

# Vaccine manufacturing in Africa

DCVMN member briefing – Presentation document

17 March, 2021



This study has been funded by UK aid from the UK Government; however, the views expressed do not necessarily reflect the UK government's official policies

# What will we discuss today?

**Introduction to Vx manufacturing work conducted to date** 10 mins

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**Sharing findings: Our learnings on vaccine manufacturing in Africa** 40 mins

African Vaccines for Africa: why now?

Market landscaping across Africa

Potential models and investment opportunities

Potential roadmap

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**Hearing from you: What are opportunities from here?** 40 mins

Discussion: Understanding private sector stakeholder priorities

Next steps: How we plan to engage you going forward

## Objectives for this session

Provide an overview of the current state of vaccine manufacturing in Africa

Share potential opportunities and potential actions required for expanded local vaccine manufacturing

Hear perspectives on the African vaccine manufacturing opportunity from DCVMs

### ⊗ But it is not:

A specific recommendation to be adopted either for countries, products, or specific investments



# Four shifts in recent years have re-triggered the conversation around vaccine manufacturing in Africa, leading to a sense of urgency



## The impact of COVID-19 and Africa-specific outbreaks.

African and global public health leaders do not want African countries to be last in line for vital supplies. Nor do they want to rely on others to make Africa-specific outbreak vaccines.



## Strong demand growth.

Not only is Africa's population growing faster than most other regions', but significant immunization coverage gaps remain and new products, such as vaccines for Lassa fever or malaria, could be licensed and used widely on the continent.



## Evolving economics driven by new technologies.

Fast pace of technology innovation seen in recent years at every step of the biomanufacturing workflow may mean that production costs are no longer a showstopper for African vaccine production. Small scale disposable technologies, high-density bioreactors, and innovation in fill-and-finish steps are boosting yields, and are available to smaller manufacturers.

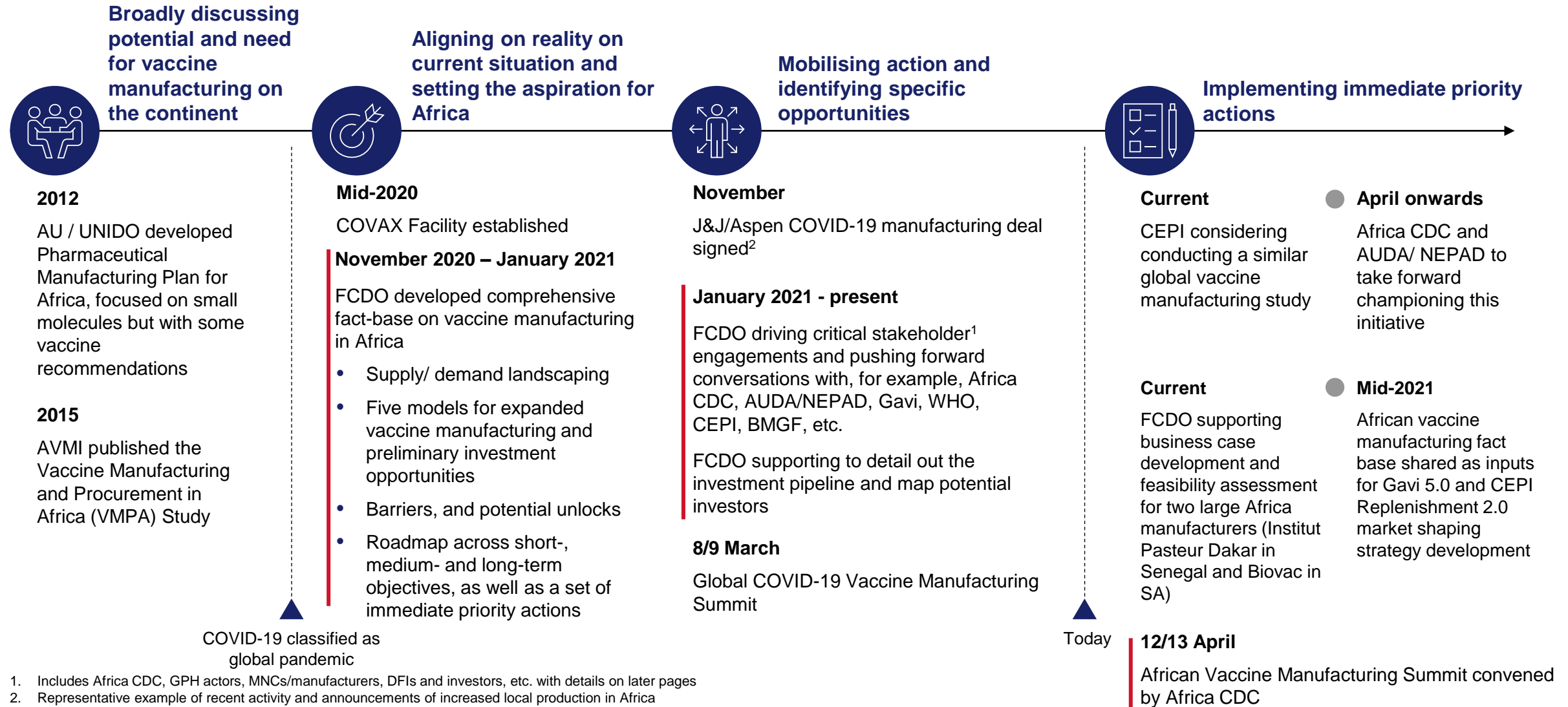


## More supportive environments.

Recent deepening of the political and regulatory support required to manufacture vaccines locally. Notable shifts include increased political commitments from African and global leaders in steering the local vaccine manufacturing agenda, and improvements in regionalization (e.g., AfCTA) and the integration of vaccine markets across the continent, largely led by the Africa Centres for Disease Control.

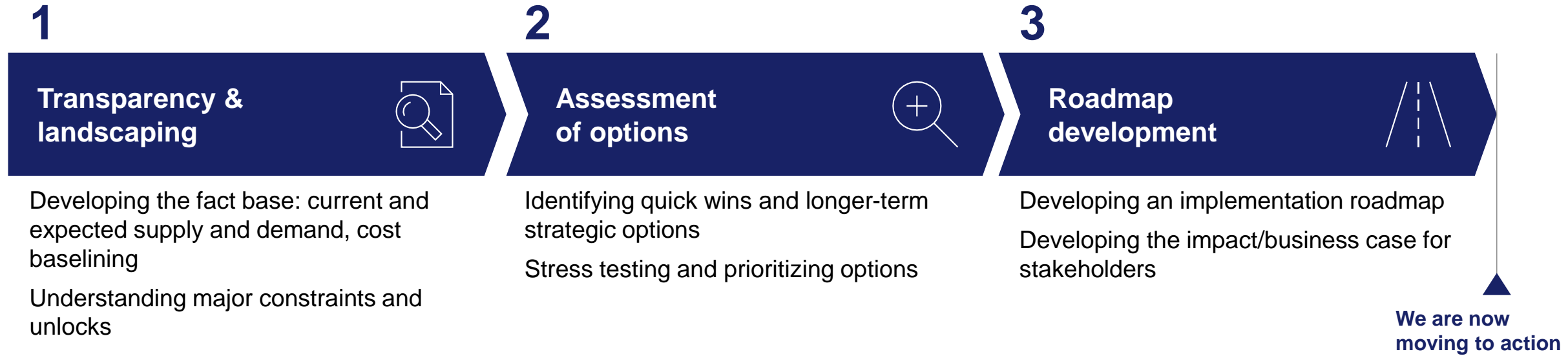
# There has never been this level of activity around vaccine manufacturing in Africa

Activities supported by our team ● Activities not yet confirmed



1. Includes Africa CDC, GPH actors, MNCs/manufacturers, DFIs and investors, etc. with details on later pages  
2. Representative example of recent activity and announcements of increased local production in Africa

# This study engaged a core group of stakeholders to develop a perspective on what it will take for Africa to expand Vx manufacturing



As a part of this effort, stakeholders have been engaged across organizations, including >40 people from >20 organizations who have attended the 3 workshops, as well as >50 that have engaged in individual interviews

**Global health actors and funders** (agenda-setters, global advocates and funders) – *non exhaustive*



**Pan-African development and health entities** – *non exhaustive*



**Vaccine/ technology players and partners** - *non-exhaustive*



# Learnings to date: High-level executive summary (1/2)

## Why now?

**Current forces driving a new moment of significant prioritization across stakeholders:** vaccine security concerns, technological developments, and market shifts

**Impact potential across public health and economic development targets**

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## The market opportunity

**Large and growing market in Africa: ~\$1.3B today, and up to ~\$2.3-5.4 Bn by 2030**

Strong growth fundamentals on the continent level: growing populations, improved coverage, new country introductions, and novel product introductions

Majority of countries supported by Gavi today; significant volumes expected to transition from Gavi by 2030

Most individual countries and regions are likely to have domestic markets too small for manufacturer economies of scale; manufacturers may need to export

**Currently, <1% of Africa's vaccines are locally manufactured, presenting an untapped opportunity for local manufacturers to enter or expand production**

Competition from large incumbent Indian players (~70% of total volumes) has historically made COGS parity difficult to achieve for smaller players; Indian DCVMs face low costs/ low margins given significant economies of scale

The ten identified African manufacturers consolidated in 5 countries and only a few conducting upstream manufacturing activities - may provide short-term expansion opportunities

# Learnings to date: High-level executive summary (2/2)

## Moving forward

**Five models identified to expand, with different investment opportunities associated with each, depending on existing facility capacity, timelines, and proposed level of risk and return**

These models are: 1) Downstream model, 2) Expanding routine model, 3) Product leapfrog model, 4) Adjacency model, and 5) Outbreak model

**The market currently faces five major barriers to local players. These are: no clear agenda or co-ordination across efforts, weak regulatory environments, bifurcated market demand dynamics (Gavi vs non-Gavi), restricted access to finance, and limited local talent**

Several efforts are underway to unlock Africa's enabling environment, which will be critical for the success of any investment in Vx but some market, project and other risks remain

## Emerging insights from ongoing stakeholder discussions

**It is becoming clear that stakeholders may need to signal interest to the market more clearly to push forward investment in vaccine manufacturing**

Few actors have been willing to take necessary action to de-risk the opportunity; however, many are showing interest if others move too

**There is a mismatch between available financial support and the needs of local vaccine manufacturers - for deal financing to occur, several project development and ecosystem challenges need to be addressed**

Limited support exists for upstream development including domestic, regional and continental enabling environments, and project-specific development. Actors are willing to support but need clear co-ordination and alignment on roles

A clear commercial business case is required; hinges on secured offtake for locally produced vaccines, which requires commitments from African leaders and global procurers

**We are continuing conversations with stakeholders, which is expected to yield additional insights on current challenges/needs, and associated areas for potential support**

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**Why now?**

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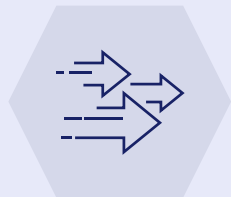
Market landscaping

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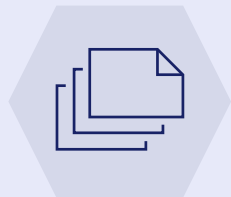
Investment opportunities

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Moving forward

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Appendix



# Why now? COVID-19 and other outbreaks have led to a sense of urgency and renewed public commitments, creating unprecedented alignment around African Vx manufacturing

## COVID-19 has exposed Africa's lack of local production capacity...

GLOBAL VIEWS | SPONSORED BY IOP

### Opinion: A call to boost African manufacturing for COVID-19 and other vaccines

By Ferrer Tasso, S&P

**AVMI** Push for Local Vaccine Production as race for COVID-19 antidote continues

6th July 2020. Cape Town/South Africa - The World is facing an unprecedented health challenge that has seen the loss of over 500,000 in just 7 months. The novel 2019 Corona Virus Disease (COVID-19) was first reported on 31st December 2019 and declared a global pandemic a month later by the World Health Organization on 30th March 2020. The first case in Africa, which has since reported over 350,000 cases, was reported 14th February 2020 in Egypt.

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**AVMI**  
AFRICAN VACCINE MANUFACTURING INITIATIVE

Push for Local Vaccine Production as race for COVID-19 antidote continues

6th July 2020

Cape Town/South Africa - The World is facing an unprecedented health challenge that has seen the loss of over 500,000 in just 7 months. The novel 2019 Corona Virus Disease (COVID-19) was first reported on 31st December 2019 and declared a global pandemic a month later by the World Health Organization on 30th March 2020.

“African countries must invest in the development of their own capacity to create the necessary instruments (manufacture of vaccines, diagnostics, medicines...), which are essential to guaranteeing the health of their population.”

- Dr John Nkengasong, Africa CDC

## ... pushing African leaders to accelerate local manufacturing expansion...

**Egypt readying to produce Chinese COVID-19 vaccine: Official**

December 6, 2020  
3:54 pm



AVMI  
Egypt Independent

Facebook, Twitter, Email, Print icons



**Nigeria**

Nov 2020: Federal government has announced plans to set up a vaccine production company in Nigeria to boost local COVID-19 Vx production



**Morocco**

Aug 2020: Morocco and China National Biotec Group Company Limited (CNBG) signed two cooperation agreements on COVID-19 vaccine trials to allow Morocco to produce a vaccine


## ... and encouraging some local manufacturers to commit to new Vx projects

**Morocco World News**

### Pasteur Institute of Morocco to Create Unit for Vaccine Production

The Pasteur Institute of Morocco is set to establish an industrial unit for the manufacturing of vaccines and other biomedical products.

Jan 1st (63 kB)




Aspen Pharmicare readying to make Johnson & Johnson Covid vaccine

By Edward West | Jan 5, 2021

CAPE TOWN - Global healthcare group Johnson & Johnson (J&J) will decide if any of the 230 million doses of Covid-19 vaccine scheduled to be produced at Aspen Pharmicare's



**Morocco**

Nov 2020: Russian Direct Investment Fund (RDIF) signed a deal with Moroccan pharmaceutical manufacturer Galenica to produce the Russian COVID-19 vaccine locally



**SA**

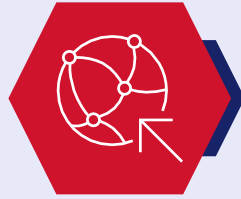
Jan 2021: Aspen Pharmicare could start production of Johnson & Johnson Covid-19 vaccines in South Africa by late March or early April if all approvals are in place

# Contents



Why now?

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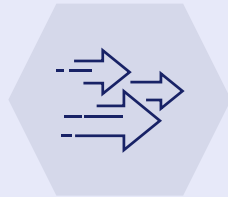
**Market landscaping**

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Investment opportunities

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Moving forward

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Appendix

## Understanding the Africa Vx market landscape addresses 3 questions



**A:** How big is the need and the opportunity in Africa?



**B:** Which products are most attractive in terms of value and volume?



**C:** What are the relevant supply-side dynamics?

# The African Vx market could grow from \$1.3bn today to ~\$2.3-5.4B by 2030, as a result of five key drivers

Large upside (~\$5.4bn) estimates exists under higher assumptions on novel product entry/coverage

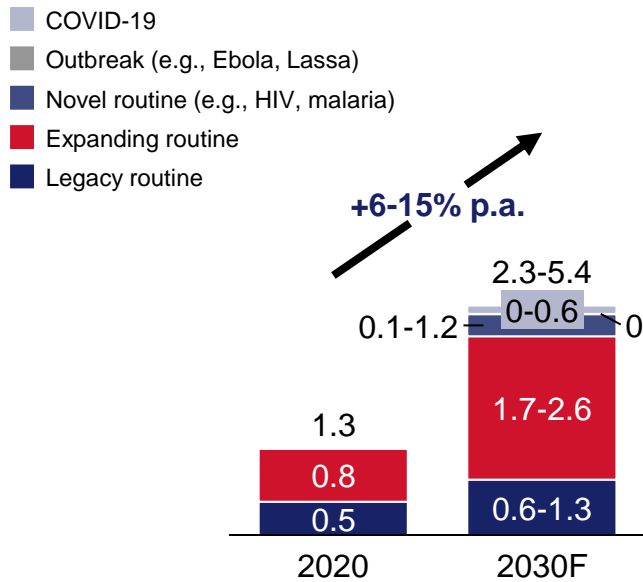
PRELIMINARY

DETAILED DESCRIPTIONS OF DRIVERS IN BACKUP

Ongoing refinement of scenarios and market sizing forecasts as COVID-19 epidemiology evolves; private market size currently being estimated

## Projected public market value,

\$ Mn, 2019 - 2030E (range from scenarios 1 to 3)<sup>2</sup>



Volumes,  
# of doses, Bn



Avg. prices<sup>1</sup>,  
\$/dose



### Drivers

### Examples

### Overall expected impact on market value

#### Increased access



Improvements to country-level vaccine programs through donor and public sector investment  
Introduction of existing Vx products into new countries (e.g., HPV, rotavirus)



#### Demo-graphic



Sustained, if slowing, population growth in most countries  
Declining infant mortality leading to larger population of surviving infants and adolescents requiring vaccination



#### Pricing



Stable prices expected for established products (or growing at inflation), with some newer products such as pneumo and HPV experiencing declining prices  
Change in dose presentations (e.g. multi vs single dose vaccinations; prefilled syringes) could impact pricing



#### Trans-itioning from Gavi



Impact on price and volumes for transitioning countries not yet clear (given that few countries have transitioned)



#### Emerging Vx products and novel technologies

Multiple products are under development and may be licensed by 2030 (e.g. Malaria, HIV)








Novel technologies could impact vaccine introductions, for example to reduce the overall development time of new vaccines. Initial prices likely to be higher than legacy products but expected to decline over time



1. Weighted average price per dose of vaccine, across all products, noting that product prices differ significantly (e.g. \$0.12/dose for BCG and \$23.52 for DTaP hexavalent)
2. Scenarios mainly driven by price tier of transitioning countries (e.g., will they have access to Gavi-negotiated prices or pay LMIC prices?) and emerging vaccine (e.g., COVID-19, HIV, malaria) assumptions (detailed in backup) and ; first 2 scenarios included as more conservative forecasts than third

# Forecasting scenarios output: ECOWAS and COMESA expected to continue as largest regional markets given pop. size despite low prices

Ongoing refinement of scenarios and market sizing forecasts as COVID-19 epidemiology evolves; private market size currently being estimated

Regional blocs <sup>1</sup> (# of members)	Population (2020) Mn	Public market value, USD mn		Avg. prices <sup>2</sup> , USD 2019	Comments
		2020	2030 estimates <sup>3</sup>		
 <b>EAC</b> (6)	195	138	180-630	0.9	Ethiopia constitutes 9% of continental value and ~50% of the EAC region (due to large volumes of Rota Vx). HIV and COVID are ~half of upside value
 <b>SADC</b> (15)	363	530	810-1.4B	1.9	Includes several self-financing countries paying higher prices, e.g., SA, Botswana, Mauritius, Namibia etc. SA constitutes 43% of SADC value
 <b>ECOWAS</b> (15)	397	289	430-1.7B	0.9	Region characterized by high volumes due to Nigeria and low prices given that all countries are Gavi eligible. Nigeria constitutes approx. half of ECOWAS market
 <b>IGAD</b> (8)	290	199	235-640	0.9	Region characterized by high volumes due to Nigeria and low prices given that all countries are Gavi eligible
 <b>COMESA</b> (19)	570	451	940-1.5B	1.1	Large region with large population and mix of Gavi and self-financing countries (e.g., Egypt, Botswana)
 <b>AMU</b> (5)	104	206	290-335	3.6	Majority self-financing countries, therefore region is characterized by higher prices
 <b>Africa total</b>	1,339	1,310	2.4-5.4B	1.4	African Vx market is ~6.5% of global vaccine by value, but up to 25% by volume due to its large birth cohort



Large ranges in value between conservative and upside scenarios driven primarily by assumption on price tier transitioning countries will pay (e.g., Will Nigeria procure at Gavi or LMIC prices?)

