Vaccine Manufacturing In Africa – Current State Supply Map

Enhancing the sustainability of investment for vaccines manufacturing in Africa

Addis Abeba, 27 June 2023

Funded by:

Sponsored by:

To move beyond public announcements, Africa CDC, CHAI, and PATH engaged suppliers & developed an up-to-date and nuanced understanding of their plans

Objectives

- Develop a detailed technical and commercial understanding of vaccines and their production volumes in Africa in the short, medium, and long-term to inform market shaping for sustainable African Vaccine Manufacturing.
- Assess the accurate installed capacity on the continent and evaluate proposed plans for AVM while considering the technical and commercial capabilities of companies involved.
- Understand the challenges individual firms are facing - to support & accelerate high-potential plans or increase their probabilities of success

Data collection

Short, medium, and long-term data on . . .

- Business Capabilities
- Commercial strategy and plans
- Manufacturing capabilities and plans
- Required areas of commercial and technical support

Output

Confidential

Created from fact-finding reports

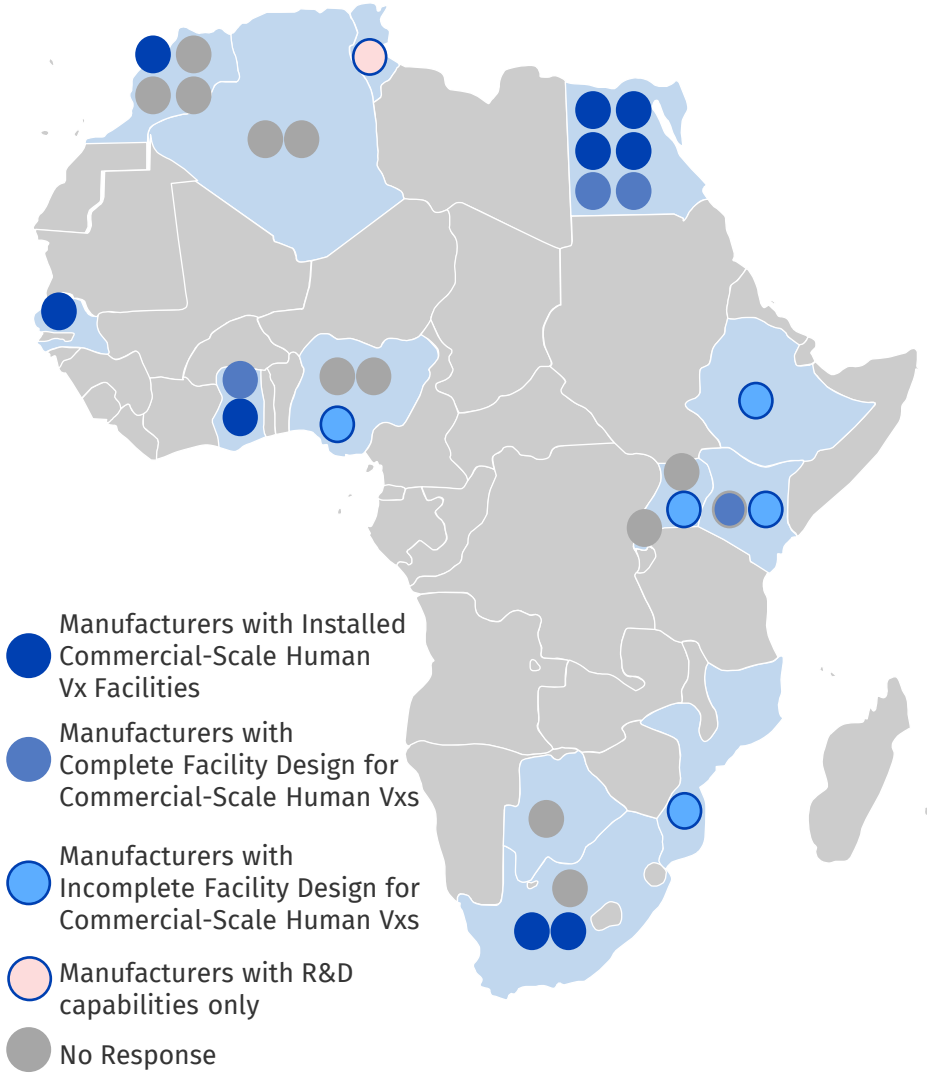
Outcomes

- Anonymized, risk-adjusted forecast of Vx production for next 2-5 years
- Supportive market shaping recommendations of vaccine production to key African & global stakeholders
- Allocation of direct support packages for individual firms

