

Subject **African Vaccine Manufacturing Accelerator (AVMA)**

Agenda item **11b**

Category **For decision**

Executive Summary

In December 2023, the Gavi Board approved 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 a set of key terms. Following the Audit and Finance Committee's review of the treasury arrangements and the Risk Management Framework; the Governance Committee's review of governance arrangements; and the Policy and Programme Committee's review of the modified key terms, the MEL framework and key dependencies, this paper seeks approval for the final operational arrangements for AVMA ahead of its proposed launch in June 2024 including (i) a modification of the key terms approved in December which refines the manufacturers eligible for AVMA subsidies and (ii) its interim Treasury arrangements.

The report provides supplementary information requested by the Board covering (i) AVMA's role in the broader ecosystem covering mapping of key dependencies, (ii) monitoring and oversight covering legal and regulatory risks and intermediate milestones and review points, (iii) governance and treasury arrangements.

Action Requested of the Board

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

- a) **Approve** the amendments to the key terms of AVMA as set out in Annex A to Doc 11b.
- b) **Note** the AVMA MEL framework, including proposals for periodic course correction as set out in Annex B to Doc 11b.
- c) **Note** the key dependencies as set out in Annex C to Doc 11b.

The Gavi Alliance Audit and Finance Committee (AFC) **recommends** to the Gavi Alliance Board that it:

- a) **Approve** the Gavi Secretariat as interim treasury manager of the African Vaccine Manufacturing Accelerator (AVMA) until 31 December 2024.
- b) **Note** that the Gavi Secretariat will recommend a long-term treasury management arrangement for AVMA and make a proposal on the use of interest income to the AFC, in the second half of 2024.

Next steps/timeline

Pending Board approval, AVMA is set to be launched at a high-level event jointly convened by the Government of France, the African Union and Gavi at the Quai d'Orsay, Paris on 20 June 2024. At that point, AVMA would be immediately open for Expressions of Interest and applications from eligible vaccine manufacturers.

Previous Board Committee or Board deliberations related to this topic

In May 2024 PPC meeting book: Doc 12 *African Vaccine Manufacturing Accelerator (AVMA)*

In 7 May 2024 AFC meeting book: Doc 07 *African Vaccine Manufacturing Accelerator (AVMA)*

In April 2024 Governance meeting book: *African Vaccine Manufacturing Accelerator*

In December 2023 Board meeting book: Doc 10b *Gavi's role in Pandemic Prevention, Preparedness and Response: African Vaccine Manufacturing Accelerator*

In October 2023 PPC meeting book: Doc 10b *Gavi's role in Pandemic Prevention, Preparedness and Response: African Vaccine Manufacturing Accelerator*

In December 2022 Board meeting book: Doc 08 *Gavi's Role in support to Regional & African Vaccine Manufacturing*

In October 2022 PPC meeting book: Doc 05 *Gavi's role in support to Regional and African Vaccine Manufacturing*

Report




1. Strategic rationale

- 1.1 Following the access, equity and supply security issues experienced during the COVID-19 pandemic, the African Union (AU), G7 and G20 called for an international effort to improve access to medical countermeasures to better prepare for future health emergencies. This has led to substantial upstream investment in African vaccine manufacturing, including both multilateral and bilateral commitments. However, high startup costs mean that despite over 30 headline announcements, the commercial sustainability required for ongoing supply security is unlikely to develop without complementary downstream incentives.
- 1.2 With Africa accounting for less than 0.1% of the world's vaccine production, yet 20% of its population, a minimum level of vaccine sovereignty and pandemic security is far away. As the largest global financier of vaccines for developing countries, Gavi has committed to playing an active role aligned with its comparative advantages of market-shaping and innovative finance. The Board approved a four-pillar strategy to support sustainable regional manufacturing, with a key focus on the African continent, in December 2022.
- 1.3 This paper presents the final operational arrangements for Pillar Four of that strategy, **the US\$ 1 billion African Vaccine Manufacturing Accelerator (AVMA), which was approved by the Board in December 2023**. Since that decision, the Secretariat has heard support for AVMA from many constituencies over the course of a further 50 individual consultation sessions with AU counterparts (including Africa CDC) manufacturer associations, donors, implementing countries, technical experts, CSO, financial institutions and Alliance Partners.
- 1.4 Over a ten-year period, AVMA will provide incentive payments to manufacturers, to **de-risk investment, support manufacturers' long-term sustainability and the continent's vaccine sovereignty**. The incentive payments have been carefully calibrated to support business cases into viability, whilst minimising undesired disruptions to global market health, such as the crowding out of existing suppliers.
- 1.5 Board approval is now being sought for the final operational elements of AVMA set out in this paper. This would be followed by a **launch event on 20 June 2024** in tandem with the Gavi 6.0 Investment Opportunity. The high-level event will be hosted by Gavi, the AU Presidency and France – it will send an immediate investment signal of Gavi's long-term commitment to support a sustainable African vaccine manufacturing base and to improve African pandemic and outbreak vaccine supply resilience.