Other driver is novel vaccines (e.g., HIV, malaria and COVID-19) with uncertain demand and prices

1. There is some overlap with certain countries considered in more than one region

2. Weighted average price per dose 3. Range is difference between scenarios 1 (conservative) and 3 (upside) - detailed in backup

# Products can be classified into four aggregated categories with unique demand and supply dynamics

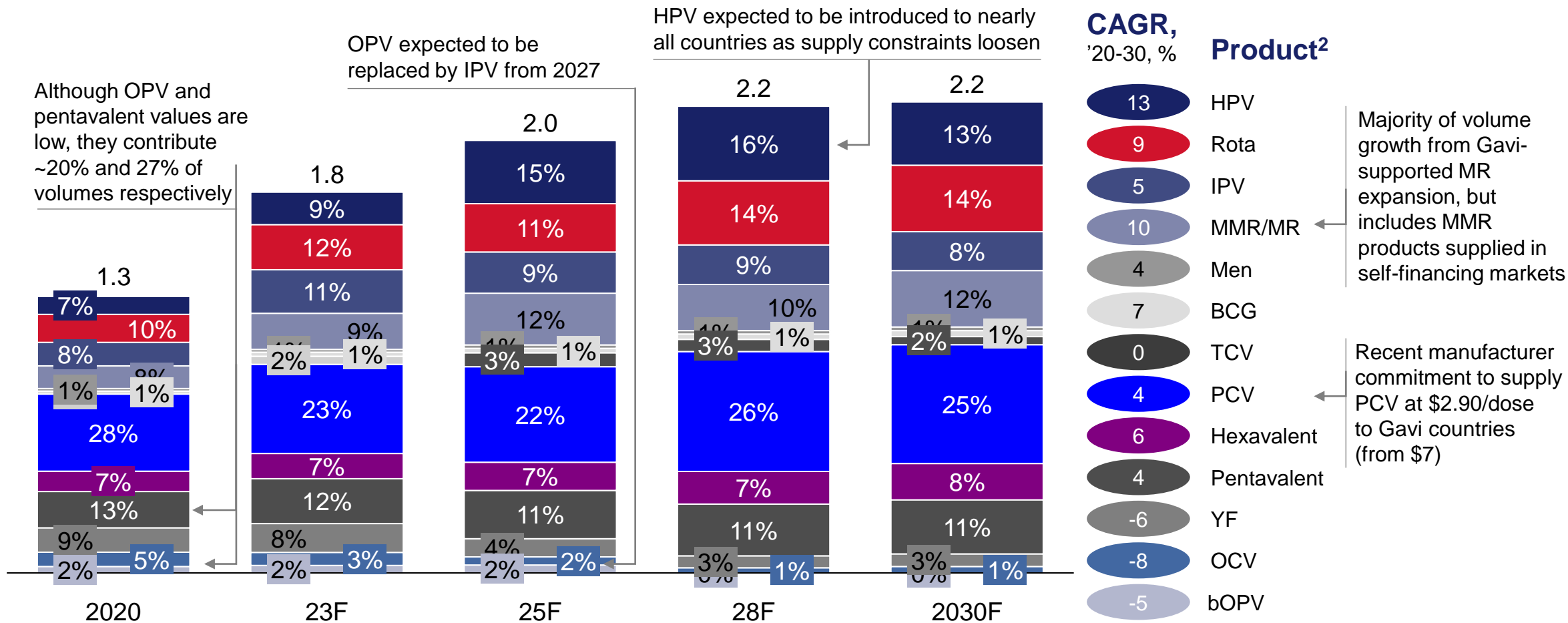
	Market dynamics 	Product dynamics 
		Manufacturing complexity of product
		Example products
<b>Group 1 Legacy routine</b>	<p>Relatively high coverage (e.g., 80-90% for DTP and BCG, 65% for Yellow Fever) due to being established in all national immunisation programs</p> <p>Primarily produced by Indian players at high volumes with low unit price (&lt;\$1/dose)</p>	<p>BCG, measles, rubella, pentavalent, polio, yellow fever<sup>1</sup></p> <p>Low Medium High</p>
<b>Group 2 Expanding routine</b>	<p>Not-yet-commoditized, often supplied by originator companies at relatively higher prices, although this is expected to change</p> <p>Fast-growing coverage in many countries and introductions to new countries leading to high growth (e.g., HPV in 22 African countries to date)</p>	<p>Influenza, HPV, Meningococcal<sup>1</sup>, Pneumococcal, Rotavirus</p> <p>Low Medium High</p>
<b>Group 3 Africa-specific outbreak vaccines</b>	<p>Emerging vaccines with unpredictable demand driven by outbreaks, often with higher prices due to lower scale and urgent need</p> <p>Large volumes often stored in global stockpiles which can be accessed by countries in event of an outbreak</p>	<p>Ebola, Chikungunya, Rift Valley Fever, Disease X</p> <p>Low Medium High</p>
<b>Group 4 Novel routine</b>	<p>Not-yet-licensed products in development which have the potential to become part of large-scale immunization programs</p> <p>Unclear exactly which vaccines will emerge when, their specific characteristics, and how they will be scaled / rolled-out</p>	<p>Malaria, HIV, COVID-19, Lassa Fever</p> <p>Low Medium High</p>

1. Used in both routine and outbreak/stockpiling strategies

# High growth products (by value) include those expanding via new or recent country introductions, such as HPV, IPV, rotavirus and MMR

Total vaccine demand (value) for Africa for existing products<sup>1</sup>, USD bn, 2020-2030F

SCENARIO 1 (EXCLUDES ALL NOVEL PRODUCTS)<sup>3</sup>



1. Emerging products (e.g., COVID-19, outbreak, novel routine) excluded here due to high levels of uncertainty in demand forecasting

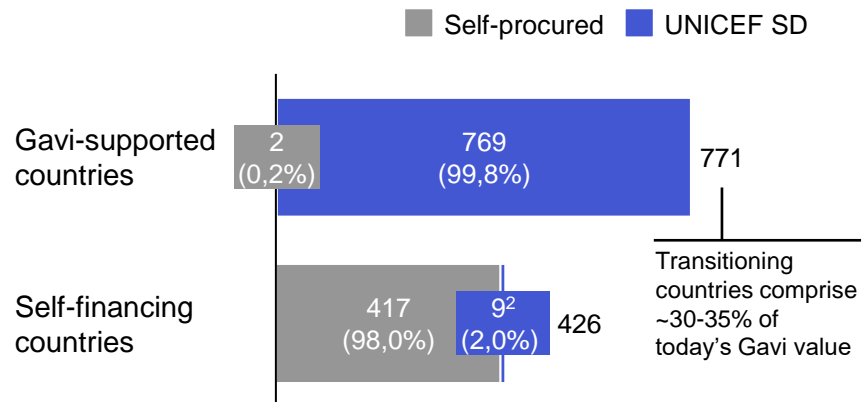
2. HPV: Human Papillomavirus, IPV: Inactivated Polio vaccine, MMR: Measles, mumps and rubella, Men: Meningitis, PCV: Pneumococcal conjugate vaccine, Hexavalent: DTP, Hib, HepB and IPV, Pentavalent: DTP, Hib, HepB, YF: Yellow Fever, OCV: Oral polio vaccine, OPV: Oral polio vaccine, TCV: Typhoid conjugate vaccine 3. In scenario 1, transitioning countries are able to retain Gavi-negotiated prices. Only existing products modelled annually given uncertainty around novel product authorisation dates (scenario 2 equivalent page in backup)

# Gavi/UNICEF SD play a significant role in the African Vx landscape, but transitioning countries may shift the demand dynamics

Today, there is significant buyer consolidation in the market, with Gavi/ UNICEF SD financing and procuring approximately two-thirds of total market value

- Eligible for Gavi support, with no indication of transitioning by 2030<sup>1</sup>
- Preparatory transition ■ Accelerated transition<sup>3</sup>
- Gavi transitioned ■ Never eligible for Gavi support

Total value of vaccines, \$mn, 2019



## Implications for manufacturers:

Overall, suppliers using Gavi channels experience greater demand certainty and larger procurement volumes, often including advanced purchases, in exchange for price reductions (~2-4X less than self-financed countries)



By 2030, several African countries could transition from Gavi<sup>4</sup> – it is currently uncertain how this might influence procurement channels, volumes, and prices

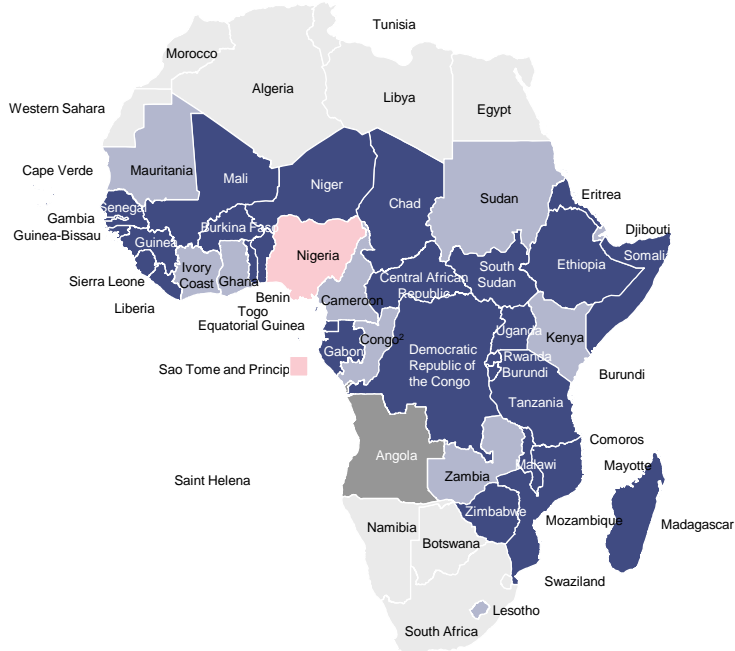
## Transitioning countries may have different procurement options...

- Maintain procurement via UNICEF SD (maintaining low, Gavi-negotiated pricing)
- Self-procure through bilateral contracts
- Enter into some other pooled procurement (e.g., regional)
- Follow some mix of the above

## ...with unclear price/volume implications:

Prices could be driven up if countries no longer leverage UNICEF SD; it is unclear whether this would reduce volumes procured

However, countries that have transitioned from Gavi in other markets (e.g., Indonesia) have secured low prices through bilateral contracts with manufacturers



1. Provided 3-year GNI per capita remains below the low-income threshold: US\$ 995 GNI per capita  
 2. Congo reached full self-financing status but was reversed in 2019  
 3. Status maintained for 5 years before transitioning to fully self-financing  
 4. Expert inputs suggest that 5 countries are likely or somewhat likely to transition (Nigeria, Sao Tome, Ghana, Kenya, Cote d'Ivoire) while others could but are less likely following COVID-19 economic shocks

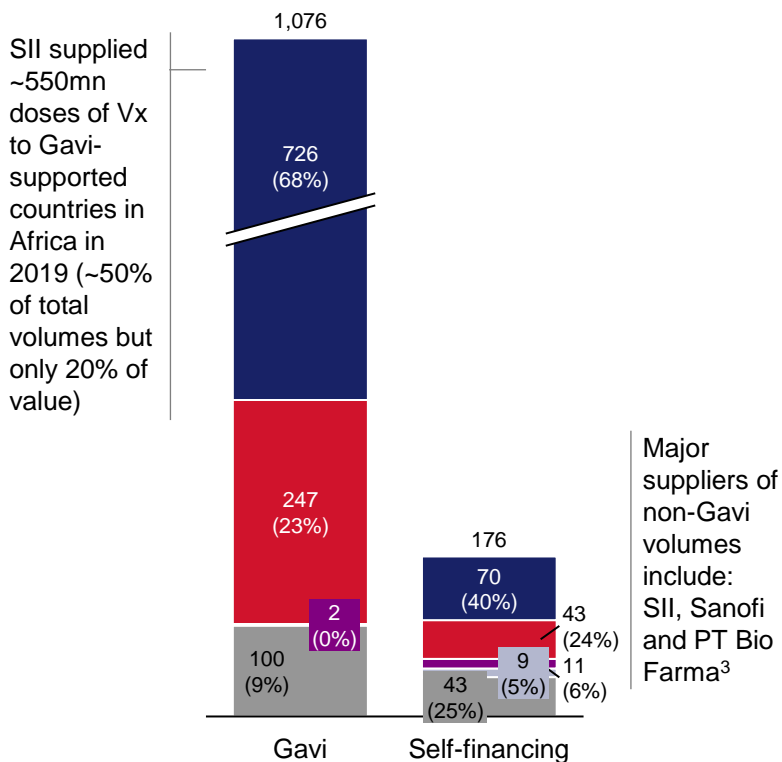


# ~70% of volumes procured for Gavi-supported countries originate in India, but only ~30% of value; this may increase in the coming years

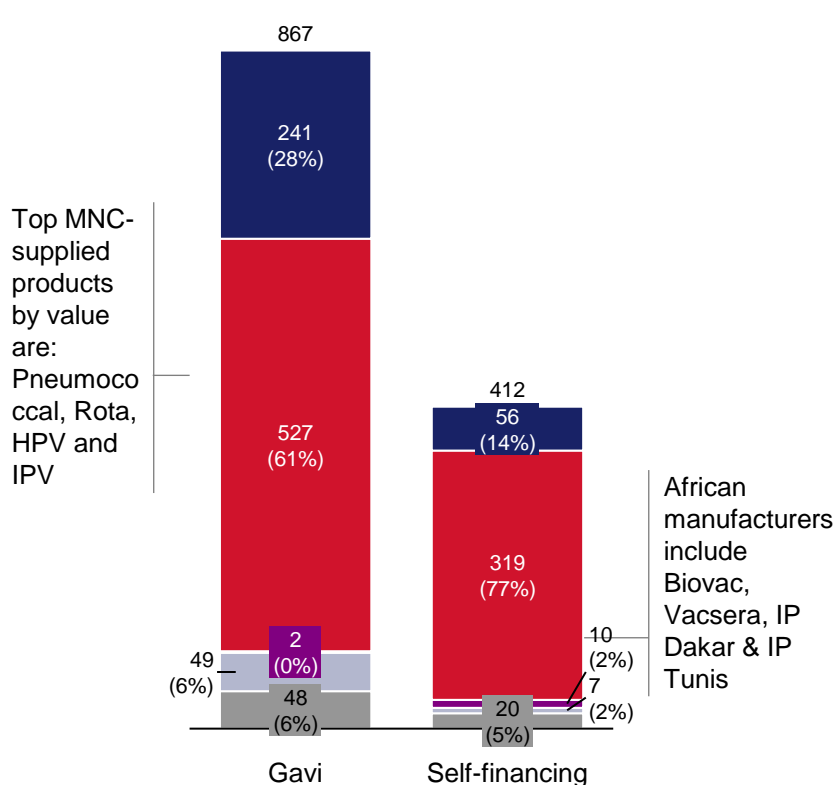
Deep dive on African DCVMs to follow

Other DCVM Other African DCVM MNC Indian DCVM

Share of African vaccines volume by manufacturer origin<sup>1</sup>, doses, mn



Share of African vaccines value by manufacturer origin<sup>1</sup>, %



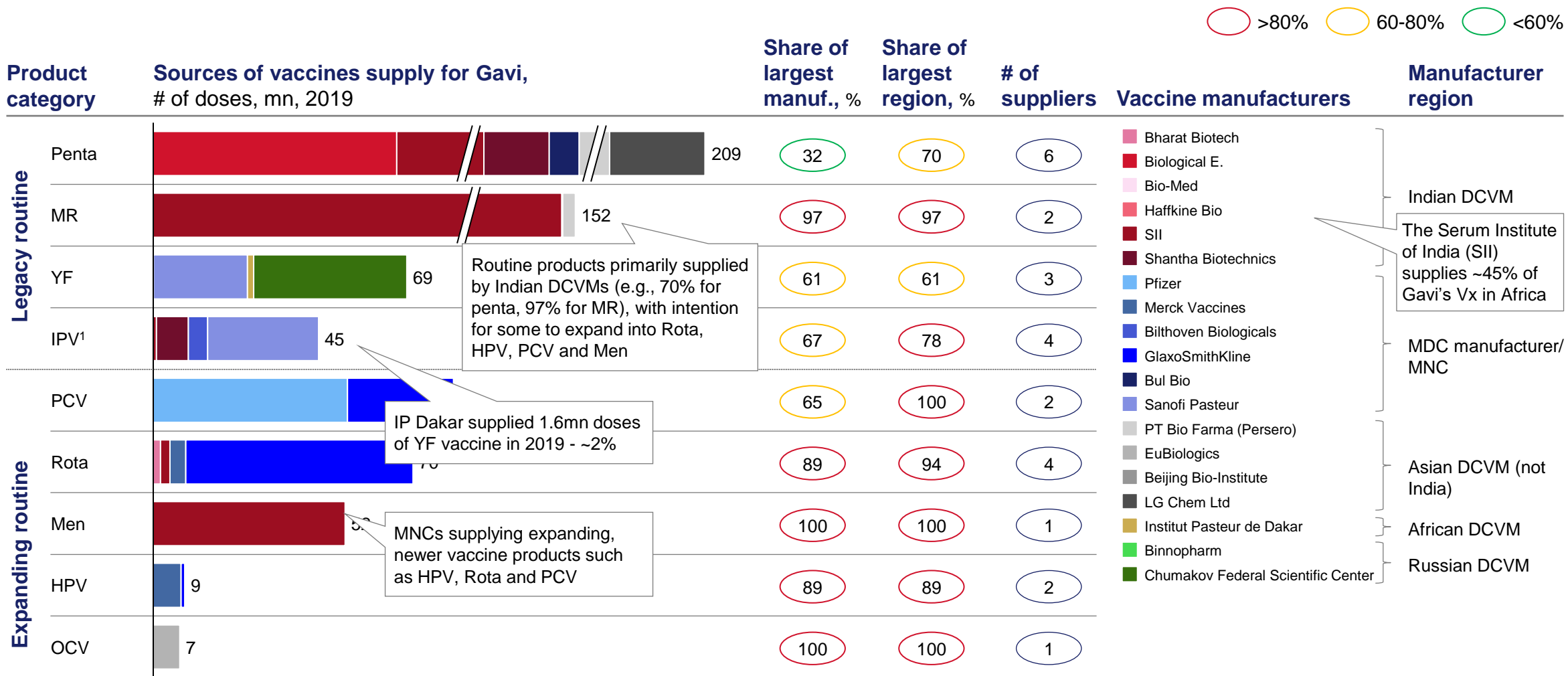
## Implications

Opportunities exist for emerging DCVMs in 4 products with high concentration of volumes produced by MNCs: IPV, pneumococcal, HPV and rotavirus – Indian DCVMs are already planning expansion into these products

