

African Vaccine Manufacturing Accelerator

BOARD MEETING

Marie-Ange Saraka-Yao

6-7 December 2023, Accra, Ghana

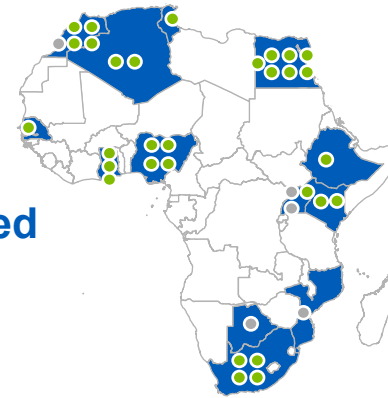


African Vaccine Manufacturing Accelerator (AVMA) supports a resilient, secure, competitive African Vaccine Manufacturing industry

Strong momentum: Substantial policy and financial commitments



>30
Announced
projects



AVMA is a key part of Gavi's support to the African Union's vision:

- African manufacturers participate competitively
- Global market health is protected
- AVMA is one component within an African Union-led ecosystem

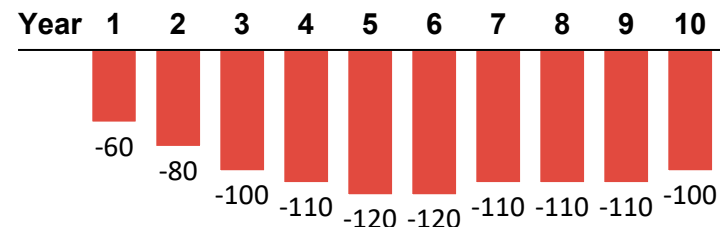
However, there are significant challenges

Higher initial costs compared with incumbent manufacturers ...

+20% operating costs
+ 40% labor costs
+50% capital expenditures



... resulting in unviable businesses. Example of Measles-Rubella cashflows (Cumulative, US\$ million)



Agreement to these key terms for AVMA will send immediate signals to investors ahead of planned launch in mid-2024

