Accelerating the licensure of Lassa vaccines Generating robust evidence on vaccine efficacy and safety

Vaccine R&D and Manufacture in Africa

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26 October 2022
Vision for African vaccine manufacturing

To ensure Africa has timely access to vaccines to protect public health security, by establishing a sustainable vaccine development and manufacturing ecosystem in Africa.
The AU has set a goal to ensure 60% of the vaccines administered in Africa are locally manufactured and mandated the PAVM to oversee this task.

**Context**

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

The AU 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.

**Ambition to be enabled by the Framework for Action**

- **2021**
  - Local: 99%
  - Imported: 1%

- **2040**
  - Local: 40%
  - Imported: 60%

The first pillar of the New Public Health Order is expanding manufacturing of vaccines, diagnostics and therapeutics.

1. Other pillars include: Strengthened public health institutions, Strengthened public health workforce, Respectful, action-oriented partnerships.
The PAVM was established under the Africa CDC with four broad objectives to guide its operations.

**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.**
The PAVM made significant progress since inception crossing many important milestones in 2021.

- Facilitated the African Vaccine Manufacturing Summit which mandated PAVM and set the target ambitions.
- The PAVM was approved by AU Executive Council and will be presented to AU Assembly of Heads of State in February 2022.
- Finalised Draft 1.0 of the FFA that was peer reviewed by independent experts and scientists.

**Timeline:**

- **12-13 April**
  - 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.

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

- **November**
  - 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.

- **6-7 December**
  - Hosted a successful Stakeholder Engagement Event in Kigali where significant decisions were made on the FFA bold programs.

- **17 December**
  - The PAVM was approved by AU Executive Council and will be presented to AU Assembly of Heads of State in February 2022.
The PAVM has maintained its momentum into the implementation phase of the initiative in 2022

- **February 2022**: FFA has been endorsed by AU member states at the Heads of State Assembly.
- **March 2022**: Framework for Action officially released to general public.
- **March 2022**: Project Management Office (PMO) to oversee implementation of FFA set up.
- **June 2022**: Bold program task-teams reconvened with weekly meetings to drive implementation.
- **June 2022**: Market Intelligence and Demand Workshop organized for stakeholders to establish a vaccine procurement architecture for the continent.
PAVM’s journey has been structured in 3 phases

<table>
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<th>Phase 3b Implementation of the FFA</th>
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<td>Getting the PAVM Task Force up and running</td>
<td>Developing a detailed Framework for Action (FFA)</td>
<td>Developing FFA implementation plan and release support</td>
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<td>Definition and establishment of the PAVM Task Force and its workstreams</td>
<td>Stand up the PMO</td>
<td>Strengthen execution of the PMO</td>
<td>Onboard implementing partners and set up the bold program teams</td>
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<td></td>
<td>Operationalization of the PAVM Task Force</td>
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<td>Develop detailed FFA implementation plans</td>
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<td>Lead the key analysis for each workstream in collaboration with the PAVM Task Force</td>
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<td>Initiate the first steps of the FFA’s implementation plan</td>
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<td>Definition of action plans for each workstream and integrating them into a Continental Framework for Action (FFA)</td>
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Deep dives to follow
PAVM developed a continental strategy that outlines diseases, technology platforms and manufacturing value chain steps that Africa needs to prioritise.

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

### Prioritized 22 diseases...
- **Legacy**
  - Tetanus
  - Tuberculosis
  - Cholera
- **Expanding**
  - HPV
  - Pneumococcal
  - HIV
  - COVID-19
  - Malaria
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- **Outbreak**
  - Ebola
  - Influenza
  - Chikungunya
  - Lassa fever
  - Rift valley fever
  - Disease X

### Technology focus...
- **Traditional**
  - Live attenuated
  - Inactivated virus
  - Subunit
  - Virus-like particle
- **Innovative**
  - Viral vector
  - RNA/DNA

### Potential value chain focus
- **Fill & Finish (F&F)**
  - Fill & finish for all priority vaccines, enabling achievement of local production targets.
- **Drug Substance (DS)**
  - Expand drug substance mostly in established platforms.
- **R&D**
  - Expand R&D activities to develop new vaccines for Africa, support more efficient manufacturing and improve vaccine characteristics.
R&D and talent development are two of the 8 bold programs which PAVM have defined to support the vaccine manufacturing ecosystem and continental strategy.