This could lead to increased geographic concentration of supply, which could be a potential vaccine security risk<sup>4</sup>

1. Excludes Algeria due to missing manufacturer data
2. Includes: Merck, Sanofi, Pfizer and GSK
3. Indonesian state-owned manufacturer producing OPV, DT and TT
4. For example, India has restricted SII's COVID-19 exports until 1mn doses have first been supplied to meet local demand

# Almost all Gavi products are highly concentrated by supplier and / or region

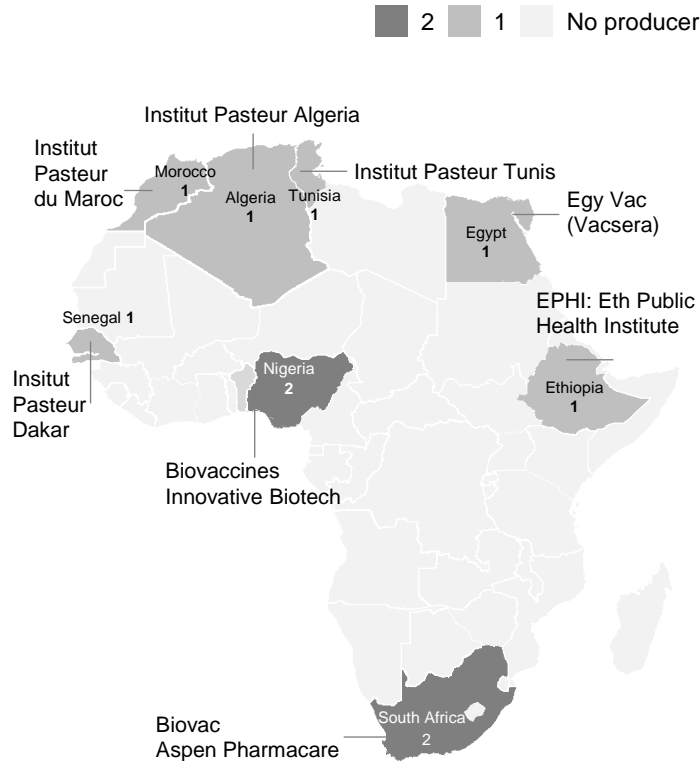


1. Includes all IPV-containing products, including, for example, pentavalent with IPV



# There are 10 known existing local vaccine value chain players in Africa, mostly concentrated in North Africa, South Africa, and Nigeria

Africa's vaccine value chain players by country<sup>1</sup>, 2020, total = ~10



Africa's vaccine value chain players by value chain step<sup>5</sup> 2020, total = ~10

Manufacturer	Products	Value Chain Step				
		R&D	Drug substance mfg	Fill & finish	Pack & label	Import for distribution
Institut Pasteur Dakar	Yellow Fever		✓	✓	✓	
Egy Vac (Vacsera)	BCG-T, Tuberculin, Tetanus, DTP, Typhoid, Cholera			✓	✓	
Institut Pasteur Tunis <sup>2</sup>	BCG		✓	✓		
Biovac	BCG <sup>6</sup> , Measles <sup>6</sup> , Pneumococcal conj. <sup>3</sup> , Hepatitis B <sup>3</sup> , Hexavalent, GBS <sup>7</sup>	✓	✓	✓	✓	✓
Aspen Pharmacare	Covid-19 candidate			✓	✓	
Institut Pasteur Morocco	BCG, DT, Yellow Fever, Typhoid Fever, Influenza, Rabies					✓
EPHI: Eth Public Health Institute	Plan to produce vaccines <sup>4</sup>		✓		✓	✓
Biovaccines	Plan to produce Hep-B Plan to produce Tetanus Plan to produce DTP+Hep-B Plan to produce Yellow Fever Plan to produce Measles		✓		✓	
Innovative Biotech	HIV	✓				
Institut Pasteur Algeria	Rabies		✓			✓

## Insights

The African vaccine manufacturing landscape is mostly focused on fill / finish, and packaging / labelling

Opportunities for existing Vx manufacturers exist to expand along the value chain into DS manufacturing and/or introduce new product lines

1. Local companies have ownership and headquarter in respective country of Africa, Others (n=24) touch the manufacturing value chain (e.g., import and distribution, some packaging steps), but are part of international MNC pharma operations and are not locally owned 2. Very small scale API manufacturing 3. Currently only visual inspection, labelling and packaging of imported vials or pre-filled syringes  
4. Planned vaccine portfolio is not confirmed yet or construction not completed 5. Kenya and Ghana have indicated some interest in entering vaccine manufacturing but with no firm commitments to date  
6. Limited to import for distribution steps 7. Group B streptococcus (GBS) vaccine currently under development

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Why now?

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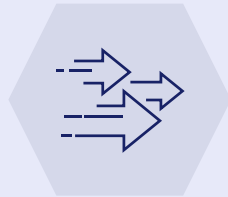
Market landscaping

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**Investment opportunities**

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Moving forward

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Appendix

# Five models have been identified as potentially viable across different products /process advancement opportunities

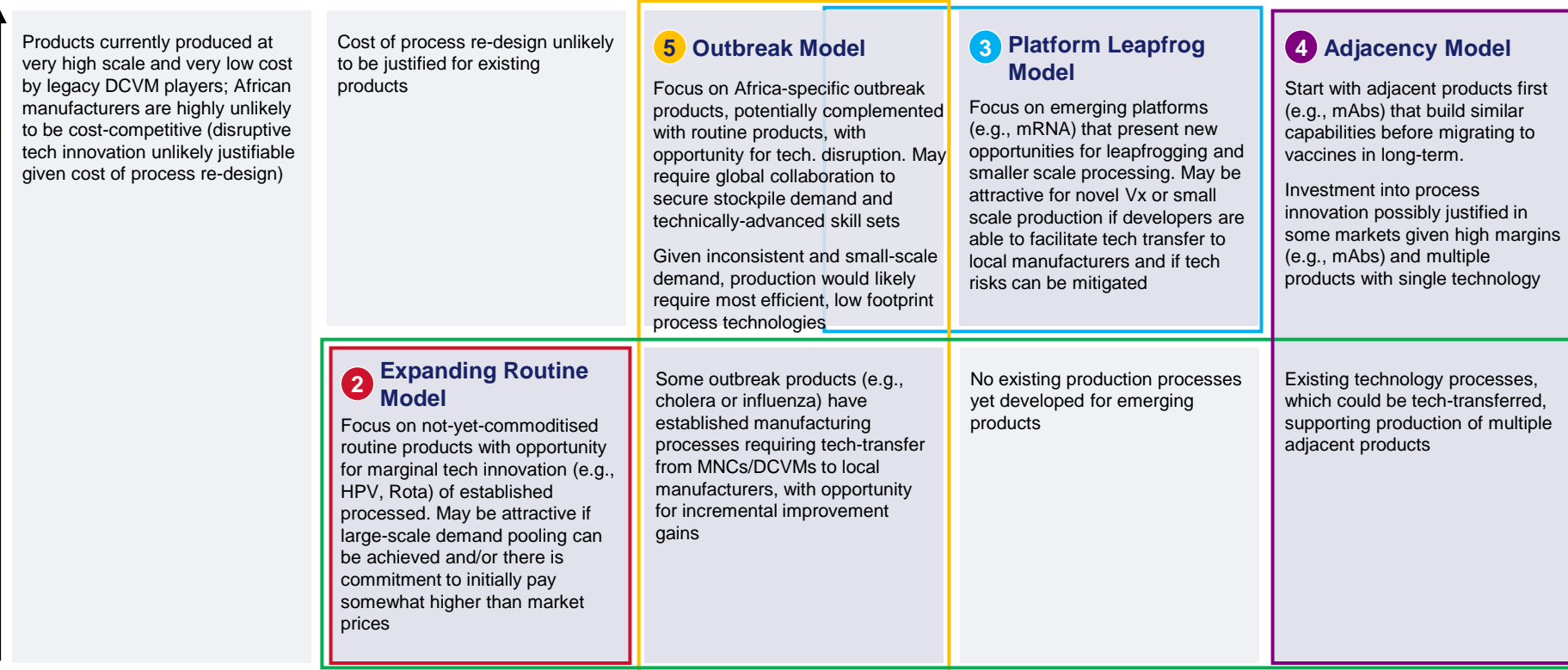
De-prioritized based on low feasibility ranking

Potential overlap to produce outbreak products (e.g., influenza, Ebola, Lassa) utilising novel platforms (e.g., DNA, mRNA, viral vector)

Level of technology/  
process  
innovation

Disruptive,  
innovative  
technologies

Traditional  
processes  
with  
incremental  
innovations



**1 Downstream Model**


Focus on a) package and labelling and/or b) fill/finish steps for multiple products. May be most attractive for domestic markets with ability to export regionally, if quality compliance could be assured

Routine (legacy EPI)      Routine (expanding EPI)      Outbreak      Novel routine      Adjacent

Vx/ Vx-like product categories

# These models translate into various pathways for potential investors

NON-EXHAUSTIVE

--> Optional path     Model reference     Investment opportunity

Today's starting position



**Shorter term: Initial transition investment opportunities**



**Longer-term: End-state transition investment opportunities**



**Greenfield: No existing capacity**

Set-up a product agnostic packaging facility

Examples: Biovac

 Downstream model

 i


Expand to existing downstream capacity to include full value chain production (incl. drug substance production)

Example: Biovac

 Expanding Routine model

 iii

Establish new site producing full product(s) using novel platforms (e.g., mRNA)

 Platform leapfrog model

 iv

Expand to include outbreak products in existing plants

 Outbreak model



 v



**Brownfield: Existing Vx capacity (e.g., package/label and/or fill/finish)**

Expand existing downstream capacity to include full value chain production (incl. drug substance production)

Examples: Biovac, IP Dakar

 Expanding Routine model  
 Outbreak model

 iii

 v

Expand to existing downstream capacity to include full value chain production (incl. drug substance production)

Example: Biovac

 Expanding Routine model

 iii



**Brownfield: Existing Vx-related capacity (e.g., Sterile injectables, mAbs etc.)**

Expansion of downstream capacity (fill/finish, visual inspection and package/labelling) of existing manufacturers (non-vx)

Examples: Aspen, Serum Institute

 Downstream model

 ii

Expand to include outbreak products in existing plants

Example: Aspen

 Outbreak model






 v

# Investment opportunities have different timelines, which may appeal to different investors based on timeframe and risk of investment

NUMBERS PRELIMINARY

Scale of plant was set to 60 mn doses p.a. to be in a competitive range to current market prices for Vx; specific values for countries in scope are covered within range; evaluation can look different if parameters are changed

Initial high level evaluation of economics

	Model reference	Investment opportunity	Description	IRR (pre tax), %	Investment size (per facility), \$ mn	NPV (not risk adjusted, 10 yrs), \$ mn	Risk level ● Low ● High	Timeframe <sup>1</sup> for setting up
Short-term	i 	Greenfield: Setup a product agnostic packaging facility	Facility imports unlabeled/labeled filled vaccines (e.g., vials, syringes) from MNCs/DCVMs and handles labelling, packaging and distribution of several finished product with capacity of >60 mn doses p.a. Secondary packaging materials sourced locally, competitively priced Facility has strong local ties with distributors and regulators	30-35	50	50-60	● Low	4 years
	ii 	Brownfield: Expansion of downstream capacity (F/F, VI and P/L) of existing manufacturers	Reverse integration of packaging and labeling activities towards Fill and Finish using existing vaccine or mAbs manufacturers capacity of >60 mn doses p.a. Brownfield expansion of facility that is focused on downstream steps for routine immunization products or has sterile filling capabilities for non-Vx products (e.g., due to mAbs production)	25-30	80	40-50	● Low	4-6 years
	iii 	Brownfield: Expand existing downstream capacity to include end-to-end value chain production (incl. drug substance production)	Expansion of existing facility to include domestic drug substance production capabilities with aspiration to setup large-scale, end-to-end plant (e.g., >60mn doses p.a.) that achieves cost competitiveness for routine products Significant additional CAPEX required for drug substance production (Bioreactors and purification line) as well as need for additional skilled employees (e.g., microbiologists etc.)	25-30	190	90-120	● Low	5-10 years
	iv 	Greenfield: Establish new site producing end-to-end product(s) leveraging novel platform technology (e.g., mRNA)	Smaller footprint facility producing products on novel vaccine technology using (e.g., mRNA, DNA) that requires lower CAPEX investment for drug substance production due to process efficiency of novel technologies (e.g., smaller bioreactors) capacity of >60 mn doses p.a. Highly-skilled labour necessary given novel, complex technologies (e.g., mRNA, DNA)	30-40	190	170-210	● High	5-10 years
	v 	Brownfield: Expansion of existing manufacturers to incorporate outbreak products into existing plants (incremental investment)	Introduce additional production line to existing facility that focuses on outbreak products (e.g. Ebola) for stockpile production with capacity of >0.5 mn doses p.a.. Possibility to further ramp-up production quickly if necessary. Upskilling and training of labour required to manufacture novel products / work across products. Ideally developed alongside manufacturers with existing production on same platform technology as the outbreak product	20-25	25	10-15	● Low	5-10 years

Add-on to existing Vx production

Long term

**Disclaimer:** methodology is based on initial high level assumptions and represent an average given the difference in multiple parameters (e.g., productivity, purchasing cost of raw material, scale, etc); calculations do not include disruptive technology innovations that can change the evaluation

1. Assuming enabling factors (e.g., NRA strengthening) are developed along this time

2. Economics shown for Nigeria and Ethiopia only

# Country opportunity overview: 9 countries have been profiled for their potential for Vx manufacturing, each with their own opportunities and risks

*Deep dives on each country to follow*

## Morocco



- ⊕ Recent announcement by Institut Pasteur du Maroc to establish new manufacturing site, established manufacturers with sterile capabilities
- ⊖ Logistics and distribution challenges, small domestic market; NRA<sup>1</sup> not ML3<sup>2</sup> certified

## Senegal



- ⊕ WHO PQ'd manufacturing capacity, knowledge of vaccine manufacturing through Institut Pasteur Dakar
- ⊖ Logistics and distribution challenges, relatively smaller domestic market; NRA not ML3 certified but actively working on it

## Ghana



- ⊕ Strong engagement from leaders, recent announcement for Vx mfg. facility in Accra; NRA is ML3 certified; expected to transition from Gavi
- ⊖ Logistics and distribution challenges, small domestic market, no existing Vx capacity

## Nigeria



- ⊕ Large domestic market to secure volumes expected to transition from Gavi, Nigerian companies working towards Vx manufacturing
- ⊖ Currency fluctuations, no existing manufacturing capacity in place; NRA not ML3 certified (but actively working on it)



## South Africa



- ⊕ Home to large facility with experience across full value chain, limited government transitions with experience in self-procurement, strong ties and trust with MNCs, Zazibona access
- ⊖ NRA not ML3 certified (but actively working on it)

## Tunisia



- ⊕ Established Vx manufacturing capacity with history of export, recent discussions with Chinese MNCs to mfg. COVID-19 Vx, knowledge of vaccine manufacturing through Institut Pasteur Tunisia
- ⊖ Small domestic market, limited regional harmonization; NRA not ML3 certified, limited air connections to the continent

## Egypt



- ⊕ Strong existing facility and knowledge, recent announcement by MOH to locally manufacture COVID-19 Vx
- ⊖ Limited regional harmonization (in Africa), NRA not ML3 certified (but actively working on it)

## Ethiopia



- ⊕ Large and growing domestic market, strong support and favorable industrial policy for pharmaceuticals, air transport hub
- ⊖ Recent security challenges, continued forex constraints; NRA not ML3 certified but has begun initial work, limited existing Vx capacity

## Kenya



- ⊕ Strong support and favorable industrial policy, high investment in infrastructure, good connections with MNCs, expected transition from Gavi in next 10 yrs
- ⊖ Medium-sized domestic market, no existing Vx capabilities; NRA not ML3 certified but has begun initial work

**Disclaimer:** There may be other interested or relevant countries; these nine were selected based off expert perspectives or communicated opportunity/interest



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Why now?

