



## Webinar Series: Facilitating Partnerships



**African Development Bank's vision and strategy to advance vaccine manufacturing capacity in Africa.**

Date: 23 November 2023

# Webinar Program

1	Opening and Welcome Remarks	VP Solomon Quaynor and Patrick Tippoo	10 mins
2	The Banks' Plans and Financial Tools	AfDB: Richard Fusi and Ghada Abuzaid	15 mins
		AfreximBank: Zitto Alfayo	15 mins
3	The Manufacturers' Voice	Patrick Tippoo	5 mins
	Challenges and Needs	Biovac: Craig Mitchell	35 mins
		Institute Pasteur Maroc: Abderrahmane Maaroufi	
		Biovax Kenya: Michael Lusiola	
4	Discussion on potential collaborations	All Moderated by Patrick Tippoo	30 mins
5	Summary and Way forward	Ghada Abuzaid and Patrick Tippoo	10 mins

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# Support to Africa's Pharmaceutical and Vaccine Manufacturing Industry: 2030 Vision and Action Plan

AfDB

AfDB and AVMI Webinar, 21 November 2023



## Agenda

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Context, Rationale and Objectives of Bank's Pharmaceutical Industry Study

Findings from Diagnostic Study

Pharmaceutical Vision for Africa

AfDB's planned flagship programs in support of Vaccine Manufacturing

AfDB's Instruments in support of Vaccine Manufacturing

Q&A and Next Steps





## Context and Rationale

- The COVID 19 pandemic has exposed the **fragility of health systems** and highlighted the **necessity of countries' ensuring at least a minimum level of security of supply for health products**
- **Like many governments globally, some governments in Africa are thinking of developing local pharmaceutical sectors:** mostly for security of supply but also potentially to make medicines more affordable to patients, to release the pressure on the balance of payments, and to create wealth more broadly
- The development of the African pharmaceutical industry is **limited by structural challenges** such as small and fragmented markets, logistical constraints, tariff and non-tariff barriers, and limited know-how
- **African production falls well short of local demand;** on average **30–40% of demand is produced locally**, with very diverse levels of manufacturing maturity among the different countries
- **Currently, less than 1% of Africa's vaccines needs are manufactured locally**, presenting both a **risk** due to geographic and supplier consolidation with **many monopolistic situations on different vaccines** and an **untapped opportunity** for local manufacturers to enter or expand production



## The Pharmaceutical Study's Deliverables

Defined a Vision and an Action Plan to support the development of-Africa's pharmaceutical industry:

1. Provided a clear **diagnostic of the current African pharmaceutical market** in terms of maturity and size as well as an **overview of supply and demand dynamics**
2. Set an **ambition for the African continent in terms of local production** by 2030 and beyond
3. Defined **AfDB's vision, model of intervention** per cluster, to support the development of a robust local pharmaceutical industry
4. Structured an investment **roadmap**, composed of a **pipeline of strategic initiatives and quick wins, examples of projects**, and a **communication plan**

# 7 strategic orientations arose from the diagnostic and informed the thinking around the development of a pharmaceutical industry in Africa



Potential to further develop the African Pharmaceutical Industry...



... under certain conditions

1

Clear potential to develop African pharmaceutical manufacturing capacities, for **strategic, public health and economic reasons**

2

Mid-sized local and international pharmaceutical companies have increasingly shown interest in increasing **their manufacturing capacities within the continent**

3

Solid forms of **generics seem to be the primary focus** for further development of local production in most African markets; however, **more complex forms and products** can help increase local production in more mature markets

4

Fragmented market with countries showing limited demand **emphasizing the need to create pharmaceutical hubs** in some regions to attain sufficient and economically competitive scale

5

Logistic integration **needs to be strengthened** to foster the development of regional hubs and enable efficient intra-African and international trade

6

The **harmonization of sector quality standards from education to manufacturing to distribution** is necessary to enable sustainable growth of the African pharmaceutical industry

7

Limited R&D activities that should increase to **address specific needs** related to African **disease burden and heterogeneous genetic pools** compare to the rest of the world

Strategic orientations

Strategy pillars and enablers



Increase the maturity of the industry by supporting the development of local production capacities



Enable regional logistic integration



Help the implementation of quality industry standards



Seed the creation of R&D capacities



# Local Vx manufacturing provides development impact and public health benefits for the continent



## Development impact of local vaccine manufacturing for Africa



### Health

#### Improve self-reliance for sustainable, secure supply

- Improve availability for middle-income African countries left out between Gavi countries and high-income countries
- Continue production of less profitable vaccines of public health importance for Africa
- Improve efficiency and reliability for outbreak response

#### Address Africa-specific burden and context

- Potentially stimulate research for Africa-specific products
- Adapt vaccines for Africa-specific contextual considerations



### Socio-economic

#### Support diversified, value-adding socioeconomic growth

- Provide direct high-skilled job and skill creation in value-adding industry
- Reduce trade deficits in long-term
- Ease FOREX requirements
- Provide indirect impacts of developing the industry (e.g., crowd-in of other scientific industry, other investors etc.)

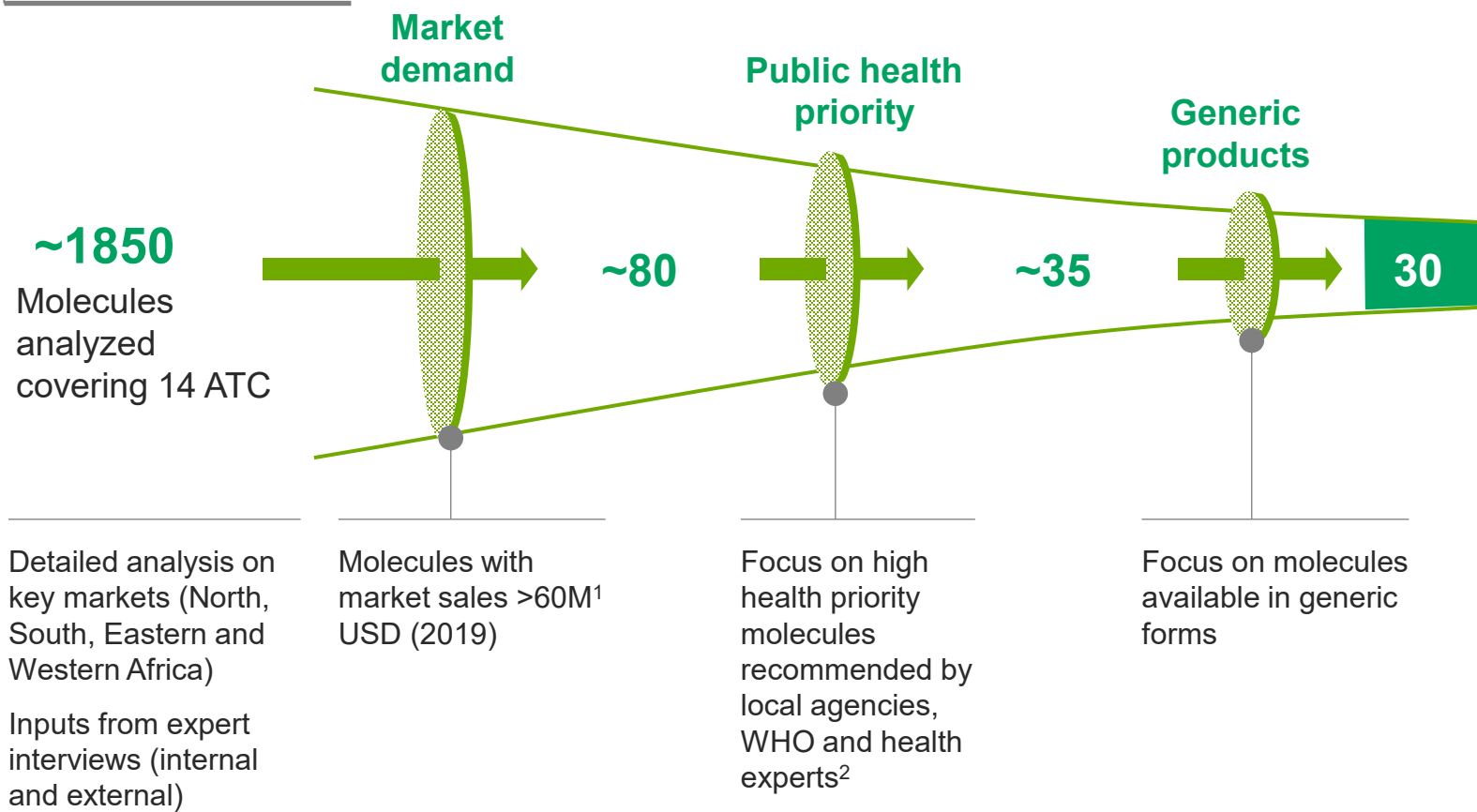


# 30 potential molecules could be considered for local production given their importance in terms of market demand, public health, and their availability in a generic form









## High potential molecule analysis methodology

NON EXHAUSTIVE LIST



Detailed analysis on key markets (North, South, Eastern and Western Africa)

Inputs from expert interviews (internal and external)

Form / Technology	2019 sales, Mn USD	Manufacturing complexity
 Solid oral form	 5.692	 High
 Biosimilars	 624	 Very High

<sup>1</sup> Market sales allowing for economic viability for potential manufactures. ~80 molecules covering ~50% of total market in sales  
<sup>2</sup> Priority given to high African disease burdens. Duplicate drugs further shortlisted to account for therapeutic area diversification

# A target of 45-55% of local production would be highly ambitious yet achievable by gathering a diversity of partners around AfDB



## Target as % of local production by 2030



60-70%

## Equivalent in units

~115-120 Bn

## Ambition level



- **Highly ambitious target** matching the levels observed in developed countries<sup>1</sup> and BRICS with an increase of 30pp vs. today (~30-40%)

## Achievability



Preferred path Low Medium High Very high

- **Very large investments required** from all public and private players (>USD220 Bn<sup>2</sup>)
- **Protectionist measures to be put in place**, putting at risk patients' access to medicines



45-55%

~85-90 Bn



- **Very ambitious target**, adding ~15pp vs. today's level of local production



- **Significant investments required** from both public and private sector (~USD110 Bn<sup>3</sup>)

The target could be achieved by focusing on **30 identified molecules in generics oral form**



