VACCINE PROCUREMENT
Pratictioners Network (VPPN)

WEBINAR

Localisation Series: What to consider for local vaccine manufacturing?

DISCUSSION WITH

EGYPT

SOUTH AFRICA

20 May 2025, 10am – 11.05am GMT+2

unicef | for every child

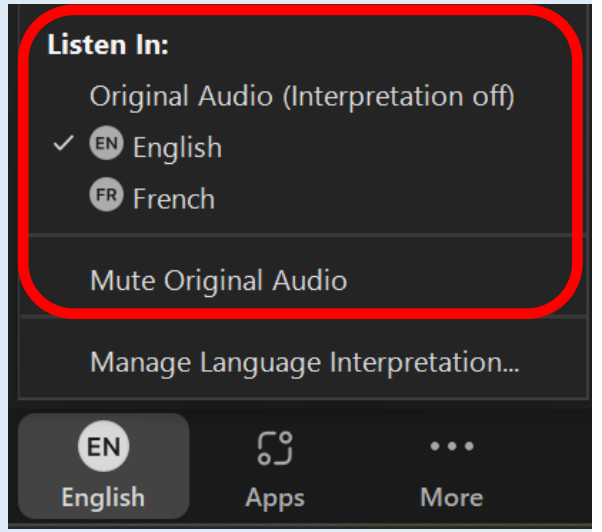
AGENDA

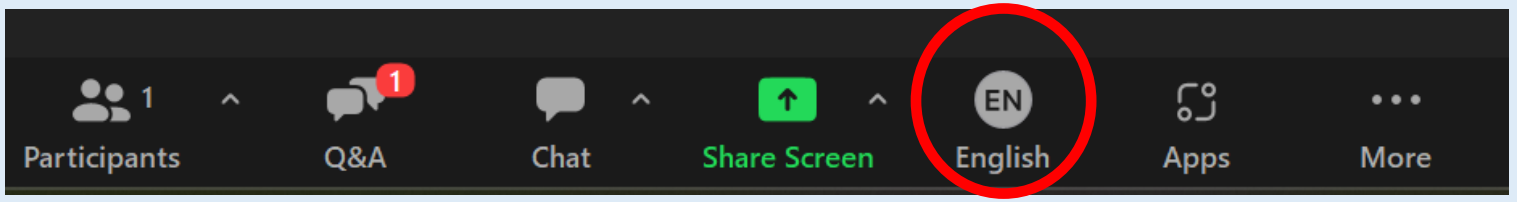
Time	Topic
10:00am GMT+2 *(3 mins)*	Welcome and introduction *Suhwa Seo & Kristina Lorenson, UNICEF*
10:03am GMT+2 *(15 mins)*	Local Vaccine Manufacturing *Mohammed Badat, The Clinton Health Access Initiative (CHAI)*
10:18am GMT+2 *(15 mins)*	Egypt National Strategy for Vaccine Manufacturing Localization *Mostafa Ghorab & Rania Mohsen, Egypt*
10:33am GMT+2 *(15 mins)*	Localizing Vaccine Production in South Africa: The Biovac Initiative *Marione Schonfeldt, South Africa*
10:48am GMT+2 *(15 mins)*	Questions & Answers
11:03am GMT+2 *(2 mins)*	Closing *Kristina Lorenson, UNICEF*
11:05am GMT+2	End & Further E-discussion on the VPPN

ZOOM FUNCTIONS

Interpretation

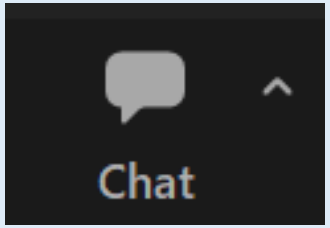
- Click on the Language button and choose the language you wish to hear. For this webinar, English, Arabic, Russian and French are available.
- To hear the interpreted language only, click ‘Mute Original Audio’.
- The presentation is also available in English, Arabic, Russian and French in the Chat box.





ZOOM FUNCTIONS

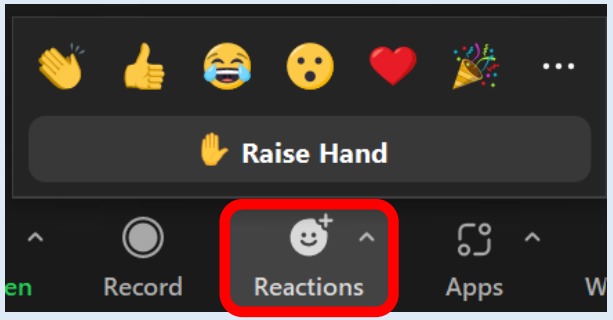
Chat



Use the Chat feature:

- For all your questions (regarding the topic or the logistics)
- To introduce yourself (name, organisation, country)

During the Q&A, you can also raise your hand to ask a question.



RECORDING AND SHARING ON THE VPPN

Recording

These sessions are recorded and your attendance is consent to be recorded.

Knowledge Sharing

The presentations and recording will be shared on the Vaccine Procurement Practitioners Network (VPPN).

INTRODUCTION

Key Learning Objectives

- ✓ Outline the historical and emerging objectives of local vaccine manufacturing
- ✓ Provide an overview of the key components needed to create an enabling environment for local vaccine manufacturing
- ✓ Discuss key common challenges faced with countries when creating the enabling environment, and share respective experiences and lessons learned
- ✓ Answer questions on the topic

SME (CHAI) Presentation

Local Vaccine Manufacturing

Mohammed Badat
Senior Associate, Vaccine Markets,
The Clinton Health Access Initiative (CHAI)

With local vx mfct emerging as a strategic priority, especially in Africa, countries are exploring market opportunities to ensure sustainability

The push towards localization of vaccine manufacturing was triggered by experiences during COVID-19…

- Africa CDC aims to manufacture **60% of the continent's vaccines** by 2040, a significant increase from less than 1% today.
- Up to **~$4.5 billion** may be available **to support African vaccine manufacturing** through funding initiatives, including the GAVI AVMA, Afrexim, HDX, and the Transform Health Fund.
- PAHO[1] is leading initiatives to build **local vaccine manufacturing capacity** in Latin America and the Caribbean.
- ASEAN[2] is **advancing local vaccine production** through the ASEAN Vaccine Security Self-Reliance (AVSSR) initiative, driving regional collaboration, and private sector investment for vaccine security.

…but it has also raised questions from country stakeholders

- What is the current vaccine manufacturing **landscape**?
- What are the **benefits** of localized vaccine manufacturing?
- How much does localizing vaccine manufacturing **cost**?
- **How long** does it take to localize vaccine manufacturing?
- What vaccines are **most suitable** for localizing manufacturing?