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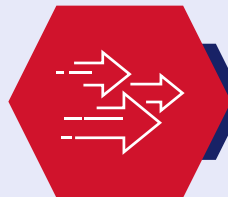
Market landscaping

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Investment opportunities

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**Moving forward**

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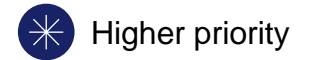
Appendix

# Current state: Additional work to support five cross-cutting enablers impacting the enabling environment will be required

	Barriers	Ongoing efforts
<b>A Agenda-setting and coordination</b>	 <p>No current unified and operational continental strategy with unclear ownership and roles for stakeholders</p>	<p>Some national governments have shown political commitment for local pharma production</p> <p>Some Pan-African entities have vaccine-specific strategies, but these are not fully coordinated across organizations</p>
<b>B Regulatory strengthening</b>	 <p>Continent-wide harmonization is not yet implemented under AMA; regional harmonization not yet expanded to joint approval for vaccines</p> <p>National regulators facing capacity and capabilities constraints</p>	<p>Continental and regional regulatory reform related to the COVID-19 Vx is ongoing in critical areas (e.g., marketing authorization, reliance, post-market surveillance)</p> <p>Pan-African initiatives (e.g., AVAREF) have streamlined pre-market authorization activities for emergency-use for COVID-19 vaccines</p>
<b>C Demand certainty</b>	 <p>Low demand volumes and uncertainty unless for Gavi-supported countries, but these markets require low prices and strict regulatory hurdles</p>	<p>Opportunity for demand certainty in some regions and/or large domestic markets (e.g., Nigeria). Some development of very nascent forms of regional pooled procurement, mostly for non-Vx products (e.g., medicines, medical supplies) and mostly in response to stockpile threats during emergencies</p>
<b>D Access to finance</b>	 <p>Limited financing for local manufacturing in Africa, primarily due to perceptions of high risk and unclear business case articulation</p>	<p>Initial investments made in local Vx manufacturing, including using non-traditional financing models (e.g., PPPs and joint ventures – like Biovac in South Africa and Biovaccines in Nigeria)</p> <p>Several announcements of partnerships and investments related to COVID-19 Vx manufacturing have been made recently</p>
<b>E Talent and know-how</b>	 <p>Skills shortages of pharmaceutical, biotechnology, and industrial talent driven by scarcity and brain drain of local talent, resulting in the reliance on foreign expertise</p>	<p>Experience from a few ongoing tech transfers (e.g., Pneumococcal Vx at Biovac) is growing, but the need for know-how transfers may increase as novel vaccine products, platforms, and technological processes are introduced</p>

# Should Africa wish to access this opportunity, stakeholders will need to initiate several immediate actions to develop the enabling environment

## Potential activities – immediate priorities for next 6 months



Higher priority

### Agenda-setting and coordination



- ✳ Identify champion organization, develop initiative structure and governance and generate momentum among key political leaders
- ✳ Mobilize key regional / national leaders, clarify Africa-wide aspiration and strategy (clear articulation of success metrics)
- ✳ Confirm network of partners across sectors and align on clear priorities, roles, and responsibilities across stakeholders

### Regulatory strengthening



- Support finalization of AMA strategic plan, including Vx-specific plan, and identify gaps
- ✳ Institutionalize and expand emerging COVID-Vx regulatory harmonization (e.g., Africa Regulatory Task Force) to broader Vx scope
- ✳ Develop NRA-strengthening plans to achieve ML3 certification where needed

### Demand certainty



- ✳ Engage with funders (e.g., Gavi) on market shaping strategies for Vx procurement

### Access to finance



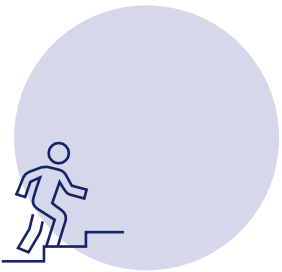
- ✳ Conduct investor roundtables and prepare for roadshows for preliminary Vx-investment opportunities
- ✳ Conduct MNC/DCVM engagement to clarify interest in African Vx opportunities
- Conduct robust investor and pipeline mapping, facilitate individual conversations
- Identify needs for technical assistance and transaction facilitation to support investments

### Talent and know-how



- Identify existing programs that provide Vx-specific trainings and determine scalability
- Develop strategy for taskforce on African Vx talent strengthening

# Discussion questions



How has your perception of local vaccine manufacturing in Africa changed in the past months?

What has made you excited about African vaccine manufacturing opportunities? What has previously held you back?

What do you think will be important topics to discuss at the Summit?

How best could African manufacturers and DCVMs work together? What opportunities exist for collaboration and partnerships?

# Next steps: We would be interested in having some 1:1 conversations with select DCVMs to understand opportunities for African Vx manufacturers

Leading up to the African Vaccine Manufacturing Summit, we would appreciate offers for 1:1 conversations with you to better understand...

- |  |  |
|--|--|
| <b>1. Potential for collaboration and partnerships in African Vx manufacturing</b> | Assess the appetite of DCVMs to partner/collaborate with existing or potential African vaccine manufacturers |
|  | Understand the roadblocks and challenges that could prevent partnership/collaboration                        |
|  | Understand what would be required for DCVMs to consider partnering with local African players                |
| <b>2. Lessons learned and case studies from other DCVMs</b>                        | Understand the approach and process to securing successful technology transfers with vaccine developers      |
|  | Develop lessons learned potentially applicable for Africa  |

## How we plan to reach out

We will share a **follow-up mail after this session requesting time with you**

Please feel free to connect us to the most appropriate individuals in your organisations with whom we could speak

Please reach out to us and Tertia Bailey (FCDO) if you have any further questions on our work to date, findings or if you wish to share your perspectives with us

All specific company information shared through conversations will be kept confidential, unless consent is provided

**Backup**

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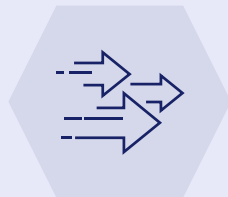
Market landscaping

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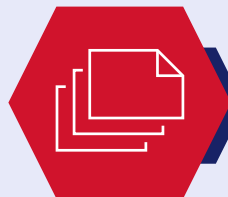
Investment opportunities

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Moving forward

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**Appendix**

# African Vx: recent announcements related to local vaccine manufacturing are mostly connected with COVID-19 Vx production

PRELIMINARY

LAST UPDATED 29 JANUARY 2021

## Ghana

**April 2018:** New vaccine manufacturing facility is planned to be setup in Accra, Ghana by Merck to streamline the value stream (currently on hold)

## South Africa

**July 2020:** South Africa plans to build a coronavirus vaccine plant. Higher Education, Science and Technology minister Blade Nzimande said that the plant would be headed up by both government officials, pharmaceutical companies and private-sector vaccine specialists.

**Nov 2020:** Aspen's South African subsidiary Aspen Pharmacare has signed a preliminary agreement with two Johnson & Johnson (J&J) subsidiaries for the technical transfer and proposed commercial manufacture of their COVID-19 vaccine candidate

**Jan 2021:** Aspen Pharmacare could start production of Johnson & Johnson Covid-19 vaccines in South Africa by late March or early April if all approvals are in place

## Nigeria

**Nov 2020:** Federal government has announced plans to set up a vaccine production company in Nigeria to boost local COVID-19 vaccine production

## Egypt

**July 2020:** Egypt's Health Ministry announced it has began preparing to manufacture a coronavirus vaccine once proven to be effective in trials, in cooperation with the Chinese government

## Morocco

**Aug 2020:** Morocco and China National Biotec Group Company Limited (CNBG) signed two cooperation agreements on COVID-19 vaccine trials to allow Morocco to produce a vaccine

**Nov 2020:** Russian Direct Investment Fund (RDIF) signed a deal with Moroccan pharmaceutical manufacturer Galenica to produce the Russian COVID-19 vaccine locally. A delivery of 8 million doses of Russia's Sputnik-V vaccine is expected during the first half of 2021

**Jan 2021:** The Pasteur Institute of Morocco is set to establish an industrial unit for the manufacturing of vaccines and other biomedical products (antidotes against snakebites and scorpion stings) near Casablanca. The planned industrial unit is very likely to produce COVID-19 vaccines together with the Chinese pharmaceutical company Sinopharm

## Angola

**Oct 2020:** The Russian government has submitted a proposal to the Angolan government for construction of a factory to manufacture vaccines, the Russian ambassador to Angola announced on Wednesday in Luanda

The above profiles vaccine-specific announcements (other pharma-related events have occurred recently but are not included unless specifically relevant for vaccine production) which have to be noted with reservation as it does not guarantee the success of the projects

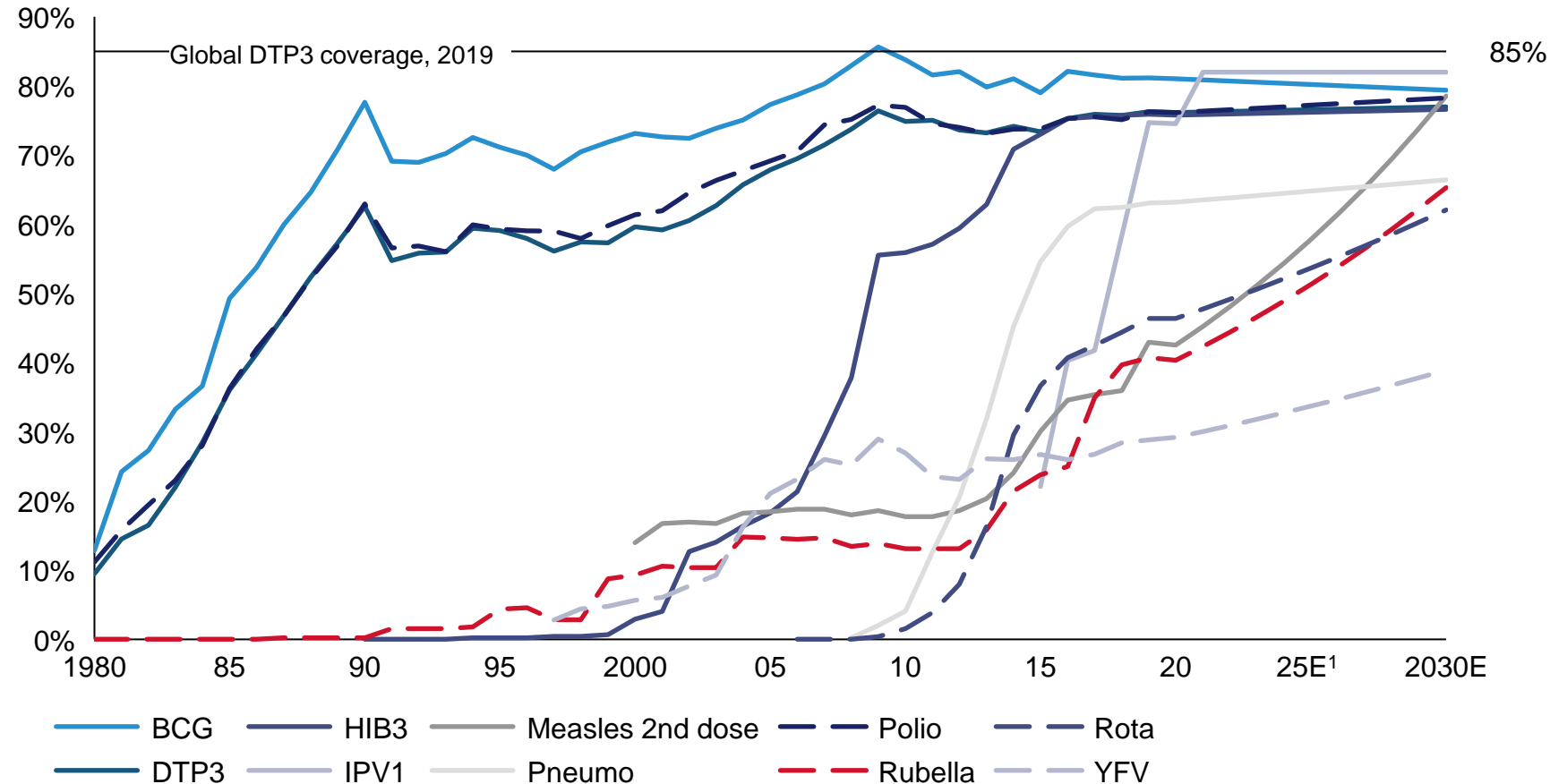


# 1. Immunisation coverage established routine products has plateaued, but saturation compared to global average has not yet been reached

PRELIMINARY

## Africa immunisation coverage rates over time

% of target population



## Takeaways

Aggregate coverage in Africa has **stagnated in recent years** due to:

- Challenges securing sustainable funding and resources
- Stock-outs and supply shortages (e.g., HPV, Yellow Fever, cholera)
- Logistics challenges in vaccinating hardest-to-reach populations

Africa-wide immunisation coverage remains below global average, **indicating that saturation has not yet been reached**, even for routine products

Recently scaled products such as Pneumo and Rota are expected to continue to grow, but **at current growth rates, will only reach 80% coverage well beyond 2030**

1. Grown at 3-year historical CAGR, except IPV which reaches 82% coverage in '20 and then assumed to stagnate

# 1: In addition to increased coverage within countries, new country introductions are expected to drive demand for vaccines in Africa

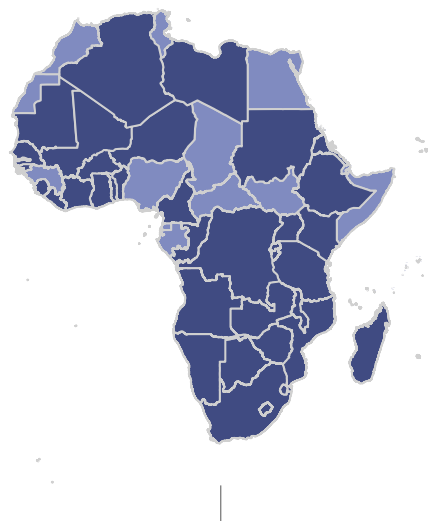
Disease prevalence is low<sup>1</sup>
 Current program in place
  Opportunity to introduce program<sup>2</sup>

## HPV



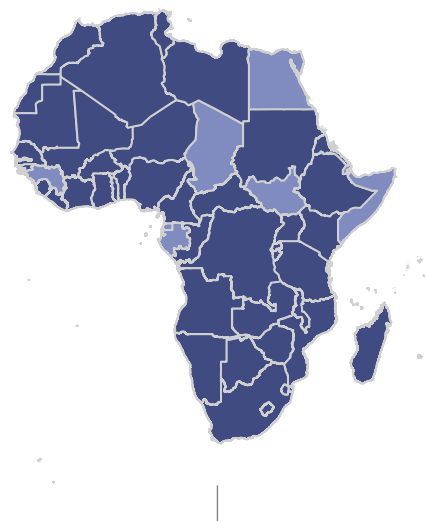
HPV vaccination has been rolled out in 22 African countries, with opportunity to expand coverage to 32 others in the next 10 years, provided sufficient supply is made available. Additional countries<sup>3</sup> are conducting pilots with Gavi support

## Rotavirus



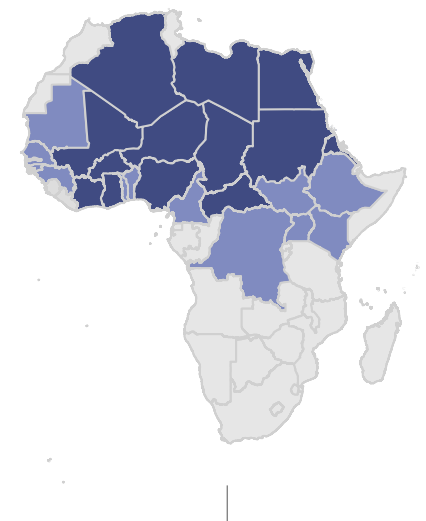
13 countries currently do not have routine Rotavirus programs, but may increasingly see Rotavirus Vx roll-outs given WHO recommendation for all countries to immunise infants against Rotavirus

## Pneumococcal



Gavi's pneumococcal AMC facilitated rapid expansion of pneumococcal vaccine programs across Africa, with only 9 countries not currently rolling out pneumococcal vaccinations

## Meningococcal



Meningococcal outbreaks common in the so-called 'meningitis belt' are largely reduced by the MenAfriVac initiative which has scaled vaccines to 16 countries so far, with only 13 outstanding with some regional prevalence of meningitis

## Takeaways

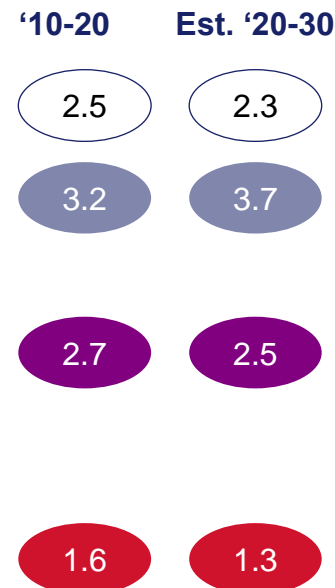
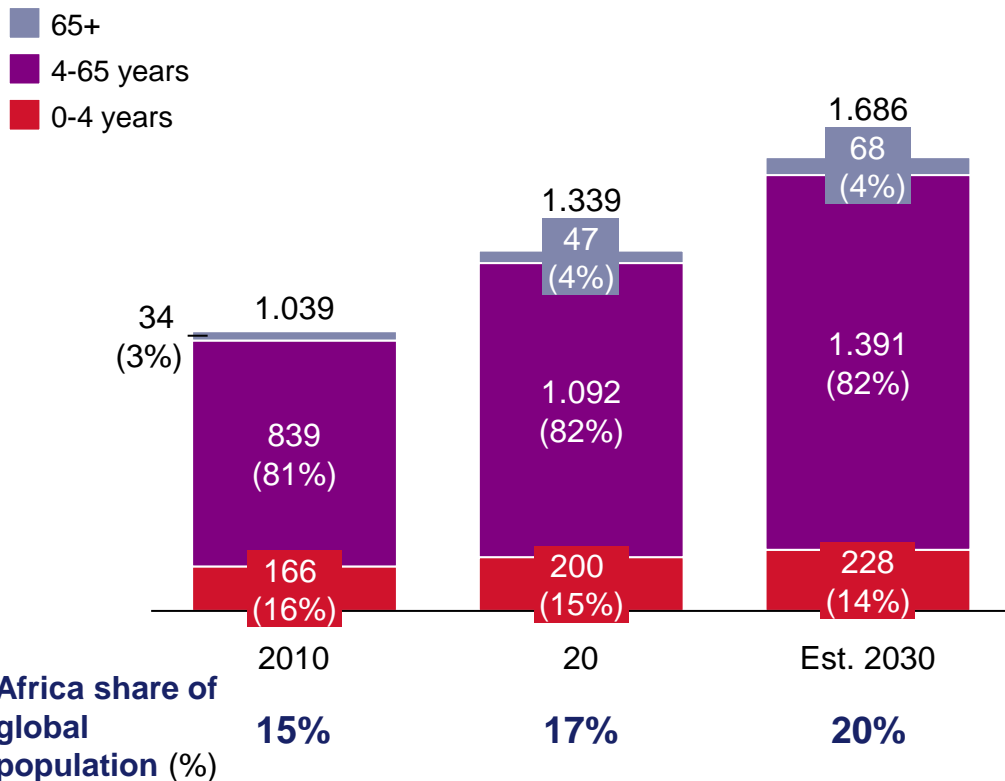
Africa is yet to reach full saturation for vaccine demand given that not all countries have introduced likely immunisation programs - the next 10 years could see largescale growth in HPV and rotavirus vaccines if introductions continue

1. Countries with low prevalence of disease and where routine immunisation is not recommended by WHO
2. Countries where disease is endemic and there is no existing immunisation program
3. E.g., Burkina Faso, Cameroon, Ghana, Madagascar, Niger, Nigeria, Mozambique etc.