- Market design and demand intelligence
- African Vaccines Procurement Pooling Mechanism
- Access to finance
  - Vaccine manufacturing deal preparation and financing facility
- Technology transfer and IP
  - Vaccine Technology Transfer & IP Enablement Unit
- Regulatory strengthening
  - Embedding Vaccines regulatory excellence in NRAs and RCOREs through AMA and AMRH
- R&D and talent development
  - Vaccine R&D centres and R&D coordinating unit
- Capability and Capacity Networks
- Infrastructure development
  - Advocacy for enabling trade policies for Vaccines
Partnerships will be key to implementing these bold programs and PAVM welcomes all stakeholders to play a role.

Focus of this presentation

Continental strategy delivery and oversight

Agenda-setting and coordination

Market design and demand intelligence

Access to Finance

Technology transfer and IP

Regulatory strengthening

R&D and talent development

Infrastructure development

Potential Lead

Central

PAVM

AVATT

Afrexim/AfDB

AVMI

AMA & AMRH

TBD

PAVM

AfCFTA

Regional

Regional R&D Centres

Research Institutions

Pilot plants

Biotechs

Capability and Capacity Network

Manufacturers

Academic institutions

R&D Centres

Partners

National

Frontrunner countries will implement country-specific vaccine manufacturing initiatives, but remain coordinated through the continental strategy.

RCOREs

REC.s
For each of the 5 African Union regions, we have identified countries with stronger R&D activity:

- **Egypt**
  - 3% of clinical trials; 6 clinical research centers
  - 17% of preclinical trials; 9 research institutes
  - *Malaria, pneumonia, tuberculosis,*

- **Mali**
  - 8% of clinical trials; 4 clinical research centers
  - 3% of preclinical trials; 1 research institute
  - *Malaria, Ebola, Diphtheria*

- **Democratic Republic of Congo**
  - 5% of clinical trials; 6 clinical research centers
  - 1% of preclinical trials; 1 research institute
  - *Ebola, Hepatitis B, HPV*

- **Kenya/Uganda**
  - 14% of clinical trials; 9 clinical research centers
  - 6% of preclinical trials; 5 research institutes
  - *HIV, Tuberculosis, Malaria, Ebola*

- **South Africa**
  - 26% of clinical trials; 32 clinical research centers
  - 30% of preclinical trials; 25 research institutes
  - 85% of relevant biotechs
  - *HIV, COVID-19, Tuberculosis, Pneumonia*

This analysis shows the current activity in each of the 5 hubs. To cover all R&D activities end-to-end on the value chain, all these countries require additional capacity and talent development.
R&D centers will regionally consolidate infrastructure, capacity and expertise across a given portion of the R&D value chain supported by a Coordinating Platform.
PAVM is creating a Capability and Capacity Network model that comprises of educational industrial and regulatory institutions to build talent and capabilities.

**Capability and Capacity network coordination**

- Manage program requirements
- Act as a networking and communication platform
- Coordinate funding for programs
- Track needs and talent across the ecosystem
- Facilitate partnerships with international & local players
- Support pipeline development via youth awareness campaigns or similar programs

**Network composition**

- **Trade / vocational schools**
  - Create specializations in existing STEM degree programs
  - Avail students for internship and mentorship programmes
  - Provide complementary vaccine-specific classroom training for experienced hires and diaspora

- **Universities**
  - Contribute to the continental strategy
  - Agree to work with other players across the entire network, including RCOREs to ensure that programmes aligns with regulatory requirements

- **Research institutions**
  - Provide industry experts as lecturers and incorporate industry-specific nuances into courses
  - Develop early internship and mentorship options to raise career awareness

- **Manufacturers**
  - Set up on-the-job development programs that provide a mix of hands-on job training and mentorship

**ILLUSTRATIVE**

- Educational institute
- Industrial institute
- Regulatory institute
- Regional talent pools
- Locations that individuals need to move to be trained
Acknowledgment

Advisory Group
Wider group to be kept involved and provide strategic and technical advice to the PAVM central Task Force

Scientific Peer Review Group
Comprised of a group of independent experts who provide periodic inputs into PAVM’s technical outputs

PAVM Task Force
Strategy setting and coordination
Lead: Africa CDC
Members: leads of all the workstreams

PAVM Secretariat
Lead: Africa CDC

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1. Listed members who joined at the inception and stayed active to date
2. Bartholomew Dicky Akanmori (WHO-AFRO), Houla Langar (WHO-EMRO), Elisabeth Ludeman, Khadijiatou Aw (USAID), Prof. Emile Bienvenu (Rwanda), Dr. Dalia Abouhussein (Egypt), Dr. Adam Fimbo (Tanzania), Prof. Bouchra Meddah (Morocco), Dr. Oumy Ndao (Senegal), Dr. Fermina Nadia (Tunisia), Dr. Stephen Ghatie (Botswana), Dr. David Nabahuma (Uganda), Dr. Fred Siyoi (Kenya)
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THANK YOU

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