Support and acceleration of high-potential plans to increase probability of African Vx manufacturing success

Outreach to 30 manufacturers with publicly announced plans to manufacture human vaccines & engagement with 19 African manufacturers

Commercial-Scale Vx Facility Installed	Minapharm Biogeneric Eva Pharma Vacsera Sensyo Pharmatech Atlantic Biotech Institut Pasteur de Dakar Biovac Aspen Pharmacare
Facility Concept Design Complete	DEK VBC Polygon Moderna
Facility Concept Design Incomplete	Ethiopia MOH Innovative Biotech Mozambique Holdings Microhaem Biovax
R&D Only	Institut Pasteur de Tunis[1]
No Response	Institut Pasteur Algeria Saidal Institut Pasteur du Maroc Sothema Galencia DEI Biopharma BioNtech Biovaccines NIBI NantBotswana NantSA

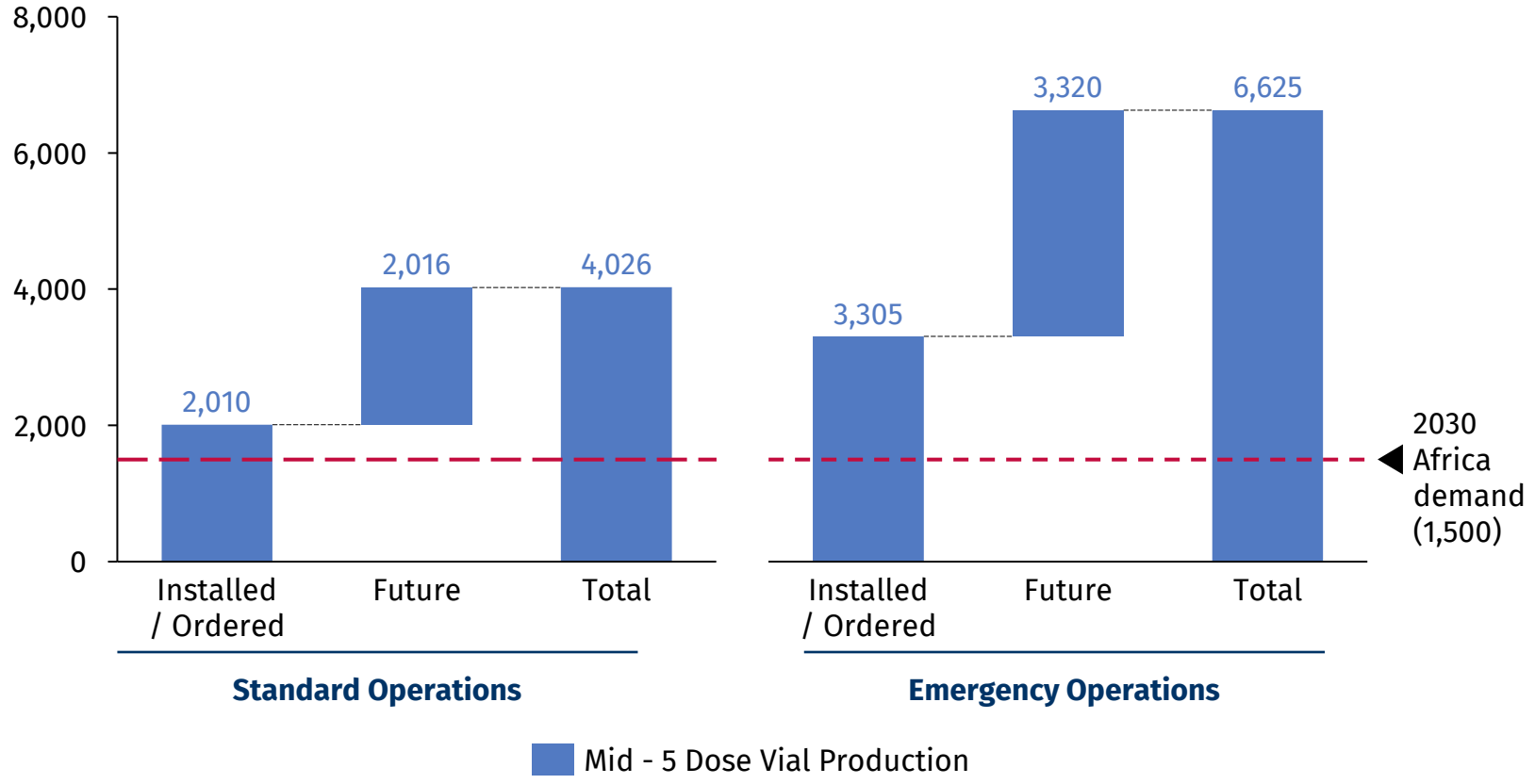


- **In-person engagement with 9 manufacturers** in 5 countries ensures that this report includes 100% coverage of the commercial scale manufacturing capacity on the continent.
- **Virtual engagement with 10 additional manufacturers** allows representative findings for earlier-stage projects:
  - 4 with facility concept design complete
  - 5 with incomplete facility concept design
  - 1 with plans for R&D only

1. The focus of Institut Pasteur de Tunis is vaccine research and development, with intentions to seek a manufacturing and commercial partner.

With ~2 Bn doses p.a. installed & ordered and a further 2Bn+ doses p.a. planned, DP capacity significantly exceeds the projected 2030 African demand

Annual 5 Dose vial drug product capacity of installed, ordered & future facilities by scenario, Doses (M)



