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

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1. Introduction

The African Vaccine Manufacturing Accelerator (AVMA) is a transformative initiative dedicated to establishing a sustainable vaccine manufacturing ecosystem. In December 2023, the AVMA Theory of Change (ToC) was presented to the Board, including a high-level articulation of the proposed Monitoring, Evaluation and Learning (MEL) strategy for the AVMA. Since then, the MEL Framework and strategy have been further elaborated – inclusive of the key outcome targets presented to the Board in December and expanding to a comprehensive "logframe" that links MEL indicators and targets to most elements of the ToC.

The AVMA MEL Framework is an integral part of the broader Gavi regional manufacturing strategy, focusing on pillar 4 and spanning from inputs to impact. It is designed to support both learning and accountability needs and draws from lessons learned from the pneumococcal Advance Market Commitment (AMC) M&E framework. It includes interim targets for the Board approved outcome targets across review cycles (2027, 2030, 2033), as well as >15 additional MEL indicators linked to immediate, mid-term, and long-term outcomes.

There are two key limitations to consider when reviewing the AVMA MEL Framework. Firstly, the success of the AVMA is dependent on various factors, some of which are beyond Gavi's control. If targets are not met, Gavi will work with relevant stakeholders to identify and report transparently on key barriers and links to dependencies (outlined in Annex C), exploring whether Gavi can do more to achieve the desired outcomes. Secondly, while the AVMA contributes to the broader ecosystem, it is challenging to unpack attribution of all its contributions and impact.

The next sections focus on the core components of the MEL Framework, as outlined in Table 1 below. These components include the ToC and its underlying key assumptions, reporting and review cycles, monitoring and evaluation, log frame and interim targets, methodology for target setting, and a learning agenda for areas not covered in the framework. It is important to note that the MEL Framework will be continuously refined and adapted as the programme evolves, particularly considering the long-term nature of the AVMA, which will be launched in 2024 with a likely 10-year duration but could potentially extend longer given tender lengths. Efforts will be made to work closely with relevant partners (such as the Africa CDC, African Union and CEPI) to align where feasible on MEL-related work and approaches and fully utilize relevant metrics, data, analyses, and learnings generated.

Table 1: Core components of the AVMA MEL Framework

MEL Framework Theme	Component / Activity	Overview
Foundation for MEL framework	Gavi Regional Manufacturing Strategy Theories of Change	• Theory of Change with complementary key assumptions documented and relevant risks included in the separate AVMA Risk Management framework for the AVMA (PPC-2024-Mtg-01-Doc 12-Appendix 2)
Reporting and Monitoring	Gavi Regional Manufacturing Strategy Reporting Framework	• Framework to underpin monitoring, reporting and accountability on AVMA performance

MEL Framework Theme	Component / Activity	Overview
		• Key indicators for Gavi Regional Manufacturing, mapped to the Theory of Change, and indicator definition sheets[1] • Baselines • Specific targets for indicators mapped to temporal milestones (2026, 2029, 2032) over the AVMA's duration • AVMA beneficiaries reporting requirements will be defined and incorporated into agreements as required to support reporting against this framework
	AVMA programme reporting	• Periodic programme and operational reporting (e.g.: biannual) on AVMA key metrics (i.e., not comprehensive overview of the entire logframe) to inform programme performance management and operations. These may be reported publicly to provide updates on progress / key milestones.
	AVMA annual reporting	• Report on the entire AVMA logframe (i.e., covering all metrics) once a year by the Secretariat, which is submitted to the Gavi Board • A version of this report is made publicly available for broader stakeholders • The first annual reporting is expected in 2024
Reviews and Evaluation	Triennial reviews and multi-stage independent evaluation of Gavi Regional Manufacturing Strategy	• External, triennial reviews of the AVMA (2027, 2030, 2033) against its objectives, including testing the Theory of Change and instrument outcomes. It is proposed that these are commissioned directly by the AVMA team (decentralised reviews). Based on the findings from AVMA MEL / Risk monitoring as well as relevant stakeholder inputs, the Secretariat develops a Course Correction Report and consults the Investors Forum before submitting it to the Gavi Board through the relevant committees (detailed process outlined in PPC-2024-Mtg-01-Doc 12-Appendix 1, Framework Report). • Planned, robust and independent evaluation of the AVMA under guidance from Gavi's Evaluation Advisory Committee (EAC), which will complement the proposed triennial reviews

[1] Found at the end of this document.

