African Vaccine Manufacturing Mapping - 2024 Supply and Demand Landscape

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AfricaCDC
Centres for Disease Control and Prevention

CLINTON HEALTH ACCESS INITIATIVE

PATH

A complete landscaping analysis was undertaken through AVM engagements

Interviews were held with 24 AVMs, 10+ funders, multiple partners, & research to collect short- & long-term data on:

1. **Technical capabilities**
   - Existing production capacity
   - Planned expansion & future capacity
2. **Market and commercial ambitions**
   - Current antigen pipeline & tech transfer plans
   - Current commercial status
   - Commercial ambition & indicative timelines
3. **Supporting functions**
   - Standards of associated NRAs required to access key markets
   - Urgent funding gaps & challenges to access financing
   - Demand uptake, and routes to facilitate demand actualization

Findings have been consolidated into the 2024 AVM Landscape analysis

Collected data has been aggregated across manufacturers to distill key findings:

Track progress made since 2023, including changes in technical and commercial plans

Identify key challenges faced by AVMs which pose risks to commercial sustainability

Recommend priority actions to address challenges and support sustainable AVM footprint

Six factors are analysed which contribute to long-term success of AVMs, but most factors are outside of AVM's direct influence

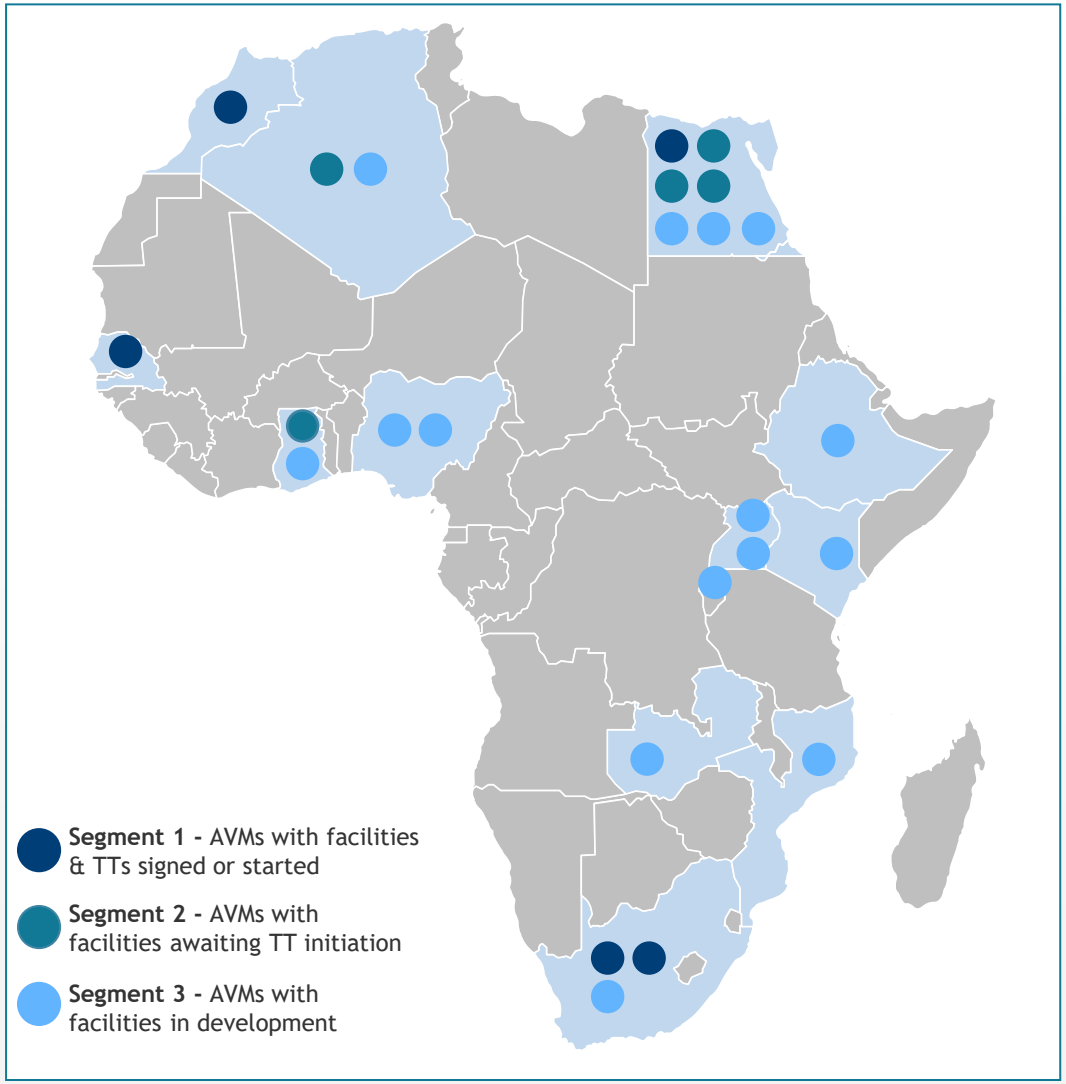
Key success factor	AVM level of control	Target state
Technical Capabilities	High	A fit-for-purpose facility equipped with appropriate technical capabilities to produce high-quality vaccines at competitive scale
Workforce	Medium	Skilled workforce to operate facilities and manufacture vaccines *(Not in scope for this analysis)*
Access to products	Medium	Pipeline of products are secured (either self-developed or through tech transfers) to be manufactured at facility
Financing	Medium	Sufficient financing is available to sustain commercial operations and strategically invest in new projects
Regulatory approval	Low	There is regulatory capacity at the required level of maturity to provide oversight for African-made vaccines in respective markets
Demand & procurement	Low	Sufficient demand for African-made vaccines to support commercial viability of manufacturer

As of June 2024, there are 25 active AVM projects which can be divided into three segments based on overall supplier maturities and capabilities

Segment 1: AVMs with facilities and TTs signed or started
- Marbio
- Vacsera
- IP de Dakar
- Aspen Pharmacare
- Biovac

Segment 2: AVMs with facilities awaiting TT initiation
- Eva Pharma
- Minapharm
- Biogeneric
- Saidal[1]
- Atlantic Biotech

Segment 3: AVMs with facilities in development
- VBC
- Polygon
- Gennecs
- IP de Algerie
- DEK
- Innovative Biotech
- BVNL[2]
- DEI Biopharma[3]
- VAI Uganda
- Biovax
- Shieldvax
- BioNTech
- Yash Life Pharmaceuticals
- Mozambique Holdings[4]
- Afrigen[5]



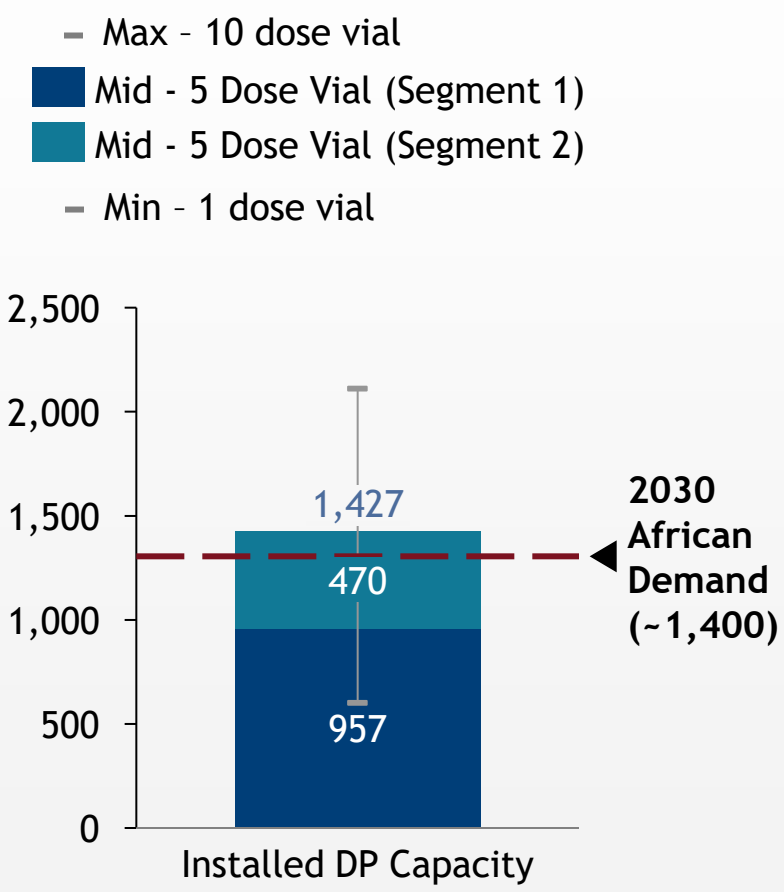
Key Findings

- 5 Suppliers in Segment 1 already have commercial scale facilities and tech transfers (TTs) underway or complete
- 5 Additional suppliers in Segment 2 have commercial scale facilities qualified and ready to receive TTs, but no TTs have been signed or started yet
- The remaining 15 suppliers in Segment 3 are in development stages, with some being closer to qualification than others
- Rationalizing the number of AVM projects is critical as the long tail of pipeline projects may struggle to gain sufficient market share by the time they are expected to commercialize

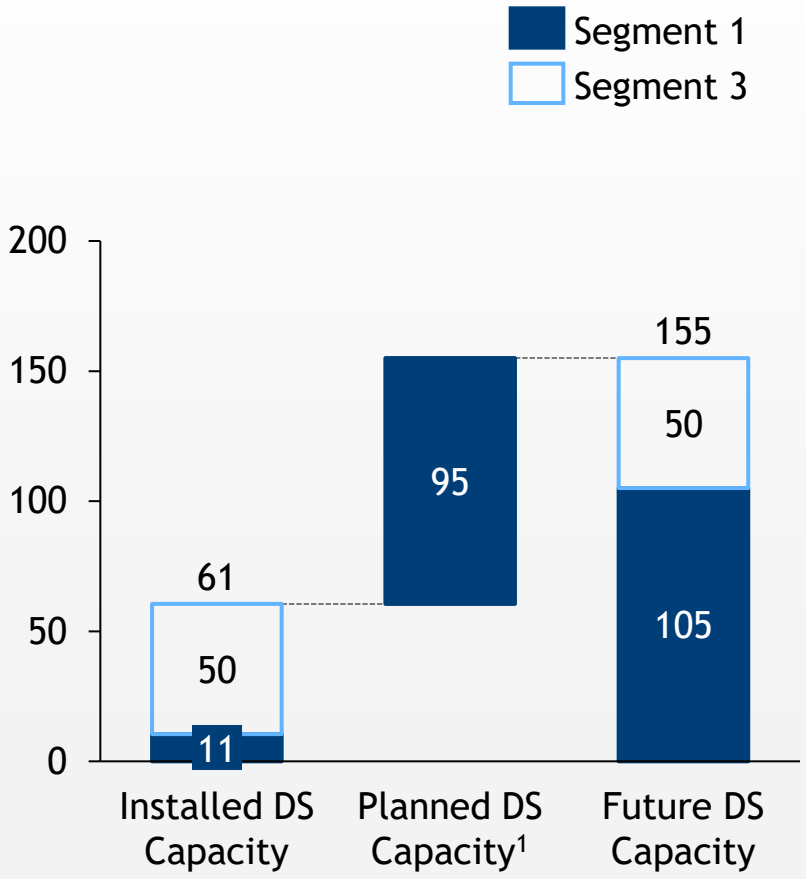
1. Interview not yet held, but initial perspective is Saidal may also have a commercial scale facility ready to receive an influenza vaccine TT 2. As per an informal meeting with BVNL they do not have a facility yet 3. Construction of a modular Vxn facility has started in the US for shipment to Uganda in 2025 4. Mozambique Holdings have broken ground on a F/F facility 5. R&D facility complete, larger commercial facility built, expecting GMP inspection in 2025; Source: CHAI/PATH/PAVM Current State Vaccine Supply Mapping

Existing DP capacities are beyond African manufacturing targets; Overall DS capacities are not sufficient to secure a robust AVM Industry

DP Production Capacity,
Doses (M)



DS Production Capacity,
Doses (M)



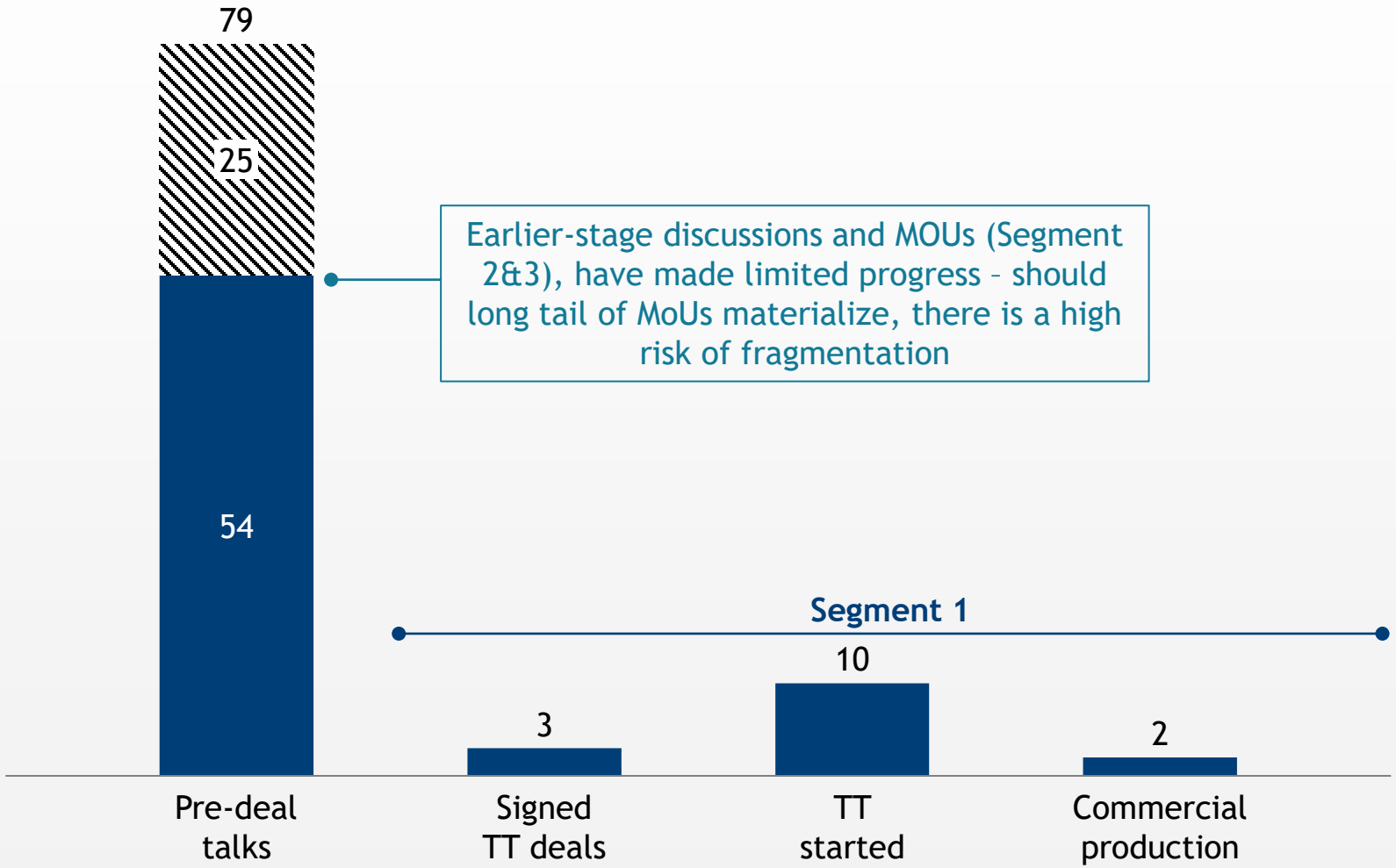
Key Findings

- Approx. two-thirds of installed DP capacity is from Seg. 1 suppliers with TT underway
- Already installed DP capacity exceeds current vaccine TTs, expected demand offtake, and Africa CDC's 60% target for AVM
- With Seg. 3 facilities to come online in future, the risk of DP over-capacitation may further increase
- Most of the installed DS capacity is for mRNA DS - to date, there are no commercialized mRNA products ready to utilize this capacity.
- Market health & pandemic preparedness goals are not sufficiently met with DS capacity at ~10% of 2030 African demand

1. 11M of the current DS capacity will be closed down once it is replaced by the planned future capacity for the same product resulting in net of 95M additional dose capacity
Source: CHAI/PATH/PAVM Current State Vaccine Supply Mapping

Seg. 1 suppliers have 13 TTs signed or started; other suppliers are in pre-deal stages with progress remaining highly uncertain

Number of TTs by self-reported maturity status



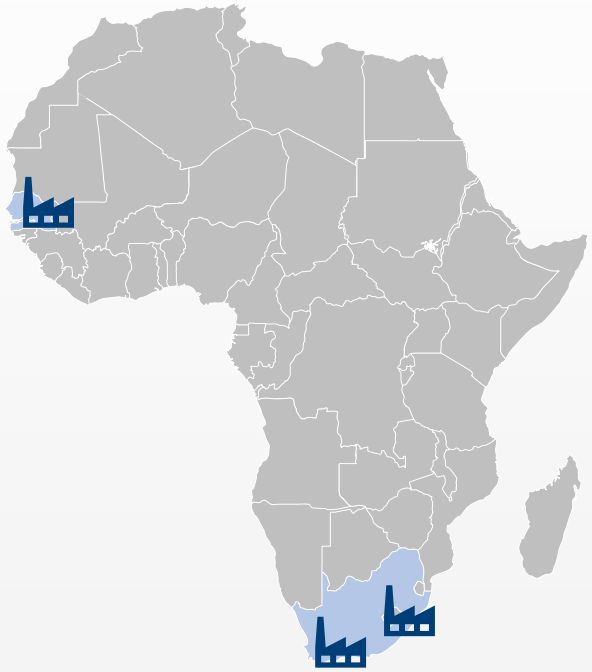
Key Findings

- Since 2023 5 TTs have started and 2 have been signed; However, 3 previously commercial vaccines are no longer produced
- Many pre-deal TT talks are underway, but these include very early-stage discussions, many of which may not materialize
- For some antigens, 5+ manufacturers are engaged in pre-deal talks with originators, creating high risk of fragmentation
- Most TTs are for DP manufacturing; only 3 tech transfers target DS[1]
- Serum Institute of India (SII) is the originator for 7 ongoing TTs, creating potential monopolistic influence over AVM

Note: TT = Technology Transfer
1. Includes 2 tech transfers signed with originators and one self-developed product
Source: CHAI/PATH Current State Vaccine Supply Mapping

8 Antigens, and 10 products, are expected to achieve WHO PQ and enter the continental market between 2025 - 2030

Drug substance Drug product



Antigen	Country & manufacturer	Year of product entry	Africa dem. 2030	% currently UNICEF proc.
Hexa (wP)	Aspen	2025-2030[1]	46 M	100%[2]
Rota	Aspen		119 M	93%
MMCV	Aspen, Biovac		19 M	100%[2]
PCV	Aspen, Biovac		126 M	90%
OCV	Biovac		32 M	100%
IPV	Biovac		94 M	92%
YF	IPD		47 M	99.9%
MR	IPD		204 M	95%

All 8 products face limited market opportunities outside the UNICEF procurement channel.

1. Timelines premised on timely review from involved regulatory authorities; 2. Estimated % when product is launched
Source: Africa CDC, CHAI, PATH analysis and landscaping activity, Demand and UNICEF data taken from Linksbridge 2024

Almost all Segment 1 & 2 suppliers still face urgent financing needs for ongoing TTs and, in some cases, expanding DS capabilities

- 9 Segment 1 & 2 AVMs asked to share their current funding gaps:
  - 2 AVMs reported no funding gaps
  - 1 AVM had not yet estimated gaps, but confirmed there are likely funding gaps for TT commercialization
  - 6 AVMs shared estimated funding gaps across the lifecycle, most urgently for TT commercialization
- **Total funding gap of ~$250M** across Segment 1 & 2 suppliers (~12% of external financing raised to date) – **potentially underestimated**

Stage in AVM lifecycle

	Feasibility & design	Construction	R&D and/or tech transfer	Regulatory approvals	Commercial operations
No. of AVMs	0 / 6	4 / 6	6 / 6	2 / 6	2 / 6
Avg gap per AVM[3] ($)	No gaps reported by Seg. 1&2 suppliers	**$5 - 30m** to purchase equipment required to expand DS capabilities	**$10 - 20m[1]** to build and strengthen R&D capabilities and commercialize tech transfers	**Up to $20m** to undertake required trials and submit regulatory applications	**Up to $25m** to retain skilled workforce and cover anticipated financing costs
Tools needed	No gaps reported by Seg. 1&2 suppliers	• Debt (pref. for concessional) • Equity	• Working capital fin. • Equity • Grants	• Grants	• Varied, likely a blend of multiple instruments

Critical gap

1. Approx. $5-10M required per tech transfer 2. Excludes funding gaps where MoUs have been signed with prospective funders, and negotiations are underway on deal terms 3. Non-cumulative average per AVM, based on self-reported funding gaps – potentially underestimates actual funding needs
Source: Interviews with AVMs

Despite carrying relatively lower risk of commercialization, Seg 1 & 2 suppliers face 4 key challenges to close urgent funding gaps

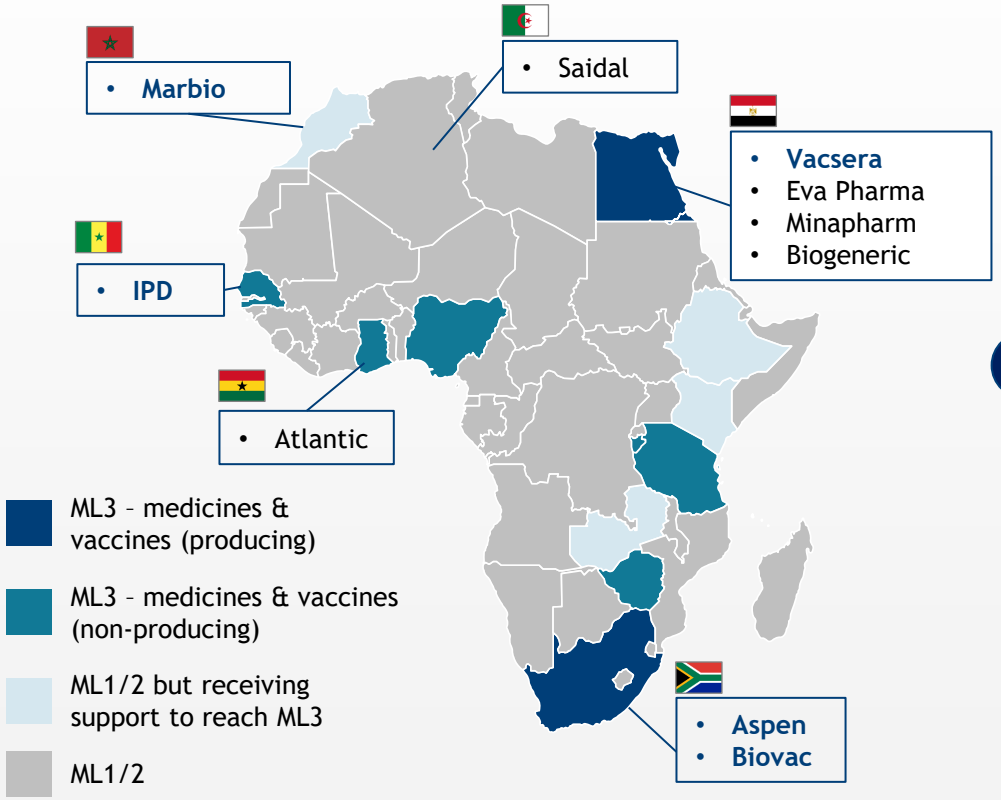
Challenge	Description of challenge	Feedback raised by Segment 1 & 2 AVMs
Unsuitable deal terms	• **Short tenors** offered (~7-12 years), whereas long tenors (15+ years) are preferred • **Unfavorable repayment rates and terms** that do not consider long timelines for commercialization	**Raised by 4 AVMs** as a key challenge: "We need more **patient capital**. The current offering will otherwise hurt our business"
Misaligned use of instruments	• **Minimum ticket thresholds** (commonly ~$20-30M) are higher than most urgent funding needs identified ($10-$15M) • **Limited use of tools that can address current funding needs** (e.g., working capital, equity, first-loss capital)	**Raised by 4 AVMs** as a key challenge: "The infrastructure lens [of funders] means that funding solutions are not fit-for-purpose. The **funding need does not stop after the facility is built**."
Absence of new investors	• **High reliance on few donors and DFIs** to address all financing needs • Lack of private capital, **restricting ability to raise equity** which further affects ability to raise additional debt	**Raised by 2 AVMs** as a key challenge: "Who is willing to put up equity for AVM? **Without new equity funders, it is difficult to improve our financial position**"
Limited awareness of funder requirements	• **Limited understanding of funder priorities** and requirements • **Limited awareness of which funders to engage** and how to do so effectively	**Raised by 5 AVMs** as a key challenge: "If we had known then what we know now, this whole process would have been much smoother. **Funders should be clear on what they will fund**, even if we [AVMs] do not like the answer."

Source: Interviews with AVMs

As of December 2024, only mfcts. in Egypt & South Africa have NRAs with required maturity level to obtain PQ - other NRA timelines are unclear

WHO African NRA maturity level, December 2024

(Only Segment 1 & Segment 2 suppliers shown)



Bold = Segment 1 supplier

Mfct. Country (S1 & S2)	NRA maturity level
	ML3 - Medicines and Vaccines (producing) NRA oversees all aspects of local manufacturing, including lot release which is required for releasing products to the market – enabling a path to obtain WHO PQ
	ML3 - Medicines and Vaccines (non-producing) NRA can locally authorize vaccines for domestic market but cannot sponsor a locally authorized vaccine for WHO PQ consideration, restricting manufacturers from potential access to UNICEF market
	ML1/2 but receiving support NRA can authorize locally manufactured vaccines for domestic use and is receiving support from multiple partners (e.g., USAID, BMGF, European Commission) to reach ML3 but timelines are undefined
	ML1/2 NRA can authorize locally manufactured vaccines for domestic use but no additional support is being received to reach ML3

Source: WHO NRA announcements, December 2024; WHO Global Benchmarking, Partner consultations

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

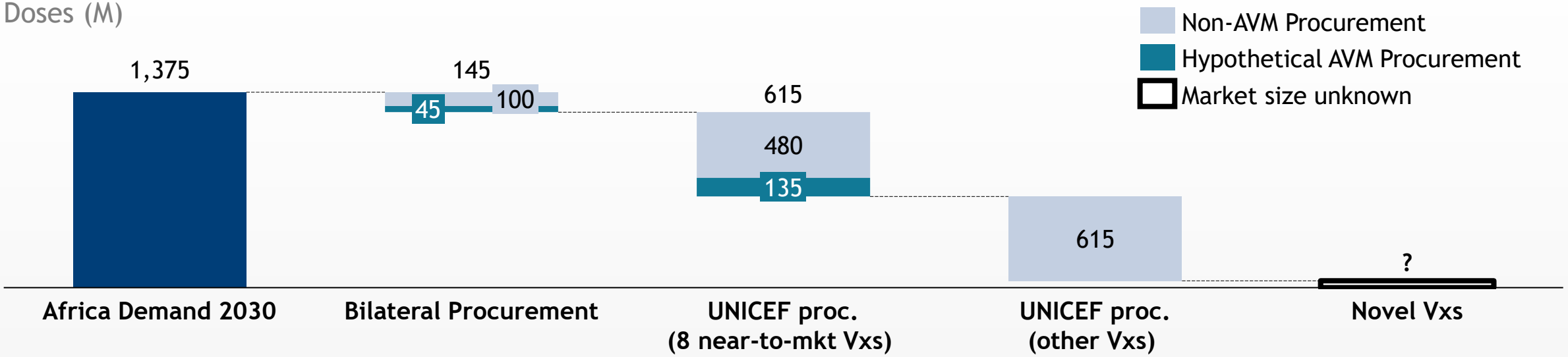
Hypothetical demand for near-to-market AVM antigens in 2030 **based on current procurement systems**.

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.

Expected hypothetical demand for opportunities for the existing near-to-market Vxs; additional opportunities are relatively limited

African Vaccine demand in 2030,

Doses (M)



