Strengthening Vaccine Production Capacity and Pandemic Preparedness

24th DCVMN Annual General Meeting 20 September 2023

Jicui Dong (MSc, PhD, MBA) 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

September 19, 2023

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.

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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**.

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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



1. Supply landscaping conducted in collaboration with $\ensuremath{\mathsf{PATH}}$ & Africa CDC Source: CHAI analysis

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.)



What needs to happen going forward from a market-shaping perspective? Four key intervention areas to achieve a sustainable manufacturing footprint



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Source: CHAI analysis



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Strengthening Vaccine Production Capacity & Pandemic Preparedness

September 2023

gavi.org

Gavi's 4-pillar strategy is aligned and connected with upstream initiatives



JOINT AMBITION

Sustainable, regionally diversified supplier base with minimized undesired market distortion

Improved pandemic response capacity, supply resilience and security sovereignty

The AVMA can play a critical downstream role to support sustainable vaccine manufacturing

INDICATIVE - NOT EXHAUSTIVE

Political announcements

African 🕥 Union

Announced vision of manufacturing 60% of all continental needs



Leader-level announcements in Senegal, Nigeria, Rwanda, South Africa, Ghana and Tanzania of nearterm 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 communique notes vaccine manufacturing agenda in paragraph one



UK, Canada, and Italy, amongst others, announced substantial support for manufacturing sectors in Africa



>€1 bn



THE WORLD BANK

Committed as part of MAV+ initiative in 2021

DFC >500 m doses

Announced a joint investment to boost vaccine manufacturing capacity in Africa in 2022

() IFC >\$600 m

Joint financing packages announced in 2022 for **individual manufacturing facilities**

>\$200 million

Committed as loan agreement to support COVID-19 responses

BILL&MELINDA GATES foundation >\$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

11 Source: Press search

100DM + Manufacturing Investments Improve Equitable Access in Outbreaks

		 100-Day Mission + Manufacturing investments + Health systems investments Vaccinations start at 100 days, no supply constraints, no delivery/implementation constraints
uity	Suite B	 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
treasing Eq	Contraction of the second seco	 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
	() A CLUB	 100-Day Mission Vaccinations start for some countries at 100 days, but initial supply constraints leads 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

CEPI

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





Revolving Fund: Interdisciplinary approach



Africa CDC PAVM Talent Development Strategy

Dr. Chiluba Mwila DCVMN 2023 AGM Manage program requirements

The RCCN is being established to address challenges facing vaccine ecosystem talent



RCCN¹ coordination

Act as a networking and communication platform



Overview of tools

The RCCN has 3 key objectives, against which several talent development initiatives will be implemented

NOT EXHAUSTIVE

Objectives of the RCCN		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 			

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

lin Susanti Production & Supply Chain Director

19 September 2023 DCVMN AGM – Cape Town

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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

Biofarma

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

2nd World Local Production Forum Enhancing access to medicines and other health technologies World Health Galvanizing regional partnerships for sustainable local production and equitable access World Health Date and place: 6-8 November 2023, The Hague World Health Provisional agenda at a glance: Date and place: 6-8 November 2023, The Hague DAY 1. 06 November 2023 Date and place:						World Health Organization	DAY 2. 07 November 2023 09:00 - 10:30 Theme 4 Reaching the most vulnerable in the regional production context		11:00 - 12:30 Theme 5 addressing the policy challenges and operational bottlenecks (3 parallel topics) arallel Panel Parallel Panel	Netw	14:00 - 15:30 Theme 6 Strengthening local production capacity of quality health products (4 parollel topics)			16:00 - 17:30 CEO Forum
08:30 - 10:30 Grand Opening of the 2nd WLPF Welcome remarks and Opening speeches Cultural interlude Global Leaders Debate Leaving no one behind: Interfacing multiple sectoral agendas for local production,	Coffee bre Networking and Ma	Keynote: Developing a conductive business eco-system for strengthening sustainable local production to improve access Neworking Market Plan Keynote: Developing a conductive business eco-system for strengthening sustainable local production to improve access of quality health products. Presentation 1: Exploring policies, investment mechanisms, and incentives to build sustainable local production capacity. Presentation 2: Leveraging science, technology, and	14:00 - 15:30 Theme 2 Leveraging existing regional initiatives and promoting convergence and partnerships Keynote: Forging robust partnership to improve productivity and production efficiencies of sustainable local production. Panel discussion 1: Regional perspective Fostering local production through existing regional partnerships and initiatives.	16:00 - 17:30 Theme 3 Tackling the bottlenecks of regional production Keynote: Exploring regional bottlenecks in sustainable local production: A holistic perspective. Panel discussion 1: Understanding the key policy challenges of regional production: focus on a holistic	boosting local pharmaceutical production in Africa. Presentation 1: Strengthening Africa's R&Copacities to promote technology transfer and local production. Parallel Panel discussion 2: Supporting Africa regional initiatives to promote local production and access in Africa.	dii Ov Pro Ca Lir Po Po Pa En Lo Po	scussion 1: discussion 2: discussion 2: docution papacity Limitations to Itations to Sustainable Local Production: Mechanisms and Policy Options. arallel Panel discussion 3: suring Sustainability and Quality in cal Production: Mechanisms and plicy Options.	Lunch break rking, Market Place and Side Events	approaches to accelerate regional API development and manufacturing in Africa. Seminar 3: Understanding the diagnostics and devices value chains for sustainable production and access.	Strengthening the scalability and sustainability of vaccine production. Showcase 1: Addressing climate change through eco- friendly local production.	Coffee break Vetworking and Market Place	CEO's forum: The role of Industry leadership in promoting local production of medicines, vaccines and medical devices.		
timely access, and health equity. Setting the Scene Spotlighting WLPF: Connecting the dots of global health Initiatives for regional production for equitable access of essential health products.	ak arket Place	the IP system to stimulate innovation and drug development. Presentation 3: Promoting regulatory reliance to ensure the quality and accessibility of health product: Panel discussion 1: Leapfrogging local production in LMICS • needs-based innovation and talent cultivation. Panel Discussion 2: Leapfrogging local production in LMICS • through reliable market data and intelligence and pooled procurement.	e and Side Events	Panel discussion 2: Reaction from regional perspective: Fostering local production through existing regional partnerships and initiatives.	sak arket Place	approach. Panel discussion 2: What are the key implementation challenges for Regional Production? Summary of Day 1	DAY 3. 08 November 2023 09:00 - 10:30 Theme 7 Strangthening local production for globa health security and emergency preparedness Kryonte: Integrating local production as a component of the health system Panel discussion 1: Geo-diversifying manufacturing capacity through licensing and technology transfer emergencies.	bal Never the set of t			PF Website	LPA Website		tter 2

Registration to attend the 2nd WLPF is through this link

The above programs are subject to change. Simultaneous interpretation will be available in some sessions. More information will be available in due course on the WLPF and LPA websites

More information on the World Local Production Forum is on the WLPF website:

https://www.who.int/initiatives/world-local-production-forum

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Thank you

For more information, please contact:

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