MEL Framework Theme	Component / Activity	Overview

		• Tentative plans, which are subject to further refinement per EAC steers[2]:
		  ○ Evaluability Assessment to be considered in 2025 (given need to finalise MEL framework and set-up during course of 2024)
		  ○ Final evaluation not expected to occur before 2035 (exact timing of commissioning will consider UNICEF tender timelines, to align with Gavi 7.0 cycle and broader AVMA project timelines). This fully independent end-line evaluation will be expected to build upon the work done across the triennial reviews.
		• Evaluation RFPs will be developed, with fully independent evaluators selected, following a competitive bidding process, per Gavi Centralised Evaluation Unit's guidelines

Learning	Gavi Regional Manufacturing Strategy Learning Agenda	• Gavi Regional Manufacturing Strategy Learning Agenda under development and to evolve over the course of the AVMA • Gavi plans to commission work (incl. modelling and surveys) as necessary to address priority learning needs and to complement data gathered via the Gavi Regional Manufacturing Strategy reporting framework

As part of the AVMA MEL Framework, relevant risks in the ToC have been identified, along with associated risk indicators, which have been included in a separate AVMA Risk Management Framework (outlined in PPC-2024-Mtg-01-Doc 12-Appendix 2). They contribute to the monitoring and reporting of risks and thereby provide a measurable perspective on their development. The risk register is managed by Gavi's Ethics, Risk and Compliance Office (ERCO), Risk Owners, Risk Managers, and Risk Contributors. MEL and Risk are complementing each other in that risk indicators build on MEL indicators where applicable. However, in situations where this is not feasible, additional new risk indicators have been identified.

2. AVMA Theory of Change

The AVMA Theory of Change (ToC) serves as the foundation of the AVMA MEL Framework and as a strategic roadmap for the planning, execution, and modification of the AVMA's design. It outlines how the AVMA will utilise different tools to drive the desired outputs and

[2] Current plans are to bring Gavi's Regional Manufacturing Strategy as an agenda topic to the Evaluation Advisory Committee meeting in Q3 2024 for guidance.

outcomes. The ToC is a dynamic tool that is subject to review and revision over time, and it serves as a guide for measurement, evaluation, and learning activities.

2.1 Inputs

The foundation of AVMA's ToC is based on three key inputs: ecosystem mobilisation, AVMA design elements, and Gavi Secretariat process levers. These inputs can be used by the AVMA and its partners to catalyse change. Each lever can be pulled in combination to operationalise AVMA's activities under the intervention areas.

- Ecosystem mobilisation: The AVMA recognizes the importance of ecosystem mobilisation as a key input to operationalise its instrument. This lever involves collaboration and (Alliance) partnerships, such as leveraging UNICEF's pooling mechanism or WHO prequalification (PQ). It also involves stakeholder engagement and alignment, including feedback from manufacturers, and resource mobilisation from, e.g., donors.
- AVMA design elements: The AVMA design elements, including the incentive structure, value chain focus, and duration of manufacturer eligibility, are the essence of the AVMA instrument. Decisions made in this aspect are crucial inputs for AVMA's success.
- Secretariat process levers: The AVMA acknowledges that it cannot operate independently and will leverage Gavi's existing resources. Secretariat process levers are key inputs to ensure effective operationalization of AVMA's activities.

2.2 Outputs

The combination of these three inputs results in the creation of the AVMA, whose activities will lead to two primary outputs (both tangible and intangible): robust technical and operational AVMA components.

- Technical AVMA components: Aim to support Fill and Finish (F&F) and Drug Substance (DS) manufacturing investments, by providing milestone payments (upon WHO Prequalification (PQ)) and accelerator payments to eligible manufacturers. The AVMA also aims to ensure that its investments support a diverse manufacturing base and enable transparent and sustainable operations for vaccine manufacturers beyond AVMA's duration.
- Operational AVMA components: Focus on flexible governance and steering mechanisms to allow to adapt to changing contexts. The AVMA will put in place its resources to ensure that relevant stakeholders are engaged, new developments are continuously monitored and evaluated, and feedback is received.