30-40%

~60-65 Bn



- **Status-quo target**, in line with today's level of production (~30-40%) with basic needs not being covered



- **Low investments required** (<USD15 Bn<sup>4</sup>)

1 60-70% in Japan, 70-80% in the US, 75-85% in China investment

Source: Expert Interviews

2 Estimated by expert for an targeted increase twice vs. the selected path

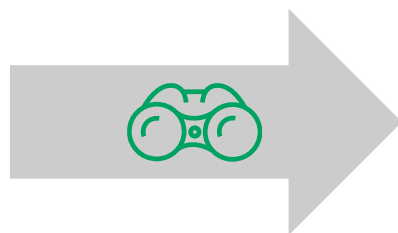
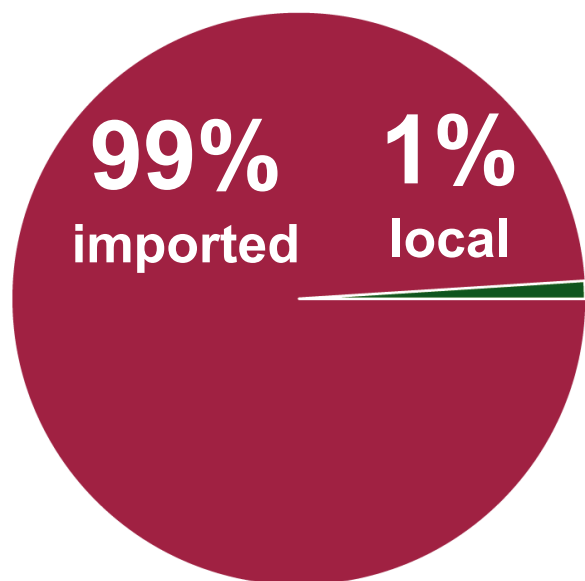
3 As detailed in the strategy

4 Assuming no infrastructure

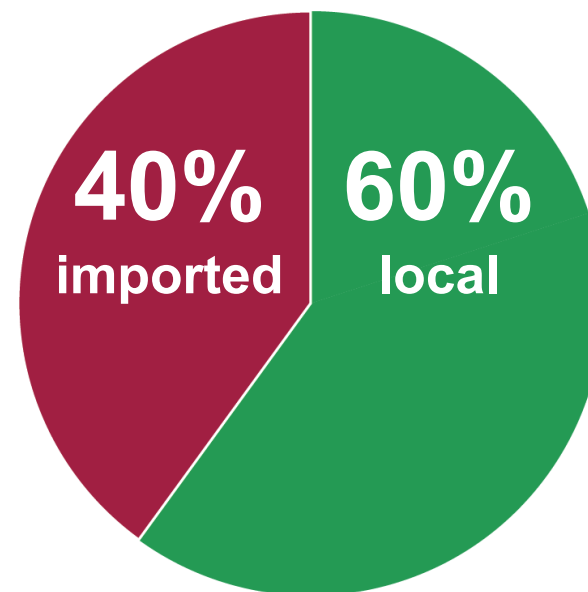
# 1. Africa CDC has set an ambitious target to manufacture 60% of Africa's routine vaccine needs by 2040



**2021**



**2040**



African Union and Africa CDC launched Partnerships for African Vaccine Manufacturing (PAVM) planning an investment of \$1,3Bn to develop the industry, and this ambition is in the process of being translated in a roadmap

# 2030 targets have been defined for the Strategic Pillar and the 4 Enablers

Value in 2019 ➔ **2030 target**

## SUPPORT THE DEVELOPMENT OF SUSTAINABLE LOCAL MANUFACTURING CAPABILITIES ADDRESSING AFRICA'S PHARMACEUTICAL NEEDS



### STRATEGIC PILLAR

**Increase the maturity of the industry by supporting the development of local production capacities**

30-40%

➔ **45-55%**

Share of local production in value by 2030

**1. Support the development of local manufacturers on essential molecules to serve their local markets**

~8-9 Bn units

➔ **35 Bn units**

Targeted production of local manufacturers

**2. Foster the expansion of African and mid-sized international companies on essential molecules within selected countries**

~11-13 Bn units

➔ **55 Bn units**

Targeted production of mid-sized global and Af. champions

**3. Help mature pharmaceutical companies diversify their product portfolio and technologies**

5

➔ **15**

Number of African companies producing biosimilars, i.e. **X3**



### ENABLER I

**Enable regional logistic integration to foster intra-African trade and the creation of trade hubs**

~USD 600 Mn

➔ **USD 1 Bn**

Intra-African pharma exports to USD1 Bn by 2030, i.e. **+70%**



### ENABLER II

**Help the implementation of quality industry standards for the African continent**

~20%

➔ **50%**

Of all pharma manufacturers adhering to GMP<sup>1</sup> standards



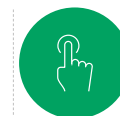
### ENABLER III

**Seed the creation of R&D capacities focusing on Africa specific diseases and needs**

~USD 1.5 Bn

➔ **USD 2.4 Bn**

Pharmaceutical R&D investment in the continent by 2030, i.e. **+~50%**



### ENABLER IV

**Pave the way for increased vaccines manufacturing on the continent**

<1% of local production

➔ **5 Plants**

Continent platforms supplying a significant share of the needs



# With fragmentated trade and inconsistent logistics/freight capacities in Africa, defining 4 pharmaceutical hubs could enable to facilitate pharma trade integration



★ Top nerve centers candidates based on manufacturing and logistics potential    Potential nerve centers    Potential hub members

## 1 West Africa



- Côte d'Ivoire ★
- Ghana ★
- Nigeria ★
- Senegal ★

- Benin
- Burkina Faso
- Cameroon
- Cabo Verde
- Central Af. Rep.
- Chad
- Gabon
- Gambia
- Guinea
- Guinea-Bissau
- Liberia
- Mali
- Niger
- Sierra Leone
- Togo

Cameroun, Gabon, C. Af. Rep., Congo and DRC were included in West Af. And South Af. as there is no potential nerve center in Central Af.

## 2 South Africa



- Mauritius
- South Africa ★
- Zambia ★

- Angola
- Botswana
- Comoros
- Congo
- Eswatini
- Lesotho
- Madagascar
- Malawi
- Mozambique
- Namibia
- Zimbabwe

## 3 East Africa



- Ethiopia ★
- Egypt ★
- Kenya ★
- Rwanda ★
- Tanzania ★
- Uganda ★

- Burundi
- Comoros
- Djibouti
- Eritrea
- Seychelles
- Somalia
- South Sudan
- Sudan

## 4 North Africa



- Morocco
- Algeria
- Tunisia

- Mauritania
- Libya

The North African hub will have a different purpose, mostly aiming at exporting to the entire continent (*detailed next*)

The definition of the hubs is meant to evolve depending on countries' economic evolutions and governments' policies

### Potential nerve centers

### Potential hub members

The fragmented trade integration of the continent and the inconsistent logistic capacities underline the need to have a regional perspective at pharmaceutical trade

4 pharmaceutical hubs were identified based on regional proximity and Regional Economic Communities

In each hub, potential nerve centers were identified. These are countries with developed or potential pharma industry

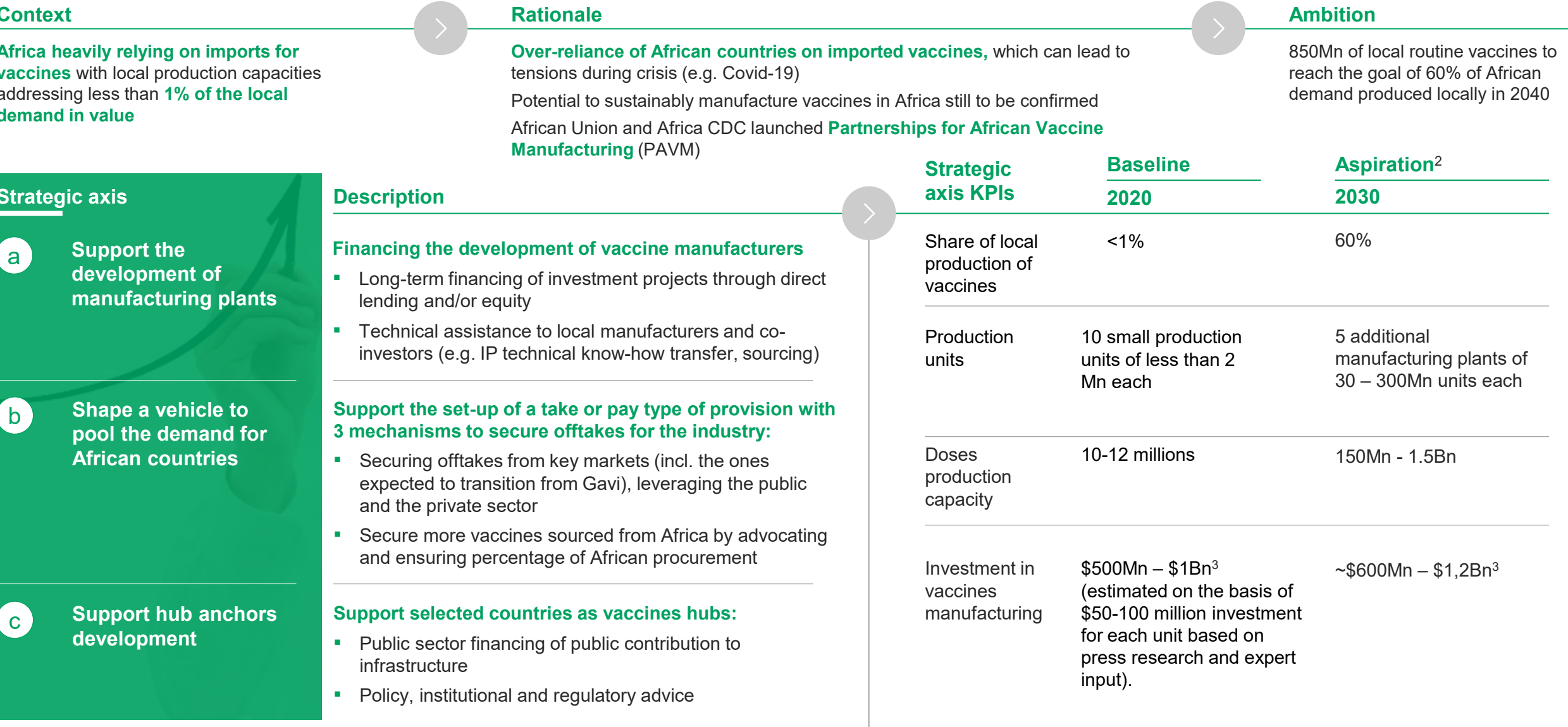
In order to supply their region, nerve centers should be well connected and integrated into their hub

1. Economic Community of West African States | 2. West African Economic and Monetary Union | 3. Common Market for Eastern and Southern Africa | 4. Southern African Development Community | 5. East African Community

Source: Expert interviews



# Enabler IV will pave the way for increased vaccines manufacturing in Africa<sup>1</sup>



1. See full section on Vaccine manufacturing slides 46 – 54.

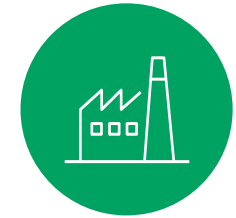
2. Calculations based on an 2040 ambition, but all budgets need to be provisioned by 2030 to meet ambition

3. Ranges depending on different technologies and parts of the value chain considered

2 transformative  
flagship programs  
have been  
identified to  
embody AfDB  
strategy for the  
African vaccines  
sector

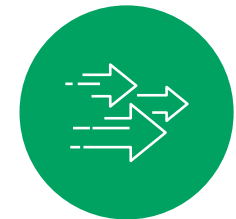
9.

