Strengthening Vaccine Production Capacity and Pandemic Preparedness

24th DCVMN Annual General Meeting
20 September 2023

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Unit Head, Local Production and Assistance Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division
**Chair:** Dr. Jicui Dong, Unit Head, Local Production and Assistance Unit, WHO

**Speakers of the Panel:**

Dr. Ali Alloueche, Vice President and Global Head of the Business Development, Alliance Management and External R&D, Hilleman Laboratories

Dr. Simone Blayer, Global Head, Chemical, Manufacturing, Control and Nonclinical Toxicology, PATH

Ms. Yalda Momeni, Senior Specialist, Future Supplier Base Strategy-Market Shaping, GAVI

Mr. Chiluba Mwila, PAVM Technical Advisor, Talent Development Program, Africa CDC

Mr. Murat Hakan Öztürk, Supply Chain Advisor, PAHO Revolving Fund, PAHO

Ms. Iin Susanto, Production and Supply Chain Director, Bio Pharma (Indonesia)

Dr. Frauke Uekermann, Director, Vaccine Markets, CHAI

Ms. Emma Wheatley, Director, Access and Private Partnerships, CEPI
Strengthening global vaccine manufacturing capacity

The building blocks for increased capabilities and sustainable manufacturing ecosystems

Dr. Simone Blayer
Global Head, Chemistry, Manufacturing, and Controls and Nonclinical Toxicology
Strengthening capacity and building sustainability requires a systemic approach

Building vaccine manufacturing capacity isn’t just about addressing the immediate needs; it’s about creating sustainable growth trajectories.

A strong manufacturing ecosystem is the key to sustainability.

Example: A project to assess the current and planned state of vaccine manufacturing capacity in Africa.

- A collaboration between Africa CDC, CHAI, and PATH.
- Work can help stakeholders and funders coordinate, prioritize development efforts, interventions, investments

Results:
- An overabundance of fill/finish capacity.
- A significant lack of capacity to produce antigen locally.
- A strong reliance on tech transfer with non-African vaccine manufacturers & a dearth of tech transfer partners.
- Unclear demand commitments for African-made vaccines.
- Unclear pathways to commercial success.
Strategic investment and stakeholder alignment drives success

An **ecosystem approach** will yield the greatest impact.

Individual or local priorities are important to understand but only part of the equation.

PATH has a long history of productive and collaborative partnerships and is dedicated to advancing sustainable vaccine access for all.

With humility, an eye on the bigger picture, and respectful give-and-take, **together we can transform the global vaccine manufacturing space**.
Strengthening Vaccine Production Capacity & Pandemic Preparedness

DCVMN AGM – 20 September 2023
CHAI findings offer a perspective on a sustainable African manufacturing footprint, market risks and market-shaping priorities

Scope of CHAI Phase 1:
Intelligence gathering & opportunity identification

Key takeaways

Target pathway: A sustainable footprint that can balance and strategically align stakeholder initiatives with goals of improved PPR, robust global antigen market, and commercial sustainability for AVMs

Key market risks:
• High cost of African products due to inherent structural cost disadvantages
• Excess Drug Product (DP) manufacturing capacity, surpassing even the 2030 African demand
• But low utilization of DP capacity to date
• Slow capacity build-up for Drug Substance manufacturing
• Uncertain demand materialization for African-made vaccines and lack of policy support from governments to date
• Comparatively weak enabling ecosystem (regulatory, industrial policy, etc.)

1. Supply landscaping conducted in collaboration with PATH & Africa CDC
Source: CHAI analysis
What needs to happen going forward from a market-shaping perspective? Four key intervention areas to achieve a sustainable manufacturing footprint

An African manufacturing footprint that represents a compromise between PPR objectives, global market health as well as minimum commercial viability

0  Alignment of stakeholders to the target pathway

1  Supply-side
   Appropriateness of incentives to support manufacturers’ competitiveness and achieve desired footprint

2  Feasible TT partnerships between originators and high-potential AVMs

3  Demand materialization for African-made vaccines

4  Enabling environment that enhances global competitiveness

Source: CHAI analysis
Strengthening Vaccine Production Capacity & Pandemic Preparedness
Gavi’s 4-pillar strategy is aligned and connected with upstream initiatives.