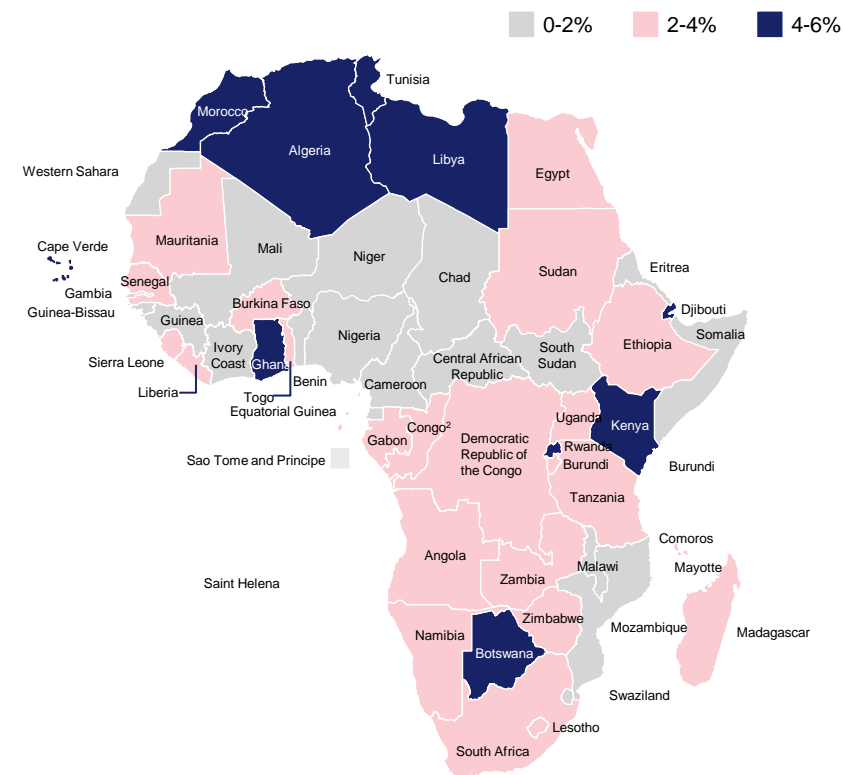
# 2: Africa's share of global population is expected to reach 20% by 2030, with older people (65+) population expected to grow fastest

Population distribution by age group (mn)

10 year CAGR, %



Age dependency growth: difference in growth between oldest and youngest populations



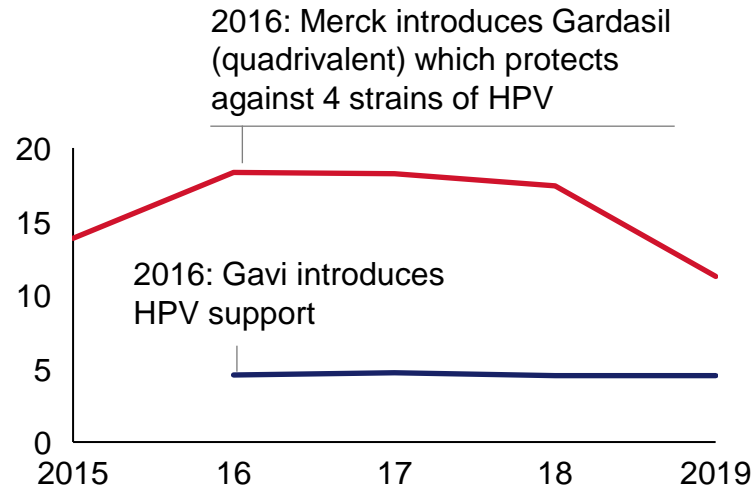
By 2030, Africa is expected to need childhood vaccinations for approx. 230 million children per year (from 0 to 4 years of age)

Vaccines for older people, particularly in North Africa, Ghana, Kenya, and Botswana, may become increasingly important given relatively high expected growth of the elderly

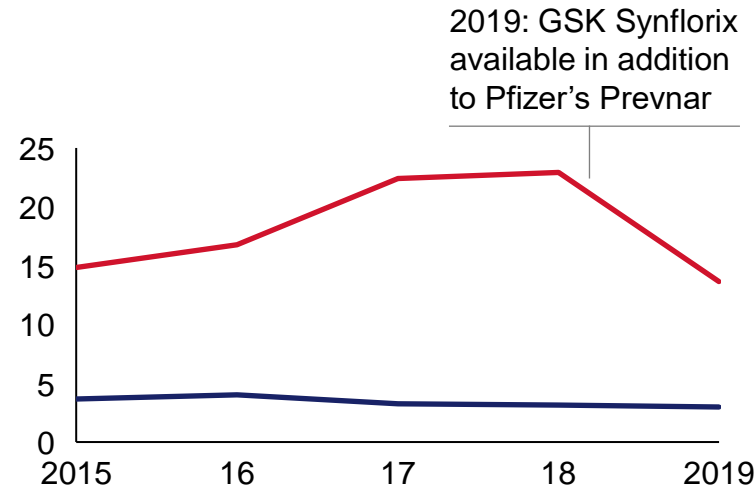
# 3: Self-financing countries typically see prices 2-4 times higher than Gavi countries, and more volatility in price

— Gavi — Self-financing<sup>1</sup>

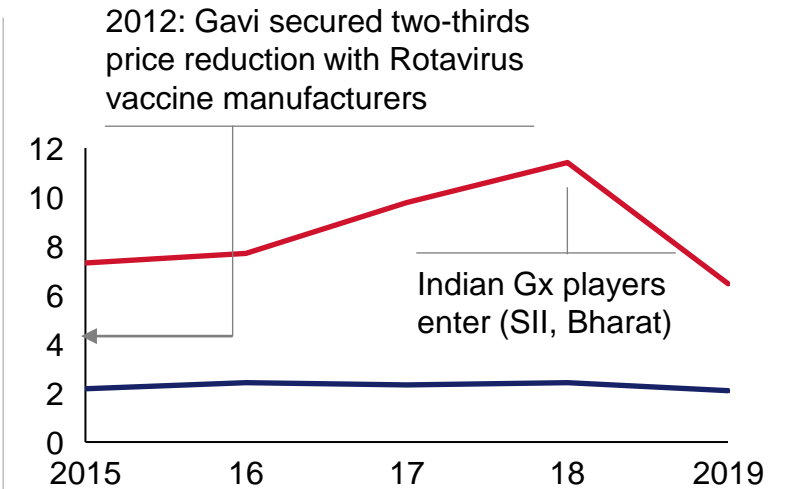
## Human Papillomavirus (HPV)



## Pneumococcal



## Rotavirus



## Greater demand certainty and larger procurement volumes for manufacturers have gone hand-in-hand with price reductions



### “Advance” purchases:

Prepaying a portion of the vaccine supply, allowing manufacturers to recoup their fixed costs earlier



### Mid-term market certainty:

To increase security of demand, manufacturers can enter extended deal periods (up to five years in the case of rotavirus)



### Pooling volumes:

By pooling country volumes together, manufacturers are able to secure large-volume orders, but at a reduced price



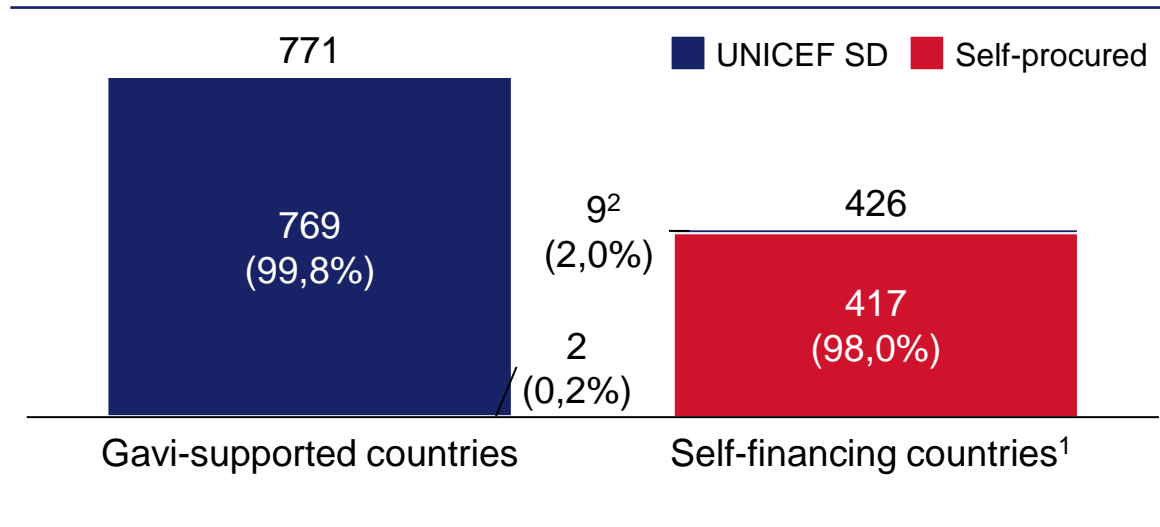
### Long-term view of the market:

Gavi signals viable market to future manufacturers, and therefore encouraging developing country manufacturers to join the market (e.g., SII, Bharat etc.)

1. Never eligible for Gavi support

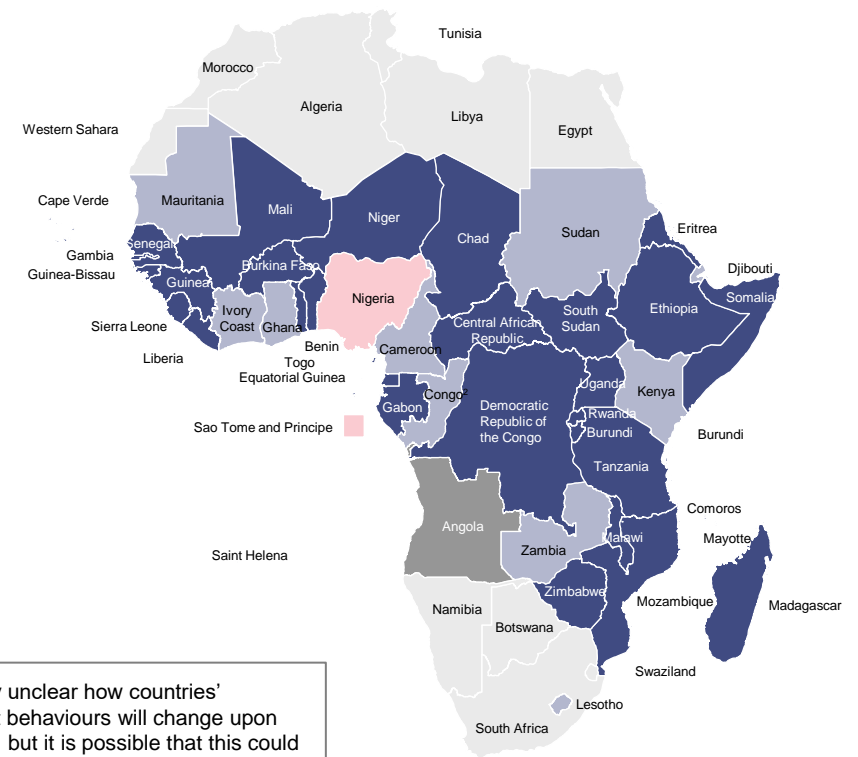
# 4. The share of value procured via UNICEF SD could decline by 2030 from 64% today, as countries open their procurement channels

Total value of vaccines, \$mn 2019



- Gavi-supported countries almost entirely procure through UNICEF SD, which has existing procurement relationships and contracts in place with international suppliers
- Although a small portion of market volumes, self-procured channels represent ~1/3 of the African market (\$419mn in 2019)
- As countries transition from Gavi, they may choose whether to procure via UNICEF or self-procure, suggesting this share could decline

■ Eligible for Gavi support, with no indication of transitioning by 2030<sup>1</sup>  
■ Preparatory transition ■ Accelerated transition<sup>3</sup> ■ Fully self-financed



It is currently unclear how countries' procurement behaviours will change upon transitioning, but it is possible that this could change the share of value procured via UNICEF could reduce, especially if Nigeria shifts procurement channels

1. Morocco, Algeria, Tunisia, Egypt, Namibia, Botswana, South Africa, Mauritius, Equatorial Guinea, eSwatini, Gabon, Libya, Cabo Verde, Seychelles  
 2. Includes: Botswana, Cabo Verde, Equatorial Guinea, eSwatini, Gabon, Morocco & Seychelles

# 4: Within the next 10 years, some African countries could transition from Gavi support, which could impact the Vaccine market in Africa

- Eligible for Gavi support, with no indication of transitioning by 2030<sup>1</sup>
- Preparatory transition<sup>4</sup> ■ Accelerated transition<sup>3</sup> ■ Fully self-financed



**It is currently unclear exactly how Gavi transitioning is expected to impact demand for vaccines and market value**

**It will be important to understand how transitioning countries procure vaccines post-transition:**

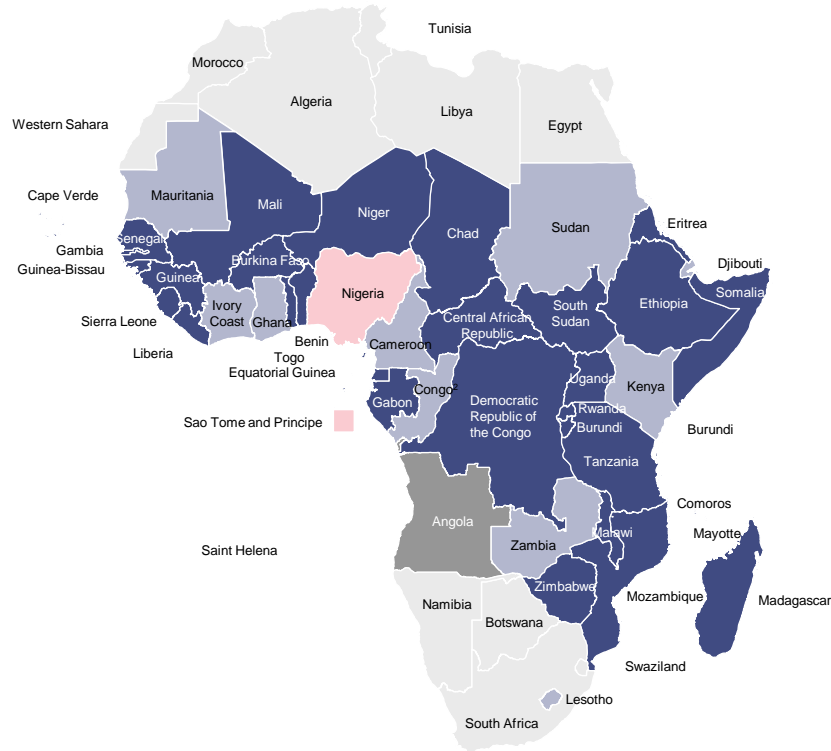
- Maintain procurement via UNICEF SD (maintaining low, Gavi-negotiated pricing)
- Primarily self-procure, which could increase pricing but not necessarily given manufacturer commitments for some products in post-Gavi transition
- Enter into some other pooled procurement (e.g., regional)
- Follow some mix of the above

Country transition remains uncertain given that Gavi's eligibility criteria is dependent on gross national income

**Country choice of procurement channel can have varied impacts on prices and volumes:**

Prices could be driven up if countries no longer leverage UNICEF SD; it is unclear whether this would reduce volumes procured

However, some large manufacturers have made commitments to maintain low prices for transitioning countries, and self-financing countries may choose to form their own procurement pools














































1. Provided 3-year GNI per capita remains below the low-income threshold: US\$ 995 GNI per capita  
2. Congo reached full self-financing status but was reversed in 2019  
3. Status maintained for 5 years before transitioning to fully self-financing  
4. Status could be adjusted based on revised GNI/capita forecasts due to COVID-19 economic impact which would impact when these countries might transition. Countries considered most likely to transition by 2030 include: Nigeria, Sao Tome, Ghana, Kenya and Cote d'Ivoire

# 4: In the past, most countries that have transitioned from Gavi continued procuring Vx via UNICEF SD while also adding other channels

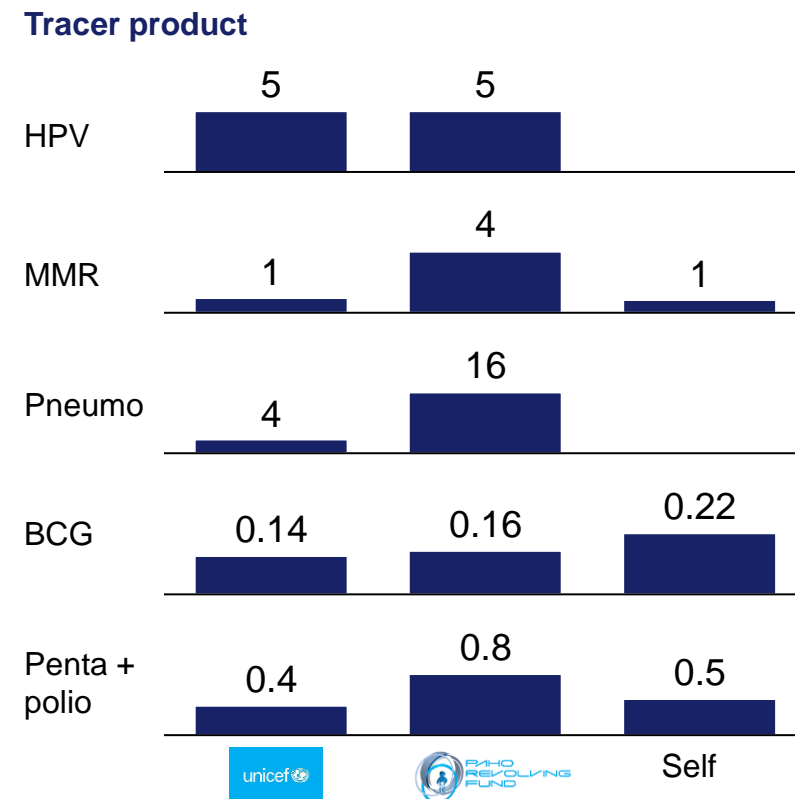
PRELIMINARY

16 countries that have transitioned out of Gavi support

 Primary channel
  Other channel

	Year of graduation	2019 procurement channel			
				Self	Other
 Angola	2018				
 Armenia	2018				
 Azerbaijan	2018				
 Bhutan	2016				
 Bolivia	2018		N/A		
 Cuba	2018				
 Georgia	2019				
 Guyana	2017				
 Honduras	2016		N/A		
 Indonesia	2017				
 Kiribati	2017		N/A		
 Mongolia	2016				
 Moldova	2017				
 Sri Lanka	2016				
 Timor-Leste	2018				
 Vietnam	2019				