Program to **upscale and transform  
African vaccines manufacturers**



10.

Program to support the development of a  
**vehicle to pool the demand for African  
countries and ensure long-term vaccine  
offtake agreements**



# List of programs

## Transformative flagship program

★ Led by AfDB

9

Program to upscale and transform African vaccines manufacturers

★

## Key components/projects (illustrative, menu of initiatives, initiatives are non mutually exclusive)

- Support to upscale through **concessional direct lending or indirect equity investment** to African-based manufacturers (for greenfield and brownfield projects)
- Technical assistance** to local manufacturers (standalone action or condition for funding) and co-investors and financing of specialized consultancy:
  - Assistance on **Greenfield financing structure** leveraging AfDB's expertise in financing large capital projects
  - Assistance and advocacy in **IP and know-how transfer**
  - Improvement of the performance of the manufacturers (e.g. sourcing improvement)

## Budget envelope

- ~\$90-210Mn to finance manufacturers based on an estimation of 30-50% of investment per plant (~\$45-105Mn) on 2 plants
- ~\$16-24Mn to support the platform development, as a cost for 2-4 consulting studies per year (\$2-3Mn per year for 8 years)

## AfDB Role

- Program Leader

## Other players involved

- Members of the Partnerships for African Vaccine Manufacturing (PAVM) (Africa Union, Africa CDC & Mastercard Foundation)
- Local governments (e.g. Ministries of Health, Ministries of industry)
- DFIs (e.g. Proparco, IFC, Asian Development Bank, Islamic Development Bank)
- Private sector (e.g. PE funds: Africa Invest, CDC Investment Works and Pharmacos: Pfizer, AstraZeneca)
- Industrial organizations (e.g. UNIDO)

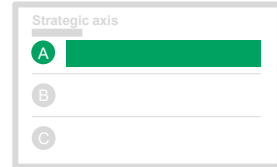
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## SO



## Strategic dimensions



10

Program to support the development of a vehicle to pool the demand for African countries and ensure long-term vaccine offtake agreements

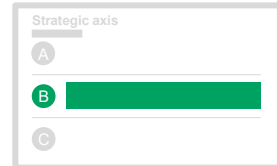
★

- Support to the set-up of a **take or pay type of provision** across the 3 mechanisms:
  - Support to the development of a **pooling and wheeling** platform to aggregate demand and benefit from economies of scale
    - Advocacy and management of cooperation between partners
    - Financing of the pooling platform through grants
  - Creation of a **concessional guarantee fund** dedicated to compensate unsold stock and secure offtake

- ~\$16-24Mn to support the platform development, as a cost for 2-4 consulting studies per year (\$2-3Mn per year for 8 years)
- ~\$200Mn-350Mn for a guarantee fund, to compensate 5% of total non-Gavi and transitioning countries market value for 8 years<sup>1</sup>

- Advocacy, coordination and funding role

- Partnerships for African Vaccine Manufacturing (PAVM) (Africa Union, Africa CDC & Mastercard Foundation) (potential program leaders)
- DFIs (e.g. World Bank, AFD)
- Guarantee funds (e.g. the Development Guarantee Group)
- Regional Organizations (e.g. EAC, CEDEAO)



1. Hypothesis made that none of the transitioning countries won't be supported by Gavi anymore in 2030, with a linear transition of market value from 2020 to 2030

# AfDB could leverage the large scope of financial tools at its disposal to bring value to each program



Transformative flagship program

9

Program to upscale and transform African vaccines manufacturers











10

Program to support the development of a vehicle to pool the demand for African countries and ensure long-term vaccine offtake agreements

	PRELIMINARY			FOR DISCUSSION		PROGRAM DEDICATED TO VACCINES		
	Line of credit	Loans	Equity	Trade finance	Grant	Guarantee	Trust Funds	Risk Management
9	✓	✓ Fixed Spread Loan	✓ Direct Equity, indirect equity and subordinated debt		✓ Technical assistance, Grants and Reimbursable grants		✓ Trust Fund	
10		✓ ADF Loan		✓ Risk Participation Agreements Trade Finance Lines Of Credit	✓ Grants and Reimbursable grants	✓ Partial Risk Guarantee, Partial Credit Guarantee	✓ Trust Fund	✓ Risk Mgt. Products

### 3 AfDB Financial tools strategy relevance to strategy (1/4)



Type of financial tools		Products	Description	Key advantages to final borrowers <sup>1</sup>	Level of adequacy of AfDB financial tools to the strategy	Relevance for pharma strategy
 <b>Line of credit</b>   <b>Loans</b>		-	<ul style="list-style-type: none"> <li>Includes a preset borrowing limit that can be used at any time</li> </ul>	<ul style="list-style-type: none"> <li>Beneficiate from high flexibility for small amounts, e.g. purchasing inputs</li> </ul>	 High	 <b>Highly relevant for manufacturers</b>
		<b>ADF<sup>2</sup> Loan</b>	<ul style="list-style-type: none"> <li>Concessional lending</li> <li>Requires sovereign guarantee</li> <li>Maturity of 30-40 years</li> </ul>	<ul style="list-style-type: none"> <li>Receive highly advantageous conditions for risky projects in emerging economies</li> </ul>	 Medium	 Relevant for <b>infrastructure, capabilities or regulatory upgrading in emerging economies</b>
		<b>Fully Flexible Loan</b>	<ul style="list-style-type: none"> <li>Maturity-based pricing, with a premium if maturity &gt; 12.75 years</li> <li>Enables financial terms customization (e.g. changing the lending currency or fixing/unfixing/re-fixing the base interest rate)</li> <li>Requires sovereign guarantee</li> <li>Maturity up to 25 years, grace up to 8 years</li> <li>Available in EUR, USD, ZAR, JPY, or Local Cur. on case by case basis</li> </ul>	<ul style="list-style-type: none"> <li>Customize the product</li> <li>Beneficiate from high flexibility even during loan maturation</li> </ul>	 High	 Relevant especially for <b>logistics infrastructure projects, capability building improvement, clinical trial infrastructures development</b> backed by governments,
		<b>Fixed Spread Loan</b>	<ul style="list-style-type: none"> <li>Fixed-spread lending</li> <li>No sovereign guarantee</li> <li>Maturity of up to 15 years</li> <li>Available in local currency<sup>3</sup></li> </ul>	<ul style="list-style-type: none"> <li>No sovereign guarantee required</li> </ul>	 High	 Highly relevant for <b>manufacturers, distributors and small/medium-size infrastructure projects</b>

1. I.e. not financial institution 2. African Development Fund, offering concessional loans e.g. to Low Income Countries  
 3. South African Rand, Egyptian Pounds, Uganda Shilling, Nigerian Naira, Kenya Shilling, Zambia Kwacha, Tanzania Shilling, Ghana Cedi, Botswana Pula, CEMAC region CFA and WAMU region CFA and Rwandan franc (RWF).

### 3 AfDB Financial tools strategy relevance to strategy (2/4)



#### Type of financial tools



#### Equity

#### Products

##### Direct Equity

#### Description

- Eligible to private companies and financial intermediaries, incl. public companies being privatized
- Bank's equity participation not to exceed 25% and ~USD10 Mn

#### Key advantages to final borrowers

- No loan to repay with interest
- Receive advisory from the bank through board representation
- Potentially fund riskier projects

Level of adequacy of AfDB financial tools to the strategy

High
 Medium
 Low
 Very Low

#### Relevance for pharma strategy

Relevant especially to support **existing manufacturers and distributors to scale up**, or to invest in **biotechs**

##### Indirect Equity

- Eligible to all types of PE funds investing in Africa, yet mostly infrastructure funds
- Bank's participation not to exceed 20% of the funds' equity

- No loan to repay with interest
- Receive funding for risky projects

Relevant especially to support **existing manufacturers and distributors to scale up**, or to invest in **biotechs**

##### Subordinated Debt (e.g mezzanine debt)

- Riskier debt that will be repaid after other kinds of debt (senior) in case of bankruptcy or liquidation

- Receive funding for risky projects

Relevant especially to support **existing manufacturers and distributors to scale up**, as well as new players to emerge



### 3 AfDB Financial tools strategy relevance to strategy (3/4)



Level of adequacy of AfDB financial tools to the strategy

High
 Medium
 Low
 Very Low

#### Relevance for pharma strategy

#### Type of financial tools



Trade finance

#### Products

##### Risk Participation Agreements

#### Description

- Agreement with a confirming bank that has large and consistent trade finance volumes (i.e. not with final borrower)
- Credit risk shared up to 50% of transaction value
- Maximum tenor of 3.5 years

#### Key advantages to final borrowers

- Finance large imports more conveniently
- Finance large exports more conveniently



**High relevance** to finance manufacturers and distributors with regional/continental scope

##### Trade Finance Lines Of Credit

- Pre and post export financing offered to banks
- Maximum tenor of 3.5 years
- Preset borrowing limit for trade finance that can be used at any time