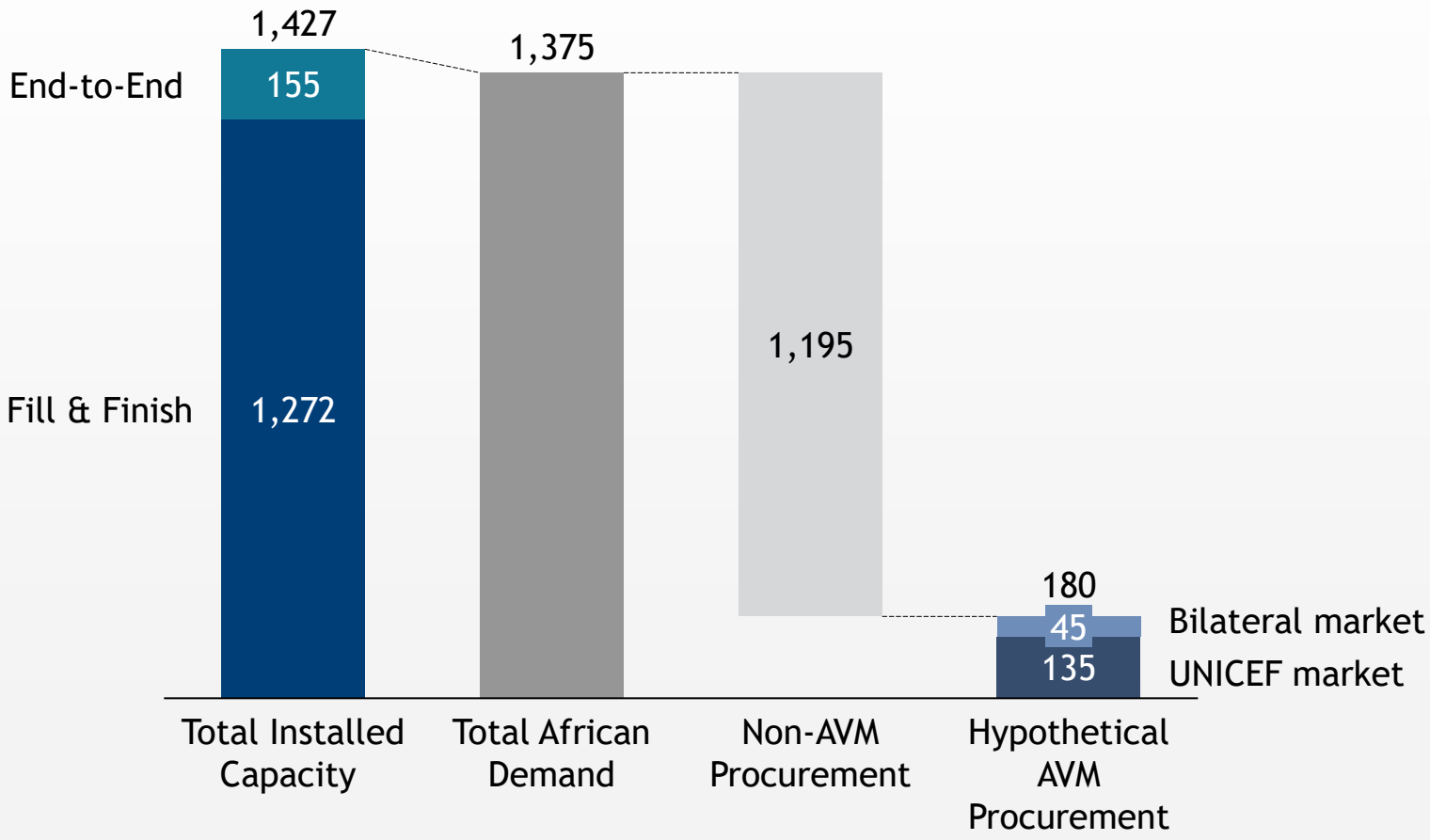
Market Opportunities	• Near-to-market Vxs are able to address a sig. portion of bilateral markets if they engage successfully with bilateral country tenders.	• ~135Mn[1] of hypothetical demand for near-to-market Vxs. • Market competition and market health considerations act as a cap on the demand allocation 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

Notes: 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

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

Presently there is overcapacity of DP & underutilisation of the capacity that is built on the continent compared to expected demand

African Vaccine Volumes in 2030,
Doses (M)



Key Findings

- There is a significant shortage of Vx TTs relative to total production capacity, limiting potential output and raising the risk of over-capacitation and under-utilization.
- Hypothetical demand analysis is based on the near-to-market antigens adhering to current mfct timelines and with a competitive price upon market entry. Deviations from this will cause changes to potential uptakes.
- **Even for this estimated demand to materialize, support will be required from key procurement stakeholders esp. Country Govts.**

Notes: 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. Commoditized vaccines, AVM ring fencing restrictions, UNICEF market allocated.
Sources: CHAI analysis, Linksbridge

6 Priority actions can address critical short-term challenges that pose material risks for commercializing vaccines

	Demand & procurement	Regulatory approval	Financing
Critical challenges	Uncertain UNICEF allocation and local demand for African-made vaccines	Expected longer timelines for new to market AVMs to obtain WHO PQ &/or local authorization to enter markets	Funding gaps for near-to-market Vxs, but funding allocated to new projects
Priority actions required	1 **Countries** to clearly signal demand for African-made vaccines, notably for near-to-market antigens, by incorporating African-made vaccines into procurement processes 2 **Global Procurement Stakeholders** to ensure procurement practices facilitate AVM route-to-market, in balance with other key market health considerations, and communicate mode to achieve this	3 **AVMs & Global partners** to ensure PQ applications are submitted with complete dossers and adjustments are timeously addressed. 4 **Countries & Global Partners** to strengthen NRAs, esp countries with manufacturing footprints to invest in striving towards ML3 vaccines (producing) status	5 **Funders** to develop risk-appropriate financial instruments that can close TT and TA funding gaps 6 **Funders, Countries, & AVMs** to strategically evaluate all new projects to determine realistic commercial opportunities before investing funding into new projects

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