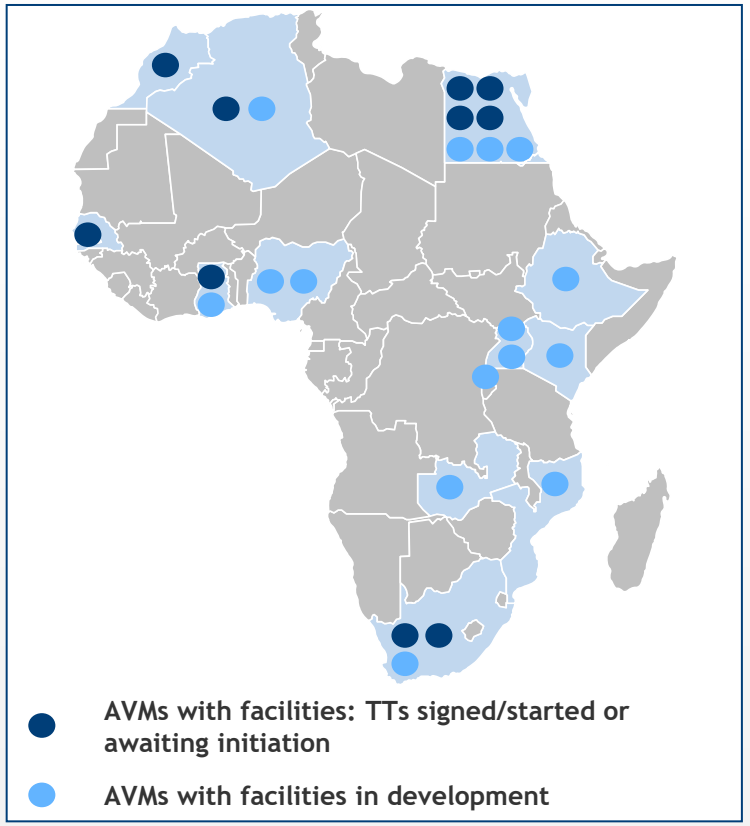
Source: CHAI Analysis, Africa CDC, Gavi, PAHO, The World Bank - ASEAN Regional Vaccine Manufacturing and Development, 2023
[1]PAHO; Pan American Health Organization [2]ASEAN: Association of Southeast Asian Nations

The Vx market is served well by existing capacity globally, with risks of over-capacity of DS and DP due to ongoing initiatives post-COVID

Global Vaccine Capacity and Consumption, 2021
(Excludes Covid-19 Vx)

WHO Region	Est. Annual Capacity Volume	Est. Annual Consumption Volume
Region of the Americas	~1 billion doses	~1 billion doses
European Region	~1.4 billion doses	~500 million doses
Western Pacific Region	~1 billion doses	~1 billion doses
South-East Asia Region	~2.5 billion doses	~1.9 billion doses
Eastern Mediterranean Region	~100 million doses	~500 million doses
African Region	~10 million doses	~1 billion doses
Total	**~5.8 billion**	**~5.1 billion**

25 active projects in Africa, with installed and ordered DP capacity of ~1.4B doses (as of June 2024)

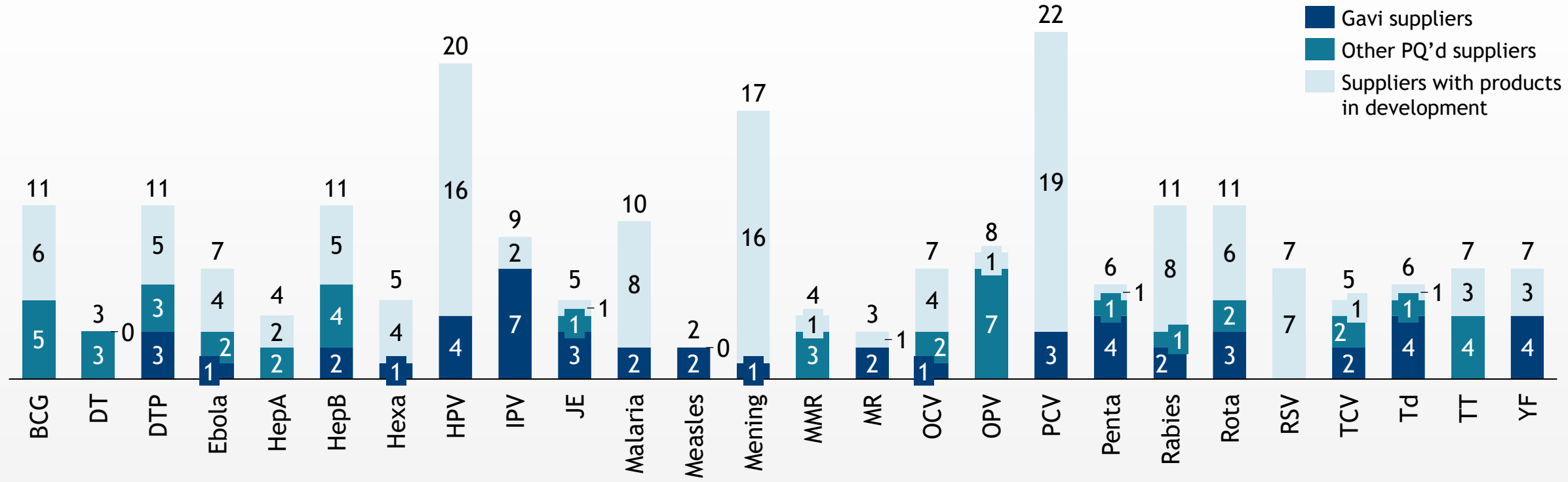


While the routine vaccine market is well-served, COVID-19 created a surge in capacity that now exceeds demand. Many populations were underserved during the pandemic despite these expansions.

Source: Guetta-Jeanrenaud, L., N. Poitiers and R. Veugelers (2021) 'A world divided: global vaccine trade and production', Bruegel Blog, 20 July; CEPI'21 vaccine manufacturing survey; WHO Global Vaccine Market Report; Africa CDC / CHAI / Path 2024 AVM Supply and Demand Landscape

In nearly all vaccine markets, there is a significant number of suppliers already operating or preparing to enter

Number of PQ'd suppliers and suppliers with products in development by antigen[1]



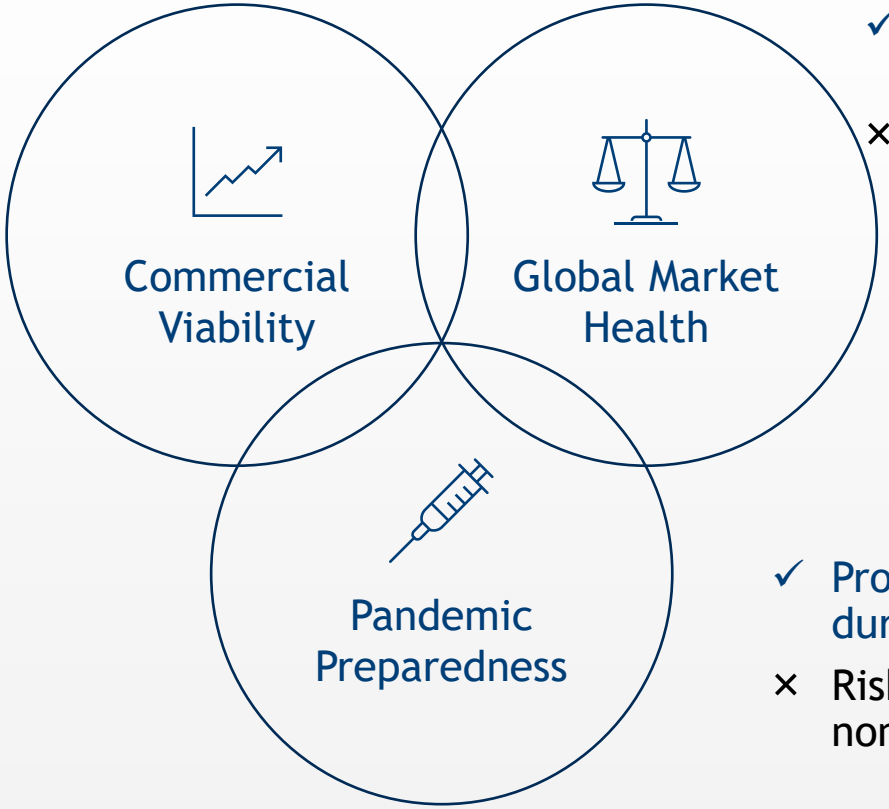
- The Vx market is increasingly saturated and expected to become even more competitive as additional suppliers enter key markets.
- Some pipeline manufacturers are looking to target private antigen markets, rather than Gavi/UNICEF procurement.