- Finance large imports more conveniently
- Finance large exports more conveniently



**High relevance** to finance manufacturers and distributors with regional/continental scope

##### Soft Commodity Finance Facility

- Input and post harvest financing offered through commodity aggregators
- Maximum tenor of 2 years

- Mitigate commodities market risk



**Not relevant** for the pharma sector

##### Technical assistance

- Technical sup provided, usually to supplement financial products

- Receive non-financial support leveraging AfDB's expertise



**High relevance** for governments, small manufacturers and distributors

##### Grants and Reimbursable grants

- Direct grants to companies and public entities, usually completing another financial tool (e.g. loan)<sup>2</sup>

- Receive non-financial support leveraging AfDB's expertise



**High relevance** for small manufacturers distributors



Grant

### 3 AfDB Financial tools strategy relevance to strategy (4/4)



Level of adequacy of AfDB financial tools to the strategy

High
 Medium
 Low
 Very Low

#### Relevance for pharma strategy

Type of financial tools	Products	Description	Key advantages to final borrowers	Relevance for pharma strategy
<b>Guarantee</b>	<b>Partial Risk Guarantee</b>	<ul style="list-style-type: none"> <li>Guarantees against political risks, e.g. currency inconvertibility, expropriation, nationalization and other force majeure risks</li> <li>Available to commercial/private sector financiers</li> </ul>	<ul style="list-style-type: none"> <li>Have the opportunity to fund projects located in emerging economies</li> </ul>	<b>Relevant</b> for manufacturers and distributors located in emerging economies
	<b>Partial Credit Guarantee</b>	<ul style="list-style-type: none"> <li>Guarantees against default of the applicant, regardless of the cause</li> <li>Available for private lenders to both private sector and sovereign</li> </ul>	<ul style="list-style-type: none"> <li>Have the opportunity to fund risky projects, e.g. manufacturer launch</li> </ul>	<b>Relevant</b> for manufacturers, biotech, distributors
	<b>Portfolio Guarantee</b>	<ul style="list-style-type: none"> <li>Guarantees offered to a portfolio of loans then offered to beneficiaries under conditions</li> </ul>	<ul style="list-style-type: none"> <li>Have the opportunity to fund risky projects, e.g. manufacturer launch</li> </ul>	Mostly relevant for <b>individuals and SMEs</b>
<b>Trust Funds</b>	<b>Trust funds</b>	<ul style="list-style-type: none"> <li>Grants and highly concessional loans for capacity building and technical support</li> </ul>	<ul style="list-style-type: none"> <li>Receive non-financial support leveraging AfDB's expertise</li> </ul>	<b>High relevance</b> for governments, small manufacturers and distributors
	<b>African Legal Support Facility</b>	<ul style="list-style-type: none"> <li>Government support in the negotiation of complex commercial transactions</li> </ul>	<ul style="list-style-type: none"> <li>Receive legal support for little to no cost</li> </ul>	<b>Not relevant</b> for the pharma sector
<b>Risk Management</b>	<b>Risk Mgt. Products</b> (e.g. interest rate swaps, currency swap, cap/collars)	<ul style="list-style-type: none"> <li>Financial risk transformation under a loan or other instrument without renegotiation or amendment</li> </ul>	<ul style="list-style-type: none"> <li>Mitigate risks incurred when trading internationally</li> </ul>	Relevant for regional/continental manufacturers and distributors

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## Webinar Series: Facilitating Partnerships



**African Development Bank's vision and strategy to advance vaccine manufacturing capacity in Africa.**

# AVMI Overview

23 November 2023  
Patrick Tippoo

Advance the establishment of  
sustainable human vaccine  
manufacturing capacity in Africa



# MISSION



# 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 **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.



# Pivotal Developments

## 3. The 1st Manufacturers Marketplace for AU Member States

29-Sep to 01-Oct, 2023, Marrakesh, Morocco

### Key objectives of the meeting



Identify the best modalities for achieving the success and the sustainability of the on-going vaccine manufacturing projects



Awareness among member states about the importance of their commitments to select and procure from African manufacturers



Criteria required to be eligible for Gavi African Vaccine Market Accelerator (AVMA)



Strengthening private-public partnership



Building and maintaining demand for African manufactured vaccines



**The AU PPM will help enable an efficient and sustainable African vaccine market**

Through a central contracting and procurement PPM model

**The AU PPM can provide the unlock required to enable an efficient and sustainable Africa vaccines market through**



#### **Demand consolidation**

that enables increased purchasing power, economies of scale



#### **Demand forecasting and offtake certainty**

that enables ability to provide local manufacturers with long term supply agreements



#### **Centralised processes and platforms**

(e.g. negotiations and contracting) that reduce transaction costs and enable purchasing power to be leveraged effectively



#### **Ecosystem enablers**

e.g. financing, harmonisation of relevant regulatory standards



Unlike other PPMs that primarily focus on reducing costs through pooling demand, the **initial focus is to support health security for the continent** and further develop and **grow local manufacturing** in support of the AU ambition and New Public Health Order



Thank You



The best time to  
plant a tree was  
20 years ago.

The NEXT best  
time is **NOW!**

Advancing Vaccine  
Manufacturing  
Capacity in Africa

Breaking the  
Cycle of  
Dependency

[www.avmi-africa.org](http://www.avmi-africa.org)

# Pivotal Developments

## 1. AVMI – UNCTAD – Africa CDC Meeting June 2023, Addis Ababa, Ethiopia

Global Event on Enhancing the Sustainability of Investment in Vaccine Manufacturing in Africa

**AVMI Statement: Accelerating Action towards Viable Vaccine Manufacturing in Africa**

- Implementing **enabling policies**
- Increasing **predictability of demand**
- Streamlining and speeding up **regulatory pathways**
- Mobilising **financial resources**

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 3<sup>rd</sup> 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;



# Pivotal Developments

## 2. African Vaccine Manufacturing Accelerator (AVMA) Gavi

The Gavi Alliance Programme and Policy Committee is requested to recommend to the Gavi Alliance Board that it:

- **Approve** the establishment of the AVMA as an instrument to provide time-limited financial support to accelerate the expansion of commercially viable vaccine manufacturing in Africa.

### Three themes

1. **Scope** – broaden the range of vaccines
2. **Scale** – increase the incentive available for the Fill & Finish component.
3. **Advocacy** – to ensure that the WHO Pre-Qualification (PQ) process supports the AVMA with prioritisation and the resourcing



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Web site: [www.avmi-africa.org](http://www.avmi-africa.org)  
Email: [info@avmi-africa.org](mailto:info@avmi-africa.org)

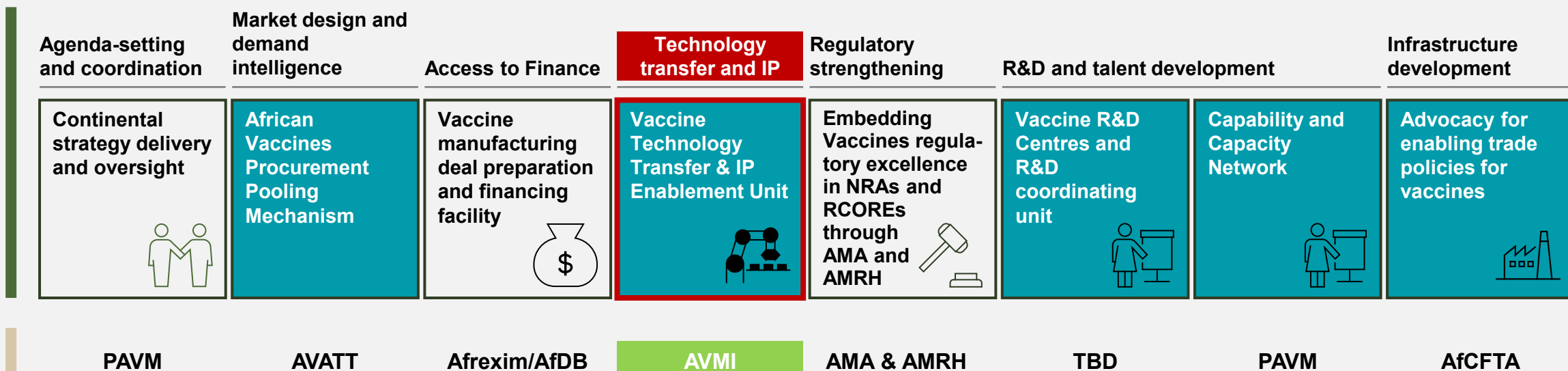
### African Vaccine Manufacturing Initiative (AVMI) Position Paper on GAVI's African Vaccine Manufacturing Accelerator (AVMA)

*The AVMI provides a consensus voice for African Vaccine Manufacturers, specifically within the context of the African Union call for a New Public Health Order aimed at safeguarding the health and economic security of the continent. This encompasses the Africa CDC / Partnership for African Vaccine Manufacturing (PAVM) objective of ensuring at least 60% of Africa's vaccine requirements is supplied by African manufacturers by 2040, up from the dangerously low 1% today.*

AVMI considers the AVMA to be a critical lever of achieving the continent's objectives and appreciates and acknowledges the efforts of GAVI thus far. We hereby request the favourable review and support of the AVMA by GAVI's Programme and Policy Committee (PPC) for approval at the December 2023 GAVI Board meeting.

This briefing note documents AVMI's position and recommendations on the AVMA given that African Manufacturers currently have no formal representation at PPC and the Board. While three African vaccine manufacturers are members of the Developing Countries Vaccine Manufacturers Network (DCVMN), the DCVMN has a large constituent base with diverse interests and therefore does not have a mandate to represent the African vaccine manufacturing industry. Given GAVI's publicly stated strategic aim to support African Vaccine Manufacturing via the AVMA, the intent of this document is to provide a consensus African industry view. In the future, it is hoped that AVMI is granted representation on the various committees of GAVI similar to what has been afforded to both the DCVMN and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), particularly as the majority of vaccines procured by GAVI are destined for the African continent.