Weighted average price by tracer product and channel, \$, 2019 (not to scale)



Indonesia, Sri Lanka and Vietnam have succeeded in successfully securing low-price deals on some routine products with Indian Gx players

# 5: New vaccines are under development, some of which could reach the African market by 2030

NON-EXHAUSTIVE – OTHER PIPELINE CANDIDATES EXIST

Disease	Manufacturer	Phase	Platform	Potential vaccination strategy <sup>1</sup>	Disease burden, % of total DALYs
Malaria	GSK	Phase 3	Virus-like particle	Routine	7.5%
	Novavax/ SII	Phase 2	Recombinant protein		
	University of Oxford	Phase 2	Recombinant viral vector		
	Sanaria	Phase 2	Inactivated whole target organism		
HIV	Janssen Vaccines & Prevention B.V	Phase 3	Recombinant viral vector	Routine, targeted vulnerable populations	6.2%
	Sanofi Pasteur	Phase 3	Recombinant protein		
	GSK	Phase 2	Recombinant protein		
Zika	GeneOne Life Science Inc / Inovio	Phase 1	DNA	Outbreak	N/A
	Themis Bioscience	Phase 1	Recombinant viral vector		
	Takeda	Phase 1	Inactivated		
	Moderna Therapeutics	Phase 2	mRNA		
Lassa fever	Themis Bioscience	Phase 1	Recombinant viral vector	Routine for targeted populations	<0.1%
	Inovio Pharma	Phase 1	dMAb		
Rift Valley Fever	Colorado State University	Preclinical	Live attenuated	Routine for targeted populations	<0.1%
	Wageningen Biovetinary Research	Preclinical	Live attenuated		
Chikungunya	Int. Vaccine Institute and Bharat Biotech	Phase 1	Inactivated	Outbreak	<0.1%
	Themis Bioscience	Phase 3	Live, vectored		
	Valneva	Phase 3	Live, attenuated		
	Emergent BioSolutions	Phase 3	Virus-like particle		
Ebola	GSK	Phase 3	Recombinant viral vector	Outbreak	0.03%
	Janssen	Phase 3	Recombinant viral vector		
	Novavax	Phase 1	Recombinant viral vector		
	Inovio Pharma	Phase 1	DNA		

1. No confirmed strategy as yet as this depends on vaccine efficacy

Source: WHO, PharmaNews, press releases, company websites, IHME

## Takeaways

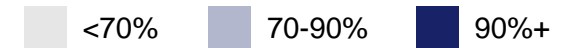
Effective and safe vaccines against malaria and HIV have the **potential to address ~13% of Africa's total disease burden**, and could fundamentally shift Africa's vaccine market if/when commercially available

Despite multiple products in Phase 2/3 clinical trials for malaria and HIV, **it is unclear exactly if/when these products will successfully launch and how rapid** their roll-out can realistically be

Novel vaccines could present interesting opportunities given that many use more **advanced platform technologies not currently scaled** in biosimilars markets



# Today, there are 9.4m un- or under-immunized children in Africa<sup>1</sup> – closing the gap will require millions of additional Vx doses



Coverage <sup>4</sup> % of target pop., 2019	African regions						Select benchmarks				
	West	South- ern	East	North	Central	Total Africa	India	Brazil	UK	US	
Immunisation	BCG	87%	94%	86%	92%	80%	87%	92	79	93	93
	MCV	79%	84%	83%	89%	60%	79%	95	91	91	90
	DTP	82%	87%	85%	91%	64%	81%	91	73	93	94
	Pneumo	82%	80%	88%	89%	65%	82%	15% <sup>2</sup>	84	91	92
	Rota	81%	85%	90%	88%	72%	85%	82	86	90	74
	YFV	75%	-	20%	-	52%	64%	-	60	-	-

Africa presents one the **largest remaining global growth opportunities for vaccine expansion** – in developed countries, immunisation coverage for existing expanded routine immunisation (EPI) products has largely plateaued, but Africa has not yet reached saturation

For non-EPI products, there is opportunity for yet more substantial growth, as products have not yet been rolled out to all relevant countries

“ 19.4 million children worldwide miss out on basic vaccines – approx. half of these are in Africa (9.4m)

**WHO/UNICEF 2019**

1. Based on DTP3 coverage, which is the main proxy for routine immunisation coverage - [https://www.who.int/immunization/monitoring\\_surveillance/who-immuniz.pdf](https://www.who.int/immunization/monitoring_surveillance/who-immuniz.pdf)  
 2. Only recently introduced to routine immunisation in 2018, so still being scaled up  
 3. US and UK no longer include BCG vaccination in routine immunisation schedules due to low rates of tuberculosis infections. Only targeted populations with high TB prevalence receive the BCG vaccine  
 4. Coverage averaged across countries where product has been introduced (e.g., Rota is present in 41/54 countries today)

# Forecasting scenarios: 3 different scenarios have been modelled to estimate 2030 demand (detailed assumptions in the backup)

Ongoing refinement of scenarios and market sizing forecasts as COVID-19 epidemiology evolves; private market size currently being estimated

PRELIMINARY



**Scenario**

**1 Conservative case: High likelihood products**

**2 Mid case: Expanded portfolio with higher prices**

**3 Upside: Full portfolio with higher coverage and prices**

**Group 1: Existing products**

Volumes: Expansion of routine products already in portfolio (increased coverage, new introductions)<sup>5</sup>  
Price: transitioning countries retain Gavi prices

Volumes: Same as scenario 1  
Price: transitioning countries pay LMIC prices

Volumes: Same as scenario 1  
Price: transitioning countries pay LMIC prices

**Group 2: Outbreak vaccines<sup>7</sup>**

Ebola stockpiles (250K doses)

Ebola stockpile (250K doses)  
Rift Valley Fever / Chikungunya<sup>1</sup> (~100K doses)

Ebola stockpile (250K doses)  
Lassa fever (10mn doses)  
RVF/Chik (~250K doses)

**Group 3: Emerging routine<sup>8</sup>**

Malaria introduction  
Covid-19: No routine immunization for COVID-19<sup>4</sup>

Malaria + HIV<sup>2</sup> introduction in countries with >3% prevalence  
Covid-19: 60% coverage of vulnerable population biennially<sup>3</sup>

Malaria + HIV introduction<sup>2</sup> in countries with >10% prevalence + Lassa  
Covid-19: 60% coverage of full population every 10 years – similar to Yellow Fever

**Population**

Population growth at UN assumptions

Same as scenario 1

Same as scenario 1

***These scenarios have been refined with some of your inputs – thank you***

1. Currently in phase 3 trials
2. Two candidates currently in Phase 3 trials but previous candidates have failed in Phase 3, so success of vaccine is unclear
3. Healthcare workers given that booster shots are given regularly
4. Assumes that population becomes immune over time
5. Volume estimates based on Linksbridge GVMM forecasts
6. Assumes a single dose booster
7. Uncertainty exists around which vaccines will be licensed and when, as well as how many doses will be required
8. Some emerging products are not included in the forecast model given limited data

# Overview of vaccine products

## PRELIMINARY

	Vaccine	Complexity Assumption <sup>1</sup>	Avg Prices 2019, \$/dose	Annual Doses, mn		Value, \$ mn		Avg coverage, %, '19	Gavi-supported
				2020	2030 Estimated	2020	2030 Estimated		
Legacy routine	BCG	Lower	0.1	93	120	21	~30	87	
	MMR	Medium	0.6	127	210	107	260-330	79	✓
	Pentavalent <sup>3</sup>	Lower	0.6	273	330	400	250-260	81	✓
	Yellow Fever	Higher	1.2	68	50	102	60-560	64	✓
	OCV	Medium	1.5	44	30	11	30-35	No data	✓
	bOPV	Lower	0.2	193	0	73	0	81	✓
Expanding routine	Flu	Medium	3.3	3	8	8		No data	
	HPV	Higher	4.5-9.8	10	30	84	290-470	No data	✓
	Meningococcal	Higher	1.1	1	1	12	~17	No data	✓
	Pneumococcal	Higher	4.0	84	120	362	550-980	82	✓
	Rota <sup>2</sup>	Medium	2.4	53	110	120	310-420	85	✓
	IPV	Medium	2.3	39	100	100	180	No data	✓
	Hexavalent	Medium	41.0	4	5	173	170-290	No data	
Novel products Hypothesis based on latest available thinking and forecasts	Ebola	Medium	17.0	0.25	0.25	4	4	N/A	✓
	Malaria	High <sup>5</sup>		0.4	67		134	N/A	Some indication <sup>4</sup>
	HIV	High <sup>5</sup>					4	N/A	
	Covid-19	High <sup>5</sup>						N/A	
	Lassa	High <sup>5</sup>						N/A	
	Chikungunya	High <sup>5</sup>						N/A	

1. Literature indication (Plotkin S, Robinson JM, Cunningham G, Iqbal R, Larsen S. The complexity and cost of vaccine manufacturing - An overview. *Vaccine*. 2017;35(33):4064-4071. doi:10.1016/j.vaccine.2017.06.003

2. In 2018, two Indian Gx players supplied rotavirus vaccines to African markets - SII and Bharat

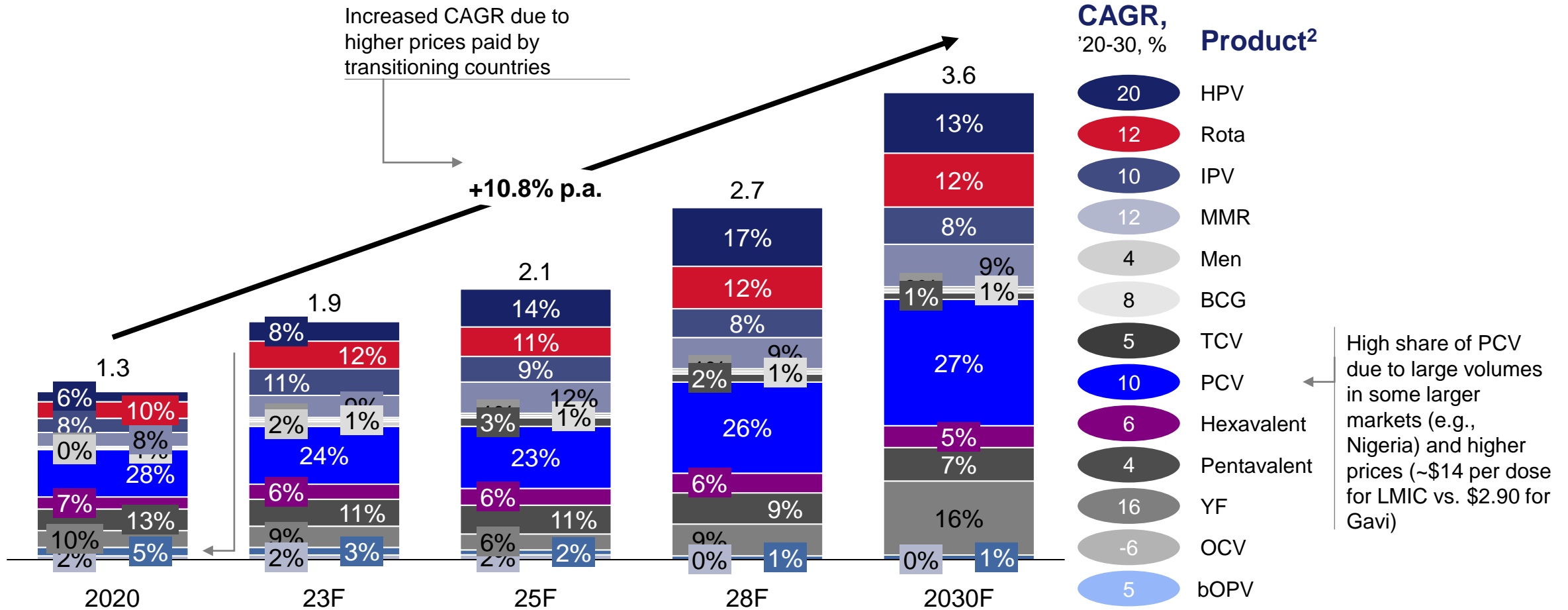
3. Includes multiple products (e.g., DTP, Penta, Pentavalent, HepB etc.), where each individual drug substance has relatively lower complexity; however, producing a tri-, penta-, or hexavalent product is complicated to formulate.

4. Mentioned in Phase 5 strategy as potential opportunity in the next cycle for the Vaccine Investment Strategy (VIS) 5. Platforms still under development

# Medium and upside scenarios product growth estimates for existing products

Estimated vaccine demand (value) for Africa for existing products<sup>1</sup>, USD bn, 2020-2030F

SCENARIO 2/3 (EXCLUDES ALL NOVEL PRODUCTS)<sup>3</sup>



1. Emerging products (e.g., COVID-19, outbreak, novel routine) excluded here due to high levels of uncertainty in demand forecasting

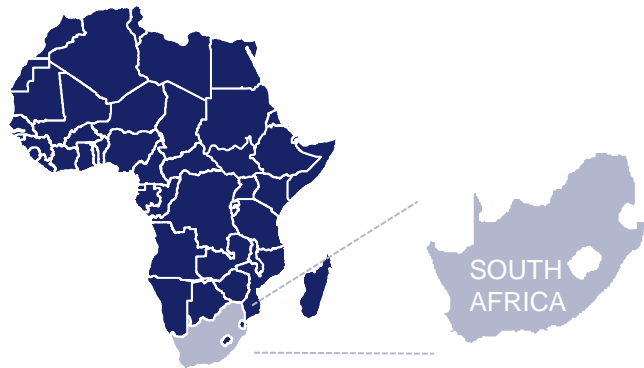
2. HPV: Human Papillomavirus, IPV: Inactivated Polio vaccine, MMR: Measles, mumps and rubella, Men: Meningitis, PCV: Pneumococcal conjugate vaccine, Hexavalent: DTP, Hib, HepB and IPV, Pentavalent: DTP, Hib, HepB, YF: Yellow Fever, OCV: Oral cholera vaccine, OPV: Oral polio vaccine, TCV: Typhoid conjugate vaccine 3. In scenario 2, transitioning countries are pay LMIC tier prices. Only existing products modelled annually given uncertainty around novel product authorisation dates

# Model viability will be enhanced with commitments from public, social, and private stakeholders

HIGHLY PRELIMINARY AND NON EXHAUSTIVE

	 <b>1 Downstream model</b>	 <b>2 Expanding Routine model</b>	 <b>3 Platform Leapfrog model</b>	 <b>4 Adjacency model</b>	 <b>5 Outbreak model</b>
<b>Model viability criteria:</b>	<p><b>DCVM/MNC agreement to offload</b> downstream value chain steps to African players</p> <p><b>Successful regional harmonisation and coordination</b> to enable easier downstream labeling and distribution logistics</p> <p><b>Ability to secure raw materials at competitive prices</b>, given low margins of downstream activities</p>	<p><b>Remaining supply gaps</b> even after DCVMs scale these products</p> <p><b>Procurer commitment to paying slightly higher prices</b> to secure a local value chain vs. traditional procurement from established, foreign players</p> <p><b>Investors/manufacturers willingness to accept slightly lower margins</b> than established suppliers in order to compete on retail price</p>	<p><b>Novel technologies prove relevant</b> in Africa</p> <p><b>Ability to access technology transfer</b> for novel products</p> <p><b>Remaining supply gaps</b> for emerging platform vaccines even after global manufacturers scale-up to produce COVID-19 Vx, or <b>ability to be cost competitive with global producers</b> given advantageous small-scale production economies for novel platforms</p>	<p><b>Business case for adjacent products is significantly better than for Vx</b>, attracting investment faster than would the Vx market</p> <p><b>Adjacent product manufacturers are interested in expanding or shifting to Vx production</b> over time</p> <p><b>Enablers developed have relevant synergies for Vx</b> (e.g., regulatory strengthening, skill-building, and logistics), making the transition easier and more attractive over time</p>	<p><b>Procurer commitment to annual stockpile replenishment</b> to develop demand certainty for niche outbreak products</p> <p><b>Ability to access technology transfer</b> for novel products</p> <p><b>Ability to leverage platform synergies</b> to produce multiple products on the same line or with rapid transitions to maximize facility utilization</p> <p><b>Attractiveness of mixed-product models (esp. mAbs)</b> to private investors, attracting added funding</p>
<b>Commitments that could improve viability:</b>	<p><b>Continued investment in infrastructure and logistics enablers</b> from donors/ODA, DFIs and national governments</p> <p><b>Continued national, regional, and continental championing of harmonisation efforts</b>, and countries buy-in</p> <p><b>Productive DCVMs engagement</b> to ensure continued supply of drug product</p>	<p><b>Offtake commitments, potentially through regional consolidation / co-ordination</b> (e.g., pooled procurement) to improve economies of scale and offtake certainty</p> <p><b>De-risked or lower cost of capital investment</b> from donors, DFIs, to provide longer-term capital with lower return requirements</p>	<p><b>Incentives for tech-transfers from developers</b> for new, Africa-specific products, potentially from donors</p>	<p><b>Continued investment in regulatory enablers</b> from donors/ODA and national governments</p> <p><b>Commitment to transition to Vx over time</b> from manufacturers of adjacent products</p>	<p><b>Incentives for tech-transfers from developers</b> for new, Africa-specific products, potentially from donors</p> <p><b>Annual procurement commitment</b> by Gavi irrespective of stockpile drawdown</p>

# South Africa: Vaccines market estimated to be worth ~\$520-540mn in 2030, with an established supplier and recent announcement for second underway



## Overview of SA macroeconomic fundamentals

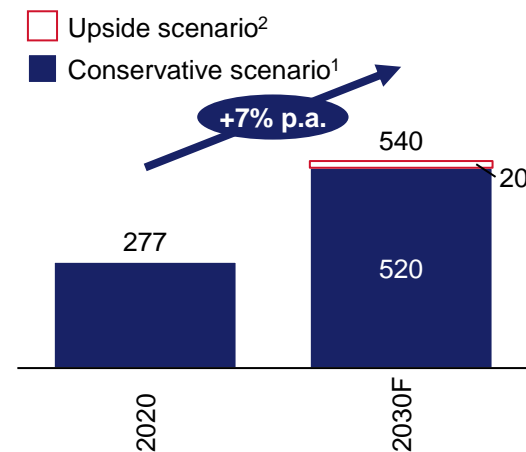
<b>Population</b>	Total population (2019)	: 58M
	Population growth rate (2019)	: 1.3%
<b>Economics (2019)</b>	Total GDP	: \$350B
	GDP growth rate	: 0.15%
	GDP/capita (current \$)	: \$6000
	Gini coefficient (2017)	: 0.69
	WB country classification	: UMIC
	Exports of goods and services	: \$105B
<b>Health</b>	Health spend/capita (2018)	: \$525
	Health spend/GDP (2018)	: 8.2%
	Private health expenditure (2018)	: 44%
<b>Local pharma market</b>	Pharma market size (2019)	: \$3B
	Development stage	: Established
	Regulatory body	: SAHPRA

## Overview of SA vaccines enabling environment

South Africa has historically led much of Africa's vaccine production through its PPP with Biovac, which currently manufactures several products (BCG, Measles, Pneumococcal, Hexavalent, DTP, Polio, Hib and HepB)

- **Regulatory:** SA is an active member of Zazibona, with potential for current market authorization joint assessment processes to expand to vaccines in the near future. NRA is not yet WHO ML3 certified, but is in active discussions with WHO for benchmarking in the near term
- **Procurement:** Established government bilateral procurement experience; incentives for local manufacturing in tender processes (e.g., for specific vaccines a technology transfer is required to apply to the tender) and government has committed to a domestic procurement premium in the past (although not consistently)
- **Government participation:** SA government has partial ownership of the Biovac institute (PPP) which has enabled early manufacturing of vaccines

## Expected vaccines demand in SA (2020-30F), US\$ million



## Current local manufacturing landscape

### Current Vx manufacturing landscape:

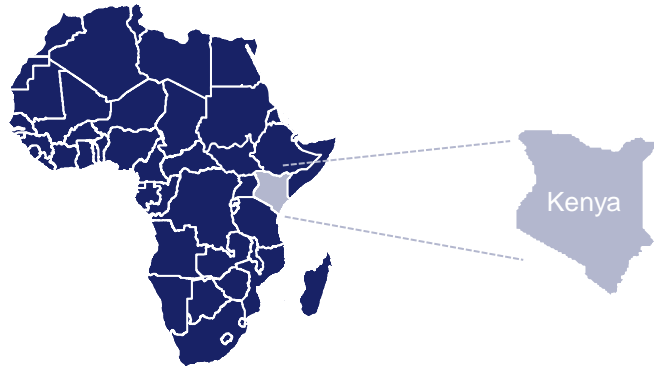
- **Biovac:** Vaccine filling capacity ~30 mn doses p.a. with 2 filling lines, packaging capacity can be ramped up according to specific needs
- **Aspen:** Large-scale sterile filling capacity with some available capacity depending on order situation of pharma clients, recent announcement of tech transfer for fill and finish of J&J COVID-19 vaccine
- Recent announcement (July 2020) made by Ministry of Higher Education, Science, and Technology to build COVID-19 vaccine plant through public-private collaboration

### Vx-related manufacturing landscape:

- Strong existing sterile injectables plants (PharmaQ, Aspen, etc.) and animal Vx players

1. Conservative case: High likelihood products (no COVID-19, transitioning countries pay Gavi-country prices) 2. Upside: Full portfolio with higher coverage and prices (COVID-19, HIV, outbreak stockpiles for Lassa and RVF/Chikungunya)

# Kenya: Vaccines market could grow substantially by 2030, depending on Gavi transition; no Vx mfg today, but strong ties with MNCs



## Overview of Kenya's macroeconomic fundamentals

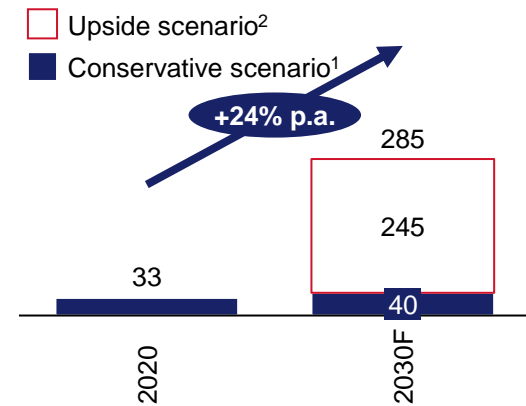
<b>Population</b>	Total population (2018)	: 53M
	Population growth rate (2018)	: 2%
<b>Economics (2019)</b>	Total GDP	: \$95B
	GDP growth rate	: 5.4%
	GDP/capita (current \$)	: \$1816
	Gini coefficient (2017)	: 0.41
	WB country classification	: LMIC
	Exports of goods and services	: \$12B
<b>Health</b>	Health spend/capita (2018)	: \$88
	Health spend/GDP (2018)	: 5%
	Private health expenditure (2018)	: 42%
<b>Local pharma market</b>	Pharma market size (2019)	: 1,180M
	Development stage	: Growing
	Regulatory body	: PPB

## Overview of Kenyan vaccines enabling environment

Kenya does not currently have any vaccine manufacturing capabilities, but has a strong local pharmaceutical manufacturing sector which has enabled it to develop ties with global MNCs

- **Regulatory:** Working towards ML3; expected to achieve in medium term. PPB has a strong biologics unit with vaccines expertise and is a Regional Center of Regulatory Excellence in pharmacovigilance
- **Demand:** Moderate domestic market currently Gavi-financed, but may transition to self-financing before 2030. Member of the EAC trading bloc, which supports regional trade
- **Government participation:** Kenya's Big Four Agenda promotes increasing local pharmaceuticals manufacturing
- **Talent:** Some expertise in biologics and animal Vx manufacturing and sizeable, highly skilled workforce in-country and in the diaspora

## Expected vaccines demand in Kenya (2020-30F), US\$ million



Post-Gavi price tier is a major driver of 2030 market value uncertainty (i.e., will Kenya retain Gavi pricing or typical LMIC pricing?), as well as uncertainty around future demand for novel vaccines

## Current local manufacturing landscape

### Current Vx manufacturing landscape:

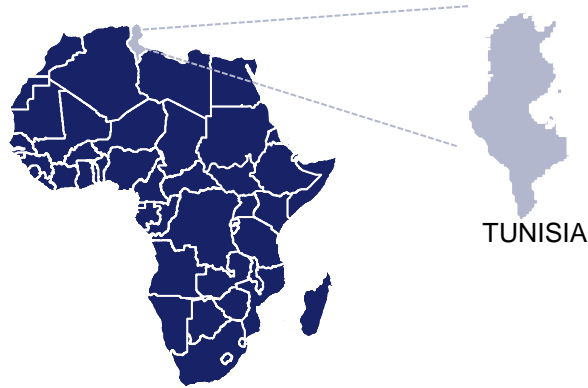
- N/A; some MNCs appear to have interest in exploring

### Vx-related manufacturing landscape:

- Animal Vx players (e.g., Kenya Veterinary Vaccines Production Institute) as well as limited sterile filling capabilities (5 companies)

1. Conservative case: High likelihood products (no COVID-19, transitioning countries pay Gavi-country prices) 2. Upside: Full portfolio with higher coverage and prices (COVID-19, HIV, outbreak stockpiles for Lassa and RVF/Chikungunya)

# Tunisia: Vaccines market estimated to remain small, worth ~\$15-20mn by 2030; one existing manufacturer producing BCG vaccine in low quantities



## Overview of Tunisian macroeconomic fundamentals

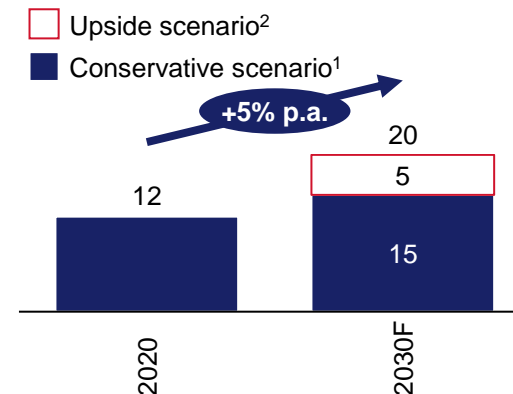
<b>Population</b>	Total population (2019)	: 12M
	Population growth rate (2019)	: 1.1%
<b>Economics (2019)</b>	Total GDP	: \$38.8B
	GDP growth rate	: 1%
	GDP/capita (current \$)	: \$3 317
	Gini coefficient (2017)	: 0.33
	WB country classification	: LMIC
	Exports of goods and services	: \$19B
<b>Health</b>	Health spend/capita (2018)	: \$252
	Health spend/GDP (2018)	: 7.3%
	Private health expenditure (2018)	: 42%
<b>Local pharma market</b>	Pharma market size (2019)	: \$770M
	Development stage	: Growing
	Regulatory body	: DPM

## Overview of Tunisian vaccines enabling environment

Tunisia's experience in vaccine manufacturing is limited to the Institut Pasteur, which manufactures BCG Vx in very small quantities, but there are some adjacent experience and fill/finish capacity for sterile injectables

- **Regulatory:** Perceived by local companies to be transparent but under-resourced. Appears that there are no existing plan to apply for ML3 certification of the regulator. However, NRA is connected to FDA and EMA due to existing PharmaCo landscape. Generally, limited activity around regional regulatory harmonization in North Africa
- **Demand:** Self-financed country but local demand expected to be remain small with limited economies of scale for the local market alone, requiring export market; local companies have experience exporting to Europe, but there is limited regional procurement coordination in North Africa
- **Government participation:** Tunisian Government perceived as enthusiastic about local Vx, as they have seen fiscal incentives from MNCs
- **Talent:** Existing relationships with EU for talent exchange programs and experienced scientist available at IPT that could be involved

## Expected vaccines demand in Tunisia (2020-30F), US\$ million



## Current local manufacturing landscape

### Current Vx manufacturing landscape:

- **Institute Pasteur de Tunis:** has drug substance manufacturing and filling capacity for very small quantities (~<5 mn doses) of BCG vaccine and appears to have interest in supporting expanded private sector (e.g., through a PPP or scientific support); however, experience seems concentrated in single Vx product with older equipment
- Potential production of COVID-19 in cooperation with Chinese and Russian Pharmacos announced after clinical trials

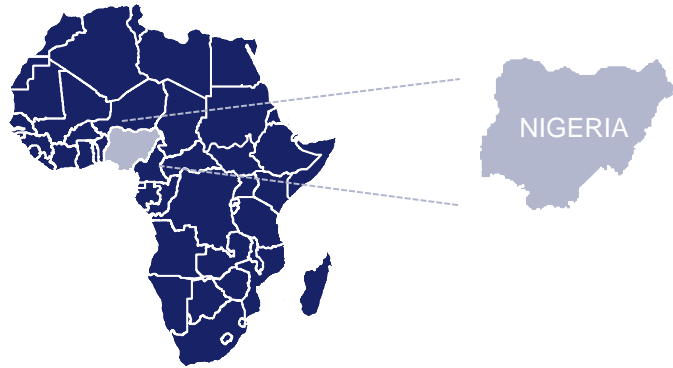
### Vx-related manufacturing landscape:

- ~7 companies producing injectables, 3 of which include biologics

1. Conservative case: High likelihood products (no COVID-19, transitioning countries pay Gavi-country prices) 2. Upside: Full portfolio with higher coverage and prices (COVID-19, HIV, outbreak stockpiles for Lassa and RVF/Chikungunya)



# Nigeria: Vaccines market expected to be large (or very large) by 2030, depending on Gavi transition; no active Vx mfg today, but multiple plans



## Overview of Nigerian macroeconomic fundamentals

<b>Population</b>	Total population (2019)	: 210M
	Population growth rate (2019)	: 3%
<b>Economics (2019)</b>	Total GDP	: \$450B
	GDP growth rate	: 2.2%
	GDP/capita (current \$)	: \$2 229
	Gini coefficient (2017)	: 0.39
	WB country classification	: LMIC
	Exports of goods and services	: \$64B
<b>Health</b>	Health spend/capita (2018)	: \$74
	Health spend/GDP (2018)	: 3%
	Private health expenditure (2018)	: 77%
<b>Local pharma market</b>	Pharma market size (2019)	: \$600M-1B
	Development stage	: Nascent
	Regulatory body	: NAFDAC

1. National Agency for Food and Drug Administration and Control

2. Federal Government of Nigeria

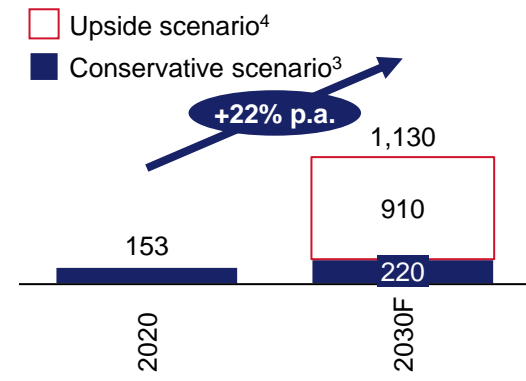
3. Conservative case: High likelihood products (no COVID-19, transitioning countries pay Gavi-country prices) 4. Upside: Full portfolio with higher coverage and prices (COVID-19, HIV, outbreak stockpiles for Lassa and RVF/Chikungunya)

## Overview of Nigerian vaccines enabling environment

Nigeria historically manufactured a number of vaccine products, and is looking to revive the industry leveraging PPPs and private sector investment

- **Regulatory:** NAFDAC<sup>1</sup> is currently working towards ML3 status. The regulator also has a biologics and vaccine sub-unit and is a Regional Center of Regulatory Excellence in quality control
- **Demand:** Currently Gavi-financed but expected to transition in the next 5 years. Nigeria is the largest domestic market in Africa by volume and member of ECOWAS regional bloc
- **Government participation:** Relatively strong government support and established innovative financing partnerships with international vaccine producers
- **Talent:** Limited existing Vx manufacturing expertise on the ground, but there is a sizeable, highly educated diaspora and favorable policies for hiring foreign expertise

## Expected vaccines demand in Nigeria (2020-30F), US\$ million



Major drivers of 2030 market value uncertainty are: Post-Gavi price tier (i.e., will Nigeria retain Gavi pricing or typical LMIC pricing?) and novel Vx demand (large pop.)

## Current local manufacturing landscape

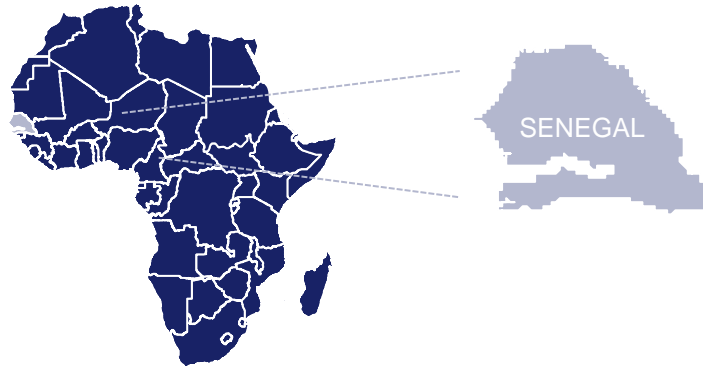
### Current Vx manufacturing landscape:

- **Biovaccines:** PPP between May & Baker and Govt. of Nigeria, with plans to produce a range of EPI products. Biovaccines recently signed an MOU for market access to manufacture and sell COVID-19 vaccines
- **Innovative Biotech:** Focused on R&D steps to produce an HIV vaccine candidate, with no manufacturing capacity today. Aspiration to develop manufacturing capacity for expanding routine products, with some MNC/DCVM partnerships discussed

### Vx-related manufacturing landscape:

- ~11 companies producing injectables and 1 company focusing on animal Vx

# Senegal: Vaccines market expected to be small (~\$15-25mn) by 2030; has a single WHO prequalified manufacturer with plans to expand capacity



## Overview of Senegalese macroeconomic fundamentals

<b>Population</b>	Total population (2018)	: 16M
	Population growth rate (2018)	: 2.8%
<b>Economics (2019)</b>	Total GDP	: \$24B
	GDP growth rate	: 25.2% <sup>2</sup>
	GDP/capita (current \$)	: \$1 446
	Gini coefficient (2017)	: 0.4
	WB country classification	: LMIC
	Exports of goods and services	: \$5.3B
<b>Health</b>	Health spend/capita (2018)	: \$58
	Health spend/GDP (2018)	: 4%
	Private health expenditure (2018)	: 62%
<b>Local pharma market</b>	Pharma market size (2019)	: \$216M
	Development stage	: Nascent
	Regulatory body	: DPM

1. Conservative case: High likelihood products (no COVID-19, transitioning countries pay Gavi-country prices) and prices (COVID-19, HIV, outbreak stockpiles for Lassa and RVF/Chikungunya)  
 2. Upside: Full portfolio with higher coverage and prices (COVID-19, HIV, outbreak stockpiles for Lassa and RVF/Chikungunya)  
 2. Large fluctuations in GDP growth seen annually

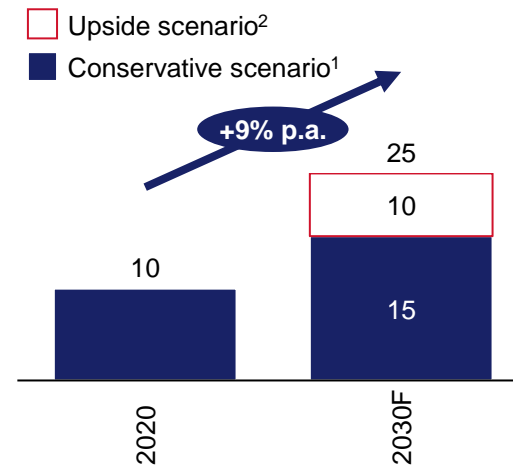
Source: MI4A, Linksbridge GVM, World Bank, BMI, expert interviews, press search

## Overview of Senegalese vaccines enabling environment

Senegal has a single vaccines manufacturer, the Institut Pasteur Dakar, which is the only WHO PQ'd vaccines manufacturer in Africa. IPD has been manufacturing vaccines for 80 years in Senegal

- **Regulatory:** Senegal produces the only WHO PQ-ed product (Yellow Fever, from Institut Pasteur Dakar); however the regulator is not yet ML3 certified, but is currently working towards it. The regulator has a vaccines and microbiology unit
- **Demand:** Gavi-financed country (not expected to transition in the next decade) with small domestic market but advanced regional trade within ECOWAS region and neighboring Francophone countries (e.g., Cameroon, Cote d'Ivoire)
- **Government participation:** TBC
- **Talent:** Existing relationships with EU for talent exchange programs and experienced scientist available at IPT that could be involved. Potential to build vaccine knowledge alongside potential Institute Pasteur facility ramp up. There are favorable policies for hiring foreign expertise

## Expected vaccines demand in Senegal (2020-30F), US\$ million



## Current local manufacturing landscape

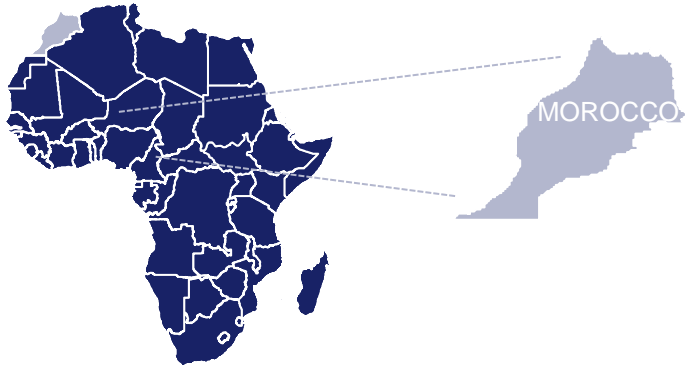
### Current Vx manufacturing landscape:

- **Institut Pasteur de Dakar** manufactures small quantities of WHO PQ'd egg-based Yellow Fever vaccines (~5 mn doses p.a.), with plans initiated to expand capacity through development of a new plant (~30 mn doses p.a.) with some interest in expanding to other products

### Vx-related manufacturing landscape:

- Limited adjacent and sterile filling capabilities (~3 companies)

# Morocco: Vaccines market forecasted to ~\$120-140mn USD by 2030; limited current Vx mfg but plans to expand capacity to supply COVID-19 vaccines



## Overview of Moroccan macroeconomic fundamentals

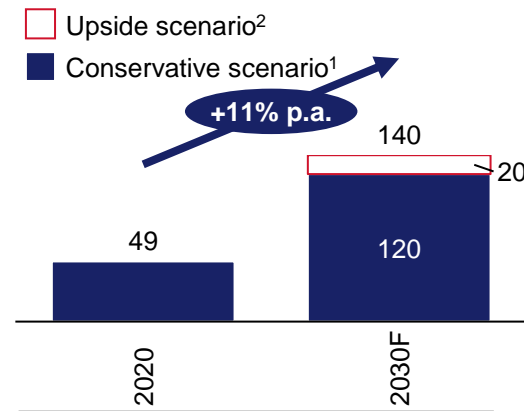
<b>Population</b>	Total population (2018)	: 36M
	Population growth rate (2018)	: 1.3%
<b>Economics (2019)</b>	Total GDP	: \$119B
	GDP growth rate	: 2.5%
	GDP/capita (current \$)	: \$3 204
	Gini coefficient (2017)	: 0.4
	WB country classification	: LMIC
	Exports of goods and services	: \$47B
<b>Health</b>	Health spend/capita (2018)	: \$175
	Health spend/GDP (2018)	: 5%
	Private health expenditure (2018)	: 60%
<b>Local pharma market</b>	Pharma market size (2019)	: \$1.8B
	Development stage	: Established
	Regulatory body	: DMP

## Overview of Moroccan vaccines enabling environment

Morocco has a large local pharmaceutical manufacturing industry. The government, via their vaccine importer/distributor Institut Pasteur Morocco, has signaled interest in expanded vaccine production recently

- **Regulatory:** Morocco's NRA does not appear to have plans to initiate WHO benchmarking towards ML3, but is familiar with processes of other stringent regulatory authorities (e.g., EMA, FDA)
- **Demand:** Self-financed country but local demand expected to remain small with limited economies of scale for the local market alone, requiring export market; local companies have experience exporting to Europe, but there is limited regional procurement coordination in North Africa
- **Government participation:** Favorable industrial policies with SEZs and incentives that promote local production of pharmaceuticals
- **Talent:** Availability of some pharma talent given presence of MNCs for general pharma manufacturing

## Expected vaccines demand in Morocco (2020-30F), US\$ million



High growth explained by planned introductions of pneumococcal, rota and HPV

## Current local manufacturing landscape

### Current Vx manufacturing landscape:

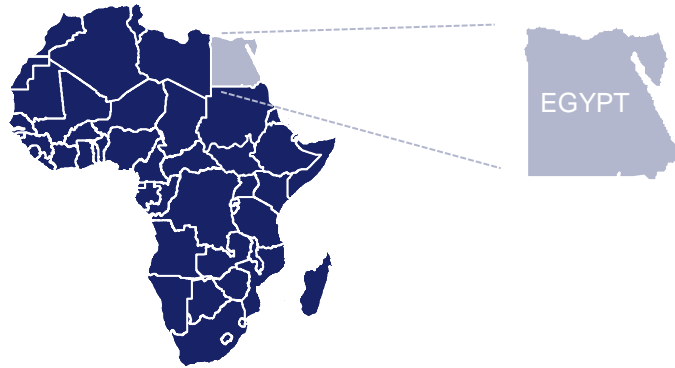
- **Institut Pasteur Du Maroc:** Currently manages import and distribution steps across a variety of products but appears to have interest in supporting expanded domestic manufacturing in collaboration with private sector players (e.g., via a PPP)
- Recent agreement would allow Morocco to produce COVID-19 vaccine of China National Biotec Group (CNBG) after successful domestic clinical trials

### Vx-related manufacturing landscape:

- ~6 companies with sterile filling capabilities (e.g. Sopharma), some with FDA and EMA certification and adjacent capabilities (mAbs production) and limited animal Vx players

1. Conservative case: High likelihood products (no COVID-19, transitioning countries pay Gavi-country prices) 2. Upside: Full portfolio with higher coverage and prices (COVID-19, HIV, outbreak stockpiles for Lassa and RVF/Chikungunya)

# Egypt: Market expected to grow significantly by 2030; established co. Vacsera has focused on downstream production; Egypt plans to add COVID-19 mfg.



## Overview of Egypt's macroeconomic fundamentals

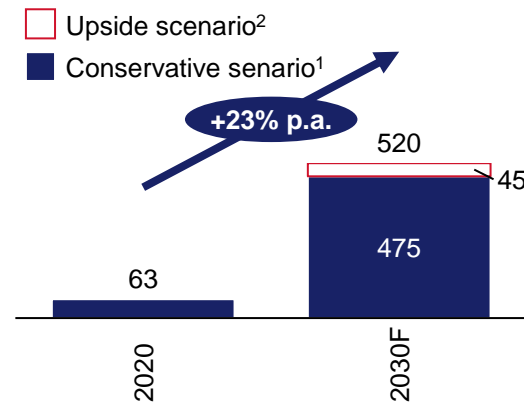
<b>Population</b>	Total population (2018)	: 100M
	Population growth rate (2018)	: 2%
<b>Economics (2019)</b>	Total GDP	: \$303B
	GDP growth rate	: 5.6%
	GDP/capita (current \$)	: \$3019
	Gini coefficient (2017)	: 0.32
	WB country classification	: LMIC
	Exports of goods and services	: \$53B
<b>Health</b>	Health spend/capita (2018)	: \$126
	Health spend/GDP (2018)	: 5%
	Private health expenditure (2018)	: 71%
<b>Local pharma market</b>	Pharma market size (2019)	: 5B
	Development stage	: Established
	Regulatory body	: EDA

## Overview of Egyptian vaccines enabling environment

Egypt has a long-established existing vaccine manufacturer

- **Regulatory:** No existing plans to conduct WHO benchmarking, but currently in discussions with WHO to engage in benchmarking in the near-term
- **Demand:** Self-financed country. Has relatively weak harmonization between the North African region, but potential export opportunities in Middle East
- **Government participation:** Fiscal incentives provided in special economic zones to support pharmaceutical manufacturing
- **Talent:** Some local manufacturing expertise on fill/finish and packaging, policies for hiring foreign expertise are also favorable

## Expected vaccines demand in Egypt (2020-30F), US\$ million



High growth explained by planned introductions of pneumococcal, rota and HPV

## Current local manufacturing landscape

### Current Vx manufacturing landscape:

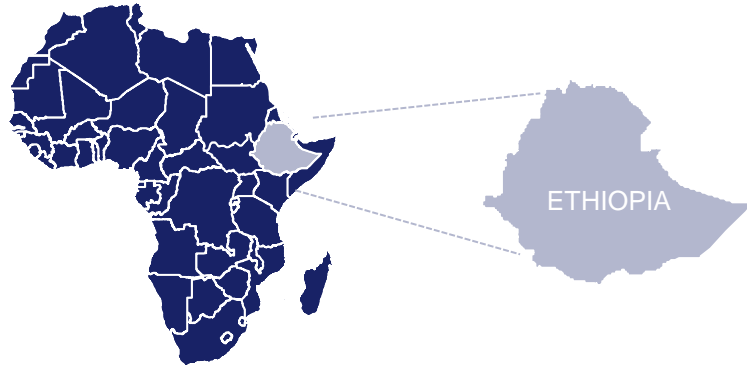
- **Vacsera:** Focused on downstream (fill/finish and package/label) steps across ~5 products; Vacsera is government-owned
- **Egypt's Health Ministry:** Announced coronavirus vaccine manufacturing in cooperation with the Chinese government

### Vx-related manufacturing landscape:

- Sterile filling capabilities available (~18 companies) including adjacent mAbs production, as well as ~4 animal Vx players

1. Conservative case: High likelihood products (no COVID-19, transitioning countries pay Gavi-country prices) 2. Upside: Full portfolio with higher coverage and prices (COVID-19, HIV, outbreak stockpiles for Lassa and RVF/Chikungunya)

# Ethiopia: No existing Vx manufacturing activities exist today, but strong governmental support for pharmaceutical manufacturing in place



## Overview of Ethiopia's macroeconomic fundamentals

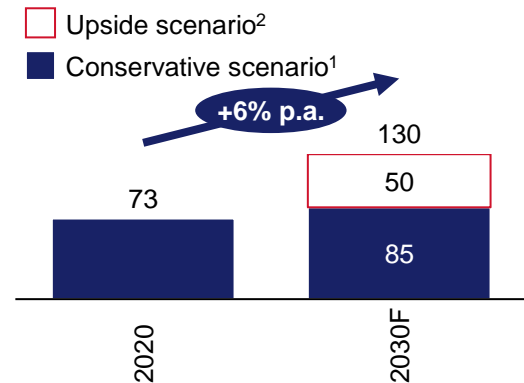
<b>Population</b>	Total population (2018)	: 112M
	Population growth rate (2018)	: 2.7%
<b>Economics (2019)</b>	Total GDP	: \$96B
	GDP growth rate	: 8.3%
	GDP/capita (current \$)	: \$855
	Gini coefficient (2017)	: 0.37
	WB country classification	: LIC
	Exports of goods and services	: \$8B
<b>Health</b>	Health spend/capita (2018)	: \$24
	Health spend/GDP (2018)	: 4%
	Private health expenditure (2018)	: 53%
<b>Local pharma market</b>	Pharma market size (2019)	: 450M
	Development stage	: Nascent
	Regulatory body	: EFDA

## Overview of Ethiopian vaccines enabling environment

Ethiopia has a nascent but developing local pharmaceutical sector, driven largely by promotional policies and financial incentives to support the industry.

- **Regulatory:** EFDA is not yet ML3 certified but is beginning work towards it
- **Demand:** Second largest domestic market in Africa by volume, but not currently integrated into the EAC regional economic community. Currently Gavi-financed and not expected to transition in the decade
- **Government participation:** Strong government support for pharmaceutical manufacturing with aspirations to transform the sector into a GMP-compliant, competitive, and innovative industry that meets the national needs of essential medicines through local production by 2025. There are also favorable incentives provided in SEZs support pharmaceutical manufacturing
- **Talent:** Opportunities to develop industrial talent in the new Kilinto pharmaceutical industrial park, some skilled diaspora

## Expected vaccines demand in Ethiopia (2020-30F), US\$ million



Major driver of 2030 market value uncertainty is COVID-19 value (given large population)

## Current local manufacturing landscape

### Current Vx manufacturing landscape:

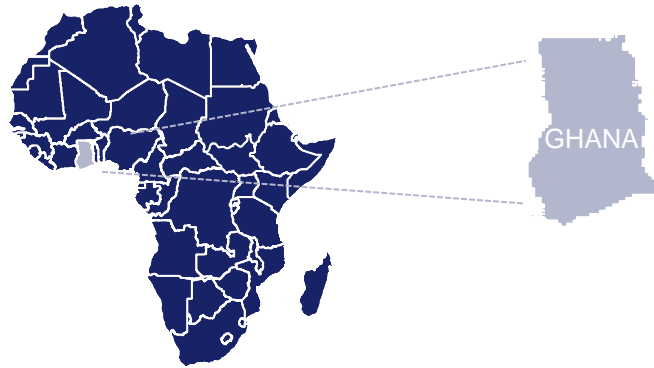
- **Ethiopian Public Health Institute:** Production of Rabies with existing plans to produce other vaccines but portfolio is not yet announced

### Vx-related manufacturing landscape:

- ~1 sterile filling plant and ~1 animal Vx player

1. Conservative case: High likelihood products (no COVID-19, transitioning countries pay Gavi-country prices) 2. Upside: Full portfolio with higher coverage and prices (COVID-19, HIV, outbreak stockpiles for Lassa and RVF/Chikungunya)

# Ghana: Market may grow significantly depending on post-Gavi transition behavior; high-quality regulator but no Vx manufacturing activity yet



## Overview of Ghana's macroeconomic fundamentals

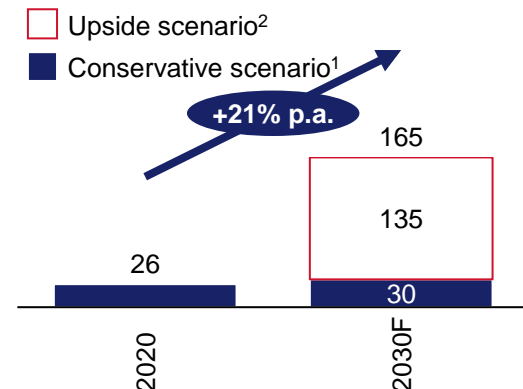
<b>Population</b>	Total population (2018)	: 30M
	Population growth rate (2018)	: 2%
<b>Economics (2019)</b>	Total GDP	: \$67B
	GDP growth rate	: 6.5%
	GDP/capita (current \$)	: \$2202
	Gini coefficient (2017)	: 0.44
	WB country classification	: LIC
	Exports of goods and services	: \$12B
<b>Health</b>	Health spend/capita (2018)	: \$78
	Health spend/GDP (2018)	: 3%
	Private health expenditure (2018)	: 49%
<b>Local pharma market</b>	Pharma market size (2019)	: 400-620M
	Development stage	: Growing
	Regulatory body	: Ghana FDA

## Overview of Ghanaian vaccines enabling environment

Ghana has a small but relatively well-established pharmaceutical manufacturing sector dominated by 2-3 key players. There have been recent successful efforts to strengthen the national regulatory capacity and the President has shown enthusiasm about Vx manufacturing (currently leading regional Vx manufacturing task force)

- **Regulatory:** One of two FDAs on the continent to have achieved ML3 certification and a Regional Center of Regulatory Excellence in pharmacovigilance and clinical trials
- **Demand:** Small domestic market and currently Gavi-financed, but may transition to self-financing before 2030
- **Government participation:** Commitment for local manufacturing of pharmaceuticals outlined in the Ministry of Trade and Industry's Strategic Anchor Initiatives
- **Talent:** Strong training programs in regulatory that can be expanded, favorable policies for attracting foreign expertise and some skilled diaspora

## Expected vaccines demand in Ghana (2020-30F), US\$ million



Post-Gavi price tier is a major driver of 2030 market value uncertainty (i.e., will Ghana retain Gavi pricing or typical LMIC pricing?) as well as uncertainty for novel Vx demand






## Current local manufacturing landscape

### Current Vx manufacturing landscape:

- Limited activity but private and public sector interest
- ### Vx-related capacity
- Limited sterile filling capabilities (4 companies)

1. Conservative case: High likelihood products (no COVID-19, transitioning countries pay Gavi-country prices) 2. Upside: Full portfolio with higher coverage and prices (COVID-19, HIV, outbreak stockpiles for Lassa and RVF/Chikungunya)

# Stakeholders can work together towards common potential aspirations to unlock enablers that support vaccine manufacturing

	Potential short-term aspirations (1-2 years)	Potential medium-term aspirations (2-5 years)	Potential long-term aspirations (5-10 years)
<b>A Agenda-setting and coordination</b> 	<p>Africa-owned coordination initiative set up, conducting advocacy, and driving activities and collaboration across stakeholders</p> <p>Clear strategies for countries/regions</p>	<p>Strengthened Africa- and country-led initiatives with strong political commitment</p> <p>Efforts are coordinated across stakeholders and topics with expanded scope</p>	<p>Entirely self-sufficient African-owned initiative with ongoing M&amp;E to refine strategy</p>
<b>B Regulatory strengthening</b> 	<p>All National Regulatory Authorities (NRAs) in focus countries have plans to achieve ML31 for Vx mfg. (2-3 going through WHO benchmarking) and have designed financial sustainability strategies</p> <p>AMA has started strategic implementation</p> <p>African marketing authorization harmonization for Vx has clear plan for expansion</p>	<p>Most NRAs in focus countries have achieved ML3 certification for Vx mfg. and implemented financial sustainability strategies</p> <p>AMA is operational and largely self-sufficient</p> <p>Marketing authorization harmonization for Vx is fully functional in initial regions</p>	<p>All NRAs in focus countries have successfully achieved ML3 or ML4 certification for Vx production and are financially sustainable</p> <p>AMA is fully operational</p> <p>Marketing authorization harmonization is complete across all regions</p>
<b>C Demand certainty</b> 	<p>Clarity on role of African Vx manufacturing in funder (e.g., Gavi) market shaping strategies</p>	<p>Gavi procurement of qualified products</p> <p>Clear procurement plans for countries transitioning from Gavi support</p> <p>Initial development of pooled procurement mechanisms for non-Gavi countries</p>	<p>Gavi procurement of new qualified products</p> <p>Clear procurement plans for new countries transitioning from Gavi support</p> <p>Established pooled procurement mechanism(s) for non-Gavi countries</p>
<b>D Access to finance</b> 	<p>A few near-term investable opportunities have secured sufficient investment, supported by required technical assistance (TA) and transaction facilitation (TF)</p>	<p>Several new investments into brownfield and greenfield projects with TA and TF where needed</p>	<p>A healthy market with continuous investment into vaccine manufacturing with limited donor-supported TA/TF required</p>
<b>E Talent and know-how</b> 	<p>Technology transfers secured for all viable investable opportunities</p> <p>Strategy developed for home-grown talent initiatives</p>	<p>Technology transfers secured for all viable investable opportunities</p> <p>Pilots for home-grown talent initiatives</p>	<p>South-south/Africa-Africa technology transfers complement traditional ones</p> <p>Expansion of home-grown initiative and shift from imported to home-grown talent</p>

1. Primary way WHO objectively evaluates regulatory systems; following evaluation by WHO each country NRA is given an Institutional Development Plan (IDP) which contains a series of recommendations for the NRA to implement before achieving Maturity Level 3 (ML3) certification