2.3 Outcomes and objectives

Building on the above, the inputs and associated outputs of the AVMA ToC operate through three pathways: driving sustainable business models, building capacities and capabilities that improve pandemic prevention, preparedness and response (PPPR), as well as sustaining a healthy global market. The ToC key assumptions are outlined in section 2.42.4. Along these pathways, the AVMA is designed to deliver changes gradually and according to different timelines, including immediate, mid-term and long-term outcomes.

2.3.1 Immediate outcomes

Immediate outcomes (to be realized within 2024 – 2026) primarily aim to signal the incentive design of the AVMA to existing and new manufacturers. It's expected that manufacturers interested in support, will share with the AVMA an Expression of Interest (EOI) outlining their plans to invest in F&F or DS manufacturing capabilities. Together with the manufacturers' motivation to obtain WHO PQ certification through milestone payments, the AVMA's incentive structure should inherently encourage a diverse landscape, especially in diverse DS platforms, to initiate their entry into the African vaccine manufacturing market. On the other hand, the AVMA should be able to showcase its flexible governance systems by adapting to evolving market conditions thanks to reliable market signals shared by Pillar 1 and 2. In parallel, AVMA prioritises full transparency and alignment with relevant stakeholders to ensure the most effective operationalisation. Based on the two outputs mentioned in section 2.2, three immediate outcomes manifest:

Immediate outcomes building on "Technical AVMA components" (output)

1. Signalling Potential: Attracts investments and manufacturers for compelling cases in African manufacturing.

Immediate outcomes building on "Operational AVMA components" (output)

2. Robust Governance: Governance processes in place that are set up to accommodate potential adaptations as necessary.
3. Enhanced AVMA Effectiveness: Ensures transparency, adaptability, and alignment with stakeholders.

2.3.2 Mid-term outcomes

Mid-term outcomes (to be realized within 2027 – 2029) assume the support of F&F manufacturers through accelerator payments and the disbursement of milestone payments to DS manufacturers. Potential adjustments to the instrument will have been implemented.

Mid-term outcomes building on "Technical AVMA components" (output)

The first immediate outcome, Signalling Potential, leads to three mid-term outcomes:

- Strengthened Fill and Finish (F&F) Viability: Enhances viability of planned and existing African platform-agnostic F&F manufacturing capacity across all antigen priority categories.
- Increased Investments in Drug Substance (DS): Boosts investments in DS AVM with a diversified platform portfolio, covering routine immunization (e.g., Covid-19) and priority platforms, including manufacturers receiving milestone payments post WHO PQ.
- Improved Enabling Environment: Strengthens the enabling environment for the vaccine market (e.g., skilled labour, enhanced regulatory capabilities) and beyond (e.g., economic and labour market development).

Mid-term outcomes building on "Operational AVMA components" (output)

The second immediate outcome, Robust Governance Processes, enables one mid-term outcome:

- Adaptable AVMA Design: Allows appropriate adjustments of the AVMA design in response to market dynamics, enabling additional investments (e.g., other antigens, platforms, manufacturers) beyond the initial AVMA design.

The third immediate outcome, Enhanced AVMA Effectiveness, enables optimised resource allocation, increased collaboration, and improved responsiveness, thereby ensuring a sustainable and efficient vaccine manufacturing ecosystem.

2.3.3 Long-term outcomes

Long-term outcomes follow a consequential progression from outputs, immediate and mid-term outcomes.

Long-term outcomes building on "Technical AVMA components" (output)

- Sustainable Vaccine Manufacturing: African vaccine manufacturers (AVMs) reach sustainability while considering investments in innovative DS platforms such as messenger Ribonucleic Acid (mRNA) for Malaria. This enhances their readiness to swiftly respond to potential pandemics through adaptable infrastructure and advanced technologies, including mRNA, facilitating PPPR.
- Positive Externalities in Pandemic Response: Strengthened labour and regulatory support enables the timely scale-up of vaccine production, resulting in an improved pandemic response.

Long-term outcomes building on "Operational AVMA components" (output)

- Sustained Market Health: Maintains market health over time through diversified platform portfolios.
- Diversified Platform Portfolio: Introduces a diversified platform portfolio into the market over time to enable a swift response to potential pandemics.

2.3.4 Objectives

Together, all these outcomes collectively contribute to the two main objectives of the AVMA, previously submitted to the Board in 2023:

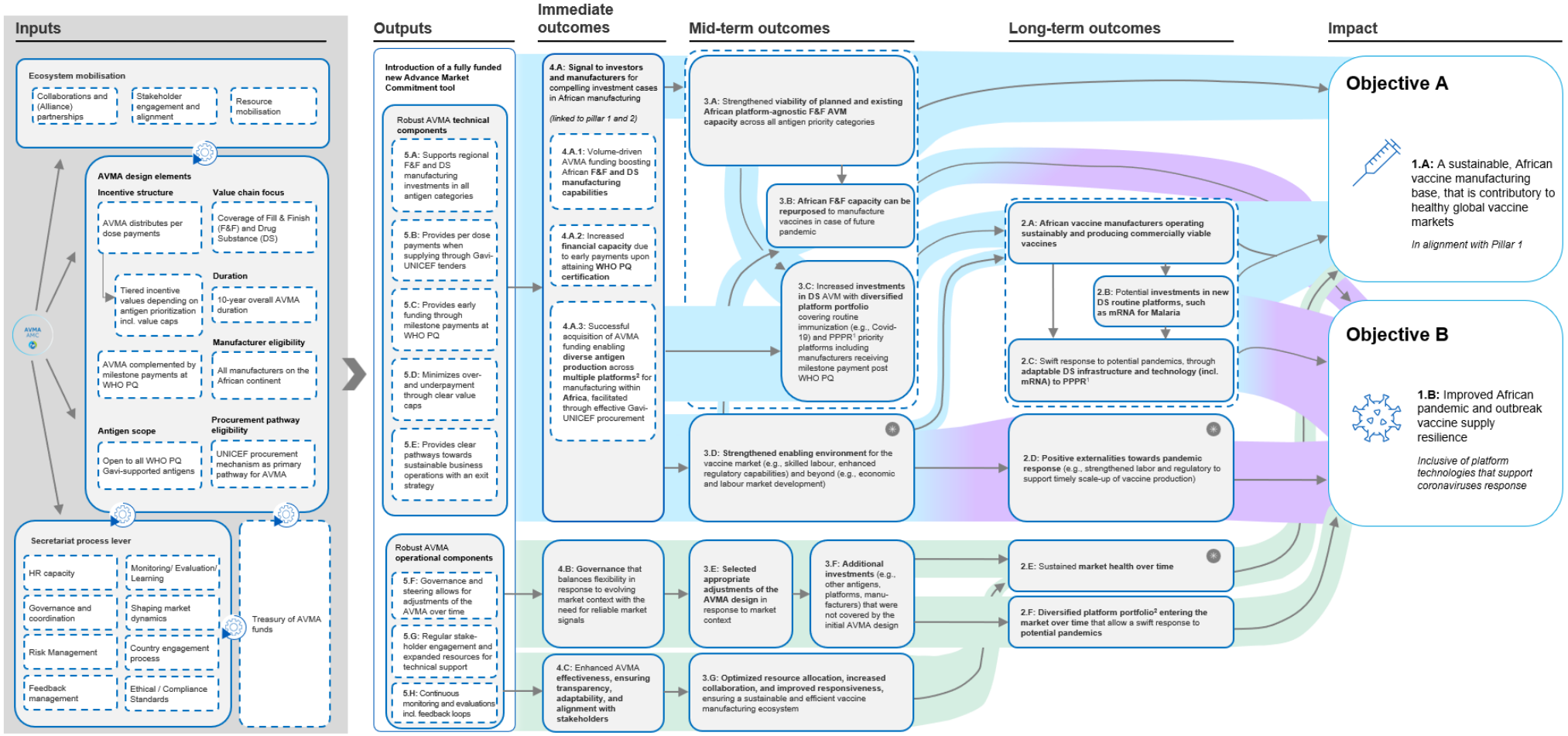
- **Objective A**: A sustainable, African vaccine manufacturing base that is contributory to healthy global vaccine markets (in alignment with Pillar 1)
- **Objective B**: Improved African pandemic and outbreak vaccine supply resilience (inclusive of platform technologies that support coronaviruses response)

A visual representation illustrating the interdependencies of the Theory of Change, including its inputs, outputs, three pathways, outcomes (immediate, mid-term, long-term) and objectives is presented in Figure 1. Specific outcome metrics for both Objective A and B are detailed in section 4.1.