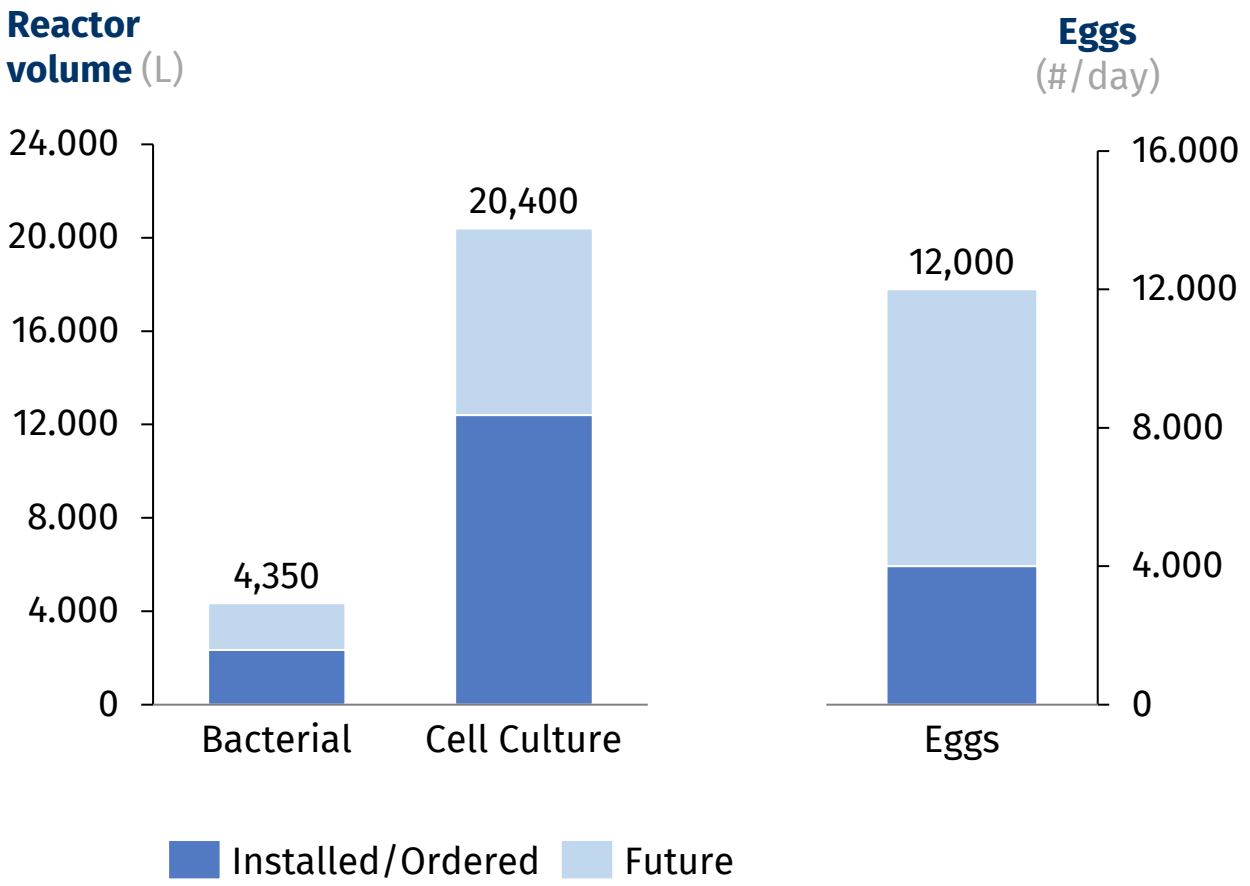
Key Findings

- The planned increase in standard operations **capacity at a continental level exceeds the projected 2030 African vaccine demand** (1.5 Bn doses) by more than 2x
- Some installed capacity may be used for Biologics production
- Although individual companies may have valid reasons for their plans, the African manufacturing ecosystem will have **excess capacity**
- Manufacturers **risk underutilization of DP facilities and long-term commercial sustainability**

Sources: CHAI/PATH Current State Vaccine Supply Mapping

Plans to expand DS capacity in the next 5 years are underway from 4 manufacturers, but will still see very limited DS capacity overall

Future Production Capacity by Company & Platform (Standard Operations), **Reactor Volume** (litres) **& Eggs** (#/per day)



