



Global event on enhancing the sustainability of investment for vaccine manufacturing in Africa, 27-29 June 2023

United Nations Conference Centre, Addis Ababa, Ethiopia

There are diverse and innovative initiatives by the industry and development partners for the realization of PAVM. To make the initiatives successful and sustainable, there is a need to address market shaping mechanisms; accelerate the rolling out of investment finance and programmes for skills development; and increase the opportunity for business-to-business interactions.



Summary of the Global event

From 27-29 June 2023, 147 industry representatives from Africa and the rest of the world, technology and finance providers and development partners came together to exchange views on how to make vaccine manufacturing initiatives in Africa sustainable; to match and create synergies between their respective offers and demands; and identify appropriate business models to move the Partnership for African Vaccine Manufacturing (PAVM) Framework For Action forward. UNCTAD, the African Vaccine Manufacturing Initiative (AVMI) and the Africa Centres for Disease Control and Prevention (Africa CDC) co-convened the event. The Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH provided the financial support, in partnership with the German Federal Ministry for Economic Cooperation and Development (BMZ). See Annex II list of industry and development partners that attended the Global event.

Following the official opening by the Ethiopian Minister of Health, Dr. Lia Tadesse, the Global event reviewed the progress of PAVM with updates and comments from Team Europe and its members (European Commission, Belgium, France and Germany), AVMI and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Participants discussed the pain points and success factors for investment initiatives for vaccine manufacturing in Africa based on study reports submitted by UNCTAD, Clinton Health Access Initiative (CHAI) and AVMI. International and African firms, and technology facilitators presented and responded to questions on their portfolios, plans and interests that facilitated business to business engagement.

While the African Development Bank, Afreximbank and Lion's Head shared their investment finance and technical assistance offerings, GAVI was joined by CHAI, UNICEF and national procurement agencies from Egypt, Ghana and Nigeria on a potential off-take mechanism to support vaccine manufacturing in Africa. In-depth discussions were held during breakout sessions on business models for fill and finish and drug substance manufacturing.

Summary Outcomes of the Global Event

Broad consensus: The Global Event demonstrated the broad consensus among firms and development partners, that:

- 1) Building vaccine manufacturing capacity should be considered together with strengthening of health systems, matching supply and demand and building regulatory capacity.
- 2) Due to the fragility of the global value chain, the bio-pharmaceutical manufacturing in Africa agenda is critical in addressing health inequities.
- 3) Not every country can manufacture everything. The continent needs a tailored strategy to consolidate supply and demand.
- 4) The private sector is an important partner for PAVM. It focuses on the 'how' to implement and achieve the goal (the 'what') in line with the overall objectives.

Strong points identified: The main strengths of the initiatives for vaccine manufacturing in Africa, are but not limited to:

- 1) Progress in key PAVM milestones including more than 30 vaccine initiatives; 3 countries' National Regulatory Authorities reaching Maturity Level 3; the operationalization of the mRNA technology hub; and training and capacity building with IVI Korea.
- 2) Increase number of investments with diverse business models, ownership structures, technology platforms and product portfolios, accompanied by extensive effort for networking with finance and technology providers. Several technology and IP transfers have taken place.
- 3) Key technical studies on capacity building were conducted, some of which were shared during the Global Event, namely, on business models for fill and finish and drug substance manufacturing.

- 4) Diverse forms of technical assistances, such as those by UNIZIMA, Lion's Head, CHAI, Afreximbank and AfDB are making a difference. The approaches of KENUP Foundation and Thermo Fischer, the unique experience of South Korean firms, and the various strategic partnerships among industry partners were also recognized.
- 5) The strengthening of Africa CDC and AVMI to support the long-term needs of the industry and engagement of UNCTAD were also acknowledged.

Weaknesses to be address and initiatives to be strengthened:

- 1) Limited progress on part of African governments on how they could collaborate at regional level: Throughout the event, industry representatives emphasized the vital need for progress on regional market shaping and off-take mechanism. While the ongoing technical work by Africa CDC and GAVI were recognized, participants were concerned that there is limited progress on part of African governments on how they could collaborate at regional level.
- 2) There is a need for a better mechanism on the means to:
 - a) Bridge the gap between initial investment and achieving (1) WHO pre-qualification and (2) price competitiveness at market entry by manufacturers in Africa.
 - b) Coordinate selection of products for manufacturing. For some antigens, up to 5 manufacturers have launched investment initiatives risking market saturation. The need to structure the market in a way that rations the product (antigen) portfolio and respective capacities across the existent manufacturers and to guide new entrants.
 - c) To utilize the already available fill & finish capacity – with building technological capacity – and at the same time to attend to the less developed capacity in drug substance manufacturing.
- 3) Slow rolling out of programmes and finance were identified:
 - a) Despite several offers, resources for skills development and capacity building are not being rolled out in an enabling manner to support the industry's needs.
 - b) There is concern on potential disconnect between the extensive programmes by AfDB and Afreximbank and the support required by industry and governments to build vaccine manufacturing capacity, including transparency on the requirements of the banks, time to conclude deals, terms and conditions attached to the funding and general awareness and experience of financing that might be available.

The way forward: The Global Event identified opportunities to enhance the sustainability of investment for vaccine manufacturing in Africa:

- a) There is an unmet need to facilitate technology transfer for over 80% of the investment initiatives and to build their capacity to meet regulatory requirements.
- b) There are outstanding investment initiatives both by African and international investors that require financing and market opportunities.
- c) Many international investors are seeking partners in Africa and there is a need to provide further support for business-to-business linkages.

- d) Leveraging support to PAVM by development partners to accelerate vaccine product development and manufacturing capabilities on the continent.

At the end of the meeting industry representatives adopted a statement for action covering four key areas, namely, (1), implementing enabling policies; (2) increasing predictability of demand; (3) regulatory pathways for African vaccines; and (4) mobilizing financial resources. See Annex I.

Taking the opportunities and other processes to support PAVM into account, the co-conveners of the event, supported by GIZ and BMZ, agreed to take forward the initiative by the industry.

Conclusion and evaluation of the event

The Global Event was highly rated and considered a success by most participants. For many the presence of diverse stakeholders and the opportunity for networking were the most important aspects of the event. ‘Openness’, ‘frankness’, and ‘quality’ were terms used to describe the discussions. Some of the discussions were, however, considered too lengthy and time for networking was noted to be insufficient. One participant stated that:

This was one of the first events where the discourse changed from a visionary ambition to discussing real trade-offs, including mentioning risks. This type of reality check is much needed now for a fit-for-purpose African manufacturing footprint to succeed.

Participants called for additional opportunities for networking, review of progress and further iterations of this Global Event.

Detailed report is available at <https://www.avmi-africa.org/>.



Annex I

African Vaccine Manufacturing Initiative

African Vaccine Industry Perspective

Accelerating Action towards Viable Vaccine Manufacturing in Africa



5 July 2023

Following the COVID-19 pandemic, African countries and development partners have prioritised investment into vaccines manufacturing capacity with a goal to produce 60% of African demand locally with a view to overcome health inequities and improve health security.

From 27-29 June 2023, the African Vaccine Manufacturing Initiative (AVMI) in collaboration with the United Nations Conference on Trade and Development (UNCTAD) and the Africa Centres for Disease Control and Prevention (Africa CDC) with support from German development cooperation, convened **A Global Event on Enhancing the Sustainability of Investment in Vaccine Manufacturing in Africa**. More than 140 participants from international and African vaccine industry, international organizations, governments, and civil society participated in the discussions. It should be noted that this represented the largest gathering of African vaccine manufacturers since the formation of the Partnership for African Vaccine Manufacturing (PAVM) in 2021. The critical need to establish local vaccine development and manufacturing capacity to ensure better health outcomes and health security in Africa cannot be overstated and is well accepted.

AVMI and African vaccine manufacturers in attendance welcomed the leadership of the Africa CDC and acknowledged the remarkable progress that the PAVM has made. Through engaging with a broad group of stakeholders, Africa CDC has established a growing movement towards building sound and viable vaccine manufacturing in Africa.

Now is the time to jointly build on these foundations to accelerate progress on key elements of the PAVM Framework for Action and adopt a market-based approach so that a competitive and viable vaccine manufacturing sector can emerge.

We, as AVMI and industry stakeholders, recognize our direct responsibility and role as implementers of vaccine development and manufacturing capacities on the ground and are committed to achieving this.

Therefore, recognising

- the substantial financial investments required;
- the importance of technology transfer in collaboration with industrial partners;
- the time it takes to achieve efficient production and that vaccine manufacturing is sensitive to economies of scale;
- the long lead-times involved in achieving WHO prequalification for vaccines;
- the need to establish vaccine R&D capacity to break the absolute reliance on 3rd parties for access to technology;
- the need for commitment from and alignment between African governments;
- that current efforts by African manufacturers and others should not be wasted and must result in tangible and viable long-term vaccine manufacturing capacities.

We emphasize the **urgent and essential requirement** for

1 **Implementing enabling policies through**

- 1.1. Time-limited supply-side incentives (e.g. interest subsidies, utility subsidies, concessionary land) in support of the domestic pharmaceutical manufacturing as part of a comprehensive industrial policy approach for the sector;
- 1.2. Establishing time-limited price premiums for African vaccine manufacturers within procurement mechanisms on the national level as well as within GAVI/UNICEF and mechanisms under development on the regional and continental level. Additional investment by both African governments and international partners will be required for the premiums as well as the full operationalization and financing of the GAVI Advance Market Commitment;
- 1.3. Operationalising regional and continental commitments for liberalisation of trade and investment to deepen the integration of the African biopharmaceutical market.

2 **Increasing predictability of demand through**

- 2.1. Consolidation of African vaccine demand on a sustained multi-year time horizon in alignment with procurement cycles by UNICEF and other procurement agencies with Guaranteed offtake agreements;
- 2.2. Commitment by African governments to choosing African-made vaccines when and where they are available under pre-defined terms and conditions;
- 2.3. Identifying a shortlist of priority antigens/vaccines for local procurement by African governments as well as regional and multilateral bodies, which manufacturers can specifically target for investments;
- 2.4. Financing a continental mechanism for pooled procurement of vaccines with targeted incentives for vaccines produced in Africa manufacturers.

3 **Streamlining and speeding up regulatory pathways for African vaccines through**

- 3.1. Expediting regional and pan-African regulatory harmonization schemes, including an accelerated ratification and operationalisation of the African Medicines Agency;
- 3.2. Utilising regulatory reliance mechanisms in the interim for expedited market authorization of African-made vaccines;
- 3.3. Working with WHO to expedite WHO prequalification of vaccines produced by African manufacturers.

4 **Mobilising financial resources through**

- 4.1. Unlocking financing to local manufacturers for preparation and implementation of bankable projects;
- 4.2. Applying innovative blended financing to develop vaccine R&D and manufacturing capabilities;
- 4.3. Supporting African governments investments in education, training and technology transfers for sustainable vaccine production.

The time is NOW!

Current and planned investments in vaccine manufacturing in Africa and emerging technology transfer partnerships are at a major risk without immediate and focussed interventions.

The AVMI and the African manufacturer constituency are poised to fully engage, support, and complement efforts to institute these practical, tangible and urgent interventions.

We are committed to working towards improved health outcomes, increased health security, and sustainable economic development through the establishment of a viable vaccine industry in Africa.

Annex II
Participants/Stakeholder mapping

A. Industry

International	Eastern Africa	Northern Africa	Southern Africa	Western Africa
Merck Lifescience	Kenya Biovax Institute (KBI)	Gennecs, Egypt	Biovac, South Africa	Innovative Biotech Ltd, Nigeria
Unizima	Pharmonova, Zambia	Institut Pasteur d'Algérie	Aspen Pharmaceuticals	Biovaccines Nigeria, Ltd.
GlaxoSmithKline PLC	Kenya Medical Research Institute (KEMRI)	BioGeneric Pharma S.A.E (BGP), Egypt	Afrigen Biologics and Vaccines, South Africa	Atlantic life sciences, Ghana
KENUP Foundation	Armauer Hansen Research Institute (AHRI), Ethiopia	VACSERA - Biological Products and Vaccines, Egypt	Syntegon Technology South Africa (Pty)	Nigeria Integrated Biopharmaceuticals Industries Consortium (NIBI)
Thermo Fisher	Revital Healthcare Kenya	MARBIO, Morocco		National Vaccine Institute, Ghana
MSD	Vaccine Access Initiative			Kinapharma, Ghana
Sanofi Vaccines				
SK bioscience				
International Vaccine Institute (IVI), Korea				
Eubiologics, Korea				
Moderna				
Kroll Inc.				
IQVIA				

B. Technical financial and development partners

1. Afreximbank (African Export–Import Bank)
2. Africa Centres for Disease Control and Prevention (Africa CDC).
3. African Development Bank
4. African Vaccine Manufacturers Initiative (AVMI)
5. Clinton Health Access Initiative (CHAI)
6. Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH,
7. European Commission
8. GAVI- Global Alliance for Vaccines and Immunization
9. German Federal Ministry for Economic Cooperation and Development (BMZ).
10. Lion’s Head
11. Ministry of Health of Ethiopia
12. Medicines Patent Pool (MPP)
13. UNICEF
14. United Nations Conference on Trade and Development (UNCTAD)
15. USAID
16. World Health Organization