

UNICEF VACCINE INDUSTRY CONSULTATION

Gavi's Strategy to Support African Regional Manufacturing

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gavi.org

Agenda

1. AVMA

2. Update on technical design of AVMA

3. Next steps

Substantial momentum towards African vaccine manufacturing

INDICATIVE - NOT EXHAUSTIVE

Political announcements



Announced **vision of manufacturing 60% of all continental needs**



Leader-level announcements in Senegal, Nigeria, Rwanda, South Africa, Ghana and Tanzania of **near-term domestic facilities**



EU-AU Summit (2022) – EU announced **substantial commitment to strengthen local pharmaceutical systems and manufacturing**



US announced 2022 **joint investment plan** to boost vaccine manufacturing capacity in Africa



Germany's G7 Presidency: **supporting sustainable local and regional production capacities in Africa**



Japan's G7 presidency communique notes **vaccine manufacturing agenda in paragraph one**



UK, Canada, and Italy, amongst others, announced **substantial support for manufacturing sectors in Africa**

Financial announcements



>€1 bn

Committed as part of **MAV+ initiative** in 2021



>500 m doses

Announced a joint investment to **boost vaccine manufacturing capacity** in Africa in 2022



>\$600 m

Joint financing packages announced in 2022 for **individual manufacturing facilities**



>\$200 million

Committed as loan agreement to support COVID-19 responses



>\$100 m

Committed to support **sustainable manufacturing capacity for future epidemics and pandemics**

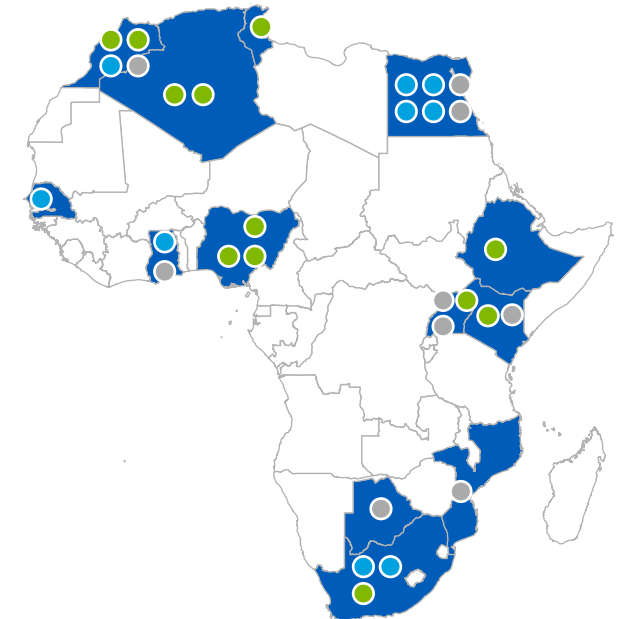
>30 project announcements

14

13

8

● installed ● planned ● in discussions



Gavi's 4-pillar regional manufacturing strategy to support the AU vision for sustainable vaccine manufacturing in Africa

AU's PAVM Framework for Action



- **Market design & demand intelligence**
- **Access to finance**
- Regulatory strengthening
- Technology transfer and IP
- Research & Development
- Talent development
- Infrastructure development
- Agenda-setting and coordination

➤ **Leads the support for the full African vaccine ecosystem**

Gavi's market shaping and innovative financing expertise

Supports and incentivizes full ecosystem

Four pillar regional manufacturing strategy



Pillar 1: Aggregate and communicate market insights



Pillar 2: Adapt Gavi product menu to prioritise regional products



Pillar 3: Build regional solidarity and predictability around demand

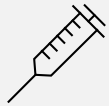


Pillar 4: 'African Vaccine Manufacturing Accelerator' (AVMA) to provide early-years financial support to African vaccine manufacturers

Gavi has finetuned the design of the African Vaccine Manufacturing Accelerator and its objectives and impacts

AVMA aims to achieve two main objectives ...