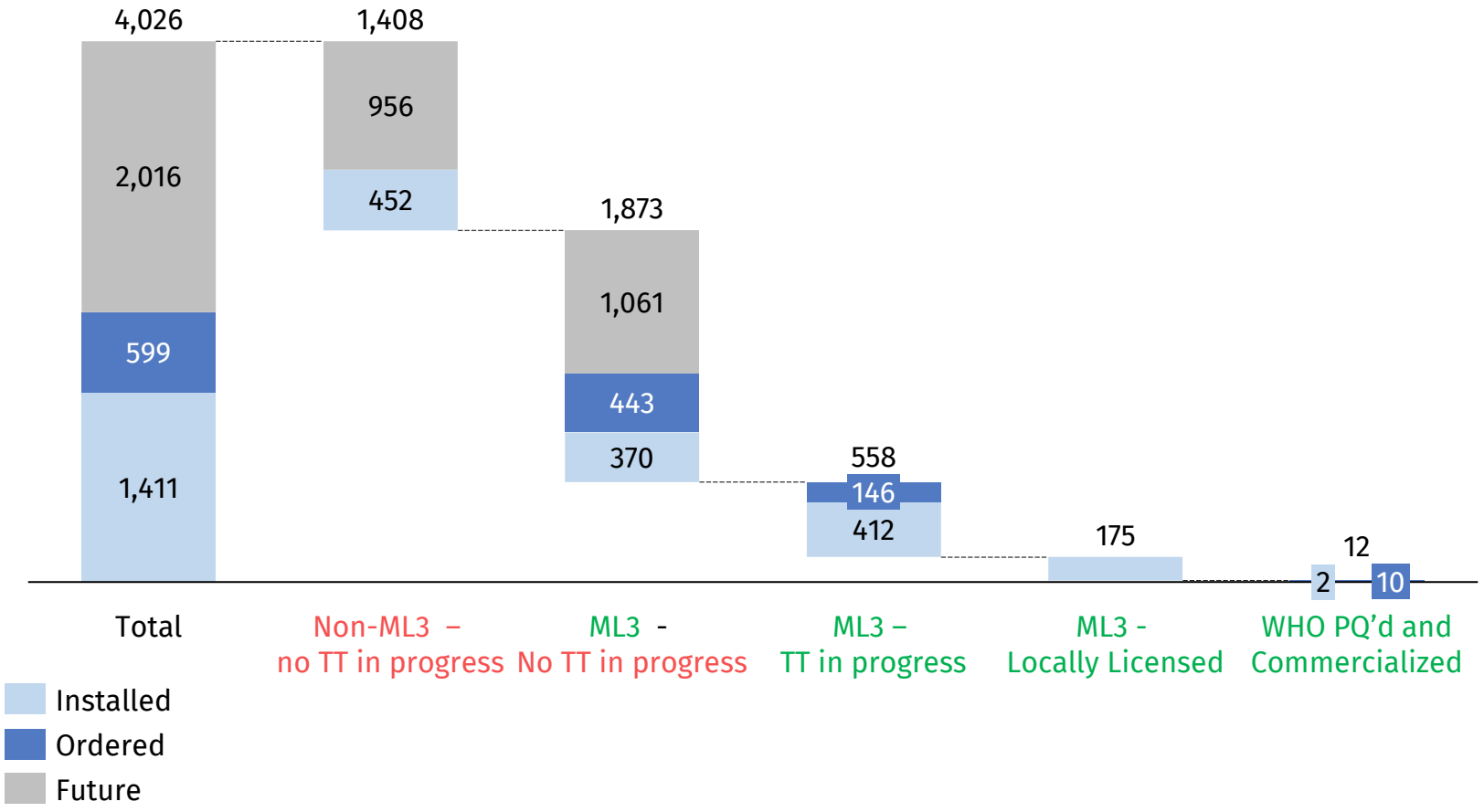
Key Findings

- **DS capacity today is relatively low**
- In the next 5 years, the confirmed plans for growth in DS are in Yellow Fever and Cholera, while others have **less defined plans**
- Growth of bioreactor capacity is based on opportunities and is only located in ML3 geographies
- **For a long-term equitable vaccine manufacturing footprint in Africa** & to strengthen pandemic preparedness more focus needs to be placed on **identifying opportunities for DS capacity**
- **Note:** mRNA capacity not included here

Sources: CHAI/PATH Current State Vaccine Supply Mapping

Absence of TTs for ~80% of the planned DP capacity as well as lack of ML3 status in some countries may constrain capacity utilization

Installed, Ordered & Future 5-Dose Production Capacity by ML3 & Product Registration Status (Standard Operations), **Doses** (M)