**Leadership and coordination:**
- **African Union**
- **AFRICA CDC**

**Technical assistance and financing:**
- **Financing**
- **Tech transfer**
- **Prequalification**
- **Others**

**UPSTREAM**
- **Downstream pull supports more attractive upstream activities given increased sustainability of business cases**
- **Alignment on foundational funding requirements**
- **Alignment on PPPR (no facilitation of tech transfer)**
- **Downstream pull supports more viable tech transfers**
- **Discussion on creative approaches to support PQ processes**

**JOINT AMBITION**
- **Sustainable, regionally diversified supplier base with minimized undesired market distortion**
- **Improved pandemic response capacity, supply resilience and security sovereignty**

**DOWNSTREAM**
- **Pillar 1: Shaping portfolios in favour of priority vaccines**
- **Pillar 2: Inclusion of new African products in the Gavi product menu**
- **Pillar 3: Improving predictability of country-led demand for regional products**
- **Pillar 4: Financing a new Advance Market Commitment to support sustainability as manufacturers scale**
The AVMA can play a critical downstream role to support sustainable vaccine manufacturing

**Political announcements**

- **Announced vision of manufacturing 60% of all continental needs**
- **Leader-level announcements** in Senegal, Nigeria, Rwanda, South Africa, Ghana and Tanzania of near-term domestic facilities
- **EU-AU Summit (2022)** – EU announced **substantial commitment to strengthen local pharmaceutical systems and manufacturing**
- **US announced 2022 joint investment plan** to boost vaccine manufacturing capacity in Africa
- **Germany’s G7 Presidency**: supporting sustainable local and regional production capacities in Africa
- **Japan’s G7 presidency communiqué** notes vaccine manufacturing agenda in paragraph one
- **UK, Canada, and Italy, amongst others, announced substantial support for manufacturing sectors in Africa**

**Financial announcements**

- **>$1 bn**
  Committed as part of MAV+ initiative in 2021
- **>500 m doses**
  Announced a joint investment to boost vaccine manufacturing capacity in Africa in 2022
- **>$600 m**
  Joint financing packages announced in 2022 for individual manufacturing facilities
- **>$200 million**
  Committed as loan agreement to support COVID-19 responses
- **>$100 m**
  Committed to support sustainable manufacturing capacity for future epidemics and pandemics

**African Vaccine Manufacturing Accelerator**

- **AVMA could offer a minimum level of support to enable facilities to reach sustainability**
- **Via a milestone payment** to manufacturers successfully obtaining WHO prequalification
- **Via a post-tender award** to manufacturers competitively winning Alliance tenders
- **As part of a holistic approach to maintaining global market health and supporting PPPR**

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**Source:** Press search
100-Day Mission + Manufacturing investments + Health systems investments
- Vaccinations start at 100 days, no supply constraints, no delivery/implementation constraints

100-Day Mission + Health systems investments
- Vaccinations start for some countries at 100 days, but initial supply constraints lead to delayed rollout in LMICs (as observed in the real world) and daily stockouts
- In-country delivery increased such that rollout is 2x faster once no longer supply constrained

100-Day Mission + Manufacturing investments
- Vaccinations start at 100 days with no supply constraints
- In-country delivery/implementation constraints create a gap between supply and uptake
- Since there are no stockouts, daily vaccination rates never decrease

100-Day Mission
- Vaccinations start for some countries at 100 days, but initial supply constraints lead to delayed distribution in LMICs (as observed in the real world)
- In-country delivery/implementation constraints create a gap between supply and uptake

Observed pandemic response
- Vaccinations start at day 326 with rollout patterns occurring as happened in COVID-19, with supply and in-country delivery/implementation constraints
Vaccine manufacturing in Africa enables 100DM, this is how CEPI enables Africa

**PAVM Framework for Action**
- Market design & demand intelligence
- Access to Finance
- Regulatory Strengthening
- Technology transfer & IP
- Research & Development
- Talent Development
- Infrastructure Development
- Agenda Setting & Coordination