***Pipeline suppliers**: products in Phase II and Phase III | **PQ suppliers**: have obtained WHO Prequalification (PQ)*

1. Each supplier may have multiple formulations with separate PQ / authorization / development status, but counted as one supplier in this analysis
Source: Linksbridge; Gavi Detailed Product Profiles

Although local Vx manufacturing offers benefits, countries must carefully navigate the trade-offs to ensure its sustainability

- ✓ Stimulates economic growth and strengthens domestic industry[1]
- × Requires ~$100M+ in financial investment (best case) over a 7-10-year period
- × Support for localization may erode immunization budget for many years



- ✓ Prioritizes endemic diseases
- × Fosters market fragmentation

- ✓ Promotes access to vx during health crises
- × Risks inefficiency during non-pandemic periods

✓ Country Opportunities × Country Risks

On RVMs…

RVMs are not a panacea for vaccine access challenges

Countries must prioritize their goals while balancing trade-offs

On AVMs…

Not all African countries can manufacture vaccines domestically

CHAI's analysis identifies opportunity for only 3-5 commercial-scale AVMs

1. Industries related to manufacturing, biopharma – benefits may differ across countries
Source: CHAI Analysis

New manufacturers face a choice between R&D and TTs for vaccine production, depending on their strategy and capabilities

DEFINITION	KEY CONSIDERATIONS
Research & Development • R&D encompasses discovery research, pre-clinical testing, and clinical trials • Achieving commercialization demands a **long, complex, and high-risk process**	• **Long gestation period and extremely risky**, taking up to 15 years[1] with extremely low probability of success. • Need for specialized infrastructure and expertise presents challenges for new entrants.
Technology Transfer (TTs) • TTs involves the transfer of vaccine manufacturing technology, knowledge, and skills between originators and recipients • It is **highly dependent on originator's willingness to engage**	• Heavy reliance on originators makes this approach prone to setbacks, as even minor misalignments **can derail timelines, disrupt operations, and increase costs** • TT partnerships **require extensive capacity building**, to ensure successful implementation and the Originator's willingness to engage

Sources: 1. Han S. Clinical vaccine development. Clin Exp Vaccine Res, 2015 2. 2 Years For Vaccine Tech Transfers COVID-19 Won't Wait, Outsourced Pharma, September 2020

Establishing and maintaining vx mfct facilities demands significant CapEx investment, OpEx & other cash expenses to sustain operations

Category	CapEx			OpEx		Other Cash Expenses
Expenses	**Facility**	**Equipment**	**Other**	**COGS, S&M, and G&A**	**R&D and/or tech transfer**	**NWC, Financing costs, and Taxes**
Examples	• Land, buildings, utilities	• Bioreactors, filling lines, lyophilizers • Lab equipment	• Capital expenses (e.g., IP) • Compliance and maintenance	• Labor, materials, and consumables • Sales and marketing costs	• Clinical trials, regulatory fees • Tech transfer coordination	• Net increase in net working capital (NWC) • Initial investment in inventory, A/R and A/P
Cost Factors	Costings vary significantly based on facility location, scale, scope, antigen type, technology use, existing vs. greenfield facility, and number of filling lines. **There is no 'one-size fits all' Vx facility.**					
Drug Product - Est. Total Cost	**Approx. $50 million - $250 million+**					
Drug Substance - Est. Total Cost	**Approx. $100 million - $250 million+** *DS is a more complex process compared to DP and, as such, requires significant financial investment*					

Source: CHAI interviews with manufacturers

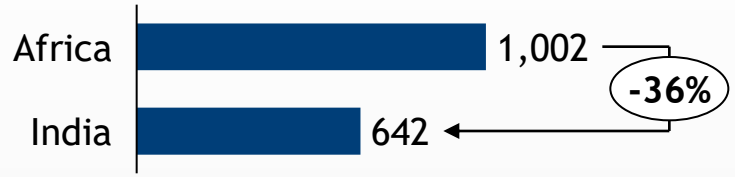
New vaccine manufacturers, particularly in Africa, likely face higher production costs resulting in higher prices and impacted demand

SIGNIFICANT COST DRIVERS

1 Facility Construction

High CAPEX costs of construction in Africa limit the cost competitiveness of manufacturers compared to other low-cost manufacturing destinations, such as South Asia.

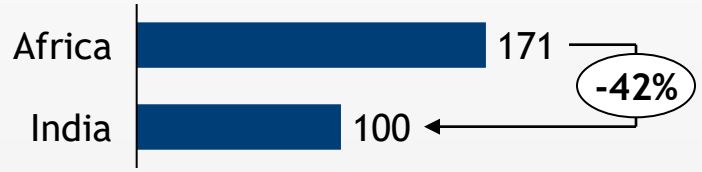
Cost per Square Meter High-Tech Construction
$USD[1]



2 Labour Costs

Although less than 15% of overall COGS, labour costs in Africa are higher compared to India, impacting the cost-efficiency and scalability of new vaccine producers.

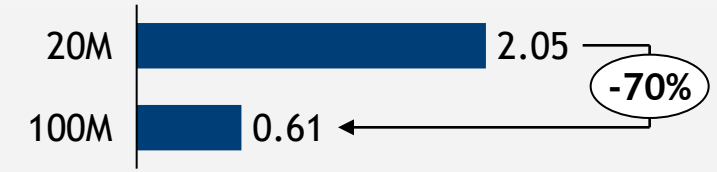
Relative Labour Costs
$USD[2]



3 Operating Scale

Economies of scale benefit larger manufacturing sites by spreading fixed costs over higher volumes, but there may be different scale benefits across different vaccine platforms.

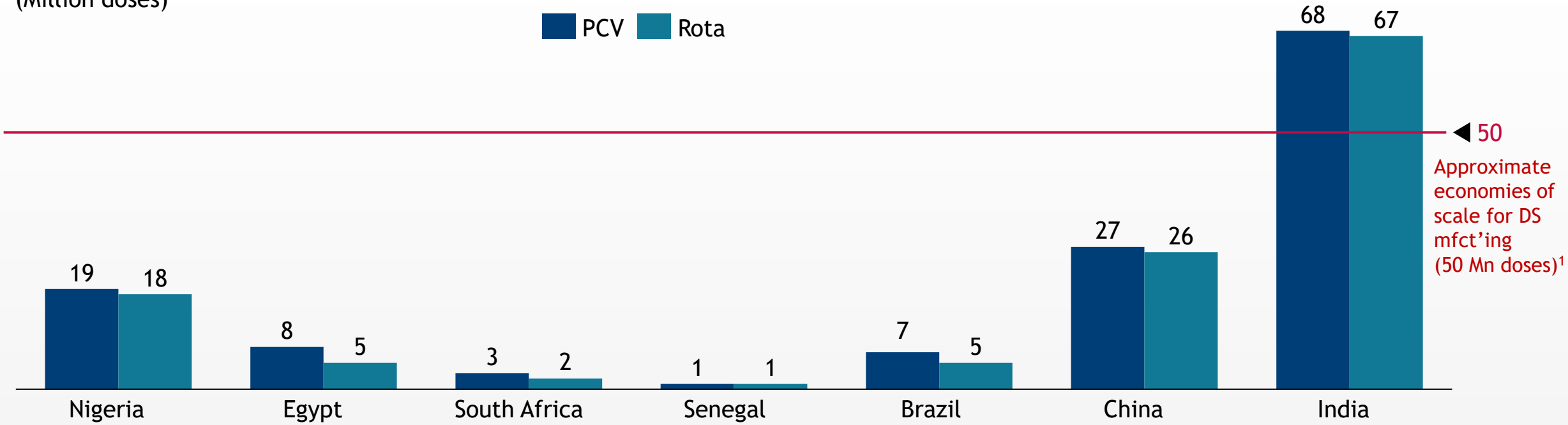
Scale of manufacturing impact on COGS[3]
$USD / dose (MR, viral)



