UNICEF VACCINE INDUSTRY CONSULTATION

Gavi’s Strategy to Support African Regional Manufacturing

YALDA MOMENI
Agenda

1. AVMA
2. Update on technical design of AVMA
3. Next steps
# Substantial momentum towards African vaccine manufacturing

**INDICATIVE - NOT EXHAUSTIVE**

<table>
<thead>
<tr>
<th>Political announcements</th>
<th>Financial announcements</th>
<th>&gt;30 project announcements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Announced vision of manufacturing 60% of all continental needs</strong></td>
<td><strong>&gt;€1 bn</strong></td>
<td>14 installed</td>
</tr>
<tr>
<td><strong>Leader-level announcements</strong> in Senegal, Nigeria, Rwanda, South Africa, Ghana and Tanzania of near-term domestic facilities</td>
<td><strong>&gt;500 m doses</strong></td>
<td>13 planned</td>
</tr>
<tr>
<td>EU-AU Summit (2022) – EU announced substantial commitment to strengthen local pharmaceutical systems and manufacturing</td>
<td><strong>&gt;$600 m</strong></td>
<td>8 in discussions</td>
</tr>
<tr>
<td>US announced 2022 joint investment plan to boost vaccine manufacturing capacity in Africa</td>
<td><strong>&gt;$200 million</strong></td>
<td></td>
</tr>
<tr>
<td>Germany’s G7 Presidency: supporting sustainable local and regional production capacities in Africa</td>
<td><strong>&gt;$100 m</strong></td>
<td></td>
</tr>
<tr>
<td>Japan’s G7 presidency communiqué notes vaccine manufacturing agenda in paragraph one</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK, Canada, and Italy, amongst others, announced substantial support for manufacturing sectors in Africa</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **MAV+ initiative** in 2021
- **Announced a joint investment to boost vaccine manufacturing capacity in Africa in 2022**
- **Joint financing packages announced in 2022 for individual manufacturing facilities**
- **Committed as loan agreement to support COVID-19 responses**
- **Committed to support sustainable manufacturing capacity for future epidemics and pandemics**

---

**Source:** Press search
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

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’s market shaping and innovative financing expertise

Supports and incentivizes full ecosystem
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 Pilar 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?

Manufacturer → WHO Prequalification → Tender application → Tender award → Tender payment

- WHO PQ obtained
- AVMA milestone payment to African vaccine manufacturers successfully obtaining WHO Prequalification (PQ)
- Application with bid factoring-in potential future AVMA payment
- Successful UNICEF tender
- Tender per dose payment

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

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
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**

<table>
<thead>
<tr>
<th>Antigen Scope: Which product will be prioritised for Gavi global healthy markets and greater pandemic preparedness?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AVMA objectives</strong></td>
</tr>
<tr>
<td><strong>Objective A</strong></td>
</tr>
<tr>
<td><strong>Objective B</strong></td>
</tr>
<tr>
<td><strong>Priority antigens</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Rationale**

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

**Priority platforms**

- **Rapid response platforms**
  - mRNA
  - Viral vector

**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

**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.

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

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

### Incentive levels

<table>
<thead>
<tr>
<th>Drug substance (per dose)</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Priority antigens and platforms base-level</td>
<td>Creates <strong>sustainable business cases for priorities</strong> contingent on winning tenders</td>
</tr>
<tr>
<td>• Other (less-priority) antigens and platforms</td>
<td>Lower incentives for lower priorities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fill and Finish (per vial)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Uniform payment per vial set lower than any Drug substance per dose payment</td>
<td>Lower incentives to manufacturers who invest in <strong>F&amp;F-only</strong> facilities</td>
</tr>
</tbody>
</table>

1. Expected number of manufacturers receiving payment according to latest modeling
## Incentive structure: Milestone payment

### Milestone payment: Incentive structure

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

### Tiered incentive values across:

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

### Incentive levels

<table>
<thead>
<tr>
<th>Drug substance rapid response platforms:</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highest milestone payment for rapid response platforms</td>
<td>Strong market signalling toward rapid response platforms</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug substance other platforms:</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uniform milestone payment across all other platforms (<em>higher than F&amp;F</em>)</td>
<td>Early access to DS funding bound to less conditions as a prerequisite for UNICEF tenders</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fill &amp; Finish all platforms:</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower milestone payment (once per manufacturer)</td>
<td>Limits disbursement to F&amp;F only facilities</td>
</tr>
</tbody>
</table>

### Relative levels

<table>
<thead>
<tr>
<th>Relative levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher</td>
</tr>
<tr>
<td>Lower</td>
</tr>
</tbody>
</table>

1. Expected number of manufacturers receiving payment according to latest modeling
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
Value Chain: What part of the manufacturing value chain will the AVMA focus on?