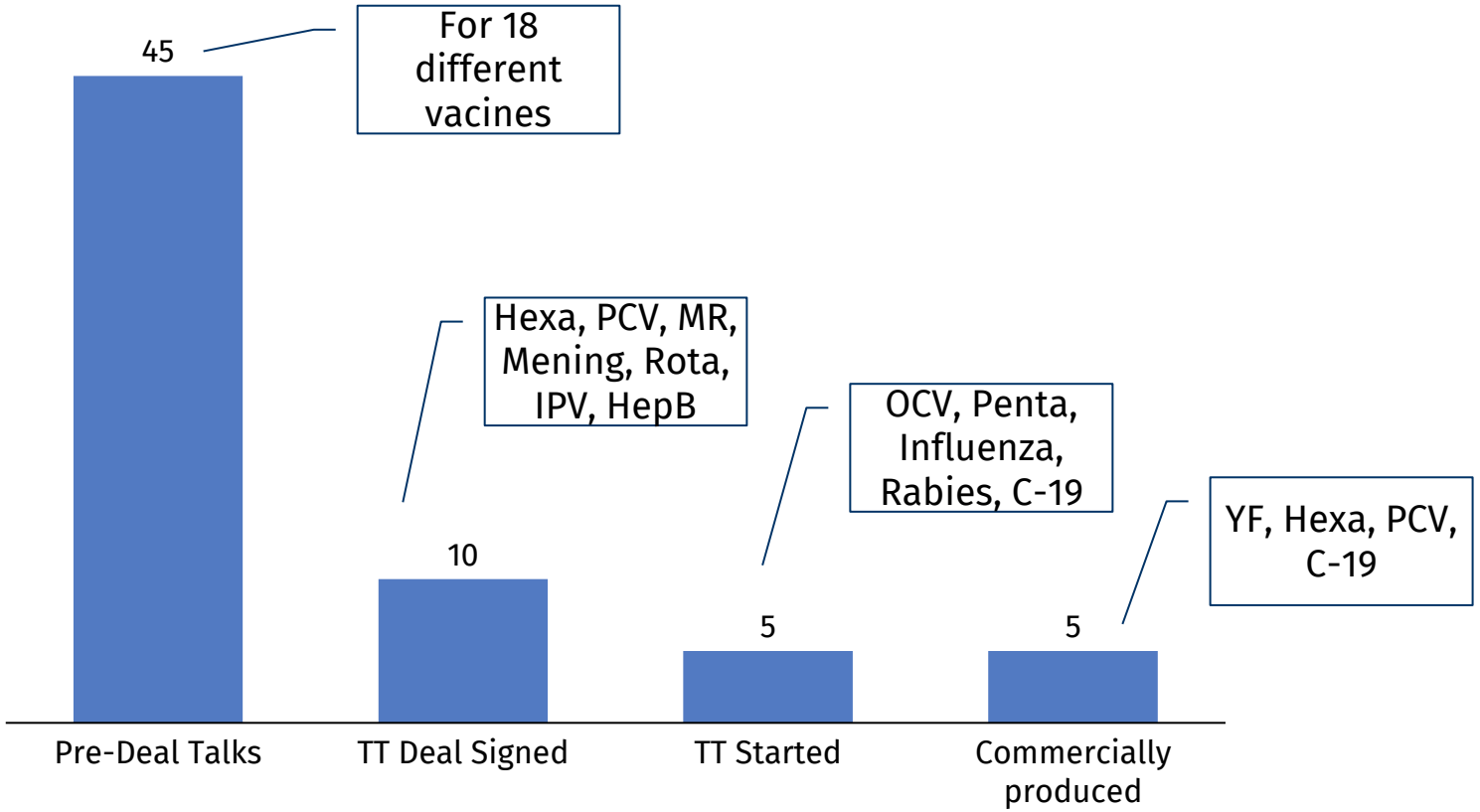
Key Findings

- Future vaccine manufacturing capacity is planned in both ML3 and non-ML3 countries, with each expecting to increase capacity by ~1B doses.
- **Tech transfers are currently not agreed for ~80% of the total installed, ordered, and future DP capacity.**
- Both factors may **limit the viability of this capacity for vaccine production.**

1. No vaccine TTs in progress but other biologics being made or transferred; 2. TT in progress for some lines whilst others are not in active TT – Capacity numbers split between categories on a line by line basis; 3. Company 5 has lost its only tender for PCV;
Sources: CHAI/PATH Current State Vaccine Supply Mapping

In addition to the 5 TTs for vaccines being produced, 5 additional TTs have started and 10 TTs have been signed, with many more in exploration stage

of technology transfers by status of maturity



Key Findings

- **Most tech transfers are for the manufacturing of DP**, only 4 tech transfer target manufacturing of DS in Africa
- For some antigens, up to 5 manufacturers are engaged in pre-deal talks with originators **risking market fragmentation**
- Two of the five "commercially produced" vaccines are Covid-19 and thus production is unlikely to be continued

Note: TT = Technology Transfer
Sources: CHAI/PATH Current State Vaccine Supply Mapping

Conclusions & emerging recommendations

- The continent already has 2 Bn doses p.a. of DP capacity installed or on order
- With new projects in the pipeline standard operational capacity could be pushed to 4 Bn doses p.a.