Objective A



Sustainable, African vaccine manufacturing base with global market health contributions in alignment with Pillar 1

Objective B



Improved pandemic response capacity, supply resilience and security sovereignty



... with four expected outcomes

At least 4

Vaccine manufacturers (of which two are end-to-end) who secure at least one UNICEF tender with AVMA support

>0.8 bn ds

Cumulative doses (Drug Product and Drug Substance) supported by AVMA

3 or more

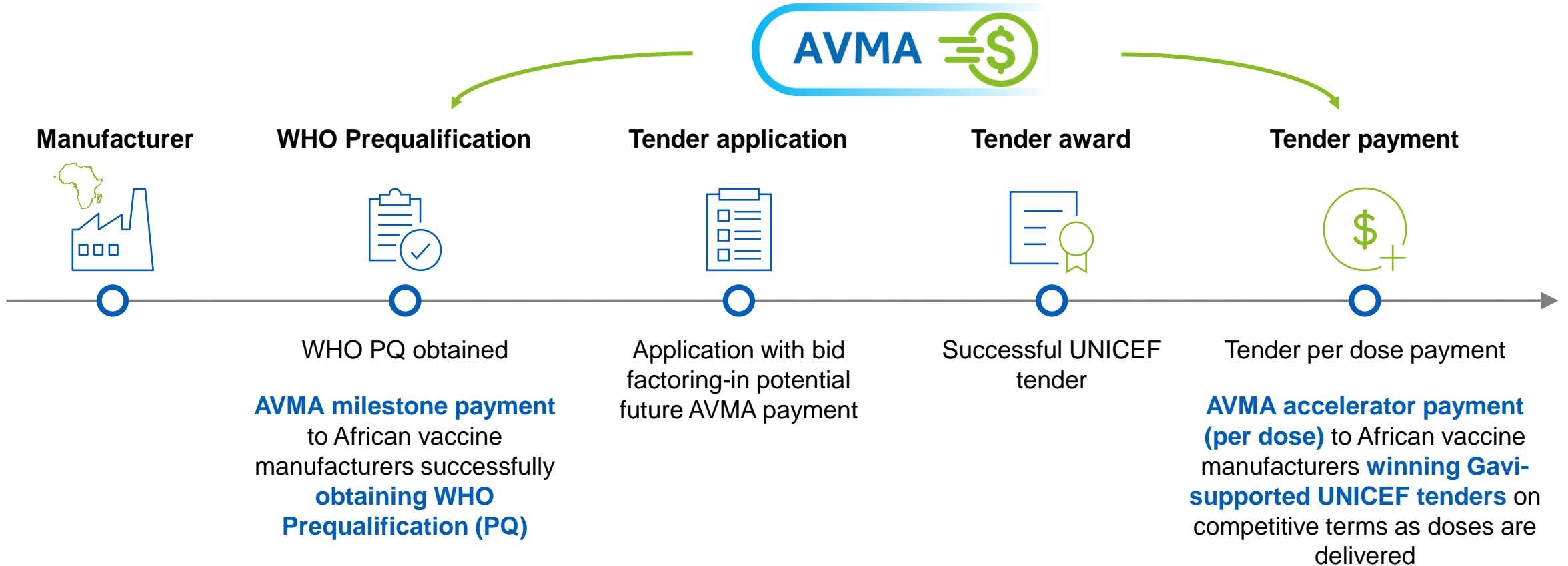
Drug Substance platform technologies supported by AVMA until 2035

>0.7 bn ds

Drug Product capacity (in doses) of AVMA supported supply base when repurposed in a potential pandemic/outbreak scenario

Outcome indicators interim – pending further modelling

How would the proposed AVMA work?



