CLINTON HEALTH ACCESS INITIATIVE

African Vaccine Manufacturing – 2026 Supply Landscape

June 2026

Funded by:

Gates Foundation

An updated landscape analysis was done through AVM engagements

27 AVMs and 5 TT originators were engaged; interviews focused on most advanced suppliers. Data collected across 3 areas:

1. **Products**
   - Current antigen pipeline and tech transfer status
   - Commercial ambitions and indicative timelines

2. **Facility progress**
   - Existing commercial facilities and planned expansion/construction timelines

3. **Key challenges affecting commercial plans**
   - Regulatory
   - Market and demand
   - Finance
   - Access to products
   - Workforce

The analysis was designed to address three objectives:

Track **progress** made since 2024 and validate expected commercialization timelines

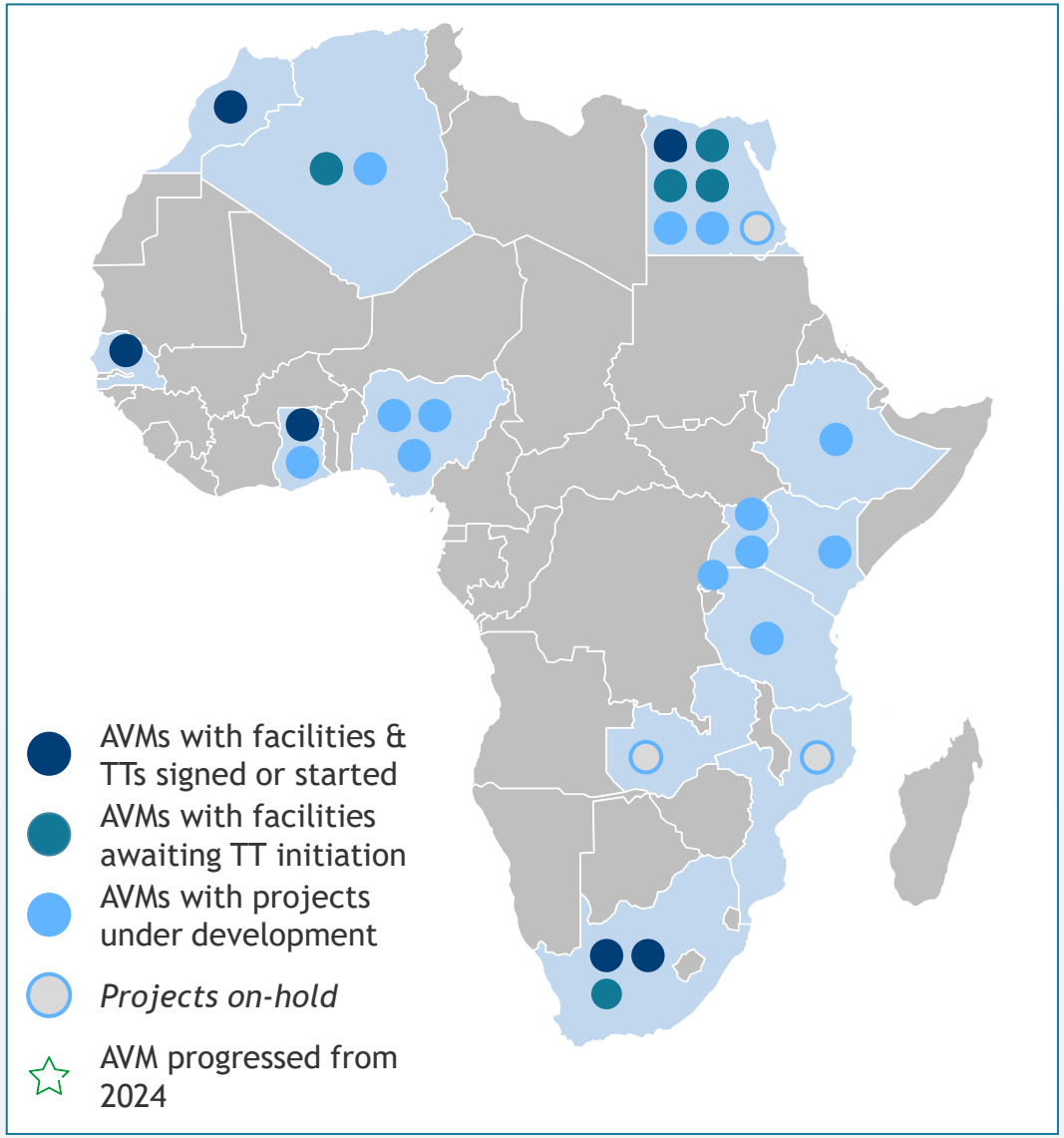
Identify key **challenges** faced by AVMs which pose risks to commercialization timelines

Identify key **enabling conditions** to support timely AVM commercialization

Originators engaged: Sanofi, SII, EuBiologics, BioE & Gates Vaccine Development Team

As of June 2026, 11 AVMs have commercial-scale facilities, including 6 with ongoing TTs; 13 additional projects remain under development

Seg 1: AVMs with commercial facilities; TTs signed or underway	Vacsera Atlantic Lifesciences ☆ Marbio IP de Dakar Aspen Pharmacare Biovac
Seg 2: AVMs with commercial facilities awaiting TT initiation	Saidal[1] Biogeneric Eva Pharma Minapharm Afrigen ☆
Seg 3: Projects under development	BioNTech IP de Algerie[1] Gennecs VBC[2] Shieldvax DEK BioVax BVNL[3] Innovative Biotech Afriqvax[4] DEI Biopharma VAI Uganda Africare Biopharma[4]
Projects on hold	*Mozambique Holdings* *Polygon* *Yash Life Pharmaceuticals*



Key Findings

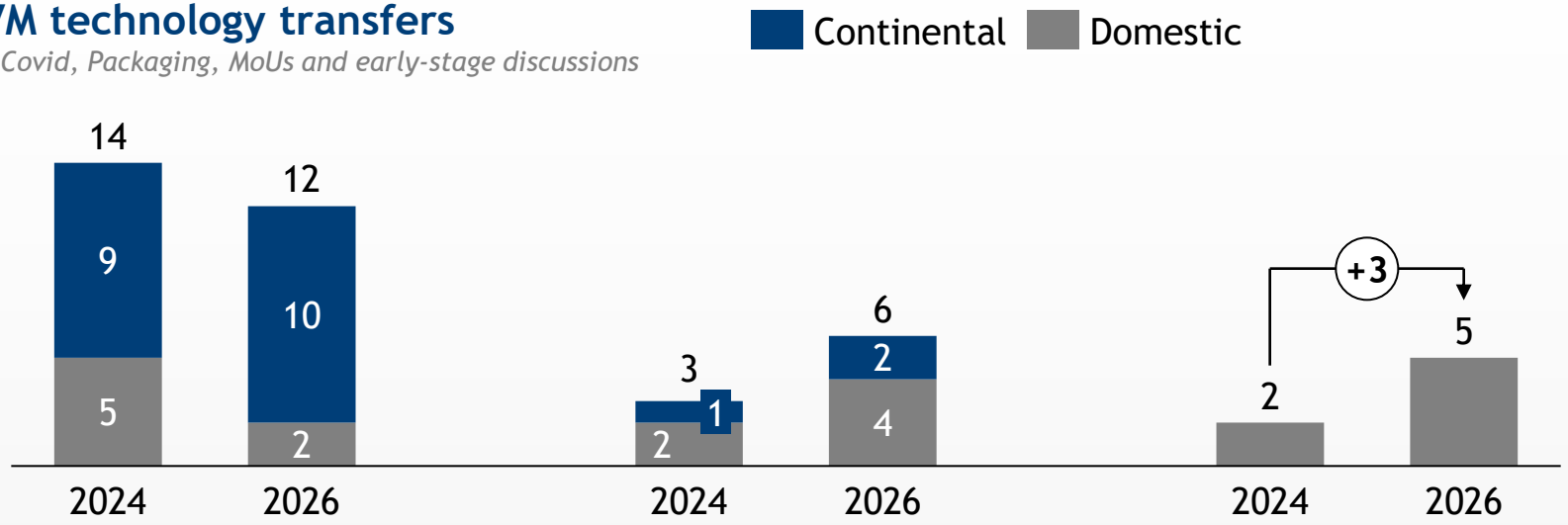
- **Segment 1**: 6 suppliers have TTs signed or underway
  - Atlantic Lifesciences started one TT since 2024
- **Segment 2**: 5 suppliers have commercial facilities awaiting TT or can start production
  - Afrigen has completed facilities
- **Segment 3**: 13 projects are still under development
- 3 projects are on hold

1. Manufacturer could not be reached for this landscape and categorization based on publicly available information; 2. VBC expected to become Seg2 by end of 2026; 3. As per informal meeting with BVNL; 4. Newly included in the landscape. Source: CHAI 1-on-1 interviews with AVMs held throughout February 2026

Since 2024, TT activity has progressed with new TTs initiated, new regulatory filings, and 3 new domestic products commercialized

Number of ongoing AVM technology transfers

Includes only DP/DS TTs; Excludes Covid, Packaging, MoUs and early-stage discussions



		Ongoing TT	Regulatory Filing	Commercialization
Notes	Continental *(since 2024)*	• 2 TT initiated • 1 TT progressed	• 1 new filing submitted	• n/a

	Domestic *(since 2024)*	• 2 TTs initiated
		• 5 TTs progressed:
		  • 3 moved to regulatory filing
		  • 2 got NRA approval and moved to commercialization
			• 3 new filings submitted
			• 1 filing got NRA approval and moved to commercialization
				• 3 new commercialization's

Note: TT = Technology Transfer
Source: CHAI 1-on-1 interviews with AVMs held throughout February 2026; CHAI/PATH 2024 Supply and Demand Landscape

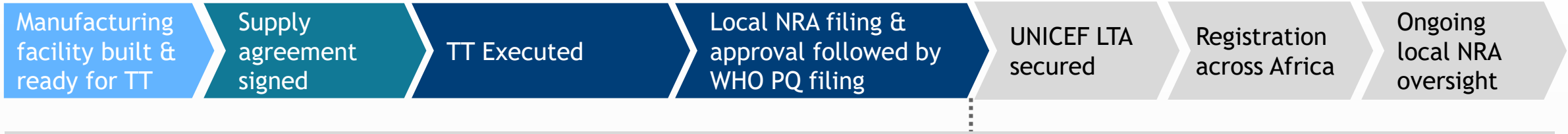
There are 11 products across 8 antigens expected to achieve WHO PQ and enter the continental market in the next 5 years

Drug substance Drug product

Antigen	Country & manufacturer	Year of product entry	Africa demand 2030
Hexa (wP)	Aspen	2026-2031[2]	57 M
PCV[1]	Aspen, Biovac		110 M
MMCV	Aspen, Biovac		5 M
Rota	Aspen		97 M
OCV	Biovac		30 M
IPV	Biovac, Vacsera		34 M
YF	IPD		39 M
MR	IPD		128 M

Aspen is making a PCV-10 and Biovac is making PCV-14; 2. Estimated timelines premised on current trajectories
Source: CHAI 1-on-1 interviews with AVMs held throughout February 2026; Linksbridge GVMM 2026 (accessed 7 Apr 2026)

The path to commercialization is long and AVMs face challenges at each step; WHO PQ is a key milestone but not the finish line



Primary challenges voiced by AVMs

- Weak or unproven business case
- Insufficient financing
- Prolonged construction timelines

- Absence of willing TT originator

- Insufficient technical assistance
- Inadequate clinical trial funding
- Slow TT originator pacing
- Insufficient market attractiveness

- Prolonged domestic NRA approval timelines
- Lack of clarity around pilot parallel review timelines (NRA/WHO)

- Misaligned LTA and AVMA course correction timelines

- Lack of streamlined in-country registration post PQ

- Maintenance of NRA ML3+ status
- Potential delays in batch release and variation approvals
- Maintenance of post-market surveillance

Segment 3 AVMs | *Segment 2 AVMs* | *Segment 1 AVMs* | *WHO PQ* | *Cross Continental Commercialization*

Source: CHAI 1-on-1 interviews with AVMs held throughout February 2026; CHAI analysis

Continental | Key challenges have already slowed continental AVM commercialization, with further risks ahead

Non-exhaustive

Challenge	Factors which have caused delays	Factors that might add further delays
Regulatory	○ Prolonged NRA approval time (up to 3 yrs)	○ NRA certification as ML3 for vaccine production ● Speed of WHO PQ target timelines for DP and AVM products ● Uncertain & fragmented country registration pathways post WHO PQ ● Producing country NRA maintain ML3+ and rapidly approve batch releases and variations with rapid recipient country NRAs approvals
Market & Demand	○ TT and commercialization decisions slowed pending clarity on Gavi 6.0 demand and AVMA course correction	○ Demand Shift - Gavi 6.0 policy creating demand uncertainty ● Price Viability – Increased price competition due to GAVI 6.0 policy ○ Misaligned UNICEF LTA tender and AVMA Course Correction ○ Uncertainty of market opportunity before next UNICEF LTA starts
Finance	○ Funding disbursement delays impacting facility readiness and product commercialization ○ Funding for clinical trials and production readiness	○ Approved funding remaining undisbursed, delaying facility build and product launch ○ Mobilization of new funding for things such as clinical trial and general production readiness
Access to Products	○ Originator pacing delays	○ TT execution delays based on originator
Workforce	n/a	● Gaps in technical assistance and skilled workforce constrain scale-up, regulatory readiness, and operational execution

Affected AVMs ○ Some ● Most ● All

Source: CHAI 1-on-1 interviews with AVMs held throughout February 2026; CHAI analysis

Domestic | AVMs with domestic-only focus, will need to clear current challenges before entering the continental market

Non-exhaustive

Challenge	Factors causing delays
Regulatory	● NRA timelines and ML3+ certification requirements remain outstanding for manufacturers ● Product registration often takes 1-2 years with ability to reduce them uncertain
Market & Demand	● Domestic demand provides some anchor, but bilateral, pooled, and export demand signals remain weak or unclear ● Products often not aligned with the current pooled procurement mechanisms' needs or prices
Finance	● Concessional financing, offtake guarantees, and upfront cost coverage are recurring requirements ● Forex constraints, tax/trade policies, and facility investment needs add to financing complexity
Access to Products	● TT progression is contingent on stronger demand certainty and commercially viable production economics ● Export pricing below domestic market levels constrains continental expansion
Workforce	● Technical assistance needs center on validation, quality assurance, and lot-release capabilities ● Originator partners offer some support but often not all that is required to fill these gaps

Affected AVMs ○ Some ● Most ● All

Source: CHAI 1-on-1 interviews with AVMs held throughout February 2026; CHAI analysis

Addressing these challenges will require action across three enabling conditions supported by stakeholder coordination

Non-exhaustive

	Regulatory Approval	Market & Demand	Supply Finance & Execution
Enabling conditions	▪ Predictable NRA review timelines ▪ Clarity around accelerated WHO PQ pathways ▪ Efficient post-PQ regulatory pathways ▪ Sustained NRA readiness and ML3 capacity	▪ Predictable demand signals ▪ Clear procurement pathways, with processes aligned with commercialization timelines ▪ Commercially viable market conditions	▪ Timely access to committed financing ▪ Sustainable financing for product scale-up and development ▪ Technical and workforce readiness

Stakeholder Coordination:

- As no single actor can do this alone, coordinated stakeholder action will be essential

Source: CHAI analysis

Project funded by the Gates Foundation

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