**CEPI Investments so far:**
- Connect with PAVM, GAVI and CHAI on sustainability
- Investments for agile capacity
- Twin, technology & harmonize
- Matchmaking, Funding & Advice
- Networked labs and trial sites. Funding for vaccine development
- QMS support
- Equipment and QMS tools
24th DCVMN Annual Meeting
Session 7: Strengthening Vaccine Production Capacity & Pandemic Preparedness

PAHO REVOLVING FUND FOR ACCESS TO VACCINES

Murat Hakan Öztürk
Regional Supply Chain Advisor for Revolving Fund

21 September 2023, Cape Town / South Africa
Pooled Procurement Mechanism Dynamics

✓ Technical support
Holistic approach for EPI programmatic support
Strengthening immunization supply chains
Regulatory guidance and harmonization
Solidarity and mutual learning

✓ Procurement planning
Accurate forecasting
Emergency preparedness & response

✓ Pooled procurement = Purchasing power
Value for money – lowest possible prices for all
Economies of scale

✓ Financial Sustainability
Financial planning and budgeting
Possible bridge financing
Africa CDC PAVM Talent Development Strategy

Dr. Chiluba Mwila
DCVMN 2023 AGM
The RCCN is being established to address challenges facing vaccine ecosystem talent.
The RCCN has 3 key objectives, against which several talent development initiatives will be implemented.

**Objectives of the RCCN**

| Objective | Example initiatives
|-----------|----------------------|
| **1.** Build and maintain a skilled biomanufacturing workforce to enable vaccine manufacturing on the continent at scale | • Sponsor and facilitate vaccinology short courses  
• Offer internships for STEM graduates to increase level of preparedness for industry  
• Provide on-the-job development programs for professionals (incl. in partnership with MNC manufacturers) to increase employee motivation  
• Develop diaspora talent return programs with attractive incentives for highly skilled professionals  
• Offer consistent regulatory training |
| **2.** Increase the relevance of sustainably funded training & educational programs to evolving industry needs | • Develop competency frameworks for both manufacturing and research, while carrying out continuous needs assessments  
• Update training curricula in line with industry needs and best practices  
• Create STEM specializations/ novel degree programs and fellowship programs |
| **3.** Incentivize R&D activities across Africa | • Create a scholarship program to subsidize post-graduate programs for researchers  
• Create R&D job placement programs for trained individuals |

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1. Entire scope of initiatives defined in RCCN concept note
HILLEMAN MANUFACTURING INNOVATION

DR. A. ALLOUECHE

HILLEMAN LABS
Hilleman Manufacturing Innovation

**Strategic Features**

- Up to 15 fold greater protein output per unit volume
- Portable equipment and disposable Technology
- Standardized, modular, flexible Design
- Integrated Continuous downstream Processing
- Real-time Quality Control release

**Operational Advantages**

- Enables smaller bioreactors for same output
- Reduces infrastructure for cleaning and sterilization
- Simplifies changeovers between products (from one week to one day)
- Fewer intermediate steps, less equipment, and faster cycle times
- Deeper process knowledge; Just-In-Time (JIT) Product Disposition
Hilleman’s lab Manufacturing innovation

• Enable speed to clinics and TT to LMICs (R&D and Operations)
• Reduce capital investment and depreciation
• Provide flexibility and geographic mobility
• Increase productivity
• Enhances compliance (standardization and Process Analytical Technology - PAT)
Local Vaccine Production
Bio Farma - Indonesia

Iin Susanti
Production & Supply Chain Director

19 September 2023
DCVMN AGM – Cape Town
Role of Bio Farma in Supporting Global Health

- Provision of vaccines domestically in support of the National Immunization Programme
- Provision of vaccines to UN agencies as well as bilateral
- Participation in global polio eradication program
Assuring resilience in vaccines particularly during pandemics

- Collaboration with international organization to support national resilience
- ASEAN regional Hub
2nd World Local Production Forum
World Forum, The Hague, Netherlands
6-8 November 2023

Registration to attend the 2nd WLPF is through this [link](https://www.who.int/initiatives/world-local-production-forum)

More information on the World Local Production Forum is on the WLPF website: [https://www.who.int/initiatives/world-local-production-forum](https://www.who.int/initiatives/world-local-production-forum)
Thank you

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