- The risk of DP overcapacity looms with all projects coming online as all future capacity would outstrip demand by >2x if utilized efficiently—greenfield projects still in the planning phase should be carefully considered
- Despite the immense DP capacity, a lack of tech transfers may constrain capacity utilization
- Conversely, well-targeted additional DS manufacturing capabilities and capacities could support pandemic preparedness and long-term competitiveness
- Greater clarity of demand for African-made vaccines is essential to advance business plans and tech transfers—less than 10Mn p.a. is currently being contracted through domestic/international tenders and risking existing facilities' viability
- At an ecosystem level, manufacturers played back strong technical DP capabilities as well as the ability to finance advanced projects
- On the other hand, commercial planning, market access, securing tech transfer partnerships, and expanding DS manufacturing capabilities were highlighted as areas requiring support as well as limitation of trained staff

———

- Complete study publication is planned for Q3

Note: Drug Substance (DS) - Production of active ingredient (i.e., antigen).; Drug Product (DP) - Formulation, filling, and finishing of vaccine products
Sources: CHAI/PATH Current State Vaccine Supply Mapping

Thank you!

Project undertaken with the kind support of the Africa Trade and Investment Program funded by USAID and the Bill & Melinda Gates Foundation, and with the sponsorship of the African Centres for Disease Control and Prevention.

Funded by:

Sponsored by: