

Global Vaccine and Immunization Research Forum 2023

Grand Hyatt, Incheon, Republic of Korea

28 – 30 March 2023

Workshop 3: Regional Manufacturing

An African Mission - Establish and Sustain

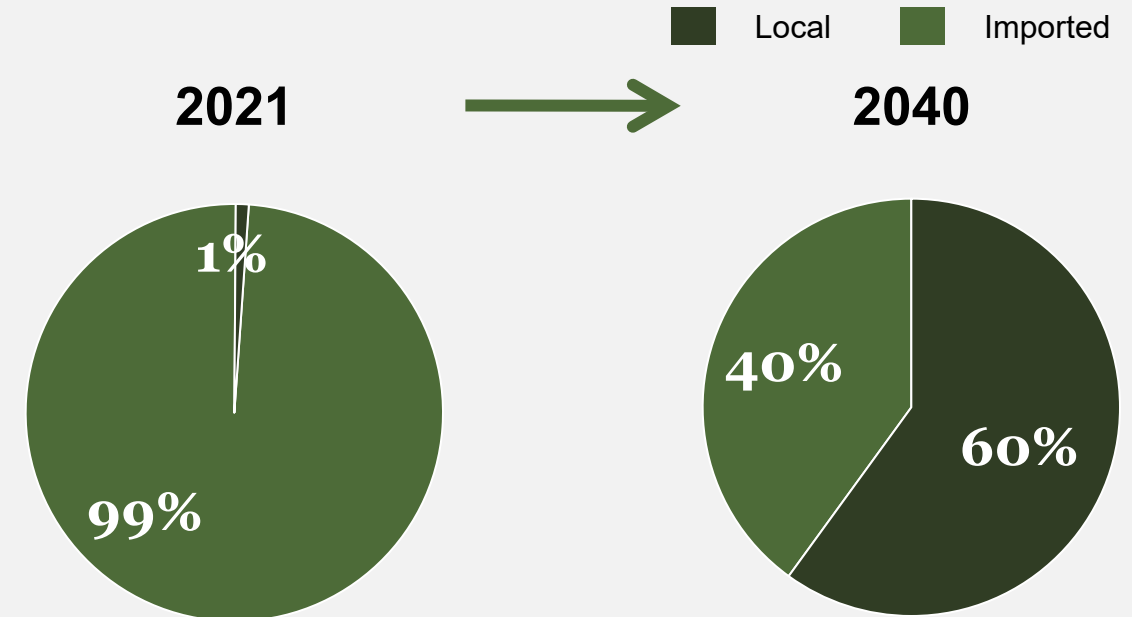


April 2021

African Union set the goal to ensure 60% of the vaccines administered in Africa are locally manufactured...



Ambition to be enabled by the Framework for Action



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

PAVM – Partnership for African Vaccine Manufacturing

Vision

To ensure Africa has timely access to vaccines to protect public health security, by establishing a sustainable vaccine **development and **manufacturing** ecosystem in Africa**

PAVM developed a continental strategy that outlines **diseases, technology platforms and manufacturing value chain steps** that Africa needs to prioritise

Vaccine exists Vaccine does not yet exist

Potential disease prioritization

Prioritized 22 diseases...

Legacy

Diphtheria	Hepatitis B	Measles	Meningococcal
Whooping Cough	Yellow fever	Typhoid fever	
Tetanus	Tuberculosis	Cholera	

Expanding

HPV	Pneumococcal
HIV	COVID-19
Malaria	Rotavirus

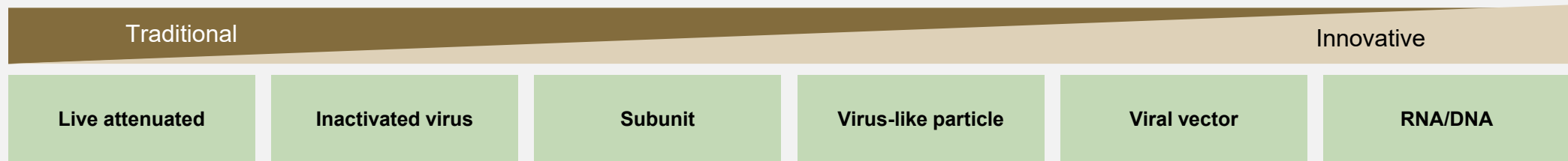
Outbreak

Ebola	Influenza
Chikungunya	Lassa fever
Rift valley fever	Disease X



Technology focus

... requiring a breadth of technology platforms...



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.

Drug Substance (DS)

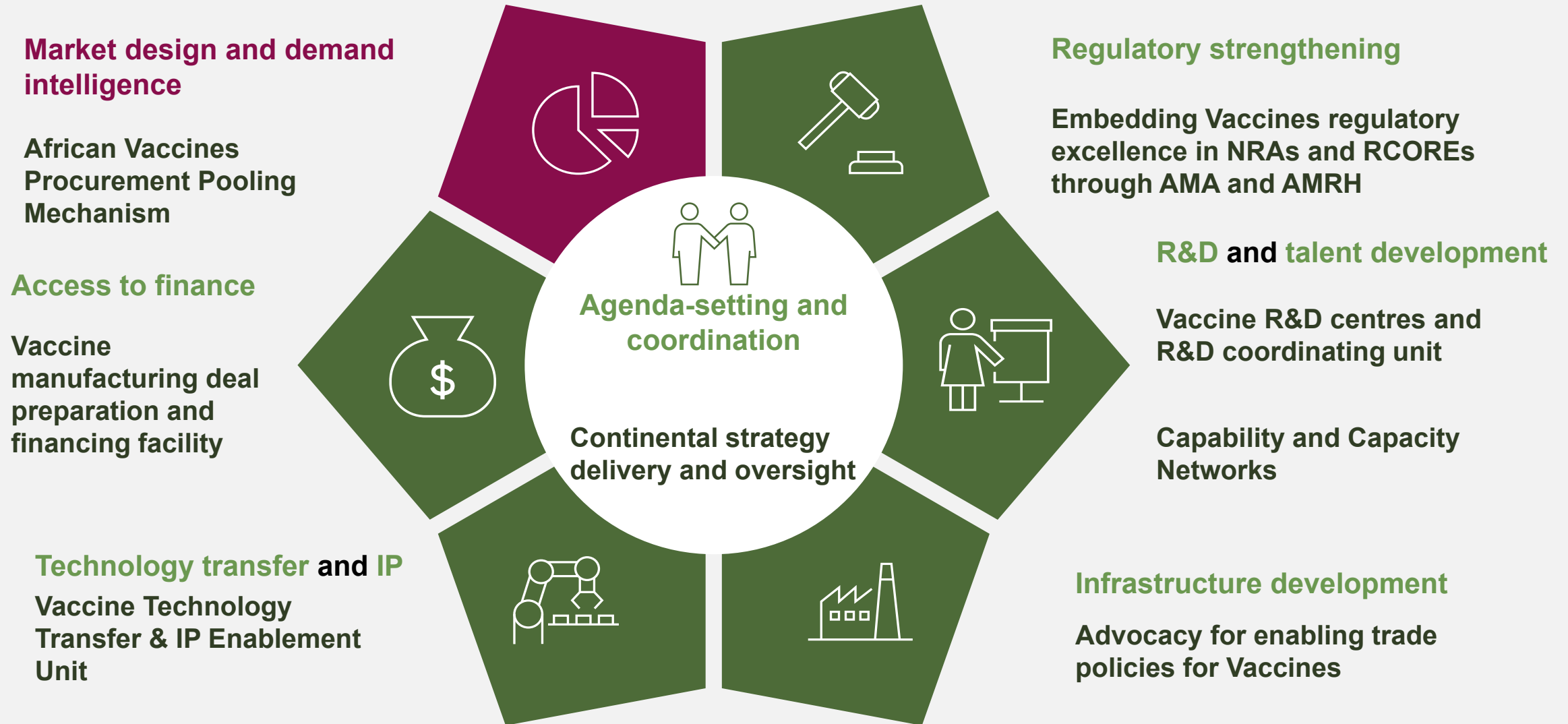
Expand drug substance mostly in established platforms

R&D

Expand R&D activities to develop new vaccines for Africa, support more efficient manufacturing and improve vaccine characteristics



PAVM developed a continental **Framework For Action (FFA)** which defines **8 bold programs** to support vaccine manufacturing ecosystem enablers



Advance the establishment of sustainable human vaccine manufacturing capacity in Africa



MISSION

Africa and beyond...

Build a diversified and sustainable vaccine development and manufacturing capability in Africa

- 1 to ensure **vaccine supply security** in Africa
- 2 as an integral part of the **global vaccine supply chain** especially in emergency disease outbreak situations

2015 VMMPA Study Conclusion



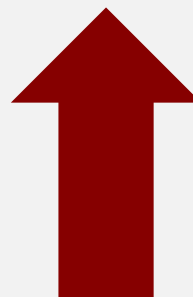
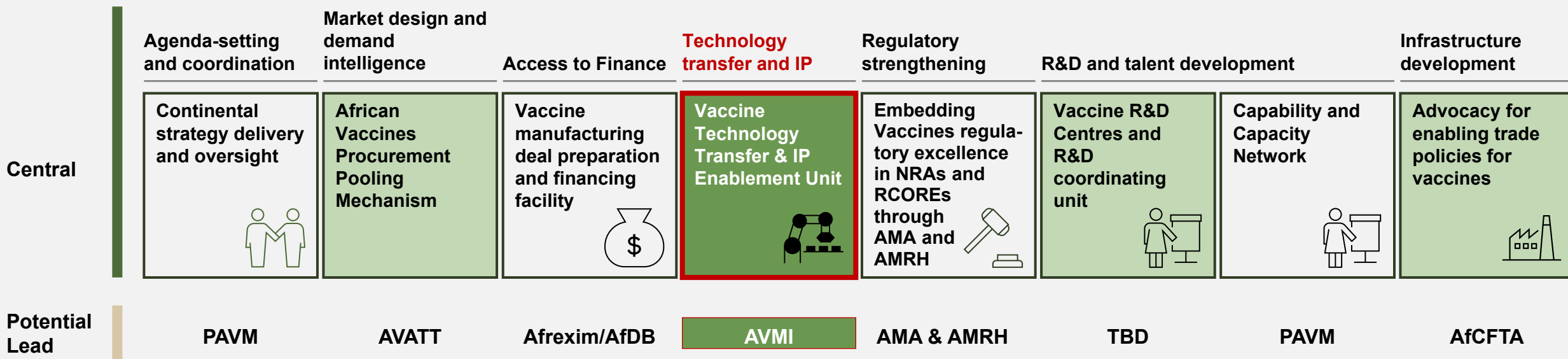
VMMPA STUDY

VACCINE MANUFACTURING AND PROCUREMENT IN AFRICA

An analytical assessment of vaccine manufacturing capacity and
procurement mechanisms for establishing sustainable vaccine
manufacturing capacity in Africa



- Space for **multiple major players** in the vaccine production field in Africa
- A number of **regional hubs** could be established.
- Requires the right level of **political** and **technical** support
 - ... to develop the necessary **ecosystem** to establish a viable, competitive and sustainable vaccine manufacturing capability.
- **Long-term vision** - tied to national (health) security and regional health security.



African Vaccine Manufacturing Industry Forum

No.	Organisation	Country
1	Biogeneric Pharma	Egypt
2	Biovac Egypt	Egypt
3	Polygon Pharma/ Biovac Egypt for Vaccines and Serums	Egypt
4	EVA Pharma	Egypt
5	Gennecs	Egypt
6	MEVAC / Vaccine and Biotechnology City (VBC)	Egypt
7	Minapharm Pharmaceuticals	Egypt
8	VACSERA	Egypt
9	Armauer Hansen Research Institute (AHRI/MoH)	Ethiopia
10	African CDC	Ethiopia
11	Atlantic Life Sciences	Ghana
12	DEK Vaccines	Ghana
13	Biovax Kenya	Kenya
14	Institute Pasteur Morocco	Morocco
15	Samsung Biologics for Institute Pasteur Morocco	Morocco
16	Innovative Biotech, Nigeria	Nigeria
17	Biovaccines Nigeria	Nigeria
18	Institute Pasteur Dakar	Senegal
19	Afrigen	South Africa
20	Aspen	South Africa
21	Biovac	South Africa

AVMI: Voice of Industry in Africa

AVMI - key point of contact for multilateral engagement with vaccine manufacturers in Africa.

1. Priority is to achieve **practical and realistic modalities for the procurement of vaccines**, both from the international agencies and also from African governments (GAVI and non-GAVI volumes).
2. Requires a **transitional procurement support fund** or similar vehicle.
 - **Pricing mechanism** needs to support journey to sustainability and provide a business case for investment.
 - **A premium per dose** that manufacturers will be guaranteed.
 - **Timeframe:** Recognise that this cannot continue into perpetuity - but it needs to be significant enough (10 years, 15 years?)

AVMI: Voice of Industry in Africa

3. Full (end-to-end) vaccine manufacturing:

- Model should support both DP and DS manufacture and ensure that incentives and design **drive full vaccine manufacturing capacity building in Africa.**
- In addition models should also support **collaborative regional, continental, and international manufacturing value chains.**
- Important if Africa is to be in a position to manufacture vaccines in **future outbreak and emergency situations** (global and regional).



Scaling Up African Vaccine Manufacturing



Wellcome, Biovac and BCG published a report in January 2023



Scaling Up African Vaccine Manufacturing Capacity

Perspectives from the African vaccine-manufacturing industry on the challenges and the need for support

January 2023



Photo by Adene Sanchez / E+ Via Getty Images

II. Executive Summary

The Covid-19 pandemic served as a wake-up call for many global health organizations and policy makers. It shed light on the compelling need for increasing vaccine manufacturing capacity and capabilities across the African continent, in order to strengthen pandemic preparedness, to improve vaccine supply security, and to better tackle endemic diseases. To meet these challenges, the next priority is to increase the value of the infectious agent market, supported by the development of African vaccine manufacturing frameworks for Africa (FMA) (FMA 2022). The African vaccine-manufacturing industry hopes to address this critical need through a number of initiatives, including the development of a continental strategy, the expansion of existing facilities, and the construction of new facilities. The industry is currently in a state of rapid growth, with many manufacturers seeking to expand their production capacity and improve their operational efficiency. The industry is also seeking to improve its regulatory and quality management systems, and to enhance its supply chain resilience. The industry is currently in a state of rapid growth, with many manufacturers seeking to expand their production capacity and improve their operational efficiency. The industry is also seeking to improve its regulatory and quality management systems, and to enhance its supply chain resilience.

V. Key findings

1. A long journey ahead to develop the African vaccine manufacturing industry

The Covid-19 pandemic provided a stark reminder of the need for building vaccine manufacturing capacity and capabilities across the African continent. However, there have been challenges in the African continent, including limited access to capital, limited regulatory and quality management systems, and limited supply chain resilience. The industry is currently in a state of rapid growth, with many manufacturers seeking to expand their production capacity and improve their operational efficiency. The industry is also seeking to improve its regulatory and quality management systems, and to enhance its supply chain resilience.

2. Scale of vaccine volume by manufacturer origin based on 2021 public vaccine purchase

Manufacturer Origin	Share of Vaccine Volume
WHO Region: Africa	6%
WHO Region: Americas	71%
WHO Region: Europe	8%
WHO Region: Eastern Mediterranean	8%
WHO Region: South-East Asia	7%
WHO Region: Western Pacific	3%

3. Scale of vaccine volume by manufacturer origin based on 2021 public vaccine purchase

The chart shows that the WHO Region: Americas is the largest supplier of vaccines to the African continent, accounting for 71% of the total volume. The WHO Region: Africa accounts for 6%, while the WHO Region: Europe, WHO Region: Eastern Mediterranean, WHO Region: South-East Asia, and WHO Region: Western Pacific account for 8%, 7%, and 3% respectively.

4. Africa's vaccine manufacturing landscape - operational establishments

The map shows the locations of various vaccine manufacturing establishments across Africa. Key locations include:

- South Africa: Pfizer (2015), AstraZeneca (2021)
- Egypt: AstraZeneca (2021)
- Kenya: AstraZeneca (2021)
- Senegal: AstraZeneca (2021)
- Uganda: AstraZeneca (2021)
- South Sudan: AstraZeneca (2021)
- Sierra Leone: AstraZeneca (2021)
- Guinea: AstraZeneca (2021)
- Sierra Leone: AstraZeneca (2021)
- Sierra Leone: AstraZeneca (2021)

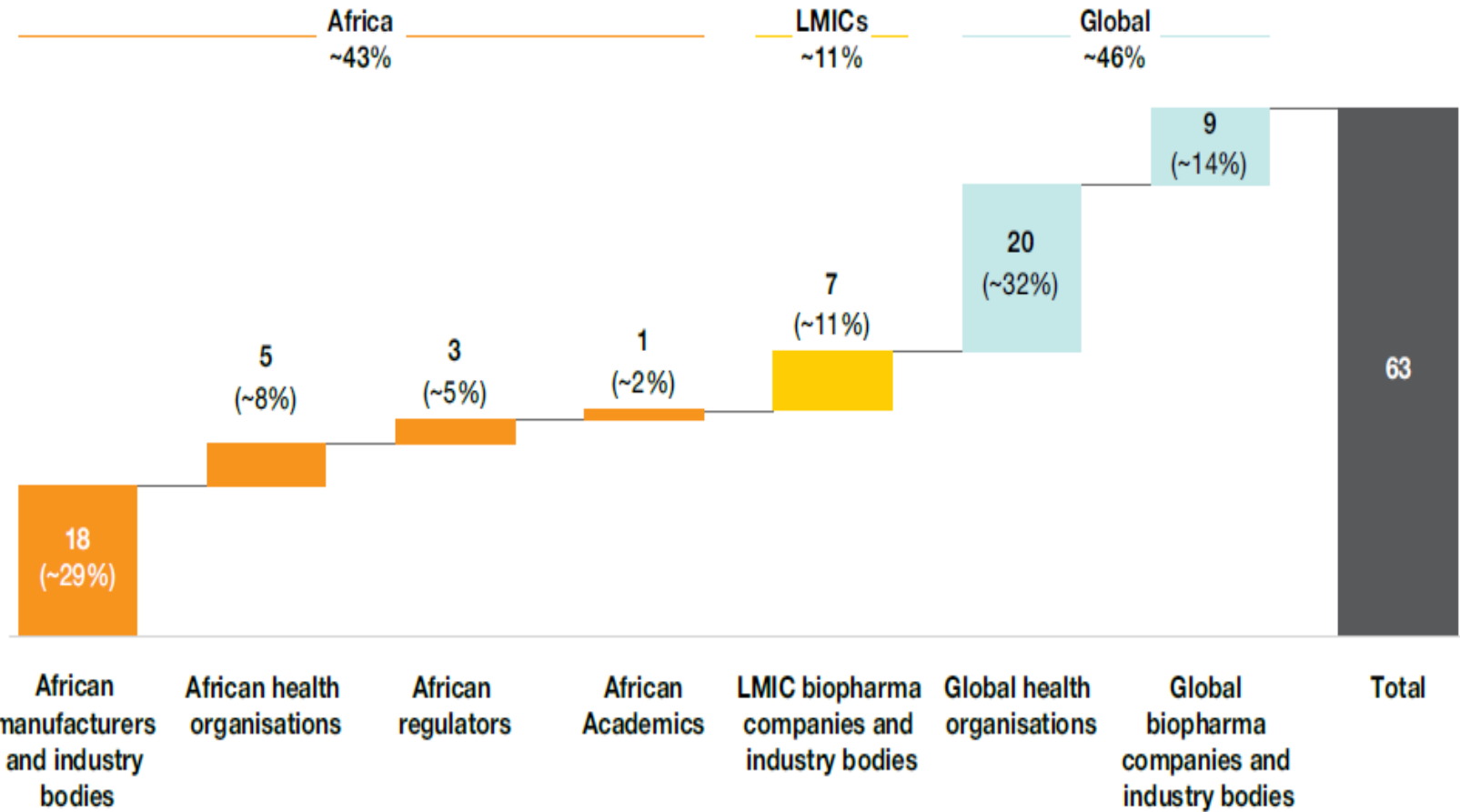
5. Ten of the manufacturers have operational FAP capabilities, and three additional manufacturers are due for commissioning.

The chart shows that 10 manufacturers have operational FAP capabilities, and 3 additional manufacturers are due for commissioning. The manufacturers with operational FAP capabilities are:

- WHO Region: Africa
- WHO Region: Americas
- WHO Region: Europe
- WHO Region: Eastern Mediterranean
- WHO Region: South-East Asia
- WHO Region: Western Pacific



Figure 1: Diversity of interviewed profiles



Source: BCG interviews



Executive summary (I/II)



There is a **compelling need** for expanding vaccine-manufacturing capacity and capabilities across the African continent - the target defined by the PAVM is a **strong rallying cry** to initiate change



The African vaccine-manufacturing industry today is still in its very early stages but is **not starting from zero**, with a dozen African players spread across the continent



The PAVM FFA has put forward **one vision of the African vaccine-manufacturing ecosystem** based on its analysis and 2040 goals



Many promising announcements have been made and initiatives have been launched in the past 18 months



Manufacturers stress that **economic viability still needs to be demonstrated**, and is crucial to the success of this strategy. A few success factors should be considered, such as:

- **Large-scale facilities** need to be prioritised
- Manufacturers should be able to export their products to the **continental market**
- A mechanism will be needed to **subsidise locally manufactured vaccines**



Executive summary (II/II)



African manufacturers identify **three major risks** to the desired economic viability:

- **Sustainability risk:** lack of concrete measures, uncoordinated effort
- **Strategic risk:** broad strategy, need for further prioritisation to guide manufacturers' efforts and investments in the short- and mid-term
- **Support risk:** concern about loss of attention and effort over time as the Covid-19 pandemic recedes



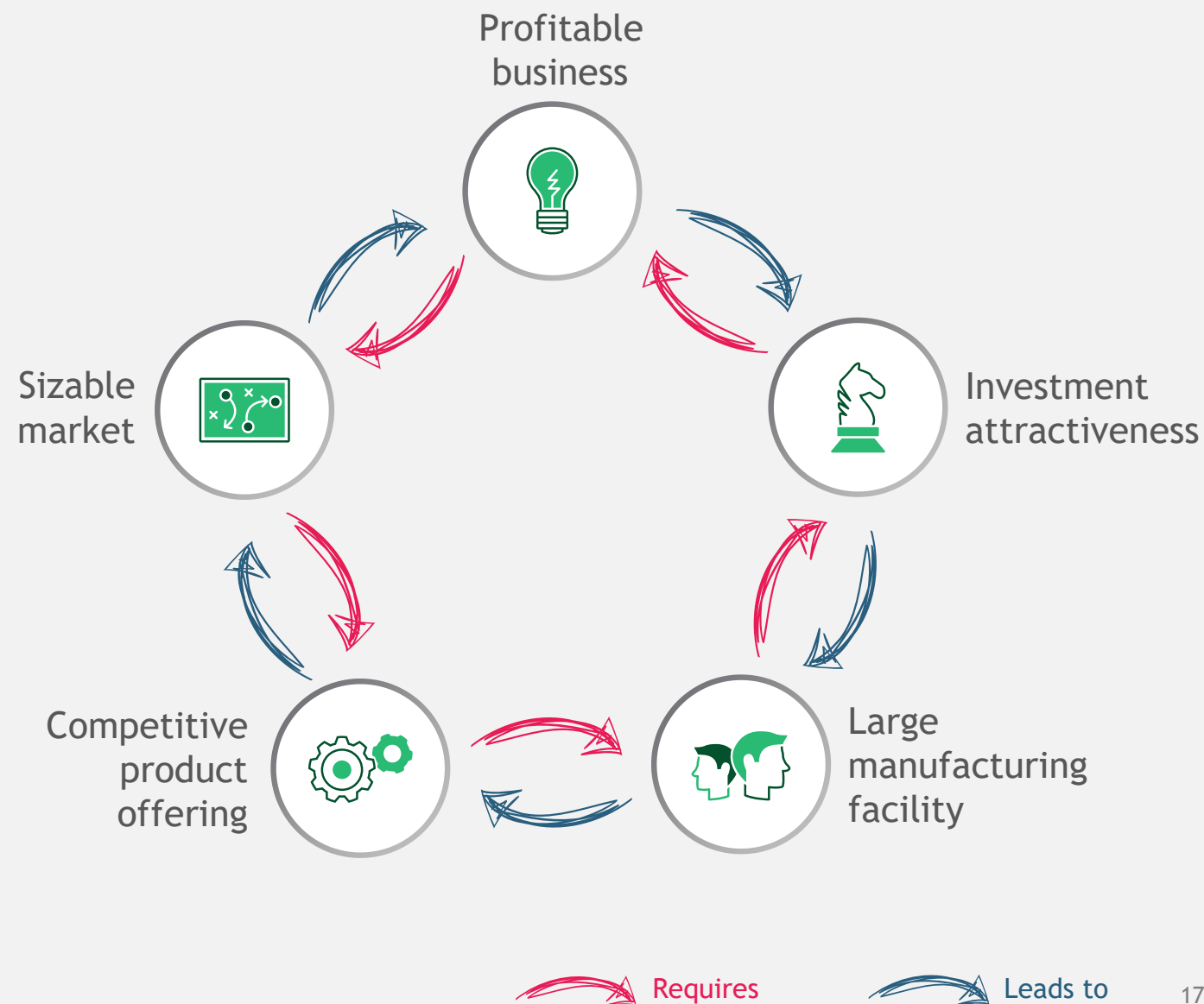
There are **several prerequisites** to creating conditions for a sustainable ecosystem for African vaccine manufacturers:

- **Advance purchase agreements** from African governments
- **A review of the procurement mechanisms**
- **Financial mechanisms** to counterbalance the lack of price-competitiveness
- **Coordination mechanisms** to improve information sharing



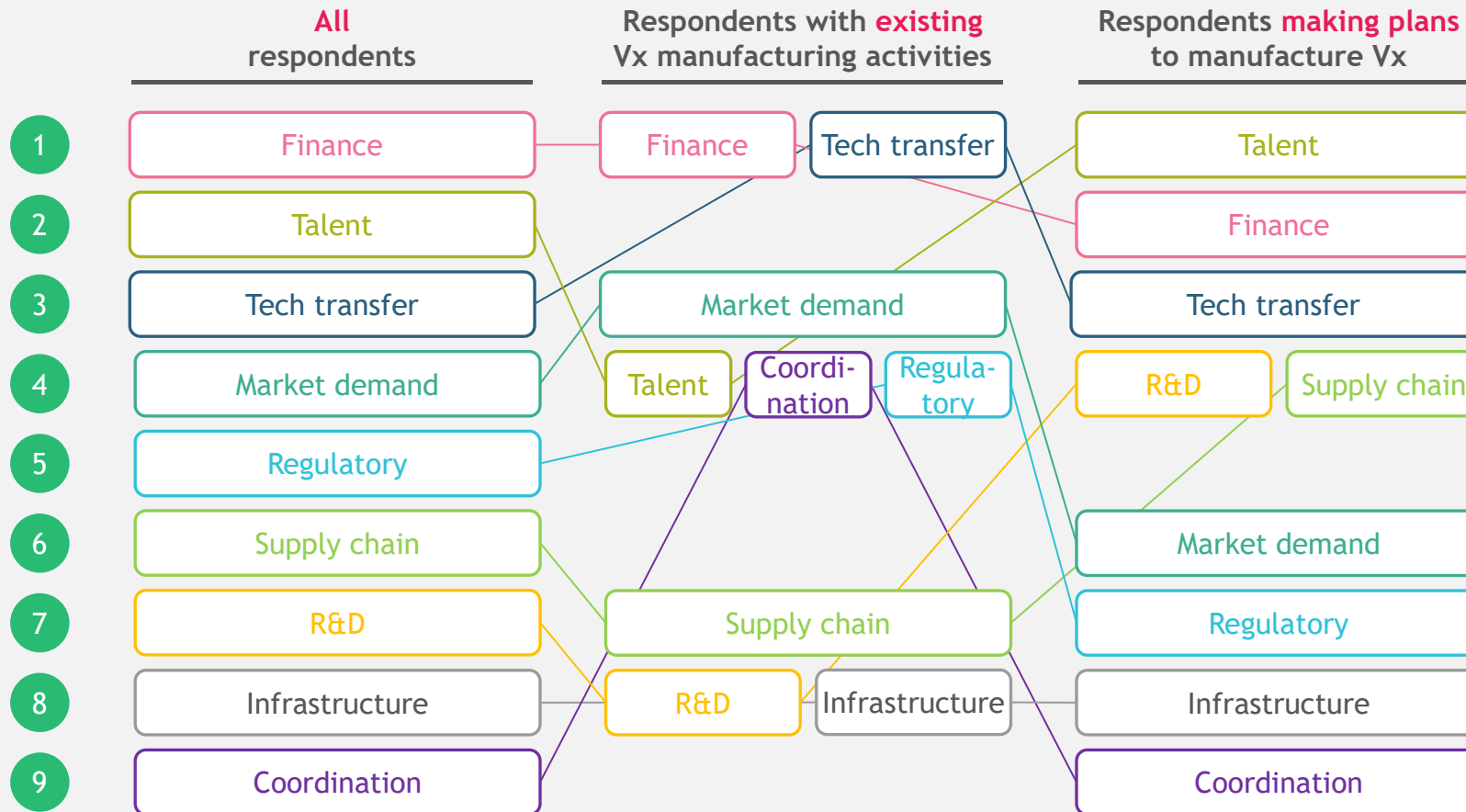
African manufacturers should focus on **strategic and realistic priorities** to initiate change. They need to prioritise supply-constrained products with less complex end-to-end manufacturing processes in the short- and mid-term

Requirements for and consequences of devising a viable business model



Assessment of key challenges by African manufacturers

Ranking of priority challenges by groups of African vaccine manufacturers

















Local manufacturers **focused on practical considerations when thinking about key barriers to scaling capabilities**

Different priorities depending on maturity - existing manufacturers prioritise more **market demand and tech transfers**

- Already have infrastructure and staff in place
- Know complexity of Tech Transfers and of finding market opportunities

Figure 4: Capacity mapping – Existing capabilities per manufacturer in Africa

Manufacturer	Country	Vaccines	R&D	DS	F&F	Import for distribution
 Afrigen	 South Africa	Covid-19 Hepatitis B Rift Valley Fever TB	● ● ● ●	●	●	
 Aspen	 South Africa	Covid-19			●	
 Biovac	 South Africa	BCG Covid-19 GBS Hepatitis B Hexavalent OCV OPV Pneumococcus Measles	●			● ● ● ● ● ● ● ●
 EPHI	 Ethiopia	Rabies		●	●	
 Innovative Biotech	 Nigeria	Covid-19 Ebola HIV HPV Yellow Fever	● ● ● ● ●			
 Institut Pasteur d'Algérie	 Algeria	Rabies		●	●	
 Institut Pasteur de Dakar	 Senegal	Yellow fever		●	●	





BIOVAC

science of protecting life

Building end-to-end vaccine development and manufacturing capacity in Africa



In Africa for the development and manufacture of affordable vaccines

- Establish **end-to-end vaccine development and manufacturing capability** for local and export markets

Product Development

Manufacturing

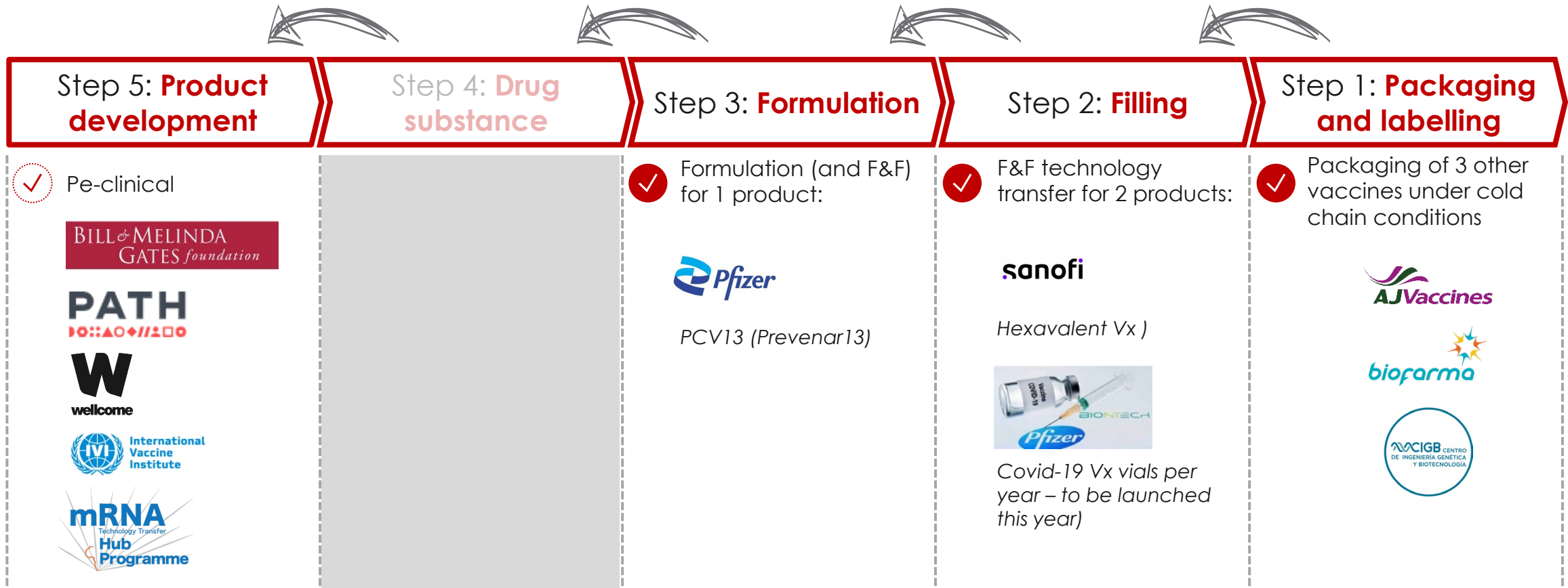
Distribution

- ...through **product development partnerships and tech transfer partnerships**

Built capabilities in formulation, fill and finish as well as product development

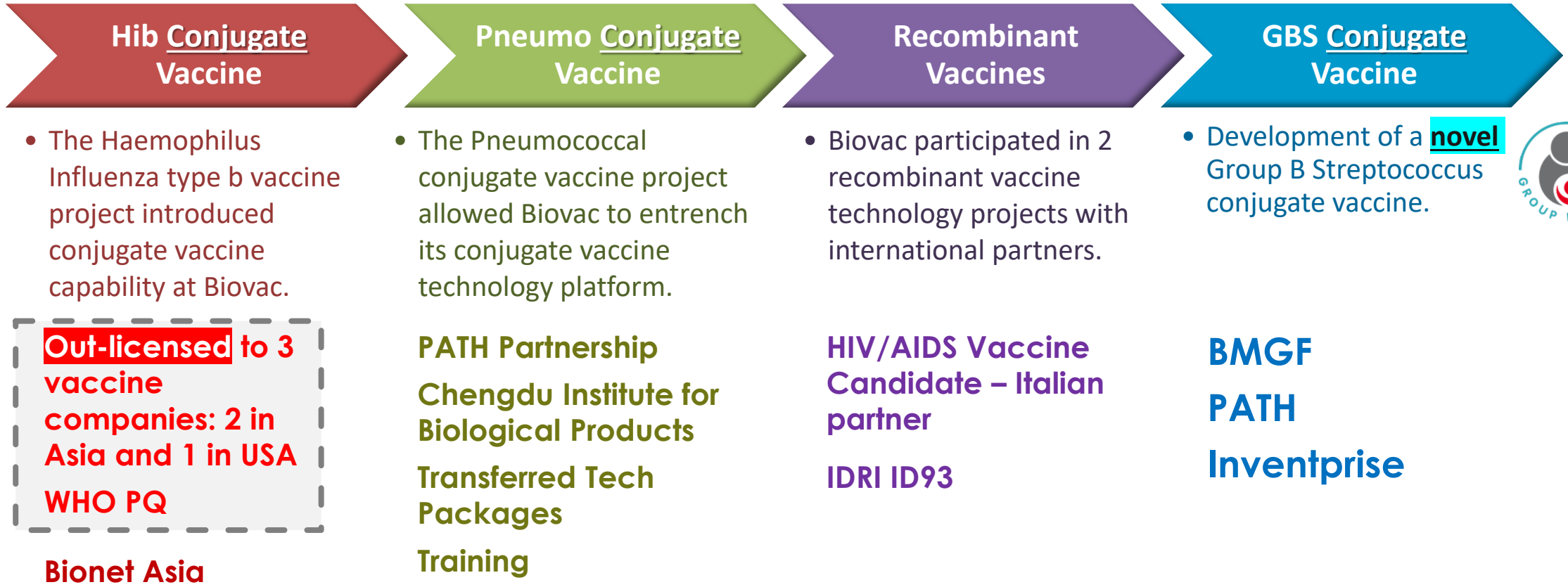


... reverse integration approach



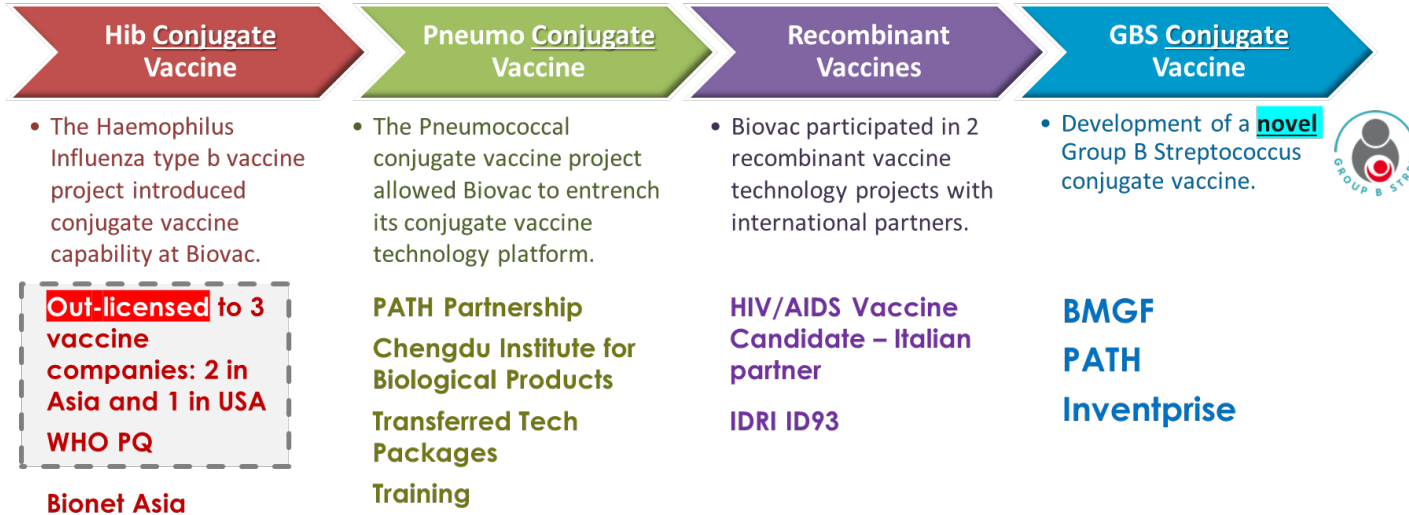
Partnered with world class vaccine organisations

Building globally recognized product development capability



International Product Development Partnerships

Building globally recognized product development capability



South Africa's Biovac Signs Deal to Produce Oral Cholera Vaccine

Agreement comes as global cholera outbreaks strain supply
 Covid-19 exposed Africa's lack of local production capacity

By Janice Kew
 23 November 2022 at 17:13 SAST

The Biovac Institute, a partly state-owned vaccine producer in South Africa, has secured a deal to make an oral cholera inoculation as recent global outbreaks of the diarrheal disease have raised demand for vaccines.

The agreement with the International Vaccine Institute includes both licensing and technology transfer and is significant for Biovac because drug substance manufacturing capability will be built.

Being able to produce the raw material needed to make vaccines is one of the last steps manufacturers on the continent are widely missing and will help scale up the local production of clinical trial products in Africa.

"The Covid-19 pandemic exposed Africa's lack of local production capacity," Morena Makhele, the...

Tech Transfer on Cholera vaccine with IVI

International Product Development Partnerships

Global mRNA Hub



Global partners



Coordinate & lead project,
monitor implementation



Draft IP / Gov. agreements,
monitor implementation

Hub

Recipient



Receive tech and
transfer to recipients



Receive tech and
produce vaccines

Biovac

responsible for scale up,
industrialisation of the process and
manufacture of the Ph III CTM.

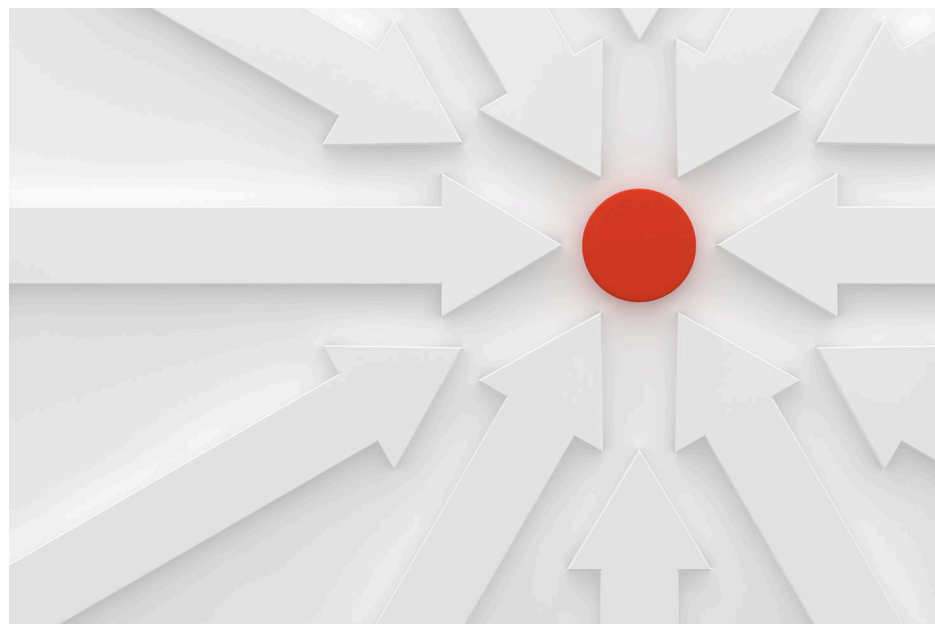
Local / Regional partners



Provide regional
expertise



Provide academic /
clinical dev. support

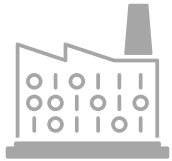
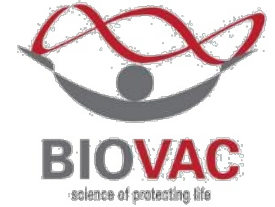


End to end Vaccine Development and Manufacturing Capacity

- Product Development
- Drug Substance
- Drug Product

Mix of technologies – scientific know-how

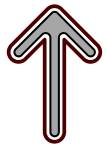
Biovac Expansion Project



Build a **state-of-the-art vaccine manufacturing facility** of global scale, aligned with international standards



Scale up manufacturing capacity (500Mn doses theoretical maximum capacity) and transition to a high-volume / low-cost model



Lead the way at a continental level by setting up a drug substance suite and being able to do **end-to-end vaccine manufacturing**



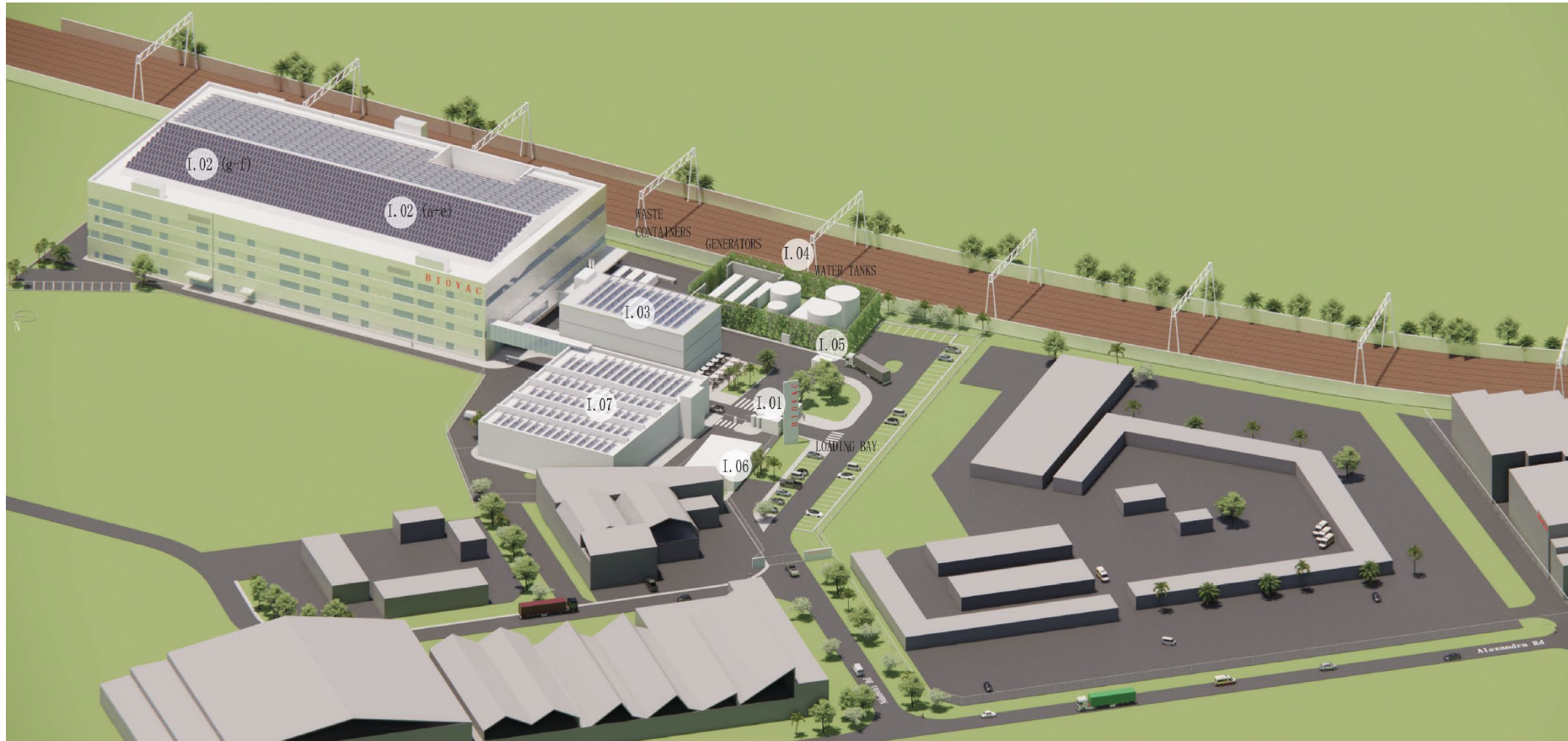
Supply most-needed vaccines to African populations and other LMICs, and ensure Africa has the capacity to respond to the next health emergency

Site master planning phase 1b: Phase 1a + OCV drug substance, fill finish block



Phase I Building extension

LEGEND PHASE I (Bio Building extension)
I.01 GATE HOUSE-MAIN ACCESS / I.02 (a-e) BIO BUILDING / I.02 (f-g) BIO BUILDING EXTENSION / I.03 CANTEN / I.04 UTILITY / I.05 GATE HOUSE-MATERIAL DELIVERY / I.06 ELECTRICAL SUBSTATION / I.07 B-BUILDING

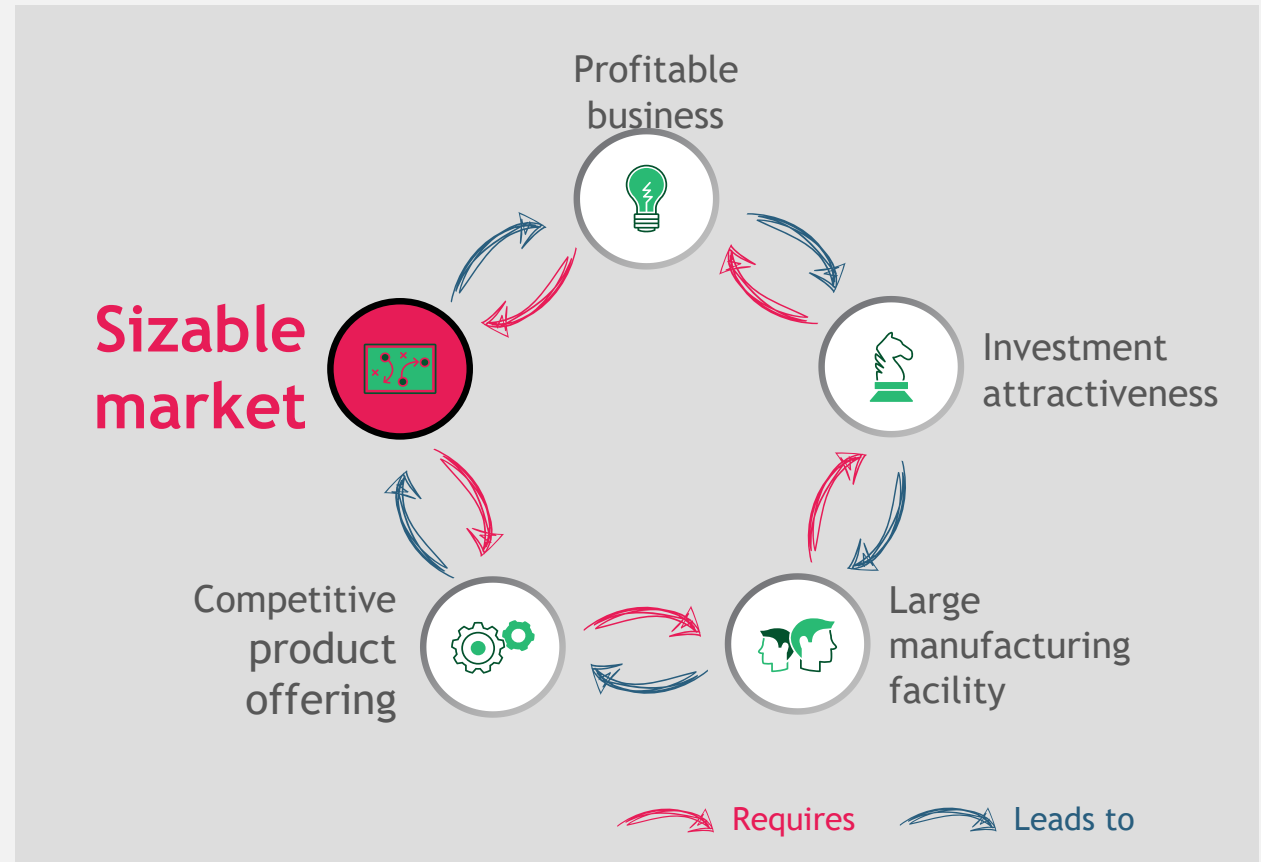




Key Issue
The market

Manufacturers stress that **economic viability still needs to be demonstrated.**

- **Advance purchase agreements** from African governments
- A **revision of current the procurement mechanisms** in Africa
- **Financial mechanisms** to counterbalance the initial lack of price-competitiveness for a defined period





Thank
You