AVMA – Theory of Change

✳ Elements of the Theory of Change where AVMA could potentially exert a positive impact, although these elements are beyond the influence of AVMA's design

Pathways: Driving sustainable business models | Building capacities and capabilities that improve PPPR[1] | Sustaining a healthy global market



1. Pandemic, Preparedness, Prevention and Response
2. Vaccine platform describes the type of technology a vaccine uses to initiate an immune response

Figure 1: AVMA Theory of Change

2.4 Key assumptions

The inputs and subsequent outputs of the AVMA Theory of Change (ToC) operate through three pathways, each with its own set of outcomes, which are underpinned by a total of 14 key assumptions. These pathways include driving sustainable business models, building capacities and capabilities that improve pandemic prevention, preparedness and response (PPPR), and sustaining a healthy global market. Each pathway is detailed in its respective table below (Table 2, Table 3, and Table 4), outlining the assumption, evidence, and supporting documents and / or consultations for each of the pathway's immediate, mid-term and long-term outcomes.

2.4.1 Driving sustainable business models

Table 2: Key assumptions for outcomes related to driving sustainable business models

Immediate outcomes	
Assumption 1	
AVMA instrument and its duration is perceived as credible by vaccine manufacturers to start investing years before receiving financial support on the African continent.	
Evidence supporting assumption	Supporting document(s) / consultations
1. As the leading platform for vaccine procurement in Africa, Gavi has substantial credibility with vaccine manufacturers who have or intend to bid for UNICEF tenders.	• Gavi Report: Expanding sustainable vaccine manufacturing in Africa: Priorities for Support
2. In the technical design phase of the instrument in H2 2023, vaccine manufacturers and other ecosystmen stakeholders were consulted in several rounds. They expressed interest and alignment with AVMA as a tool to boost vaccine production in Africa. These consultations confirmed the viability of AVMA.	• AMVA Framework Report: The approach to developing the antigen scope and priorities is detailed in the Framework Report
3. Previous benchmarks confirm the AMC's effectiveness, validating their the proof of concept. For instance, Gavi' through its past AMC showcased its ability to encourage ecosystem activation and to facilitate technology transfer e.g. final evaluation of the PCV AMC pilot was very successful at driving presentation innovation, in terms of Multi-Dose Vials (MDVs). These were key to scaling up supply and driving down cost per dose in LIC and LMIC markets.	• PCV AMC Final Evaluation

Assumption 2	
The design choices of AVMA, such as tiered incentives, incentive size, and value caps, and its accompanying communications strategy, clearly indicate the areas where AVMA aims to support manufacturers in Africa, thereby encouraging diversified investments in both fill & finish and drug substance manufacturing across various platforms	
Evidence supporting assumption	Supporting document(s) / consultations
1. Manufacturers and other important stakeholders (via AVMA) have engaged with the priorities through 60+ consulations, and specific clarifying questions were resolved. Feedback from the ecosystem on the design has been positive, indicating that the structure and the aims they communicate are aligned. Additionally, the incentive structure and values were defined through extensive modeling, which was cross-validated by external experts during stakeholder consultations. This modeling was also compared with other modeling in the same sphere, such as that of BDO Kroll, and GIZ.	• AVMA Modelling: The modelling approach was detailed in the modelling appendix submitted to PPC in October 2023 *Please note the following list of stakeholder consultations is not exhaustive.* • Roundtable with DCVMN: Strategy to support African regional manufacturing • Working session with Africa CDC: AMC design choices, AMC technical design • Roundtable with IFPMA: Gavi's regional manufacturing strategy, AMC design, collaboration • Consultation with CSOs: Gavi's regional society strategy, breakout discussions • Consultation with AVMI: Summary of AVMI feedback to AVMA, modelling approach • Working session with CEPI: Gavi's regional manufacturing strategy, AMC design, Gavi-CEPI collaboration • Consultation with CHAI: Collaboration on African vaccine manufacturing, Baseline market report outline, USAID collaboration
2. Gavi has experience in the design of innovative financing instruments (e.g., PCV AMC and COVAX AMC) and evaluations have show cased their success.	• PCV AMC Final Evaluation • COVAX Facility and COVAX AMC Formative Review and Baseline Study
Assumption 3	
Investors have committed the necessary funds to implement AVMA and to support vaccine manufacturers in Africa.	