# Perspectives

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# Pivotal Developments

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## 4. AVMI – AfDB Workshop

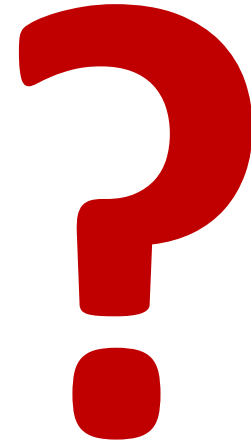
African Development Bank's Vision and Strategy to Advance  
Vaccine Manufacturing in Africa  
23 November, 2023, Virtual



Webinar Series:  
Facilitating Partnerships



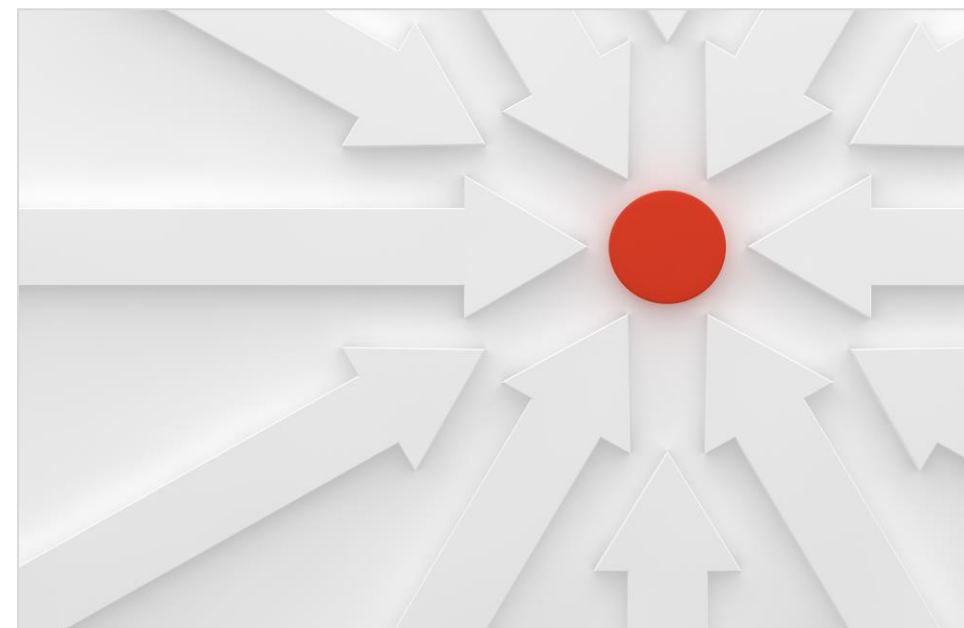
African Development Bank's vision and strategy to advance vaccine  
manufacturing capacity in Africa.



# 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	Avacare Health Group	Ethiopia / South Africa
12	Atlantic Life Sciences	Ghana
13	DEK Vaccines	Ghana
14	Biovax Kenya	Kenya
15	Institute Pasteur Morocco	Morocco
16	Samsung Biologics for Institute Pasteur Morocco	Morocco
17	MARBIO	Morocco
18	Innovative Biotech, Nigeria	Nigeria
19	Biovaccines Nigeria	Nigeria
20	Institute Pasteur Dakar	Senegal
21	Institute Pasteur Tunis	Tunisia
22	Afrigen	South Africa
23	Aspen	South Africa
24	Biovac	South Africa
25	Vaccine Access Initiative	Uganda

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



# Webinar Program

1	Opening and Welcome Remarks	VP Solomon Quaynor and Patrick Tippoo	10 mins
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**AVMI webinar series:  
Facilitating Partnerships  
23 November 2023**



# Biovac has built world class facilities capable since its inception in 2003



Pre 2003



2009-2020

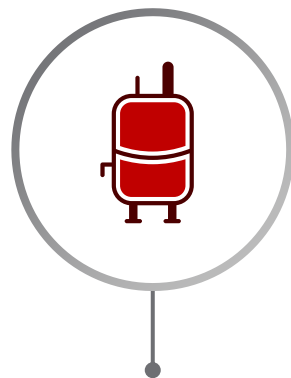


2005-2008

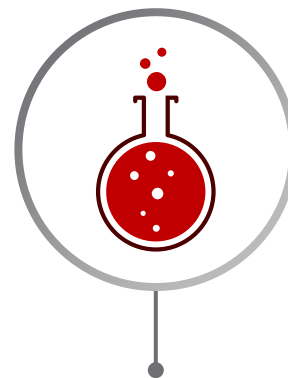


2022-current

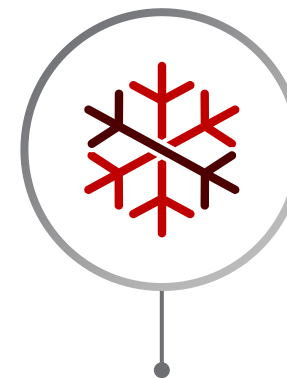
Over the last two decades, Biovac has developed unique core capabilities on the African continent



**Sterile manufacturing**  
(formulation and filling)



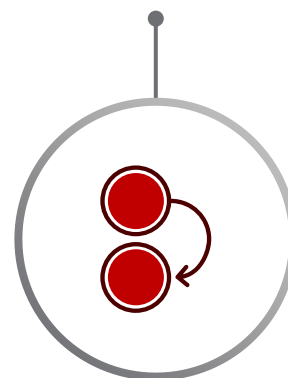
Bacterial conjugate  
**product development**



**Cold Chain & Ultra Cold Chain**  
management



**Quality Control**  
testing & laboratory  
management



**Tech Transfer**  
manufacturing &  
regulatory process



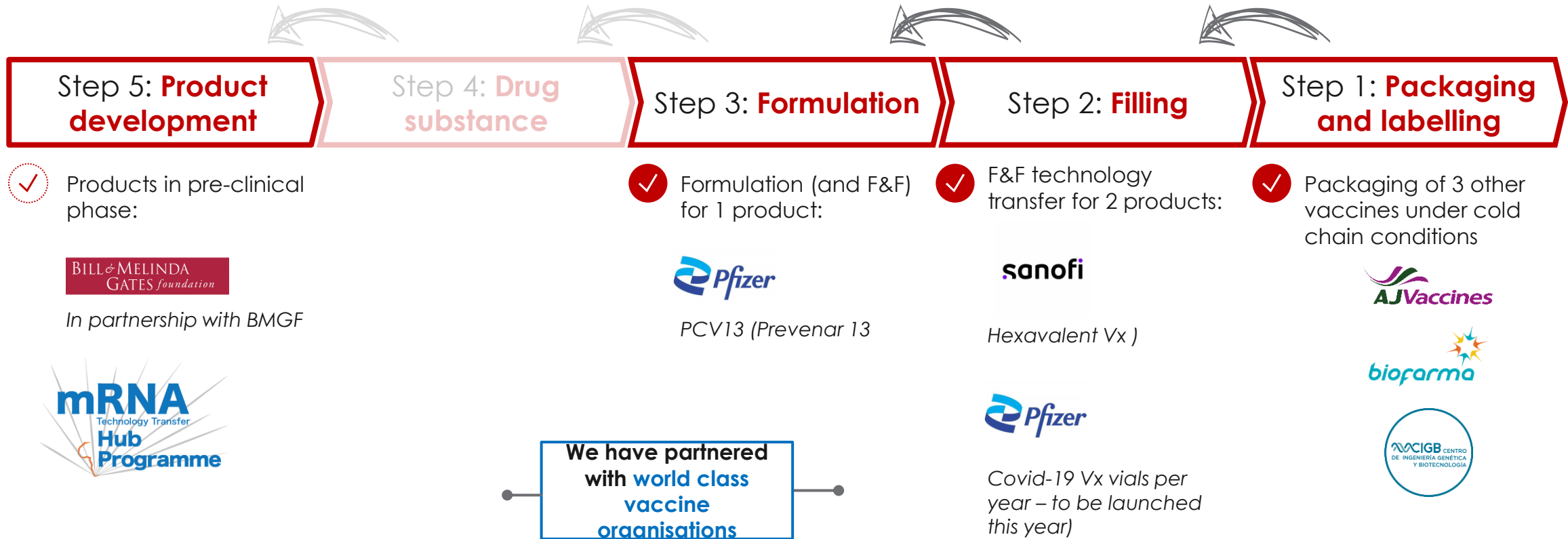
**Public Sector vaccines**  
procurement



# Biovac has built capabilities in formulation, fill and finish as well as product development



## Biovac reverse integration approach



# Talking points from Biovac's perspective as a manufacturer

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1. The ecosystem to support the development of products for commercial purposes is not entirely present, while raising funding for risky development is also not easy, leading to a lack of ownership and therefore reliance on partnerships for manufacture
2. Tender periods are short, while payback periods for new facilities would span multiple tender cycles, leaving uncertain market conditions.
3. The scarcity of skills increases costs in attracting, training and retaining talent
4. Capital intensive manufacturing with high fixed costs, with scale being the best opportunity to reduce cost
5. Localisation costs money and there is a downward price pressure on a public health good – pricing is competitive meaning the .
6. The above contributes to difficulty in creating a business case that works and has the appropriate amount of risk.

