African Vaccine Manufacturing Mapping - AVM
- Supply and Demand Landscape

DCVMN AGM
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Supply Landscape - cenário de fornecimento

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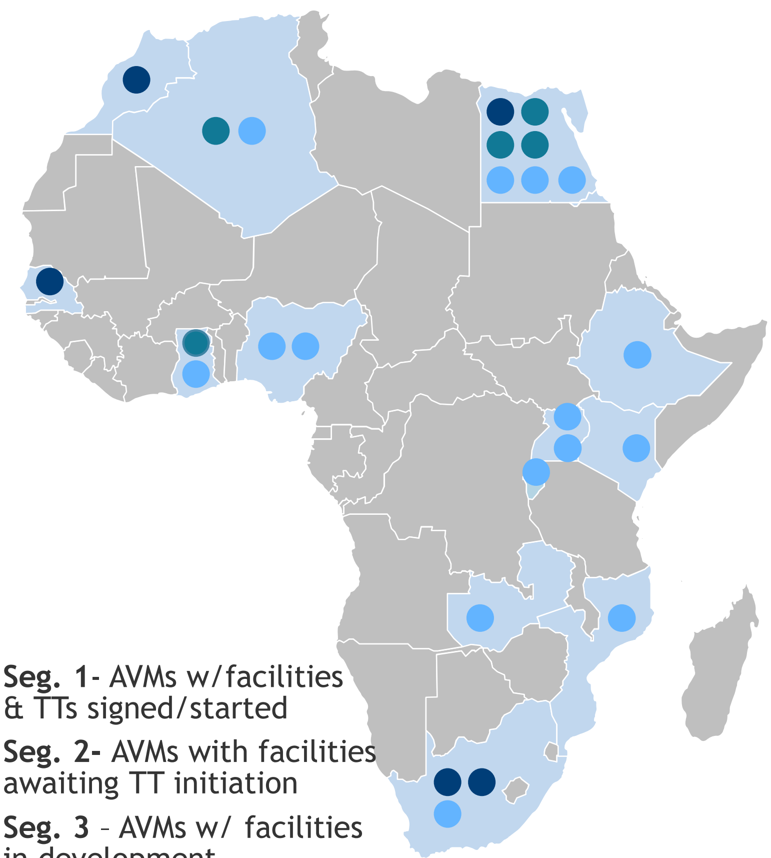
In 2024, there are 25 active AVM projects which can be divided into three segments based on overall supplier maturities and capabilities

Segment	Suppliers
Seg. 1: Facilities w/ TTs underway	Marbio Vacsera IP de Dakar Aspen Pharmacare Biovac
Seg. 2: Facilities awaiting TT	Eva Pharma Minapharm Biogeneric Saidal[1] Atlantic Biotech
Seg. 3: Facilities in dev.	VBC Polygon Gennecs IP de Algerie DEK Innovative Biotech BVNL[2] DEI Biopharma[3] VAI Uganda Biovax Shieldvax BioNtech Yash Life Pharma Mozambique Holdings[4] Afrigen[5]



Seg. 1- AVMs w/facilities & TTs signed/started

Seg. 2- AVMs with facilities awaiting TT initiation

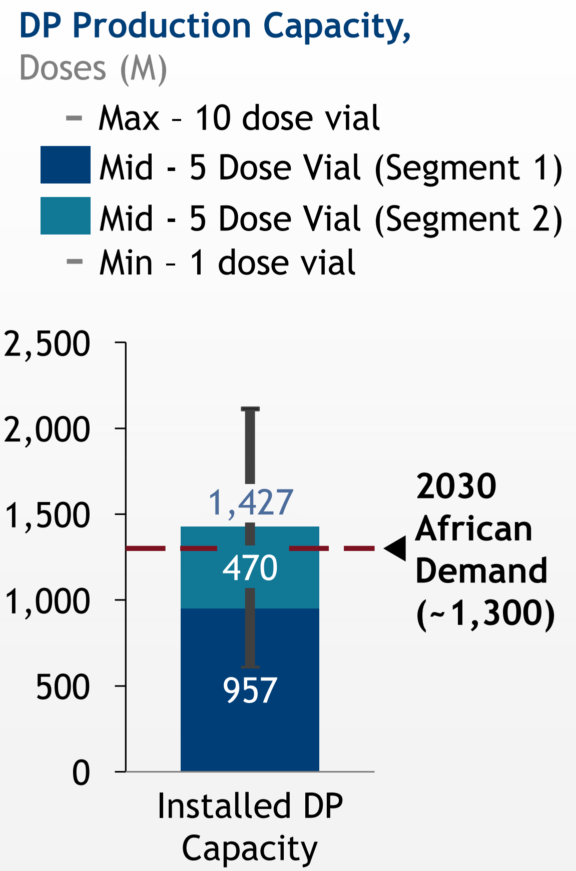
Seg. 3 – AVMs w/ facilities in development

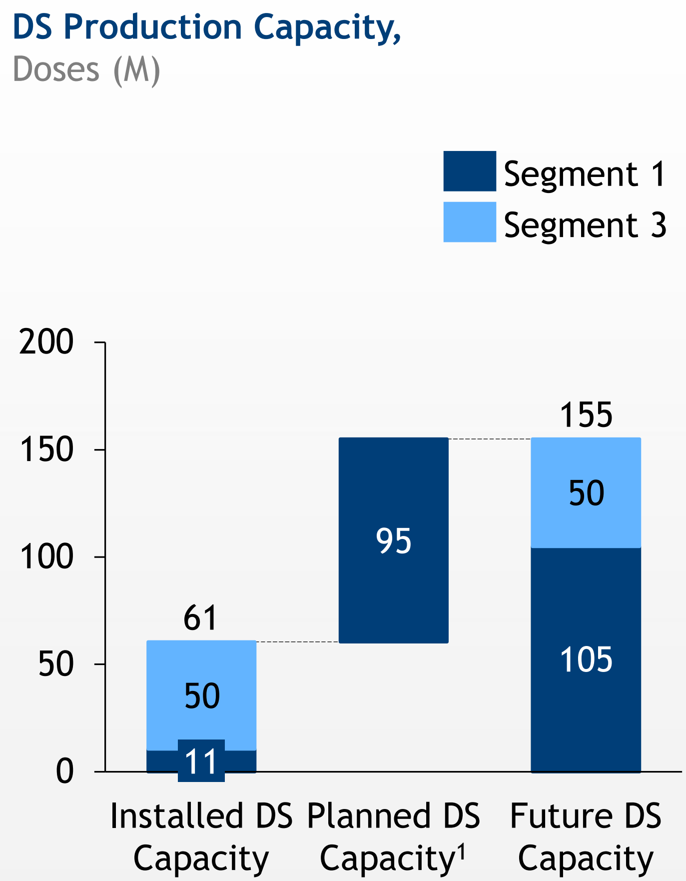
Key Findings

- 5 Suppliers in Segment 1 already have commercial scale facilities and tech transfers (TTs) underway or complete and are relatively close to commercialization
- 5 Additional suppliers in Segment 2 have commercial scale facilities qualified and are ready to receive TTs
- The remaining 15 suppliers in Segment 3 are still in development stages
- Rationalizing AVM projects remains an ongoing need as the long tail of pipeline projects may face challenges to gain a viable market share

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. Unofficial reports indicates they 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 meeting pandemic preparedness goals





Key Findings

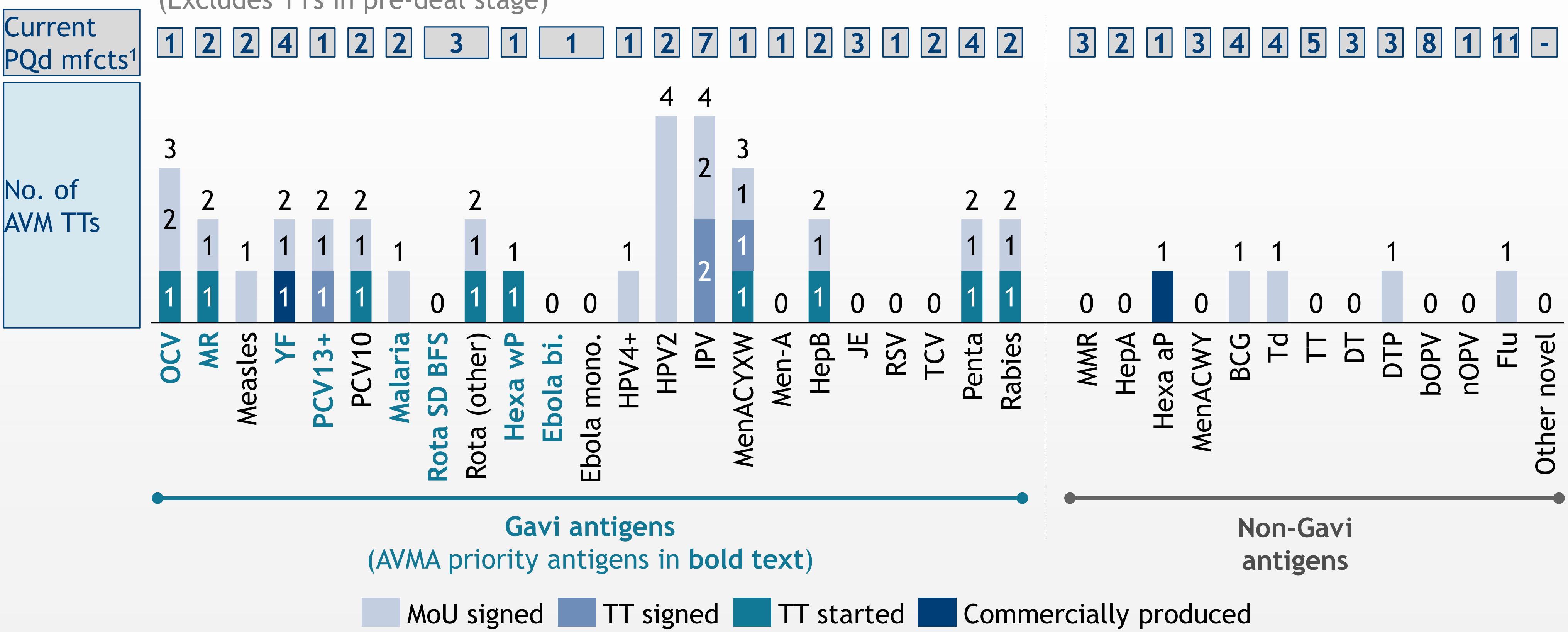
- Around 2/3 of installed DP capacity is from Seg. 1 suppliers with TT underway
- Already installed DP capacity exceeds current vaccine TTs, expected demand offtake, and Africa CDC's 60% target for AVM
- With segment 3 facilities to come online, the risk of DP over-capacitation may increase
- Most of the installed DS capacity is for mRNA DS which currently lacks a suitable vaccine for TT
- 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

While AVM improves market health through supplier diversity, the long tail of MoUs and TTs risk fragmentation risk across many antigens

Number of AVM TTs and PQd suppliers by antigen as of June 2024,
(Excludes TTs in pre-deal stage)



1. For Gavi antigens, only includes PQd suppliers on Gavi product menu
Source: Gavi detailed product profiles; Linksbridge; CHAI/PATH/PAVM Current State Vaccine Supply Mapping

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

Drug substance   Drug product

Antigen	Country of manufacture	Year of product entry	African Demand 2030	% currently UNICEF procured
Hexa (wP)			46 M	100%[2]
PCV			126 M	90%
MMCV			19 M	100%[2]
Rota		2025-2030[1]	119 M	93%
OCV			32 M	100%
IPV			94 M	92%
YF			47 M	99.9%
MR			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

Demand Landscape

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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:

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

2 Market Size for near-to-market antigens

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

3 Best case scenario Hypothetical market

Key Assumptions:

- Based on current procurement systems.
- No delays in AVM timelines.
- Globally competitive pricing.
- UNICEF uptake limited market health considerations.
- Country uptake limited by programmatic alignment & stated political commitment[3].

Key Omissions:

- Tender timelines or scale up scenarios not considered

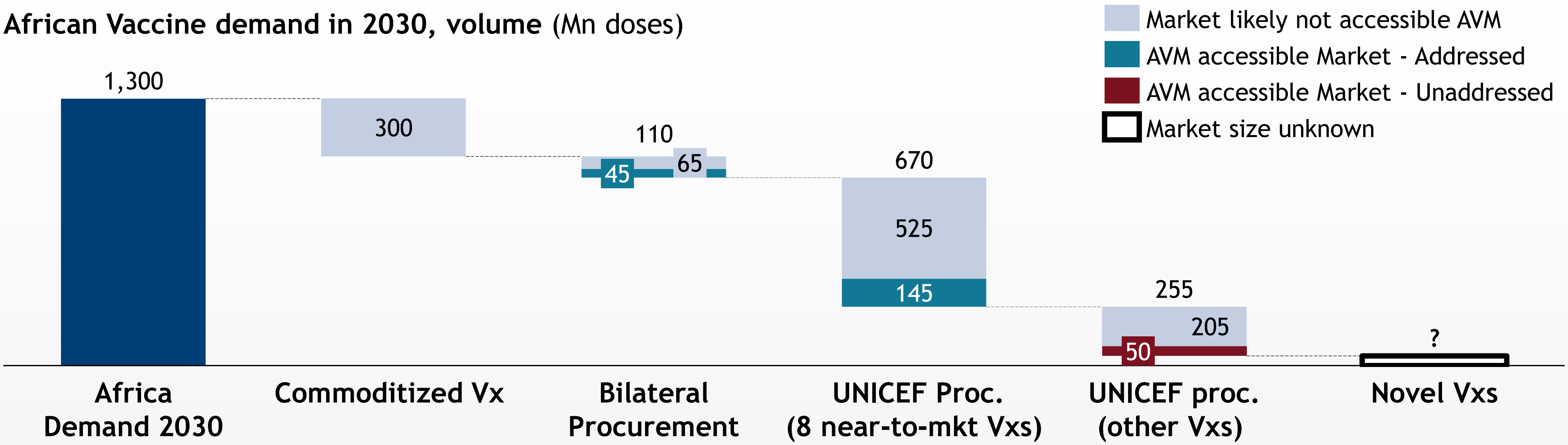
4 Conclusion

Hypothetical African demand for AVM near-to-market antigens in 2030 based on current market dynamics.

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.

There are market opportunities for the existing near-to-market Vxs; additional opportunities are relatively limited

African Vaccine demand in 2030, volume (Mn doses)

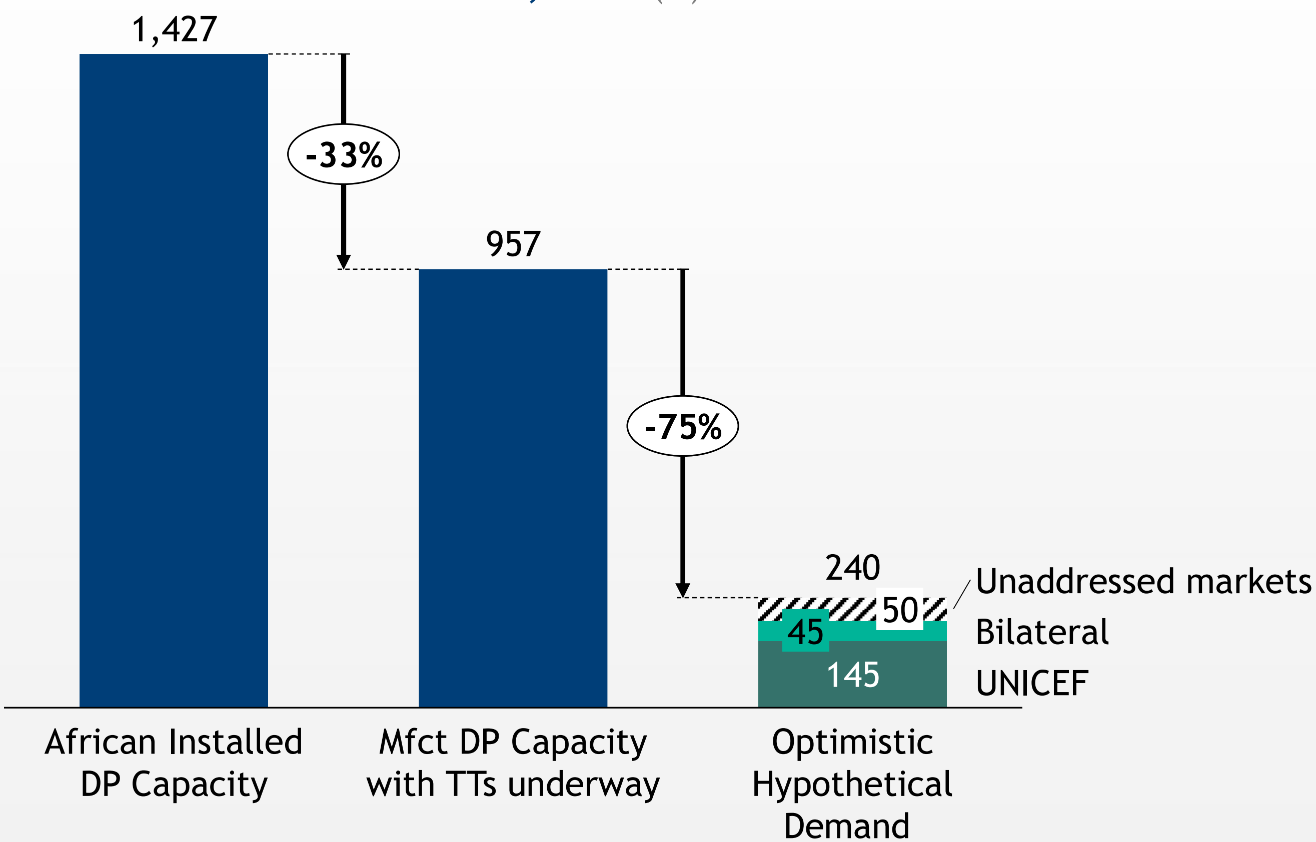


Market Opportunities	• Commoditized Vxs[1] have low margins and no AVMA support - thus a challenge for AVMs to compete commercially	• Near-to-market Vxs hypothetically likely to address a sig. portion of bilateral markets	• ~145Mn of hypothetical demand for near-to-market Vxs. • Market comp. limits opps. for additional AVMs	• Hypothetical accessible market of 50M in other UNICEF markets[2] • Limited appetite for TTs & market opps. may limit access for AVMs,	• Novel Vx market size remains unknown. May present additional market opps. for AVMs

Notes: 1. Vaccines less than $0.25 per dose i.e., BCG, DTP, Hep B & Td 2. Potential markets (200Mn doses): HPV, Malaria, RSV, TCV. Markets with minimal AVM potential (150Mn doses): Penta, Measles, MMR
Sources: CHAI analysis, Linksbridge

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.
- In relation to the African market's potential, efforts are needed to ensure demand materializes to match the available capacity.
- Even in optimistic scenarios, market opportunities for current technology transfers remain limited, highlighting the need for additional market support to sustain these businesses.

Sources: CHAI analysis, Linksbridge

African Govts. have pledged to support AVM, incl. through offtake decisions - this support needs to be better understood & actualized

- At WHA 2024, AU Member States committed to consider demand offtake for African-made vaccines in their Vx selection decisions.
- Africa CDC, CHAI, & Gavi are working in collaboration to **engage with AU member states** in the coming months to better understand country-level commitment to procuring African-made vaccines

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AfricaCDC Centres for Disease Control and Prevention

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