2. AVMA's role in the broader manufacturing landscape

- 2.1 Gavi's work in African Regional Manufacturing has been highlighted as a high risk, but high reward venture. AVMA is a critical part of Gavi's four-pillar Regional Manufacturing Strategy. Nevertheless, building African vaccine manufacturing capabilities is not a task for Gavi alone, and **AVMA is only one initiative in a larger ecosystem**. AVMA is an important, but not sufficient condition for success, and it is dependent on partners facing shared risks, and working collaboratively to mitigate them – including mutual accountability across the Alliance.
- 2.2 Following Board approval in December 2023, the **Board requested supplementary information on key dependencies**. Over the course of the finalisation of AVMA, the Secretariat has spent significant time in consultations with partners, donors, manufacturers, CSOs and experts to identify risks and dependencies related to the broader ecosystem. Figure 1 summarises the key findings from Gavi's high-level dependencies, mapped across the strategic elements of Africa CDC's Platform for Harmonised African Health Products Manufacturing (PHAHM, formerly "PAVM").

Figure 1 AVMA dependencies

Support to the manufacturing ecosystem	Africa CDC leadership	Gavi's Regional Manufacturing strategy
 Commitment across ecosystem stakeholders, e.g., Africa CDC's Pooled Procurement Mechanism	 Market design & demand intelligence	 Market insights through Pillar 1 support demand materialisation and help inform manufacturer choices
US\$ 3+ billion in early-stage financing instruments MAV+ (€1.1 billion), EIB and BMGF (€500 million), DFC (\$ 2 billion)	Access to finance	Financial incentives to de-risk new investments with the AVMA to "tip the business case"
G7 donors and BMGF investing \$110+ in African Medicines Agency and NRA regulatory strengthening	Regulatory strengthening	Creates a space for stakeholder discussions across the ecosystem through the Manufacturer forum
\$110+ million in the establishment of partnerships & initiatives through e.g., WHO Technology Hub, Wellcome Trust, IVI	Technology transfer & IP	De-risk costs of initiating tech transfers for the licensee, and the risk for the licensor
BMGF and CEPI in partnership with Africa CDC investing \$100+ million in African R&D, Mastercard foundation investing \$45 million in talent development	R&D and talent development	Labour market signalling and high-skill talent development, as well as the upfront costs of expat labour
Investment across Africa to meet its infrastructure funding gap	Infrastructure development	Strengthens the case for investment in necessary infrastructure

- 2.3 While significant challenges remain, the Secretariat's analysis demonstrates substantial investments and considerable momentum across the ecosystem. At least US\$ 4 billion of additional investment has been committed across many partners - with G7 members playing a crucial role.
- 2.4 AVMA has been designed as a financial instrument both to derisk existing investments by providing long-term funding support, but also to help drive additional upstream investment where needed – including from Development Finance Institutions (DFIs) and other providers of capital. Since Board approval of the key terms in December 2023, early indications – including through DFIs at the World Bank/IMF Spring meetings and the Secretariat's routine

engagement with vaccine market participants – have helped to validate the positive impact AMVA is already having on investment discussions.

- 2.5 Throughout the lifespan of AVMA, it will be critical to monitor the evolving ecosystem. The Gavi Secretariat will actively work together with the Africa CDC, core Alliance partners and other stakeholders to resolve bottlenecks and align on efforts, as part of AVMA's continual monitoring and oversight approach.

3. Monitoring and oversight

- 3.1 The Gavi Board requested supplementary information on the legal and regulatory risks to AVMA as well as a set of intermediate milestones and review points within a monitoring and evaluation framework. In consultation with partners, the **Secretariat has developed an extensive Monitoring, Evaluation and Learning Framework and a Risk Management Framework** which are fully integrated into each other.
- 3.2 The **Monitoring, Evaluation and Learning framework** sets out a Theory-of-Change with indicators, interim and outcome targets. The four outcome targets with interim review points are detailed in table 1. The Secretariat will report yearly to the Gavi Board and its Committees as part of Gavi routine reporting arrangements and produce an annual external report.