Agenda

1. AVMA

2. Update on technical design of AVMA

3. Wrap-up & Next steps

AVMA technical design structured around 6 key design elements

Accelerator payment (per dose) to African vaccine manufacturers **winning Gavi-supported UNICEF tenders on competitive terms** as doses are delivered

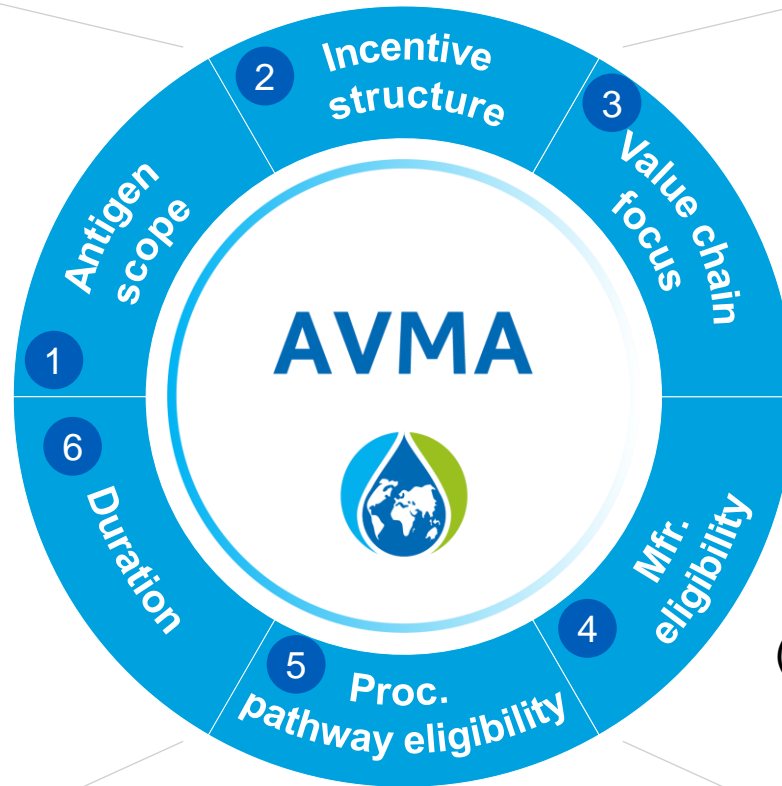
Milestone payment to African vaccine manufacturers successfully obtaining WHO Prequalification

Open to **all prequalified Gavi-supported vaccines** (*eligible for at least parts of the incentive payments*)

Fill & Finish and Drug Substance

Initially from 2024-2034 (*payments can continue for a period beyond the 10-year mark, depending on tender length*)

For **all vaccine manufacturers** (DS and/or DP) **on the African continent**



Via successful Gavi-UNICEF tenders¹

1. A potential AU pooled procurement mechanism may be accommodated in the future

1 Antigen Scope: Which product will be prioritised for Gavi global healthy markets and greater pandemic preparedness?

AVMA objectives

Objective A



Sustainable, regionally diversified supplier base with minimised undesired market distortion

Objective B



Improved pandemic response capacity, supply resilience and security sovereignty

Priorities

Priority antigens

Cholera	● ● ●
Malaria	● ● ●
Measles - Rubella	●
Hexavalent (wP)	●

● Supply-demand mismatch exists ● Benefit from supply diversification ● Benefit from improved product characteristic over current best profile

Rationale

Markets where an additional supplier is **expected to be contributory to Gavi global market health**

Priority platforms

Rapid response platforms

mRNA
Viral vector

Rapid response platforms **enable African manufacturers to repurpose drug substance facilities rapidly in case of an emergency**, incl. future potential coronavirus outbreaks or disease X

Other antigens eligible for AVMA support

- COVID-19
- Ebola
- HPV
- Inactivated Polio (IPV)
- Japanese Encephalitis
- Measles
- Meningitis A
- Multivalent Meningitis
- Pentavalent
- Pneumococcal
- Rotavirus
- Typhoid Conjugate
- Yellow Fever