Options

A. All

AVMA provides incentives for Fill & Finish and/or Drug Substance in Africa

- Supports earlier F&F and long-term DS localization
- More complex due to different incentive levels

B. Drug Substance-focused

AVMA provides incentives for manufacturers producing only drug substance in Africa

- DS has higher contribution to PPPR and health security compared to F&F
- DS localization may require more time and exceed AVMA lifetime

C. End-to-end-focused

AVMA provides incentives for African manufacturers producing vaccines end-to-end, incl. DS and F&F manufacturing

- End-to-end may best support PPPR and health security with full self-sufficiency
- Harder to achieve and may exceed AVMA lifetime

Example implications

African Manufacturing projects¹

- Number of vaccine manufacturing project
- Countries with announcements

1. African vaccine manufacturing projects expected to commence over next 10 years based on public announcements
### Manufacturer Eligibility

#### Options

<table>
<thead>
<tr>
<th>Description</th>
<th>Options</th>
<th>Description</th>
<th>Options</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Africa-based manufacturer with Drug Substance/ F&amp;F production in Africa</td>
<td><strong>A</strong> Full local player&lt;sup&gt;1&lt;/sup&gt;</td>
<td>• International PharmaCo localizing F&amp;F/DS capacity on the African continent</td>
<td><strong>B</strong> International mfg. localizing F&amp;F/DS capacity</td>
<td>• CMO in Africa conducting F&amp;F and/or DS, product sold under name of contracting manufacturer who receives incentive</td>
</tr>
</tbody>
</table>

#### Current hypothesis

1. **Full local player**
   - 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)

2. **International mfg. localizing F&amp;F/DS capacity**
   - May be most efficient way to localize DS capacity
   - May not be perceived as strengthening African manufacturing capabilities

3. **CMO**
   - 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&amp;F and/or DS considered in the above

---

1. Includes tech-transfer models
## Procurement pathways

<table>
<thead>
<tr>
<th>Options</th>
<th>Current hypothesis</th>
<th>For future consideration</th>
<th>Estimated relative volume size</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong> UNICEF volumes</td>
<td>- All Gavi supported vaccines category procured through UNICEF tenders (Gavi and non-Gavi volumes) will be eligible.</td>
<td>- Gavi supported vaccines procured through a future AU procurement mechanisms</td>
<td>1.0x</td>
</tr>
<tr>
<td>Benefits and risks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>+ Most technically and legally feasible option</td>
<td>+ Supports future AU procurement mechanism</td>
<td>1.0x</td>
</tr>
<tr>
<td></td>
<td>- May exclude volumes from Gavi-transitioned /transitioning countries, once they start self-procuring (e.g., Nigeria)</td>
<td>- May exclude domestically produced and supplied vaccines</td>
<td>tbd</td>
</tr>
<tr>
<td></td>
<td>- May exclude domestically produced and supplied vaccines</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>B</strong> AU procurement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>C</strong> Bilateral volumes</td>
<td></td>
<td>- All vaccine volumes sold from an AVM manufacturer sold through bilaterals deals outside the UNICEF tender)</td>
<td>1.6x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+ Potentially includes domestic as well as ex-Africa volumes</td>
<td>1.6x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Challenges related to validating procurement outside UNICEF tenders</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Options</th>
<th>A Hard stop mechanism</th>
<th>B Soft stop mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Timeline</strong></td>
<td>AVMA initial assumption <strong>limited to 10 years</strong>: no per dose payment thereafter, even for tenders won before</td>
<td>Initial 10-year overall duration of AVMA; volumes won during this period will be topped up until the end of the tender period</td>
</tr>
</tbody>
</table>
| **Hypothesis**| Option deprivitised due to …  
- **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 even though a hard stop mechanism would create incentives to invest early in local manufacturing (first mover) | Option prioritised due to …  
- **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 |

#### Illustrative

**Start of the AVMA**

<table>
<thead>
<tr>
<th>+5 years</th>
<th>+10 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Hard stop mechanism</td>
<td>Manufacturer A incentive</td>
</tr>
<tr>
<td>B Soft stop mechanism</td>
<td>Manufacturer A incentive</td>
</tr>
<tr>
<td>Disbursement until end of UNICEF tender, duration of award (LTA)</td>
<td></td>
</tr>
</tbody>
</table>

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