Partnerships for African Vaccine Manufacturing

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

Akhona Tshangela
Program Coordinator, PAVM
Africa Centres for Disease Control and Prevention (Africa CDC)

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

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Description</th>
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<tbody>
<tr>
<td>Improve health security and capacity for emergency response</td>
<td>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)</td>
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<td>Improve regulatory harmonization between countries to facilitate trade</td>
<td>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))</td>
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<td>Elevate technological expertise and capabilities</td>
<td>Stimulating investment in R&amp;D (currently &lt;2% of global R&amp;D projects in Africa), technological development and upskilling NRAs as well as promoting scientific research and demand for high-quality technical jobs</td>
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<td>Facilitate economic growth</td>
<td>Increasing manufacturing market in Africa which will generate substantial economic impact through job creation, increasing investments and intracontinental trade</td>
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Source: Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action
Local manufacturing as an enabler of both health and food security

Environmental
- Agrochemicals or Pesticides
- Fertilizers
- Soil conditioners, liming and acidifying agents
- Methane emission reduction agents

Human health
- Vaccines
- Therapeutics
- Diagnostics and medical devices
- Medical equipment and supplies
- Digital tools

Animal health
- Medicated feed additives
- Veterinary therapeutics and vaccines
- Vet parasiticides
- Veterinary diagnostics
Situation today: Health product and technology manufacturing in Africa, beyond Vx, is still very nascent

**Therapeutics**

Africa has limited manufacturing capacity, concentrated in a few countries that has a low level of integration along the value chain.

**Vaccines**

The vaccines market is publicly driven and supply is concentrated to a small number of importers. >80% manufacturers focus on fill and finish or packaging and labelling. Only a few companies engage in drug substance manufacturing.

**Diagnostics and medical devices**

Africa imports over 95% of its medical devices. In radiology (X-rays, MRI machines, CT scans, etc.), import dependencies is at 99%. The pandemic magnified the fractured supply chain fluctuating raw materials prices.

**Medical equipment and supplies**

As an example, Africa imports over 95% of its PPE requirements. Local manufacturers are focusing on simple consumables (e.g., gloves, disinfectant, etc.), rather than advanced medical equipment and supplies (e.g., oxygen, nebulizers, ventilators, etc.)
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**

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 diseases¹...

<table>
<thead>
<tr>
<th>Legacy</th>
<th>Expanding</th>
<th>Outbreak</th>
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<tbody>
<tr>
<td>Diphtheria</td>
<td>HPV</td>
<td>Ebola</td>
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<tr>
<td>Hepatitis B</td>
<td>Pneumococcal</td>
<td>Chikungunya</td>
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<tr>
<td>Measles</td>
<td>HIV</td>
<td>Lassa fever</td>
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<tr>
<td>Meningococcal</td>
<td>COVID-19</td>
<td>Rift valley fever</td>
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<td>Whooping Cough</td>
<td>Malaria</td>
<td>Disease X</td>
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<tr>
<td>Yellow fever</td>
<td>Rotavirus</td>
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<td>Typhoid fever</td>
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<td>Tetanus</td>
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<tr>
<td>Tuberculosis</td>
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<tr>
<td>Cholera</td>
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² Vaccine exists  ³ Vaccine does not yet exist

2. Technology focus

… requiring a breadth of technology platforms…

Traditional

- Live attenuated
- Inactivated virus
- Subunit
- Virus-like particle
- Viral vector

Innovative

- RNA/DNA

³ Vaccine exists  ⁴ Vaccine does not yet exist

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:

- **Market design and demand intelligence**
  Achieving sustainable and reliable economies of scale by launching mechanisms that create demand certainty for manufacturers while facilitating country procurement.

- **Access to finance**
  Stimulating a healthy market that result in sustainable and continuous investment in local manufacturing capabilities and broader ecosystem enablers.

- **Technology transfer and IP**
  Establishing and accelerating technology transfer and intellectual property enablement to local manufacturers.

- **Regulatory strengthening**
  Developing best-in-class National Regulatory Authorities (NRAs), regional harmonization and World Health Organization prequalification, to enable the export of products.

- **R&D and talent development**
  Building the continent’s workforce by investing in the development critical manufacturing skills and capabilities and local R&D capabilities to develop new and improve existing products -- Considered as two bold programs: Talent and R&D --

- **Infrastructure development**
  Continuing and accelerating infrastructure initiatives including investment in mega-projects, innovative technologies etc.

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**Legend**

- 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

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- The PAVM was approved by AU Executive Council.

- 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.

- 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.

- 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

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.

Africa CDC PAVM Forum

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.

**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.

**2021**

**2023**

**2023: Egypt’s MoH launched the 1st 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.**

**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

3 countries have reached **Maturity Level (ML) 3 for vaccines** status since 2021
- South Africa
- Egypt
- Ghana

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

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
- 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

**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

--- We are here

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

<table>
<thead>
<tr>
<th>Agenda setting and coordination</th>
<th>African Vx procurement pooling mechanism</th>
<th>Embedding Vx regulatory excellence in NRAs and RCOREs</th>
<th>Vaccine R&amp;D centres</th>
<th>Capability and Capacity Network</th>
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<tr>
<td>• Over 1.5Bn USD committed into the continent for vaccine manufacturing facilitated</td>
<td>• Business cases developed for vaccines to provide guidance to manufacturers on priority diseases</td>
<td>• Vaccinology training of NRA employees from 13 countries supported, in collaboration with the South Korea International Vaccines Institute</td>
<td>• Pilot R&amp;D center concept proposal defined, along with selection criteria</td>
<td>• Initial trainings provided (e.g., 50+ manufacturing employees trained through IVI, vaccinology training of NRA employees)</td>
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<td>• Taskforces to be set-up to oversee FFA implementation, PAVM bold program workstreams instated with defined implementation plans are being set up</td>
<td>• Initial consensus and buy-in of member states achieved for the African vaccines pooled procurement mechanism objectives</td>
<td>• TCs (cGMP, AVAREF, AMQF) and Vx sub-TCs reconstituted to support Vx manufacturing regulatory oversight</td>
<td></td>
<td>• Texas A&amp;M trainings: Finalized selection of ~24 candidates for hands-on biomanufacturing trainings that will be held at Texas A&amp;M’s National Center for Therapeutics Manufacturing (NCTM) in Q3-Q4 2023</td>
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<td>• PAVM, PATH and CHAI site visits with manufacturers to understand overall landscape</td>
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NOT EXHAUSTIVE
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