Conditional on final AVMA design and antigen listing on the Gavi product menu

Note: Secondary priorities include antigens in markets presenting opportunities for additional suppliers, whose product profile is at least as competitive as the current most attractive product profile as well as markets expected to present very limited opportunity for additional suppliers

2 Incentive structure: Accelerator (per dose) payment

Accelerator payment: Incentive structure

Post-tender accelerator payment to African vaccine manufacturers winning Gavi/UNICEF tenders on competitive terms as doses are supplied – with caps per antigen and manufacturer

Tiered incentive values across:

- i. **Value chain focus:** DS vs. F&F
- ii. **Priority antigens and platforms**, based on modeling with best available information



Incentive levels

Drug substance (per dose)

- Priority antigens and platforms base-level
- Other (less-priority) antigens and platforms

Fill and Finish (per vial)

Uniform payment per vial set lower than any Drug substance per dose payment

Rationale

Creates **sustainable business cases for priorities** contingent on winning tenders

Lower incentives for lower priorities

Lower incentives to manufacturers who invest in **F&F-only** facilities

Relative levels

Higher

Lower

1. Expected number of manufacturers receiving payment according to latest modeling

2 Incentive structure: Milestone payment

Milestone payment: Incentive structure

Milestone payment to African vaccine manufacturers successfully obtaining WHO Prequalification (PQ)

Tiered incentive values across:

- i. **Value chain focus: DS vs. F&F**
- ii. **Rapid response platforms vs. other platforms**, set based on modeling with best available information



Incentive levels

Drug substance rapid response platforms:

Highest milestone payment for rapid response platforms

Drug substance other platforms:

Uniform milestone payment across all other platforms (*higher than F&F*)

Fill & Finish all platforms:

Lower milestone payment (once per manufacturer)

Rationale

Strong market signalling toward rapid response platforms

Early access to DS funding bound to less conditions as a prerequisite for UNICEF tenders

Limits disbursement to F&F only facilities

Relative levels

Higher

Lower

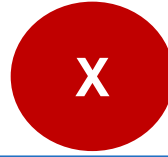
1. Expected number of manufacturers receiving payment according to latest modeling

2 Incentive structure: Types of caps being considered



Included

- Cap per antigen
- Cap per manufacturer
- Cap for F&F
- Cap for milestone payment



Not included

- Cap per platform technology
 - Though potentially covered by antigen cap
- Cap for pandemic related platforms
- Cap per country

4 Manufacturer Eligibility

+ Potential benefit for the AVMA - Potential risk for the AVMA

NON-EXHAUSTIVE

Options	Current hypothesis		
Description	A Full local player ¹	B International mfg. localizing F&F/DS capacity	C CMO
Benefits and risks	<ul style="list-style-type: none"> + May contribute to substantial and sustainable manufacturing base in Africa - Potentially long lead times to establish DS (potentially dependent on bulk provider until that point) 	<ul style="list-style-type: none"> + May be most efficient way to localize DS capacity - May not be perceived as strengthening African manufacturing capabilities 	<ul style="list-style-type: none"> + May indirectly create more business opportunities for African CMOs - Products are labelled and sold by the contracting manufacturer, potentially minimizing local capabilities

Note: Manufacturers only doing secondary packaging not considered – only F&F and/or DS considered in the above