Sources: 1. Construction (Turner and Townsend Market Survey); 2. Labour (Internal Benchmarks and United Nations Database, Employment and Wages by Industry Data on 'Chemical and Chemical Products' Industry; 3 BMGF report and (for all) CHAI Analysis 4. Considerations for Commercially Viable Vaccine Manufacturing in Africa, BDO & Kroll

Without exploring global markets, domestic Vx manufactures are highly unlikely to achieve the economies of scale necessary to be competitive

Forecasted PCV & Rota Vaccine Demand for Select Countries in 2030 Volume
(Million doses)



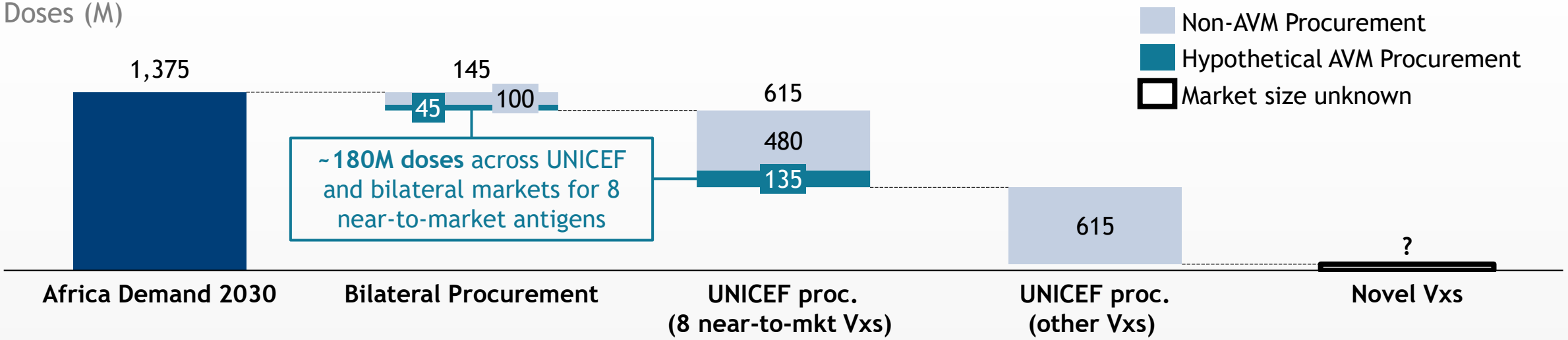
- Using PCV or Rota as benchmark examples, the 2030 demand forecast indicates that most countries that **focus solely on their domestic market** will not achieve the economies of scale (50 Mn doses) required for a viable DS manufacturing facility[1]. Even China and Brazil with their large birth cohort cannot achieve this scale and whilst **India achieves economies of scale** through large domestic markets, they also rely on exports.
- Local vx mfcts., including AVMs, must **expand beyond domestic borders** to ensure sustainability and commercial viability.

Sources: 1. Factors Contributing to Cost-Competitiveness in Regional Manufacturing, BMGF, May 2022 2. Linksbridge Data 3. CHAI Analysis

However, global markets are competitive and even suppliers of near-to-market antigens may initially struggle to gain adequate share

Illustrative analysis: African Vaccine demand in 2030,

Doses (M)



Market Opportunities (Illustrative analysis for Africa)	• Near-to-market Vxs are able to address a sig. portion of bilateral markets if they engage successfully with bilateral country tenders.	• ~135Mn[1] of hypothetical demand for near-to-market Vxs. • Market competition and market health considerations act as a cap on the demand allocation for AVMs	• No AVM supply in other markets, though this could change with new TT announcements. • Limitations here incl. limited appetite for TTs and low margins and no AVMA support for commoditized Vxs[2]	• Novel Vx market size remains unknown and may present additional market opportunities for AVMs

1. 145Mn doses is based off of the 2023 UNICEF global figure, this figure is used as it is thought to maintain a fair proxy for the 2030 African vaccine demand allocation by UNICEF as it is assumed majority of vaccines mfct in Africa will be allocated to African countries. 2. Vaccines less than $0.25 per dose i.e., BCG, DTP, Hep B & Td

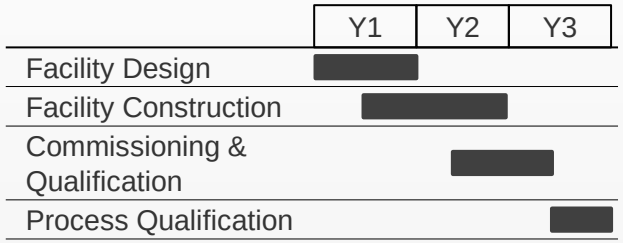
Note: Detailed assumptions in appendix

Sources: CHAI analysis, Linksbridge, Gavi Strategy, UNICEF consultations

Factoring in facility development, it can take upwards of 7 years to begin operation of a vaccine manufacturer

Facility Design & Build
Year 1 - Year 3

Breakdown of Construction Timelines[1]



Designing, building, and validating a commercial vaccine plant typically takes ~**3 years**, though estimates vary.

Product Readiness
Year 4 - Year 6

Development Pathways

Technology Transfer

In more mature markets, such as the U.S., technology transfer and regulatory approval typically take about **2-3 years**[2]. However, manufacturers that successfully commercialize one TT have demonstrated the ability to commercialize subsequent TTs in shorter timelines, leveraging built expertise

Research & Development

Discovery research, pre-clinical studies, and the multi-phase clinical development process typically takes about **10-15 years**[3]. This can be persued in parallel with facility design and build.

Regulatory Approvals
Year 7 Onwards

Estimated Regulatory Timelines

Local National Regulatory Authority Approval (NRA) (e.g. South Africa)

1 – 4 Years

WHO Prequalification (PQ) Approval

8 – 12 Months

The target NRA review period is 1 year, but the average is 4 years. Following this, WHO PQ review typically takes 8-12 months.

These timelines are variable and depend greatly on the company's ability to respond to inquiries promptly.

Sources: 1. WHO Establishing Manufacturing Capabilities for Vaccines White Paper,2017 2. McKinsey tech-transfer survey, Oct 2019 3. Han S. Clinical vaccine development. Clin Exp Vaccine Res, 2015 4.Keyter et al. (2019) & Plotkin et al. (2017)

Countries pursuing full RI schedule production from a single mfct. face major technological challenges, resulting in increased costs

Routine Immunization Schedule (Kenya)

Antigen	DS - Platform Type*	DP - Overall
BCG	Live attenuated	Live - Lyo
Hexa	Toxoid, Recombinant Protein, Inactivated, Conjugate	Non-live - Non-Lyo
HPV	Recombinant Protein	Non-live - Non-Lyo
IPV	Inactivated	Non-live - Non-Lyo
Malaria	Recombinant Protein	Non-live
MR	Live attenuated	Live - Lyo
OPV	Inactivated	Live - Non-Lyo
PCV	Conjugate	Non-live - Non-Lyo
Rota	Live attenuated	Live – Non-Lyo
Td	Toxoid	Non-live - Non-Lyo
YF	Live attenuated	Live - Lyo

Source: CHAI Analysis
*Note that there is significant divergence and variation, even within the same platform type.

