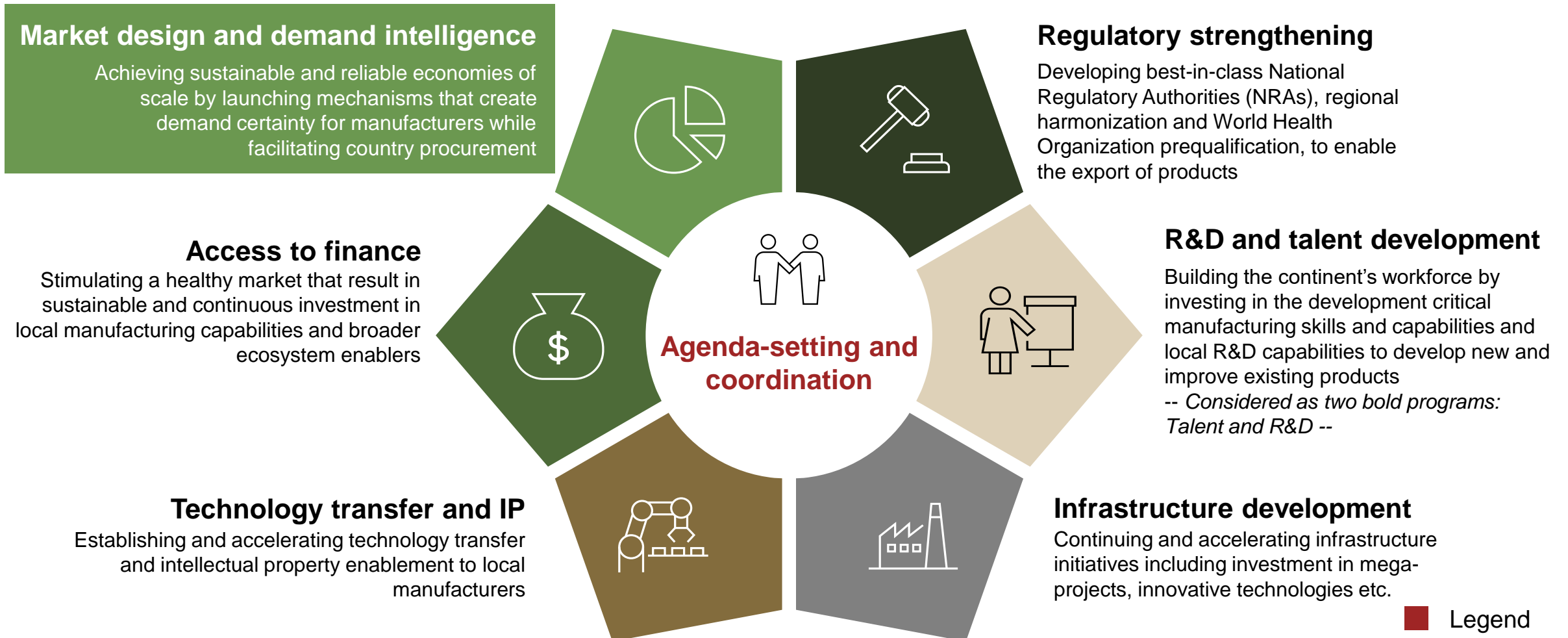
#### R&D

Expand R&D activities to develop new vaccines for Africa, support more efficient manufacturing and improve vaccine characteristics

1. The list will evolve over time based on ongoing scientific findings

# The PAVM has defined 8 bold programs to support the vaccine manufacturing ecosystem and continental strategy

 Potential key focus of support





# Over the course of 2021-2022, PAVM has played a strong role in driving stakeholder engagement, and ecosystem convening and coordination

NOT EXHAUSTIVE



The PAVM was approved by AU Executive Council



FFA has been endorsed by AU member states at the Heads of State Assembly

Many implementation lead organisations for FFA bold programs identified



Market Intelligence and Demand Workshop organized for stakeholders to establish a vaccine procurement architecture for the continent

May 2021

November 2021

6-7 December

February 2022

March 2022

June 2022

Operationalised the PAVM, setting up a task force of 7 workstreams consisting >60 members which hosted >30 hours of workshops and >100 hours of working sessions



Hosted a successful Stakeholder Engagement Event in Kigali where significant decisions were made on the FFA bold programs



Project Management Office (PMO) to oversee implementation of FFA set up



# ...this progress has continued into 2023, with PAVM hosting and participating in engagements with stakeholders

IPD, Africa CDC & SAMRC co-hosted a workshop on biomanufacturing workforce development, discussing the creation of a sustainable ecosystem for talent development in Africa



Feb 2023

PAVM convened Secretariat members, technical advisors and partners in Kigali, Rwanda to set aspirations for 2023, define successes and reassess its operating model and partner collaboration structure



April 2023

Africa CDC PAVM Forum

April 2023



Africa CDC participated in the Africa Health Agenda International Conference (AHAIC), engaging in the dialogue and action aimed at mainstreaming climate discourse into health policy conversations, and vice versa



Africa CDC participated in the World Vaccine Congress USA in Washington DC, USA, and showcased Africa CDC's initiatives contributing to the vaccine value chain through its exhibit booth



# Significant investment has already been made to develop the vaccine manufacturing ecosystem in Africa

NOT EXHAUSTIVE

**African Development Bank committed to investing ~\$3Bn** in Africa's pharmaceutical industry over 10 years

**Kenyan government finalizes an agreement with Moderna to establish the first mRNA vaccine manufacturing facility in Africa.** Moderna is expected to invest about \$500 Mn in the Kenyan facility and supply 500 Mn doses of mRNA vaccines to the continent each year

**2023: Egypt's MoH launched the 1<sup>st</sup> production line of hepatitis B and pentavalent (five-in-one) vaccines,** with the capacity to produce 100 Mn vaccines annually, as part of a collaboration between Egypt's VACSERA and the Serum Institute of India

2021

**South Africa established the first mRNA Vaccine technology transfer hub in Africa.** The objective of the technology transfer hub is to build capacity in LMC to produce mRNA vaccines through a center of excellence and training. The Hub has a 5-year budget of 92 Mn Euros (approximately 52 Mn Euro have been raised)

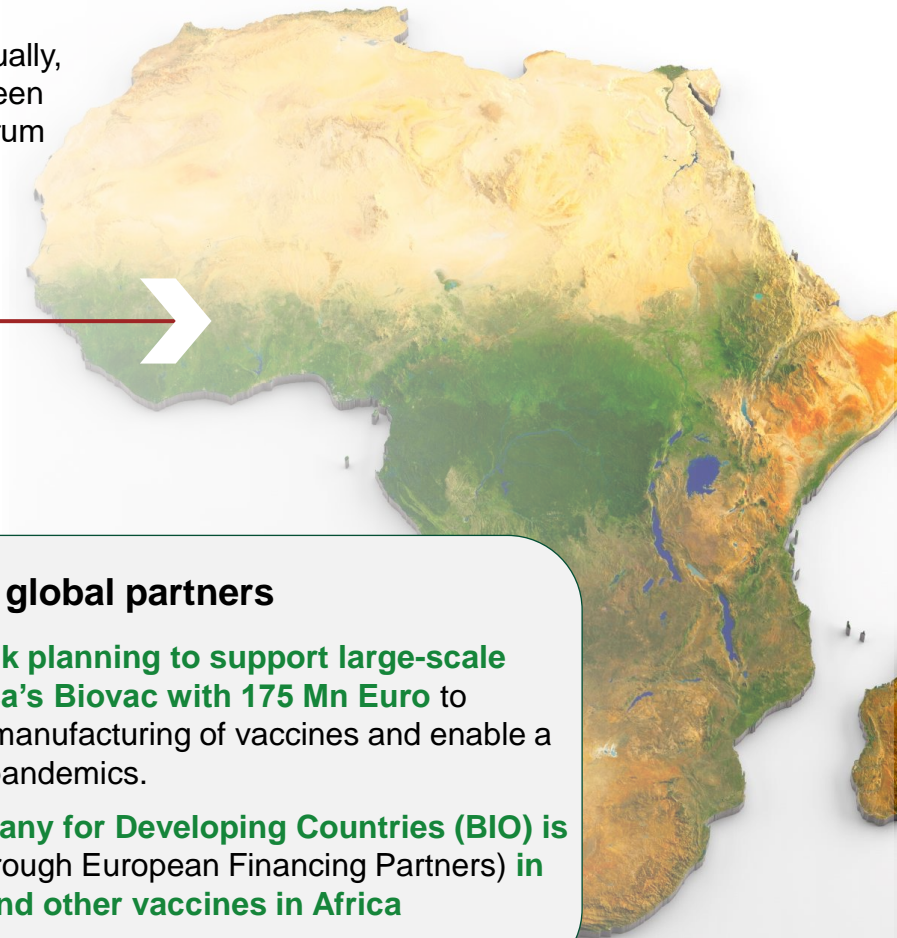
**Rwanda signed a \$3.5 Mn agreement with EU to enhance the attractiveness of the country for investments in vaccine manufacturing.** The agreement will strengthen the capacity of the Rwanda Food and Drugs Authority (FDA) which is key to enhancing the country's attractiveness for investments in vaccine manufacturing

2023

## Other investments by global partners

**European Investment Bank planning to support large-scale investment by South Africa's Biovac with 175 Mn Euro** to increase development and manufacturing of vaccines and enable a quicker response to future pandemics.

**Belgian Investment Company for Developing Countries (BIO) is investing 1.56 Mn Euro** through European Financing Partners) in the production of Covid and other vaccines in Africa

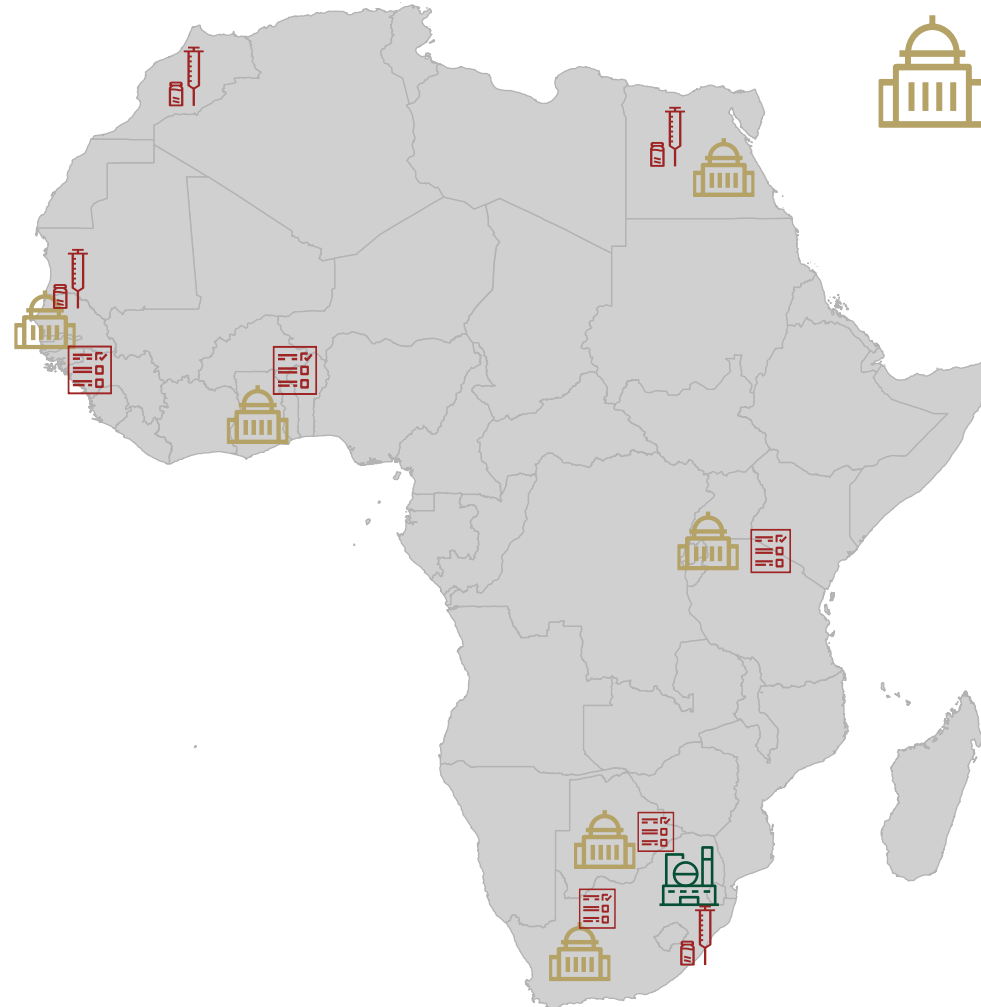


# We have a lot to celebrate, as we see shifts cross the broader vaccine ecosystem



**30+ continental vaccine initiatives and partnerships** to support local manufacturing expansion, e.g.,

- Aspen and Serum Institute
- Kenya with Moderna
- Vacsera
- Morocco with Recipharm
- Biovac and Pfizer
- Institute Pasteur Dakar with Univercells



3 countries have reached **Maturity Level (ML) 3 for vaccines** status since 2021

- South Africa
- Egypt
- Ghana



**1 mRNA Vx tech transfer hub** established to build mRNA Vx manufacturing capacities in LMIC

- South Africa



**5 NRAs with concept notes** for direct PAVM support

- SAHPRA (South Africa)
- Ghana FDA
- Botswana MRA
- Rwanda FDA
- Senegal ARP

# PAVM is on a multi-stage journey to realize the AU's public health order, with the current focus being Vx strategy implementation

## Objectives across PAVM's multi-stage journey

### 2021 Setting PAVM objectives



- Consolidated fact base
- Continental strategy for scaling Vx manufacturing (60% target)
- Launch of Framework for Action (FFA)

### 2022-2023

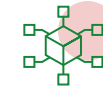
#### Driving continental Vx strategy implementation



- Operationalization of the Secretariat to drive implementation
- Launch implementation of prioritized bold program activities that benefit broader ecosystem beyond Vx
- Continental strategy for Vx manufacturing value chain<sup>1</sup>
- Continental strategy on additional interventions beyond vaccines - **therapeutics and diagnostics**

### 2024-'40

#### Extending to adjacent products

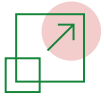


- Continued scaling of Vx focused bold program activities
- Implementation and scaling of the Vx value chain continental strategy
- Implementation and scaling of additional interventions that support local manufacturing of therapeutics and diagnostics

---We are here

### 2025-'40

#### Steady state implementation



- At pace implementation of all identified programs required to achieve Africa's self-reliance in biomanufacturing
- Continuous assessment and refinement of interventions to meet objectives of new public health order

1. Assessment of local Vx manufacturing raw material needs to enable manufacturing at scale

# We have made notable progress along these bold programs within a short time frame

## NOT EXHAUSTIVE



### Agenda setting and coordination

- **Over 1.5Bn USD committed** into the continent for vaccine manufacturing facilitated
- **Taskforces to be set-up** to oversee FFA implementation, PAVM bold program workstreams instated with defined implementation plans are being set up



### African Vx procurement pooling mechanism

- **Business cases developed** for vaccines to provide guidance to manufacturers on priority diseases
- **Initial consensus and buy-in of member states achieved** for the African vaccines pooled procurement mechanism objectives
- **PAVM, PATH and CHAI site visits** with manufacturers to understand overall landscape



### Embedding Vx regulatory excellence in NRAs and RCOREs

- **Vaccinology training of NRA employees from 13 countries supported**, in collaboration with the South Korea International Vaccines Institute
- **TCs** (cGMP, AVAREF, AMQF) and Vx sub-TCs reconstituted to support Vx manufacturing regulatory oversight



### Vaccine R&D centres

- **Pilot R&D center concept proposal defined**, along with selection criteria



### Capability and Capacity Network

- **Initial trainings provided** (e.g., 50+ manufacturing employees trained through IVI, vaccinology training of NRA employees)
- **Texas A&M trainings:** Finalized selection of ~24 candidates for hands-on biomanufacturing trainings that will be held at Texas A&M's National Center for Therapeutics Manufacturing (NCTM) in Q3-Q4 2023

# In 2023 PAVM will focus on continued momentum and practical action

PAVM has set two goals that are closely connected to each other:

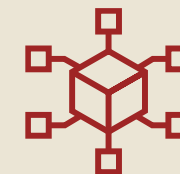
1

**Cementing a network of respectful partnerships oriented towards action and catalysing resources through PAVM** to strengthen the Vaccine Manufacturing ecosystem



2

Creating **healthy and sustainable Vx manufacturing ecosystems** that enable localization of vaccines



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# Q&A