1. Includes tech-transfer models

5 Procurement pathways

+ Potential benefit for the AVMA ● Potential risk for the AVMA

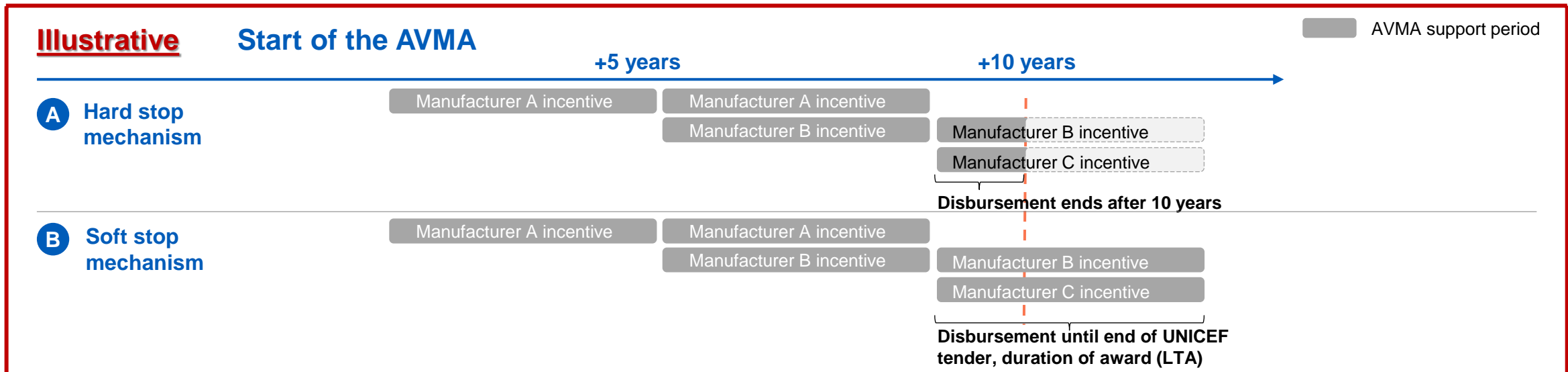
Options	Current hypothesis	<i>For future consideration</i>	
Benefits and risks	A UNICEF volumes	B AU procurement	X Bilateral volumes
<p>Estimated relative volume size</p>	<ul style="list-style-type: none"> All Gavi supported vaccines category procured through UNICEF tenders (Gavi and non-Gavi volumes) will be eligible. <p>+ Most technically and legally feasible option</p> <p>- May exclude volumes from Gavi-transitioned /transitioning countries, once they start self-procuring (e.g., Nigeria)</p> <p>- May exclude domestically produced and supplied vaccines</p> <p>1.0x</p>	<ul style="list-style-type: none"> Gavi supported vaccines procured through a future AU procurement mechanisms <p>+ Supports future AU procurement mechanism</p> <p>- May exclude domestically produced and supplied vaccines</p> <p>tbd</p>	<ul style="list-style-type: none"> All vaccine volumes from an AVM manufacturer sold through bilaterals deals outside the UNICEF tender) <p>+ Potentially includes domestic as well as ex-Africa volumes</p> <p>- Challenges related to validating procurement outside UNICEF tenders</p> <p>1.6x</p>

Source: MI4A, 2021 total procurement volumes globally for Gavi vaccines

6 Duration

Current hypothesis

Options	A Hard stop mechanism	B Soft stop mechanism
Timeline	AVMA initial assumption limited to 10 years ; no per dose payment thereafter, even for tenders won before	Initial 10-year overall duration of AVMA; volumes won during this period will be topped up until the end of the tender period
Hypothesis	<p>Option deprioritised due to ...</p> <ul style="list-style-type: none"> higher risks of creating negative business cases for manufacturers that enter closer to the end of the AVMA potential disadvantages for platform technologies that require a longer time to build and receive PQ <p>even though a hard stop mechanism would create incentives to invest early in local manufacturing (first mover)</p>	<p>Option prioritised due to ...</p> <ul style="list-style-type: none"> higher incentive for manufacturers to invest in local manufacturing towards the end of AVMA Longer support and higher chance of viability even though a soft stop mechanism potentially makes the evaluation of AVMA more difficult given the lack of clear end date



Visualization illustratively with the assumption that a manufacturer would reach the respective manufacturer value cap roughly in two UNICEF tender periods

Next steps



Next steps for AVMA design:

- **Stress testing models / AVMA design scenarios** throughout Q3/Q4 2023 and developing description of **key risks, implication and mitigation**
- Finalizing **AVMA technical design and operational model**
- **Final decision on AVMA** in Gavi board, December 2023

Thank you