Some countries aim to source their entire RI schedule locally, but this remains a significant technological challenge.

Key Considerations

- **No high-income country produces its entire RI schedule locally**.
  - China and Indonesia aim for local production but have not yet achieved it.
  - Leading manufacturers (SII, GSK, Merck) do not provide the full RI product range.
- Full RI production requires comprehensive DS capacity, making it costly and **demanding numerous manufacturing suites (and different DS facilities) and a variety of DP capacity as well.**
- Managing multiple technology transfers increases **complexity and causes delays.**
- Even with local production, producing a full RI schedule remains **prohibitively expensive and impractical**.

Summary | Domestic Vx manufacturing is highly complex and costly, and countries need to navigate many uncertainties to be competitive

Current Landscape

Global and regional efforts are **accelerating local vaccine manufacturing** in Africa, Latin America, and Southeast Asia through funding, policy, and private sector collaboration.

Benefits

While local vaccine manufacturing could improve pandemic preparedness and fuel economic growth, its success hinges on **balancing trade-offs** to ensure sustainability.

Cost

Setting up a local Vx. manufacturing facility can cost **costs ~$100s million**, with key cost drivers including labor costs, facility construction, and operating scale.

Timeline

Establishing a facility, from designing the plant to securing regulatory approvals, **can take a minimum of 7 years**, with the setup of a Drug Substance facility requiring more time compared to a Drug Product facility.

Product Access

Global vaccine markets are highly competitive with **limited opportunities for new entrants**, as many key supplier positions are already filled.

Country Presentation

Egypt National Strategy for Vaccine Manufacturing Localization

Mostafa Ghorab
Business Development Director,
The Egyptian Authority for Unified Procurement

Rania Mohsen
Project Management Department Director,
The Egyptian Authority for Unified Procurement

الاستراتيجية الوطنية لتوطين صناعة اللقاحات في جمهورية مصر العربية
The National Strategy for Vaccine Manufacturing Localization in Egypt

Presidential Directions

(WHO press conference on the sidelines of the African/European Summit in Brussels)

“Egypt has built robust medical and manufacturing infrastructure to produce vaccines not just for domestic use, but also to support other African countries in vaccinating their populations.”

“Egypt views this as a step towards a broader, comprehensive health partnership among African nations.”

Prime Minster Directions

❖ Localization of medical industries Committee :

Prime Minister's Decree No. 719 of 2024 to formulate a unified strategy to localize the vaccine industry in Egypt.

❖ Assigning the Members of the Vaccine Committee to :

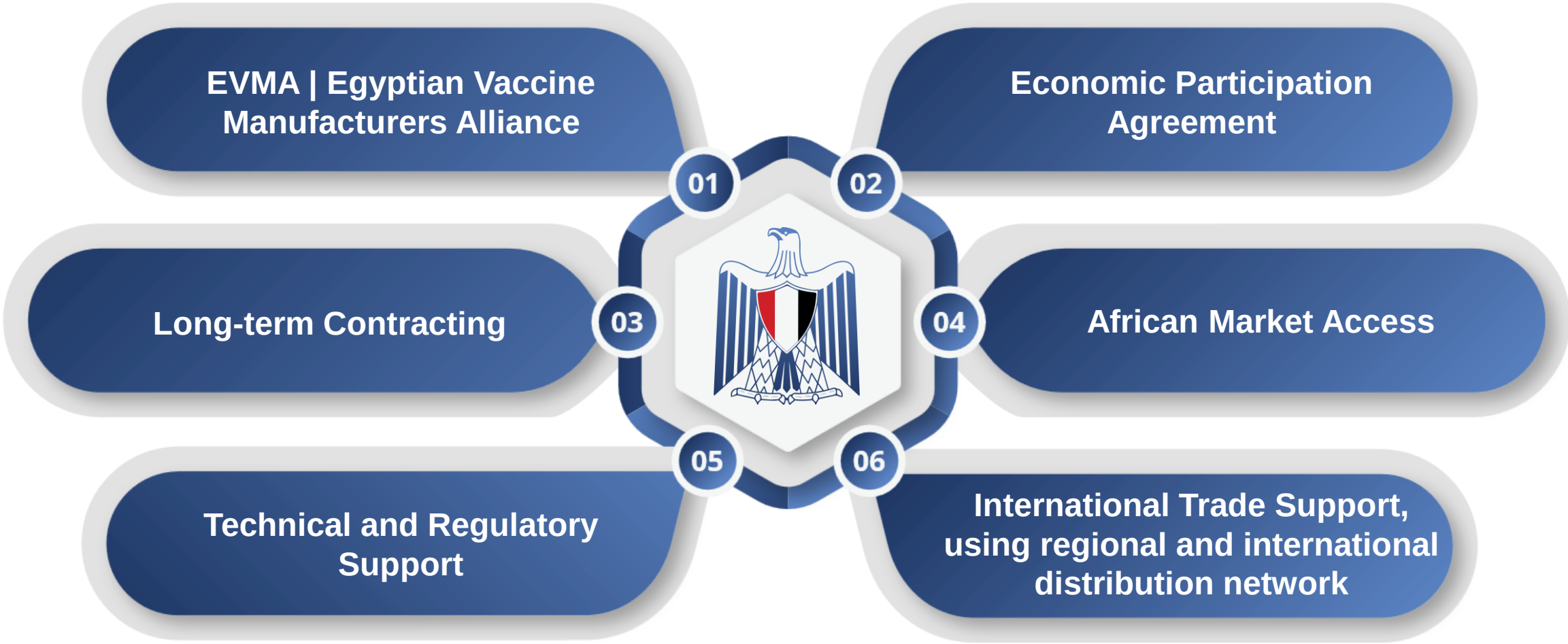
coordinate between all manufacturers to develop an action plan & implement it according to the following policies:

- **Integration rather than competition between Egyptian vaccine manufacturers.**
- **Supporting manufacturers to obtain qualified international accreditations for supplying to international agencies UNICEF & GAVI and exporting.**
- **Optimal exploitation of the manufacturing capabilities of local manufacturers to ensure the sustainability and growth of local manufacturing.**
- **Supporting the state with all its institutions.**

Egypt National Strategy for Vaccine Manufacturing Localization Main Considerations

1	**Inclusive Stakeholder Engagement**	Drafting the strategy in collaboration with manufacturers, regulators, and payors.
2	**Diverse Tech. Providers**	Agreements with various tech. transfer providers from allover the world with different technologies.
3	**Action–Oriented Strategies**	Development of the implementation pillars ready in-place (the EVMA – Economic Participation Agreement)
4	**Practical and Measurable Goals**	Development of a monitoring and evaluation system with KPIs and milestones; some are measured on quarterly or semester basis.

Egypt National Strategy for Vaccine Manufacturing Localization Pillars



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The Vacci-Nation Hub

EVMA is the execution arm of the Egypt National Strategy for Vaccine Manufacturing Localization

EVMA is a strategic alliance of vaccine manufacturers in collaboration with MOHP / UPA /EDA and several supporting international organizations

- **EVMA** role is to act as "**One Voice"** in front of external parties and to "**foster internal integration"** rather than competition that is done through:
  - **Mapping** capabilities of vaccine manufacturers
  - **Collaborating** and building partnerships among them and with other possible opportunities to reach **ideal resource utilization**
  - **Consolidating** a manufacturing plan into short, medium, and long term plans

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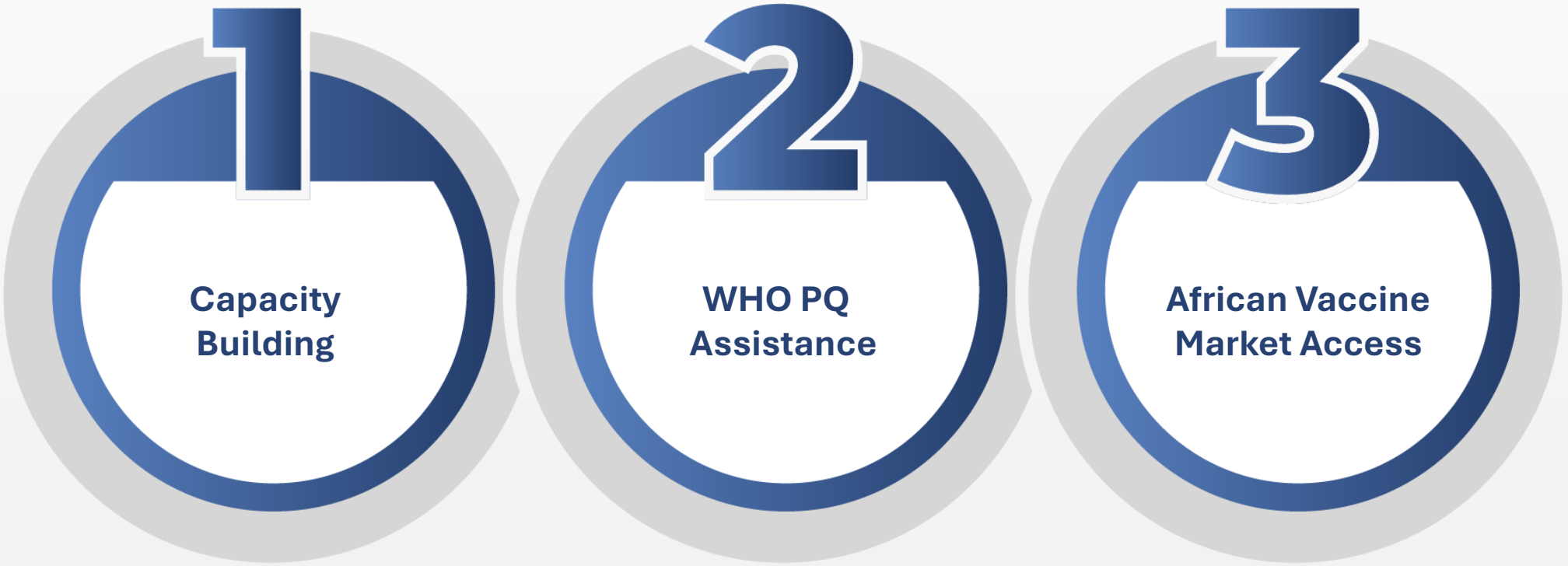
EVMA | Egyptian Vaccine Manufacturers Alliance

Priorities



EVMA
EGYPTIAN VACCINE MANUFACTURERS ALLIANCE
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EVMA | Egyptian Vaccine Manufacturers Alliance Key Partners

Technology Transfer Providers







BATAVIA biosciences

SERUM INSTITUTE OF INDIA
Cyrus Poonawalla Group

WALVAX 沃森生物
WALVAX BIOTECHNOLOGY CO., LTD.

CDBIO

AJVaccines

MINHAI

Pfizer

SANOFI PASTEUR

Bilthoven Biologicals
Cyrus Poonawalla Group

Biological E. Limited
Celebrating Life Every Day

Local Manufacturers

BGP

VACSERA

VBC

GYPTO PHARMA

EVA PHARMA

GENNECS

Governmental Partners

U.P.A

Ministry of Health & Population
وزارة الصحة والسكان

EDA
EGYPTIAN DRUG AUTHORITY
هيئة الدواء المصرية

International Organizations

World Health Organization

unicef

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

medicines patent pool

Gavi
The Vaccine Alliance

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HEALTH ACCESS INITIATIVE

EVMA | Egyptian Vaccine Manufacturers Alliance

Kickoff Plan

6	10	3	9	18
Vaccine local manufactures	Tech. transfer providers (Denmark-France-USA– Netherlands-India – China)	CMO agreements among members	MOU /contracts to be signed with tech-transfer providers	Vaccines

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HEALTH ACCESS INITIATIVE

Egyptian Vaccine Manufacturing Capacity Mapping 2026-2030

2026
Total production capacity up to:
176.5M doses

TT agreements stage:
2ry packaging:
(MMR-ROTA-Varicella-OCV)
Fill &Finish:
(Penta-DTP- DT-TD-HepB-HEXA-Rabies-PCV-Flu-IPV-HPV)

2027
Total production capacity up to:
222 M doses

TT agreements stage:
2ry packaging – Fill & Finish-Formulation Bulk Antigen

2028
Total production capacity:
290 M doses

TT agreements stage:
2ry packaging - Fill& Finish - Formulation Bulk Antigen

2029
Total production capacity:
330 M doses

TT agreements stage:
2ry packaging – Fill & Finish-Formulation Bulk Antigen-END to END

2030
Total production capacity:
380 M doses

TT agreements stage:
2ry packaging – Fill & Finish-Formulation Bulk Antigen-END to END

WHO-PQ Milestones

Group	2026	2027	2028	2029	2030	2031
Group 1	**WHO – PQ SUBMISSION (**2026-2029) (Rabies – PCV10 – Hexa – FLU)					
Group 2		**WHO – PQ SUBMISSION (2027-2030) / (PCV13 – HBV)**				
Group 3			**WHO – PQ SUBMISSION /** (2028-2031) (PCV13 – IPV – Penta - ACWY)			

Vaccine Portfolio Mapping

- HEXA
- PCV
- IPV
- FLU
- RABIES
- HEPATITIS B
- PENTAVALENT
- MMR
- Meningococcal AC
- Meningococcal ACWY
- ROTA
- HPV
- Cholera
- MR

Egypt Local Facility Readiness

Group	2024	2025	2026	2027
Ready	●● ●	●● ●	●●● ●●	●●● ●●●
Broken Ground	●●	●●	●	
Planned	●			

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Monitoring and Evaluation

Strategic Objectives

1. Track **impact** of MOUs against the Egyptian National Strategy for Vaccines Manufacturing Localization.
2. Ensure **timelines** are met for key milestones (e.g, technology transfer agreements,facility readiness, and production targets.
3. Proactively **identify** bottlenecks and deploy **support** mechanisms for timely resolution.

Key Components

1	2	3	4	5
Baseline Assessments	Continuous Monitoring	Evaluation Metrics	Risk Mitigation	Stakeholder Engagement

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Monitoring and Evaluation Framework

Key Monitoring Areas

- Technology Transfer Progress
- Production Capacity Growth
- Regulatory Approvals
- Economic Impact
- Workforce Development

Key Monitoring Tools

Digital Monitoring and Evaluation	*Data input from all MOU stakeholders, updated quarterly.*
Semester-ly Progress Reports	*Structured reviews summarizing achievements, challenges, and corrective actions required.*

Delivered to:

-Minister of Health and Population
-EDA
-UPA

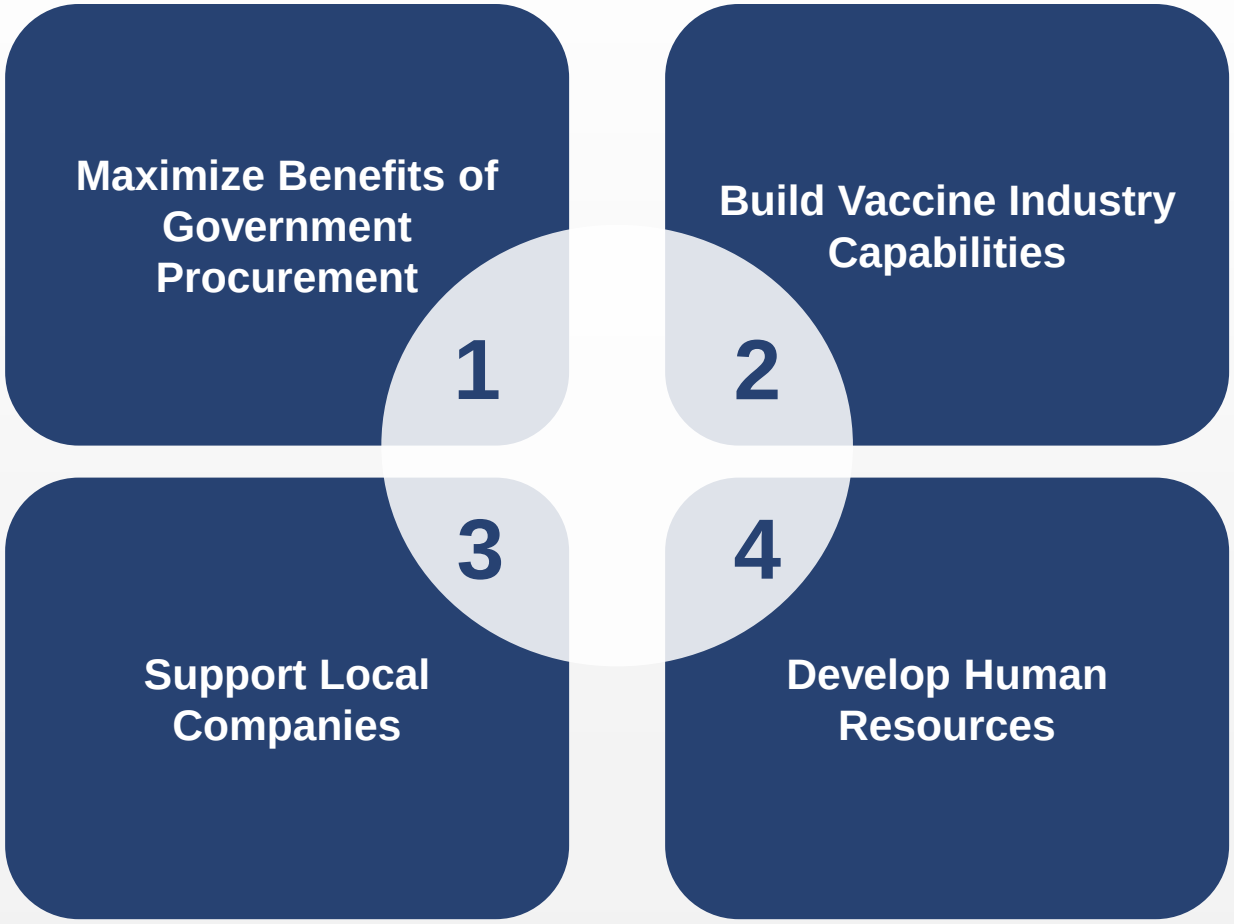
Key Supporting Mechanisms

- Technical Assistance
- Stakeholder Coordination
- Capacity Building

Economic Participation Agreements and Long-term Contracting

Legislative Arm of the Egypt National Strategy for Vaccine Manufacturing Localization

Objectives



1. Enhance value and efficiency through strategic procurement practices.
2. Strengthen local manufacturing and technical expertise.
3. Boost competitiveness and integration into global supply chains.
4. Provide training and career development opportunities.

Economic Participation Agreements and Long-term Contracting

Legislative Arm of the Egypt National Strategy for Vaccine Manufacturing Localization

Eligible Activities

Technology Transfer

- Conduct training programs.
- Provide technical support.
- Facilitate the transfer of advanced equipment.

Export Development

- Increase export revenues.
- Improve competitiveness of locally manufactured products.

Research and Development

- Support capital investments.
- Fund operational expenditures for innovation.

Localization of Industry

- Offer technical training for local teams.
- Ensure successful implementation of industrial processes.

Country Presentation

Localizing Vaccine Production in South Africa: The Biovac Initiative

A Case Study on Public-Private Partnership in Vaccine Manufacturing – South Africa

Marione Schonfeldt
Senior Pharmaceutical Policy Specialist,
National Department of Health

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

Why Localize Vaccine Production?

Healthcare Security: Reduce dependence on international suppliers to ensure a stable vaccine supply.

Economic Growth: Stimulate job creation and attract investment in the pharmaceutical sector.

Technological Advancement: Promote technology transfer and innovation tailored to local health needs.

Regional Self-Sufficiency: Align with broader public health objectives for equitable access to medicines.

Implementation Process and Timeline

- Biovac Initiative: Key Milestones

2003

Establishment of Biovac through a Public-Private Partnership (PPP) between NDoH and Biovac Consortium

2012

Completion of manufacturing facility and technology transfer agreement with Sanofi

2015

First locally produced vaccines became available

2020

Transition from PPP to open-tendering process for vaccine procurement

2021

Commencement of local manufacturing of Hexaxim and Prevnar 13.

2024: Diversified public sector procurement: Biovac (3 vaccines), Cipla (3), GSK (2), Sanofi (1).

Financial Requirements and Government Support

Investing in Local Manufacturing

Initial Funding: Government provided significant funding and guaranteed procurement through Biovac during the PPP period.

2003–2024 Investments: Grants ($5M–$10M), loans ($20M–$40M), and **PPP price premiums (~$150M).**

Post-2020 Funding: Raised ~$1.5B in external funding from donors and Development Finance Institutions (DFIs)

Policy Support: Industrial Policy Action Plan (IPAP), preferential procurement policies, and interdepartmental collaboration

Collaborative Efforts for Success

- **Government Departments:** NDoH, Department of Science and Innovation (DSI), Department of Trade, Industry, and Competition (DTIC).
- **Private Sector Partners:** Biovac Consortium, including Biovac Holdings, Heber Biotec, VaxIntel, and Disability Employment Concern Trust.
- **International Collaborations:** Technology transfer agreements with Sanofi and Pfizer.
- **Regulatory Bodies:** South African Health Products Regulatory Authority (SAHPRA), World Health Organization (WHO).

Challenges Faced - Overcoming Obstacles

- **Delays in Objectives:** Slow establishment of manufacturing facilities led to delayed vaccine production.
- **Pricing Constraints:** Long-term partnership limited ability to negotiate competitive prices.
- **Export Limitations:** Agreements with international suppliers restricted vaccine exports beyond South Africa.
- **Technology Transfer Timelines:** Lengthy processes, e.g., 9 years with Sanofi for Hexaxim.

Outcomes and Lessons Learned

- Achievements and Insights

Expanding to Africa

Developing capacity to supply vaccines and biosimilars across Africa.

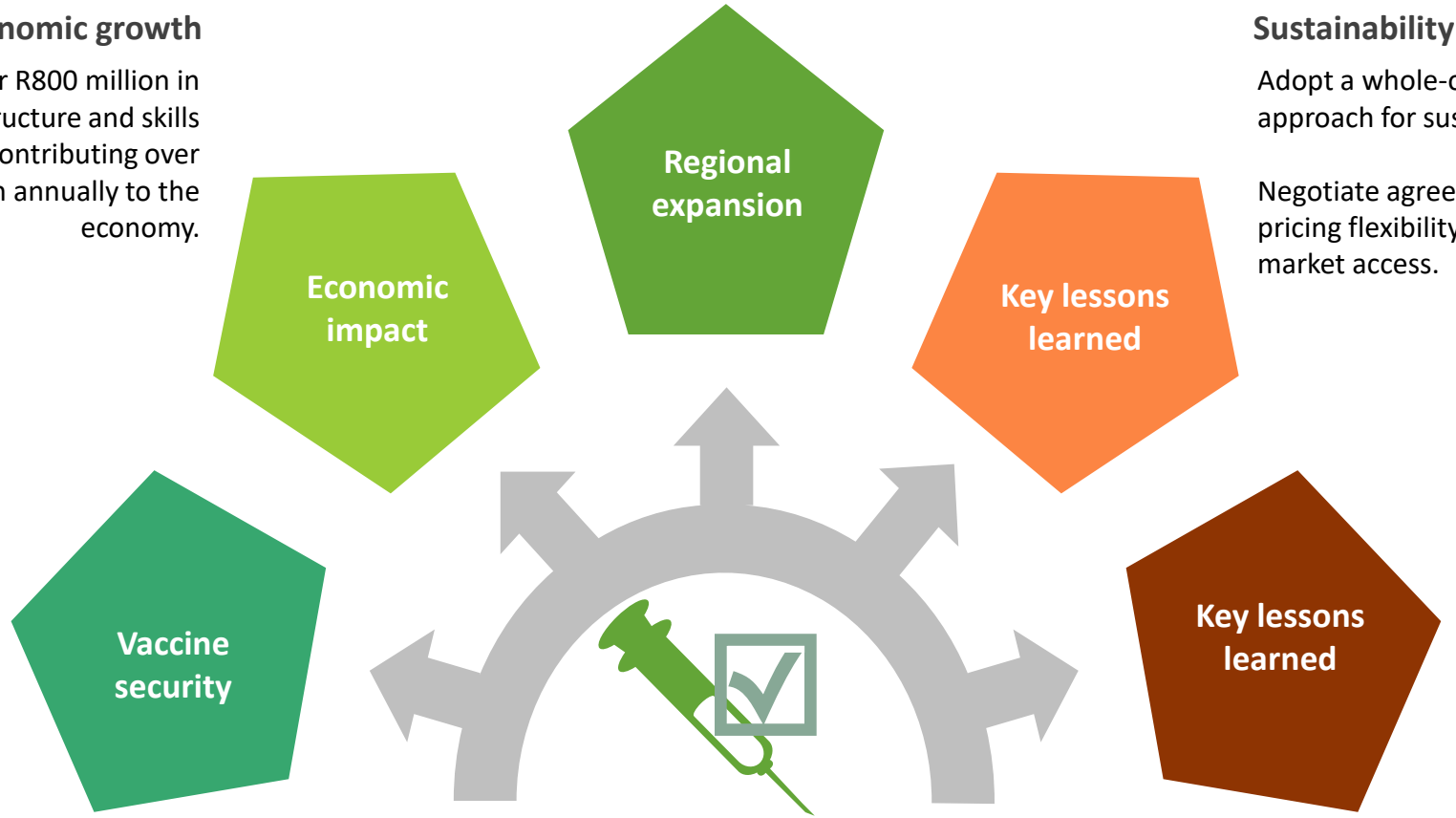
Economic growth

Invested over R800 million in infrastructure and skills development, contributing over R500 million annually to the economy.

Sustainability

Adopt a whole-of-government approach for sustainability.

Negotiate agreements allowing pricing flexibility and regional market access.



Vaccine availability

Biovac produced and distributed 450 million doses since 2003, ensuring uninterrupted supply.

Whole government approach

Ensure interdepartmental collaboration for regulatory support and investment incentives

Paving the way forward

- ✓ **Strategic Vision:** Local vaccine manufacturing is vital for health security and economic resilience
- ✓ **Collaborative Model:** Public-private partnerships can effectively build and sustain manufacturing capabilities.
- ✓ **Scalability:** South Africa's experience offers valuable insights for other countries aiming to localize vaccine production.

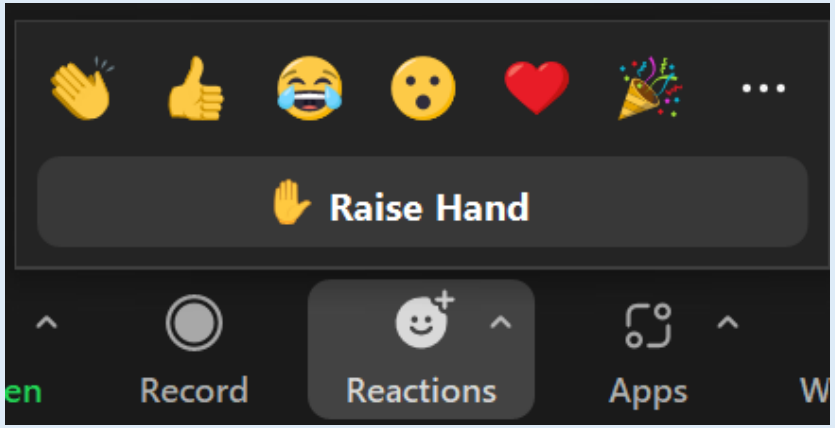
Questions & Answers session

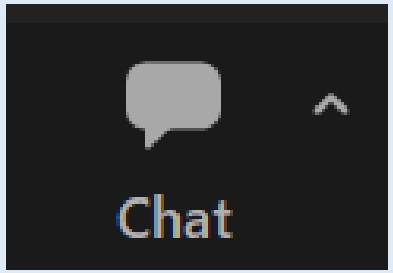
Moderated by Kristina Lorenson,
Senior Contracts Manager, Vaccine Centre, UNICEF

QUESTIONS & ANSWERS

The floor is open for your questions…

…Raise your hand to ask a question or write it in the chat.





CLOSING REMARKS

Join us on the Vaccine Procurement Practitioners Network to continue the discussion and share any other question you might have!

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Pratictioners Network (VPPN)

VACCINE PROCUREMENT
Pratictioners Network (VPPN)

THANK YOU!

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Appendix

Assumptions for illustrative African market share for AVMs

CHAI have mapped hypothetical demand offtake in 2030 for each near-to-market antigen to inform discussions on offtake for these antigens

1 Identify near-to-market AVM antigens

8 Near-to-Market AVM Vxs for continental market:

- Hexa (wP)
- PCV
- MMCV
- Rota
- YF
- OCV
- IPV
- MR

Additional domestic market antigens also considered.

2 Market Size

Linksbridge 2030 demand forecasts, with adaptations based on CHAI market intel.

For antigens with global marketing authorisation, global UNICEF market considered as potential market

3 Hypothetical Market Share

Key Assumptions:

- **Based on current procurement systems.**
- No delays in AVM timelines.
- Globally competitive pricing.
- UNICEF tenders limited by market health considerations.
  - Max. 30% of global UNICEF market allocated to new mfct.
  - New mfcts. assumed to achieve 'fair share' e.g., 25% in 4-player market, 20% in 5-player market.
- Clear procurement commitments from countries – guardrailed by programmatic alignment.

Key Omissions:

- Tender timelines or scale up scenarios not considered

4 Hypothetical Market Demand

Hypothetical demand for near-to-market AVM antigens in 2030 **based on current procurement systems**.

Notes: 1. This analysis focuses only on TTs that have been signed by AVMs and are already underway. Additional AVM products may come to market in addition. 2. Where Linksbridge forecast not available (OCV / Hexa) have developed CHAI forecasts based on product roadmaps shared by global partners. 3. Political will is measured using the commitment countries have shown to join the Africa CDC PPM and Regional mfct support TWG.

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