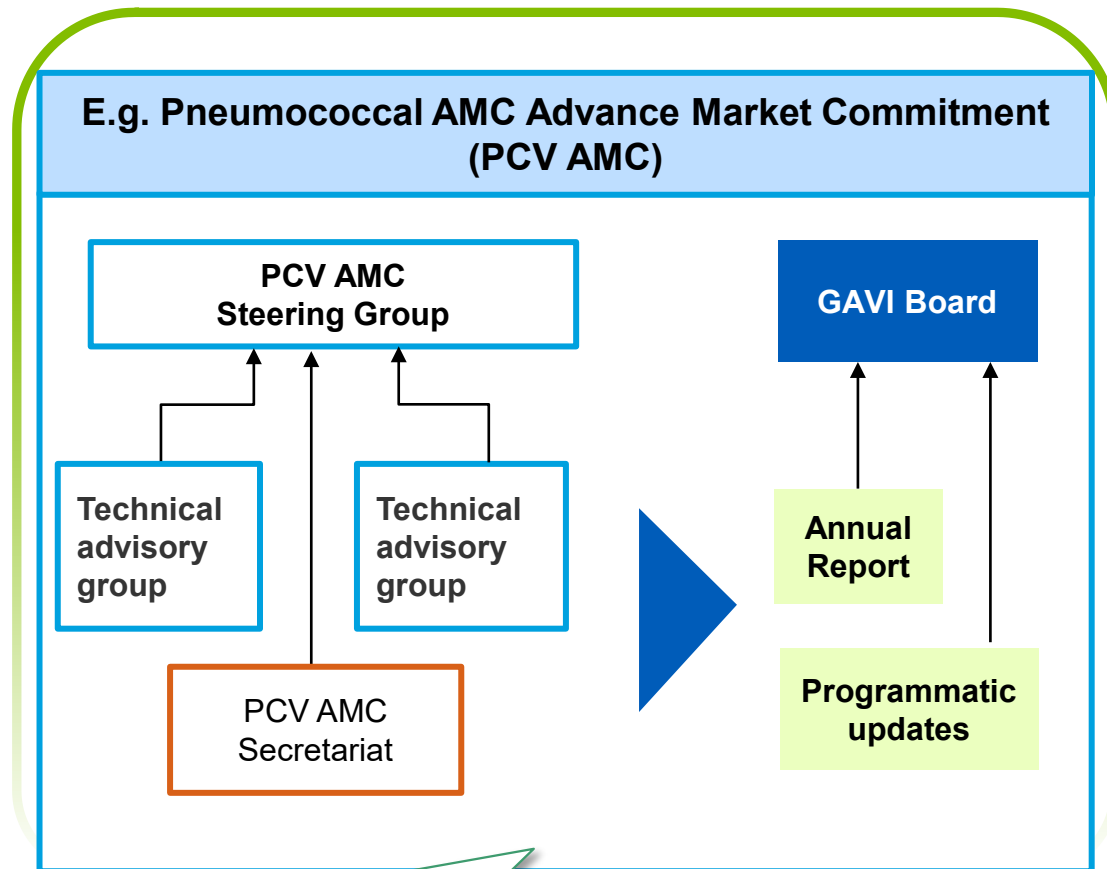


Size:	Funding requirement of US\$ 750-1,000 million – with the upper range set to accommodate an ambitious outcome for African products in terms of number of incentivised manufacturers and their commercial volumes
Scope:	All Gavi Alliance vaccines, Fill & Finish (F&F) and Drug Substance (DS)
Duration:	To be launched in 2024 with a proposed 10-year duration (payments can continue for a period beyond the 10-year mark, depending on tender length)
Eligibility:	Vaccines manufactured (DS and/or F&F) on the African continent
Procurement pathway:	Via successful Gavi-UNICEF tenders (a potential African Union pooled procurement mechanism may be accommodated in the future)
Incentive structure:	<p><u>Milestone payment</u> at WHO Prequalification of (i) US\$ 25 million for priority pandemic preparedness platforms (inc. potentially COVID-19), (ii) US\$ 20 million for priority drug substance vaccines, and (iii) US\$ 10 million for F&F-only vaccines</p> <p><u>Post-tender accelerator payment</u> of (i) US\$ 0.50/dose for priority DS vaccines and pandemic preparedness platforms (inc. potentially C19), (ii) US\$ 0.40/dose for non-AVMA-priority drug substance vaccines, and (iii) US\$ 0.30/dose with a cap of US\$ 1 per vial for F&F-only vaccines</p>

Disbursement caps:
US\$ 250 m per manufacturer
of which US\$ 50 m for F&F
US\$ 250 m for total milestone payments
US\$ 250 m for total F&F support
US\$ 300 m total per vaccine category

AVMA governance will be important, and we need time to get it right...

... we propose a six-month process to align on the final governance and operational rules for AVMA.



The PCV's operational rules determined in a framework agreement signed by donors, World Bank and Gavi.

Principles to determine AVMA governance in Q1/Q2 2024

1. **Inclusive Steering Group** – membership from donors, technical experts and relevant partners (e.g. Africa CDC)
2. **Regular monitoring** – interim milestones tracked and updated throughout with market engagement
3. **Clear links to wider ecosystem** – docked into Africa CDC/AU processes (e.g. "manufacturers' marketplaces")
4. **Ability to course-correct** – agreed pathway to update design features (without undermining incentives to invest)
5. **Alignment with the Gavi Board** – final governance model and ways of reporting presented to the Gavi Board in 2024

AVMA's operational rules to be developed into a framework agreement during Q1/Q2 2024 and presented to Gavi Board, including **legal analysis and a high-level mapping of key dependencies** such as regulatory strengthening

Recommendation

The Gavi Alliance Programme and Policy Committee **recommends** to the Gavi Alliance Board that it:

- a) **Approve** the establishment of the African Vaccine Manufacturing Accelerator (AVMA) as an instrument to provide time-limited financial support to accelerate the expansion of commercially viable vaccine manufacturing in Africa, in accordance with the base design criteria set out in Annex A to Doc 05b as amended in follow up to discussions at the PPC;
- b) **Note** that this approval is contingent on available funding from the COVAX Advance Market Commitment (AMC) Pandemic Vaccine Pool (PVP) as confirmed by the Gavi Audit and Finance Committee. Under the base proposal, a capitalisation of up to US\$ 1 billion is required;
- c) **Note** that the investment proposals were developed with full consideration of enhanced collaboration with other pandemic recovery and PPPR initiatives and considered by the COVAX AMC Investors Group, as requested by the Board in June 2023, and were supported as options for the use of COVAX AMC PVP funds; and
- d) **Request** that the Secretariat brings back to the Board the following in the first half of 2024: further analysis of legal and regulatory risks relating to the provision of Gavi's support; the articulation of intermediate milestones and review points; the establishment of a Treasury function; proposed governance arrangements with related legal terms and conditions established; and a high-level mapping of key dependencies related to regional demand, regulatory strengthening and prequalification functions at WHO.

Thank you