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## Projet de Partenariat Public-Privé (PPP) de production locale des vaccins et produits biotechnologiques

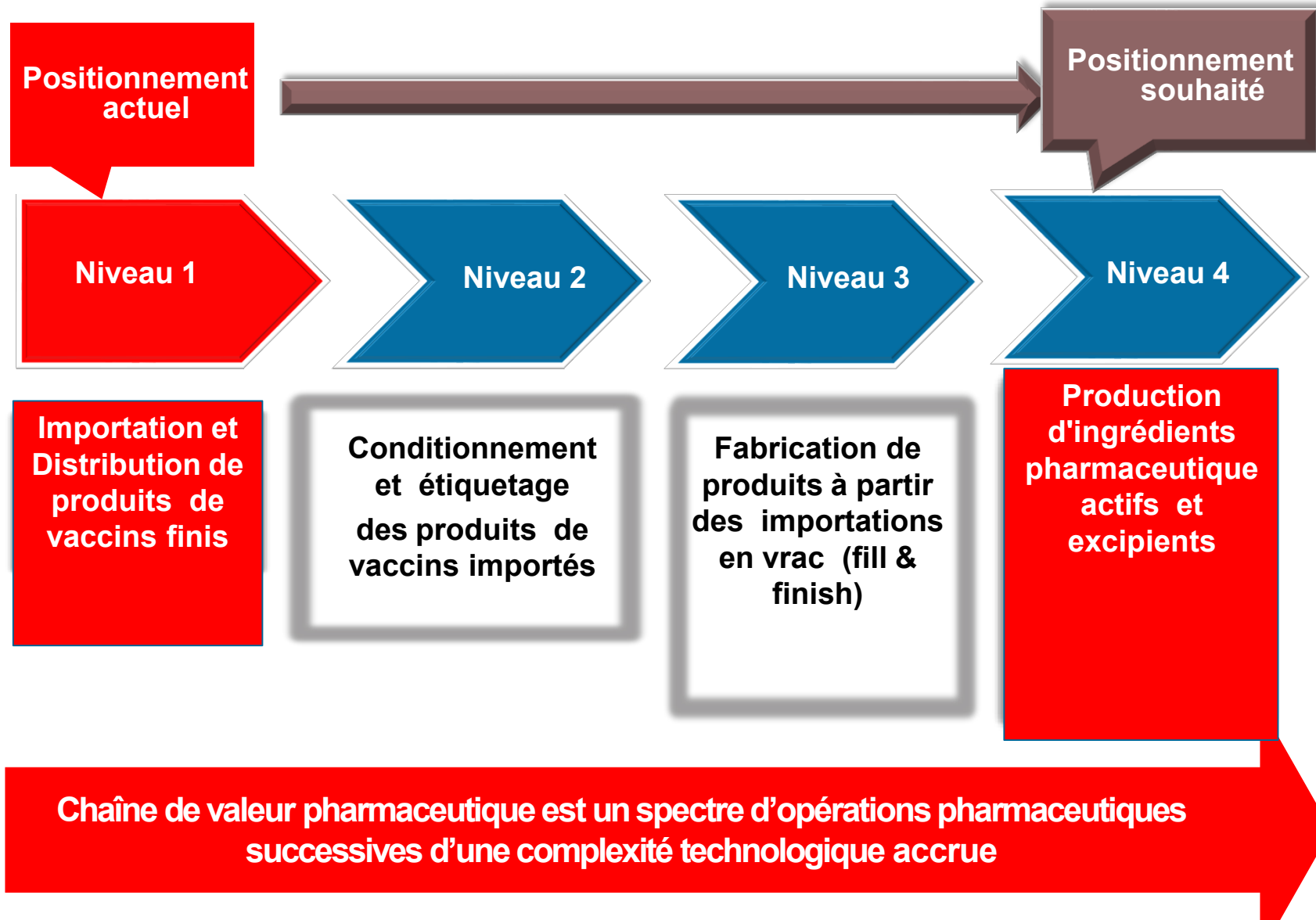


Souveraineté Médicamenteuse	Souveraineté Sanitaire	Sécurité Sanitaire
<p>"La production locale de médicaments génériques et de matériel médical de qualité, dans l'optique d'atteindre la <b>souveraineté médicamenteuse</b>"</p> <p>Célébration de la Journée Mondiale de la Santé 07 avril 19</p>	<p>"La crise pandémique a révélé le retour en force du thème de la <b>Souveraineté</b>. Qu'elle soit <b>sanitaire</b>, énergétique, industrielle, alimentaire ou autre, sa préservation est devenue l'enjeu d'une véritable compétition qui suscite des réactions fébriles chez certains."</p> <p>La première session de la 11e législature 8 octobre 2021</p>	<p>"L'intérêt bienveillant que Je porte à <b>la santé</b> de chaque citoyen marocain et à <b>la sécurité</b> de sa famille est à la une de mes préoccupations à l'égard de mes propres enfants et de ma propre famille" Fête du trône, le 30 août 20</p>