Table 1 AVMA outcome targets

Description of outcome target	2026	2029	2032	Final Target*
Number of AVMA-eligible manufacturers having secured competitively at least one UNICEF tender	1	3	4	4
Number of cumulative vaccine doses receiving accelerator payments (in millions)	0	130	490	800
Number of different drug substance platform technologies supported by the AVMA	1	2	3	3
Existing African F&F capacity which can be repurposed to manufacture vaccines in case of a future pandemic (in millions of doses)	100	400	500	700
* Please note final targets for outcomes have already been approved as part of December 2023 Board				

- 3.3 To manage AVMA risks, the Secretariat has developed a Risk Management Framework, identifying **25 risks associated with the AVMA, risk owners and risk mitigation approaches**. Ensuring an adequate enabling regulatory environment – including a well-resourced and timely WHO Pre-Qualification (PQ) – and adequate country demand from African countries for African products have been highlighted as top risks to the success of AVMA. Further developing the close partnership with Africa CDC and working across the Alliance (and external partners) to strengthen regulatory capacity will be key mitigation actions. All AVMA risks will be closely monitored in line with the Alliance Risk Policy and reported to the Gavi Board and relevant Committees. Guidance from the Audit and Finance Committee (AFC) at the May 2024

meeting called for some modification to risk ownership and further clarification on arrangements for cross-Alliance risk management and mitigation. Written clarifications have been provided to the AFC Chair and membership, with modifications planned as part of quarterly updates to the operational risk register.

- 3.4 To maintain the relevance of AVMA over its life, **three “triennial course corrections” will take place at scheduled review points in 2027, 2030, and 2033.** Recommendation for course corrections will be developed by an external review and in consultation with partners. They will take into account views expressed in the proposed AVMA Investors Forum and Manufacturing Forum and will be informed by the risk management framework.

4. Governance arrangements

- 4.1 **In line with the proposal to the Board in December 2023 AVMA will be aligned with existing Gavi governance arrangements.** The **Governance Committee** reviewed and provided guidance on how this will work, with details set out in **Annex D**. As a financing instrument, overall financial oversight would be the responsibility of the AFC, with programmatic oversight from the PPC. Two advisory forums will be leveraged to facilitate AVMA's operation and inform Board oversight - an Investors Forum (of core AVMA donors) and a Manufacturing Forum (involving a broad cross-section of ecosystem stakeholders, including manufacturers, co-convened with Africa CDC). They will help align partners across the African manufacturing ecosystem and identify key bottlenecks to achieving AMVA's objectives.
- 4.2 The **Audit and Finance Committee (AFC) reviewed and recommended the Treasury arrangements for AVMA.** They recommended an interim in-house treasury solution to manage AVMA funds until the end of 2024. The in-house solution will adhere to the established Treasury and Risk Management principles currently in effect for the COVAX Pandemic Vaccine Pool funds.
- 4.3 **A final proposal for both long-term treasury management and use of interest will be brought to the AFC in the second half of 2024 for recommendation to the Board in December 2024.** Conversations with external Treasury providers are underway. Throughout the lifetime of AVMA, it is anticipated that a substantial amount of interest will accumulate. A number of options have been identified for the use of proceeds, ranging from repurposing the funds into Gavi core; maintaining them within AVMA; or supporting AVMA's objectives via investments to support the broader manufacturing ecosystem.
- 4.4 **The Policy and Programme Committee (PPC) recommended for approval a modification to the key AVMA terms approved by the Board in December 2023,** as set out in Annex A. The eligibility conditions for AVMA now address an outstanding issue regarding the status of so-called “Contract Manufacturing Organisations” (CMOs). CMOs “fill and finish” vaccines on behalf of other manufacturers, with the Marketing Authorisation holder remaining unaffiliated

and often offshore. The modified eligibility criteria now reserve AVMA funds within the Fill & Finish cap for WHO PQ holders who exercise direct control over operations on the African continent. This means facilities operating in a pure CMO capacity will remain ineligible for direct receipt of AVMA support. Concerns were raised during consultations that inclusion of CMOs could inadvertently disincentivise end-to-end transfer of drug substance production, and rather push the continent towards becoming a “Fill & Finish hub”.

Annexes

Annex A: AVMA Term Sheet

Annex B: AVMA Monitoring Evaluation and Learning (MEL) Framework

Annex C: Strengthening Vaccine Production in Africa: A Dependency Mapping for AVMA

Annex D: Arrangements for the Governance of AVMA