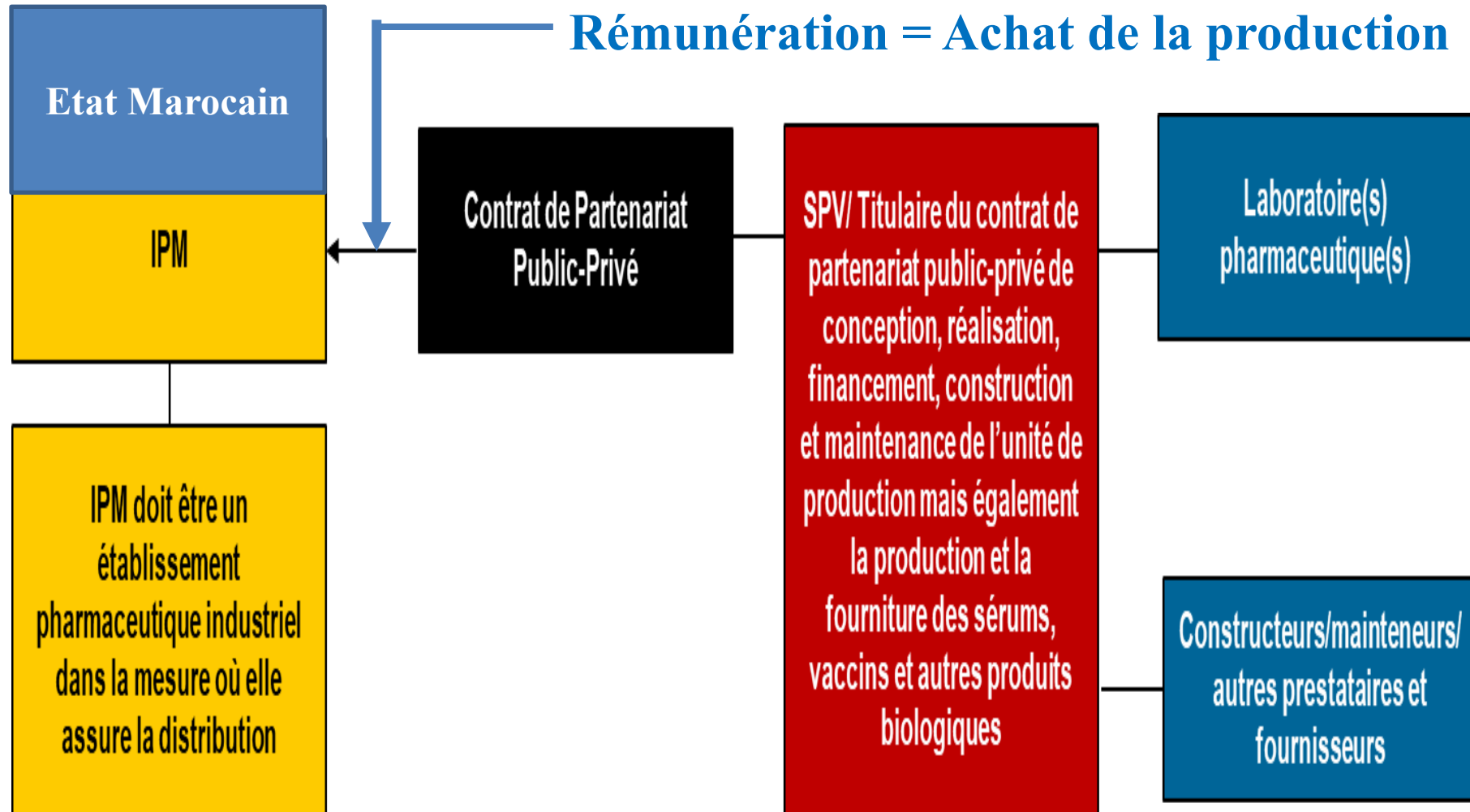




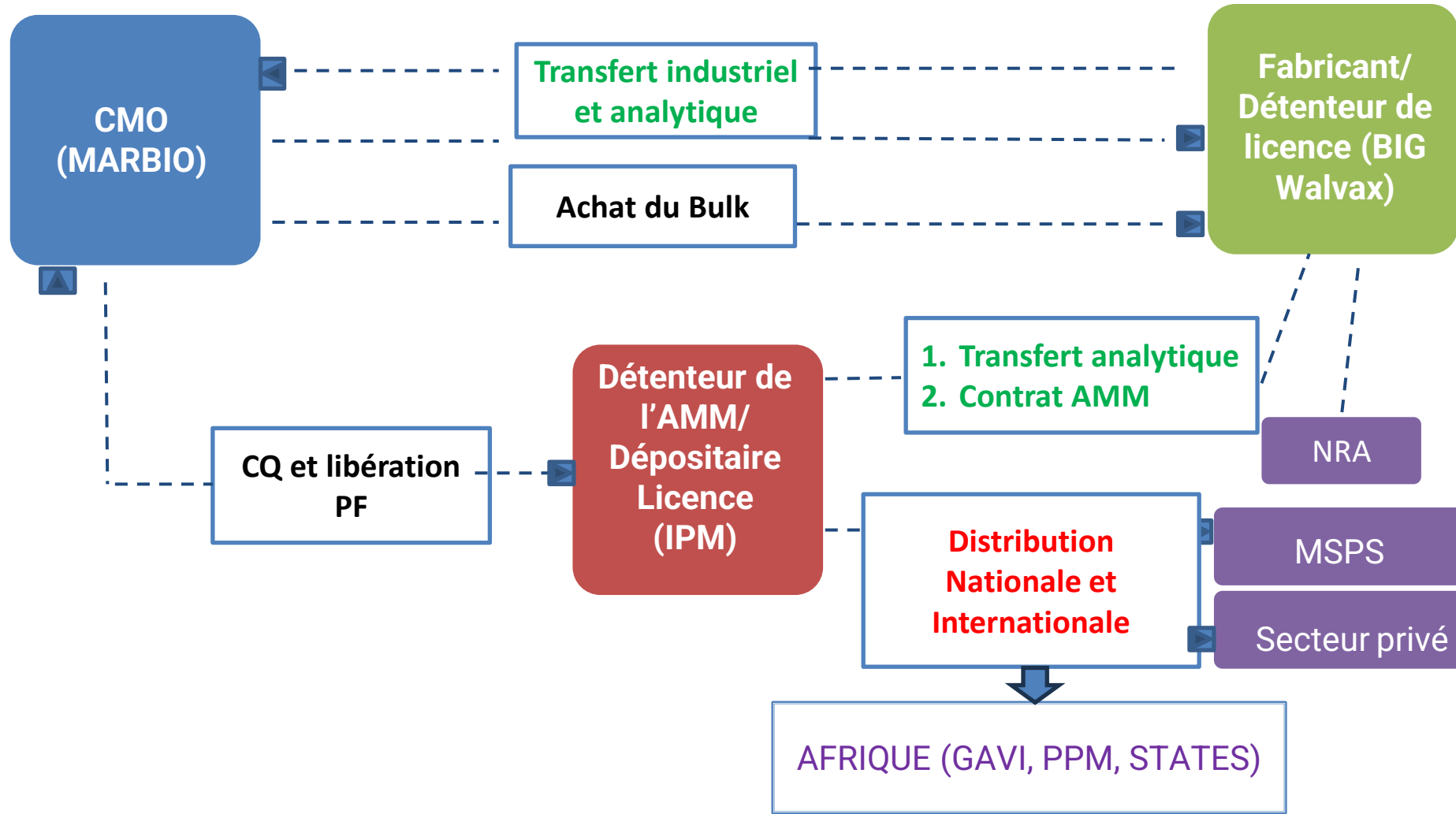
# Stratégie industrielle



# Modèle de Partenariat Public Privé Global



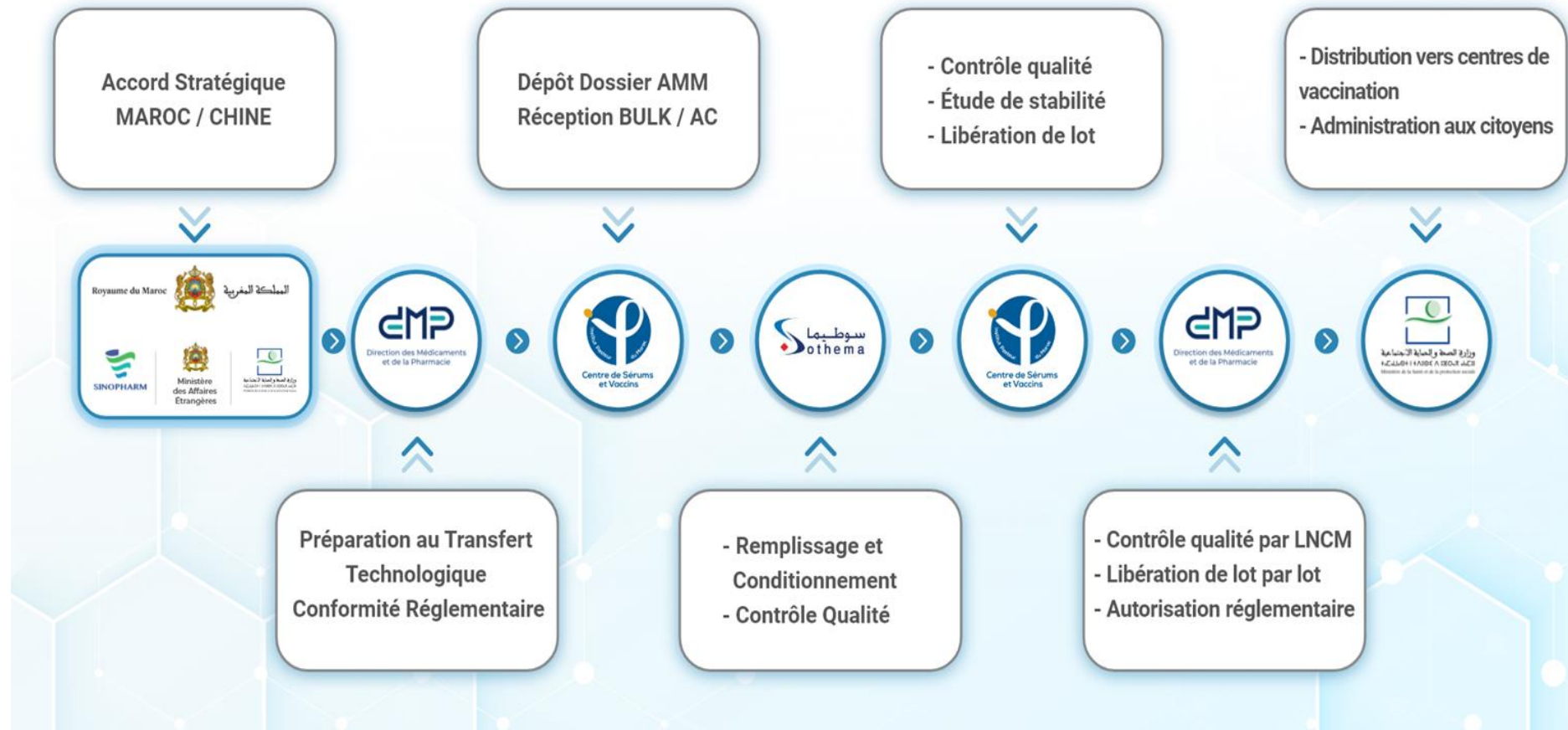
## Scénario des relations contractuelles



# **Etape I : Fill and Finsih du vaccin COVID 19 en mode PPP En 2021**

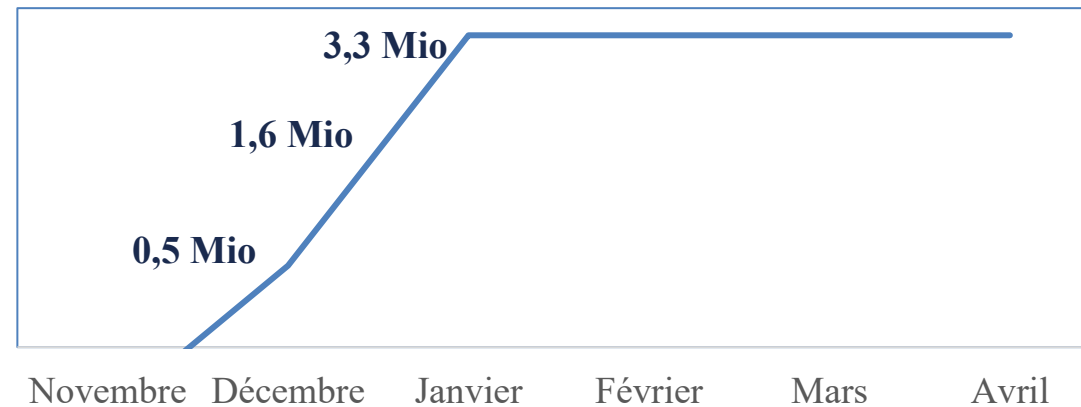
# PHASE I: PROJET ATLAS

## FILL & FINISH DU VACCIN COVID19



Production mensuelle	Nov 21	Déc 21	Jan 22
En nombre de doses (Millions)	0,5	1,6	3,3
En nombre de lots	3	10	20

	Hypothèse
Nombre de lot par jour	1
Nombre de doses par lot	166 666
Nombre de flacons par lot	33 333
Nombre de jours par mois	20





## **Etape II : Fill and Finsih du portefeuille National des vaccins et produits biothérapeutiques en mode PPP**



Centre de Sérums  
et Vaccins



وزارة الصحة والحماية الاجتماعية  
+٥٤٥٤٥٠٠+١ +٨٨٥٠٤ ٨ ٥٥٥٠٥ ٥٥٤٥٤  
Ministère de la Santé et de la Protection Sociale

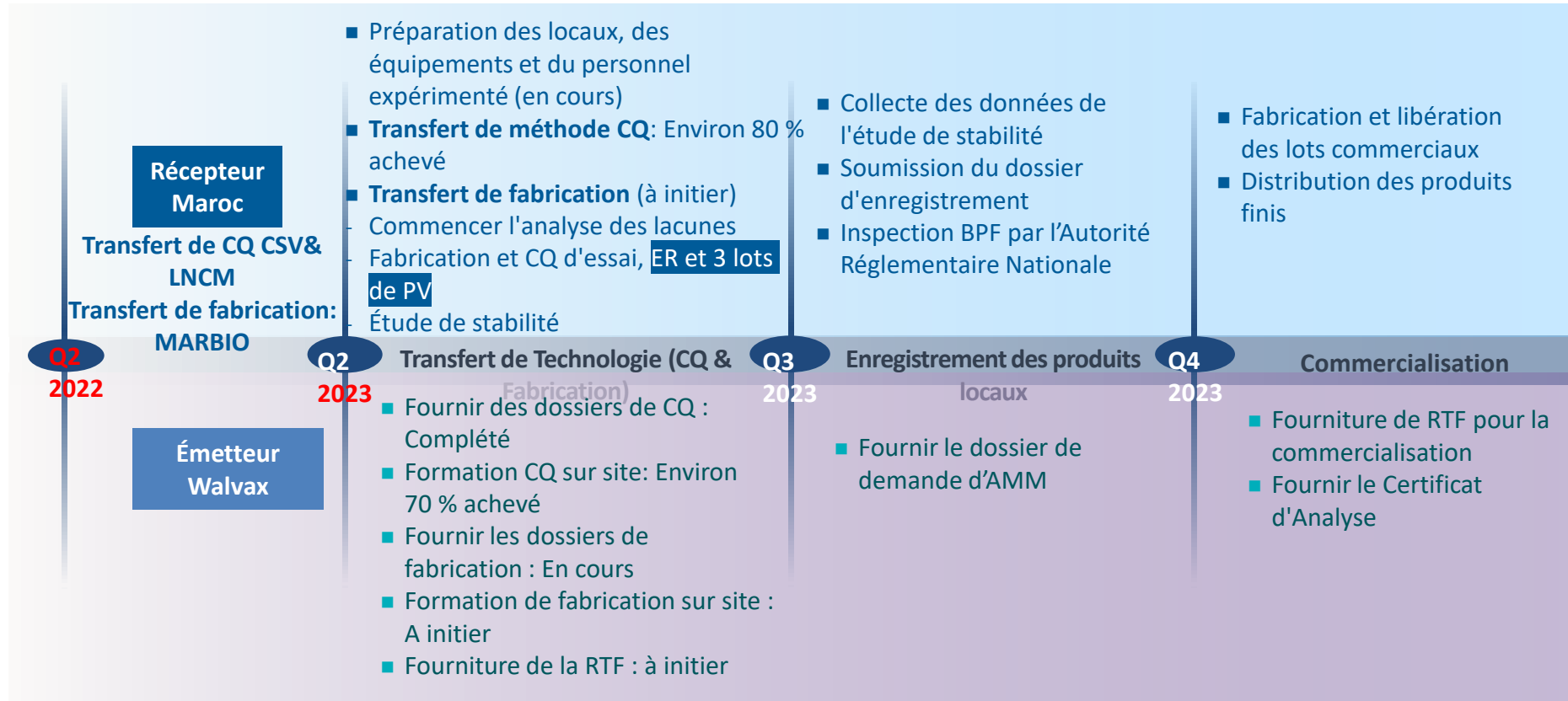
# Portefeuille National des vaccins et produits biothérapeutiques

VACCIN	QUANTITE EN DOSES
FIEVRE JAUNE	8.160,00
ANTIGRIPE	462.060,00
ANTIMENINGO	290.700,00
ANTIRABIQUE	637.500,00
DIPHTERIE-TETANOS	122.400,00
FIEVRE TYPHOIDE	45.390,00
ANTIPNEUMO	2.101.200,00
ANTIROTA	2.034.900,00
BCG	2.368.440,00
DIPHTERIE-TETANOS-COQUELUCHE	1.346.400,00
ANTITETANOS et DIPHTERIE	938.400,00
HEPATITE B ENFANT	882.300,00
POLIO ORAL	4.681.800,00
HEPATITE B ADULTES	20.400,00
PENTAVALENT DTC-HEP B-HIB	2.203.200,00
ANTIPOLIO INJECTABLE	824.670,00
ROUGEOLE RUBEOLE	2.448.000,00
HPV	459.765,00
DTCP + HIB	142.800,00
BCG par instillation vescicale	7.140,00
H.I.B	204,00
ANTIHEPATITE A	18.360,00
ROR	29.580,00
<b>TOTAL GENERAL</b>	<b>22.146.189,00</b>

## Vaccins et produits biologiques enregistrés

Produit	Etat d'enregistrement
<b>VACCIN PNEUMOCOCCAL POLYSACCHARIDE CONJUGUE (13-VALENT),</b>	<b>Enregistré Prix homologué</b>
<b>VACCIN ROTAVIRUS, LIVE ATTENUATED LYOPHILISE</b>	<b>Enregistré Prix homologué</b>
<b>HPV-2 VIRUS DU PAPILLOME HUMAIN</b>	<b>Enregistré Prix homologué</b>
<b>VACCIN CONTRE LA RAGE - INACTIVE</b>	<b>Enregistré Prix en cours homologation</b>
<b>HEXAVALENT (6 VACCINS PÉDIATRIQUES)</b>	<b>En cours d'enregistrement</b>
<b>VACCIN ANTI ROTAVIRUS LIQUIDE</b>	<b>En cours d'enregistrement</b>

# Macro-processus du transfert de technologie pour la fabrication locale de PCV13



# Renforcement des capacités de l'autorité de régulation et du Centre de Sérums et vaccins (IPM)



# Capacitation en contrôle de qualité des vaccins

## Formation et coaching des équipes



## Mise en place du QMS

22 procédures, instructions de travail, et rapports approuvés



## Transfert technologique des méthodes analytique




## Équipements







## Systèmes d'information

Développement d'une tour de contrôle qui permet de Superviser le flux industriel de production et les flux documentaires et de contrôle qualité

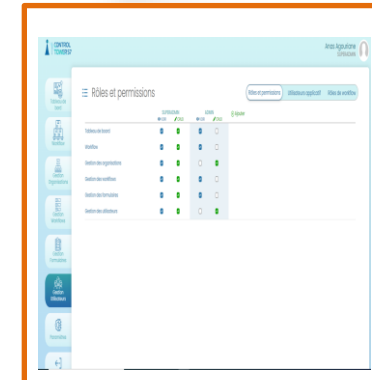


<div></div> <div>PROCEDURE GENERALE</div>				
<div>GESTION DES FORMATIONS</div>				
Code: PGM-PROG-FRM-033				
Version n° : 03				
Date d'adoption : 23 Dec 2023				
Page: 1 / 18				

HISTORIQUE DES MODIFICATIONS				
Version	Nature de la modification	Page	Date	Date de prochaine révision
1	Création	1	2020	
2	Mise à jour	1	25 Mai 2028	
3	Mise à jour selon les règlements du Conseil International d'Harmonisation (ICH) Mise en conformité par rapport à la réglementation pharmaceutique en vigueur Changement de titre et de contenu	1	17 Dec 2023	17 Dec 2024

Nom & Prénoms	Fonction	Date	Visa
Elaboré par :	Mme MADOULE N.	17 Dec 2023	
Validé par :	M. LACAZU M.	20 Dec 2023	 M. LACAZU M. Directeur Général Ministère de la Santé et de la Prévention de la Maladie
Approuvé par :	M. MARI A.	21 Dec 2023	 M. MARI A. Ministre de la Santé et de la Prévention de la Maladie
	M. MARI A.	21 Dec 2023	 M. MARI A. Ministre de la Santé et de la Prévention de la Maladie

Exemplaire n° :
Destinataire :



# Laboratoire de Contrôle Analytique des vaccins et produits biologiques



# Challenges

- Development platform and incubator for Research & Development of Vaccines and BioDiagnostics,
- Creating consortium of RD with Government & Academia, Private Research Centers,
- Tech transfer of know how for RD and manufacturing
- Talen Development



†.| [ΣQ†

# Merci



# Webinar Program

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# Kenya BioVax Institute

(A State Corporation in the Ministry of Health, Government of Kenya).

*‘...protecting health, promoting life...’*

2022

(Est. Companies Act, 2015)



# BioVax:



- **Vision**: to be the regional centre of excellence in manufacturing and commercialisation of human vaccines and other biopharmaceuticals, assuring access and availability of safe, effective, quality and affordable medicines for vaccine-preventable diseases for all.
- **Mission**: to transition the country and the region from health commodity dependency to self-sufficiency and supply-security, and to invest in the country's / region's internal capacity in biomanufacturing.

# Progress to date:



- Established end of 2021; Board inaugurated end of 2021
- CEO recruited mid-2022
- Premises:
  - Facility readiness / infrastructure development / refurbishment
- Machinery / equipment:
  - Procurement underway
  - Process - technology
- Materials / inputs:
  - Raw materials, drug products / substances
  - Strategic partnerships with vaccine manufacturers
- Operations / maintenance:
  - Human resources:
  - Recruitment
  - Workforce development
- Market shaping activities - regional, continental

I

# Kenya:

- enabling business environment
- availability of a skilled workforce
- capability to conduct relevant clinical research and development
- a strategic regional hub for commercial and health security initiatives,
- potential market size in EAC countries of over 150 million doses annually of essential childhood, adolescent girls and maternal vaccines
- rising birth-rate of over 2.3% per annum
- development could avert over 4 million deaths per year and over 206 million Disability Adjusted Life Years (DALYs) in the region



# Where we want to be...



- **World-class**, state-of-the-art facility @ Konza.
- **Regional** centre-of-excellence for **biotech**.
- 100 million doses per year of range of human routine & outbreak vaccines (public health / UHC); can **scale-up fast**.
- Biotherapeutics (insulin, mAB), diagnostics.
- >100s highly-skilled **employees**.
- **Gross margins >30%**; FOREX earner.

# Where we are today...

- Kenya requirement / market: 30m doses of 'routine' vaccines per year.
- (EAC regional requirement / market: >200m doses per year).
- Import human vaccines; donations.
- Co-finance mechanism:
  - GoK 12% (KES 4.3B\*/yr) and UNICEF / GAVI 88% (KES 31.5B\*/yr).
  - Accelerated withdrawal of GAVI support; stop in FY 2026/2027.
- Birth rate: 2.3%.
- ? Pandemic preparedness.

• \*UNICEF Report, 2021.

# Current challenges:

Key challenge:	Description:
Financials	Disbursements from Exchequer – delayed; Funding sources – uncertainties.
Technical competence	People (skilled workforce); Processes (complex); Product (drug substance and IP); Machinery & Equipment; laboratory infrastructure.
Regulatory and policy framework	Maturity level of national regulatory authority (PPB); GMP requirements; WHO pre-qualification requirements.



# Risks:

Risks:	Risk management plan:
Time-delays in construction – prolonged lead times	Pro-active planning with timely reporting. Apply project management principles from the start.
Market for product(s)	Market purchase guarantees for finished products, e.g. with GoK. Pooled procurement – UNICEF / GAVI; Africa CDC AVATT; Participate in market-shaping engagements for Africa. Justification for product selection based on critical analyses
Quality of product – unacceptable.	Manufacturing machinery, equipment, processes are GMP-certified. Certification, Qualification, Validation (CQV), incl. WHO Pre-qualification.
Goodwill / stability – uncertainties.	Communication plans and stakeholder engagements.

# Product portfolio:



- Key vaccines, based on market and financial analyses, include:
  - Vaccines for routine childhood immunisation: prevent pneumonia, influenza, diphtheria, pertussis, tetanus, hepatitis;
  - Vaccines for adolescents to prevent cancers;
  - COVID-19, Malaria, HIV and Tuberculosis vaccines.
- Other products:
  - Insulin for diabetes, Monoclonal antibodies for cancer and other chronic inflammatory diseases, Antivenoms for snake bites and Diagnostic kits for malaria, COVID, etc.

# BioVax and Universal Health Coverage:



- UHC = access to quality health interventions at a cost that does not lead to financial hardship.
- BioVax 'fit' to UHC:
  1. Access / availability:
    - Health commodity security;
    - Securing supply of vaccines for immunisation programmes
    - Lessons learned from COVID-19 pandemic
      - Exaggerated high costs,
      - Artificially imposed stock shortages due to 'vaccines nationalism'
      - Prolonged lead times in the availability of essential supplies and life-saving medical commodities, including COVID-19 vaccines
  2. Cost:
    - GAVI exit after co-financing
    - Control of healthcare costs

# Partnerships / collaborations:



- Product:
  - Vaccine manufacturers globally
  - Technology transfers for vaccine product(s)
  - Research & development: KEMRI, KEVEVAPI, KIPRE, IVI,
  - Market-shaping: Africa CDC, regional development partners
- Process:
  - Machinery & equipment
  - Good Manufacturing Practice (GMP)
  - Quality frameworks: WHO Pre-qualification
- People:
  - Workforce development / training

# Thank you.



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		Institute Pasteur Maroc: Abderrahmane Maaroufi	
		Biovax Kenya: Michael Lusiola	
4	Discussion on potential collaborations	All Moderated by Patrick Tippoo	30 mins
5	Summary and Way forward	Ghada Abuzaid and Patrick Tippoo	10 mins