Evidence supporting assumption	Supporting document(s) / consultations
Extensive engagement with donors that show clear interest in supporting the AVMA.	• Consultations with the United States, Canada, United Kingdom, France, Italy, Switzerland, Germany, Norway, BMGF and EC
Mid-term outcomes	
Assumption 4	
The incentive structure, facilitated through milestone and accelerator payments, is appropriately defined to support the development of viable commercial strategies for high-potential manufacturers in Africa. (i) The milestone payment, granted upon WHO PQ, is adequately sized to allow manufacturers to maintain operations during a critical stage. At this point, they have already invested significant capital in achieving approval but may still be years away from generating revenue through production, sales, and distribution. (ii) The accelerator payment is substantial enough to enable manufacturers to remain competitive during UNICEF tenders. Additionally, long-term agreements are secured with manufacturers.	
Evidence supporting assumption	Supporting document(s) / consultations
1. Gavi has experience in the design of innovative financing instruments e.g., PCV AMC and COVAX AMC.	• PCV AMC Final Evaluation • COVAX Facility and COVAX AMC Formative Review and Baseline Study
2. Additionally, the incentive structure and values were defined through extensive modeling, which was cross-validated by external experts during stakeholder consultations. This modeling was also compared with other modeling in the same sphere, including that of BDO Kroll.	• AVMA Modelling: The modelling approach was detailed in the modelling appendix submitted to PPC in October 2023 *Please note the following list of stakeholder consultations is not exhaustive.* • Roundtable with DCVMN: Strategy to support African regional manufacturing • Working session with Africa CDC: AMC design choices, AMC technical design • Roundtable with IFPMA: Gavi's regional manufacturing strategy, AMC design, collaboration • Consultation with CSOs: Gavi's regional society strategy, breakout discussions

	• Consultation with AVMI: Summary of AVMI feedback to AVMA, modelling approach • Working session with CEPI: Gavi's regional manufacturing strategy, AMC design, Gavi-CEPI collaboration • Consultation with CHAI: Collaboration on African vaccine manufacturing, Baseline market report outline, USAID collaboration
Assumption 5	
The perception and reality of vaccines made in Africa and supported through AVMA is that their quality is on par with vaccines manufactured elsewhere.	
Evidence supporting assumption	Supporting document(s) / consultations
1. AVMA will only give financial support if a manufacturer has obtained WHO PQ, which is well-recognized as a rigorous and independent regulatory process, used by UNICEF and others actors in procurement to make purchasing decisions regarding specific medical products (e.g. vaccines).	• Scientific paper: Dellepiane N, Wood D. Twenty-five years of the WHO vaccines prequalification programme (1987-2012) lessons learned and future perspectives.
Assumption 6	
Manufacturers will feel greater confidence in their plans in Africa based on clear demand signals to the vaccine market around the willingness (and potential preference) to select and procure vaccines from African suppliers - (Pillar 3)	
Evidence supporting assumption	Supporting document(s) / consultations
This assumption was tested during consultations with stakeholders involved in the African vaccine manufacturing ecosystem. It was aligned that offering clearer demand signals would increase the willingness to select and procure vaccines from African suppliers.	• AVMA Pillar 3 Demand Scenarios
Long-term outcomes	
Assumption 7	
If AVMA-supported manufacturers succeed in winning a UNICEF tender, it is assumed that they have become viable, produce high-quality and competitive vaccines, and therefore there is a strong likelihood of them to continue operating in the vaccine markets beyond the AVMA years	

Evidence supporting assumption	Supporting document(s) / consultations
1. Extensive modelling was performed to define incentive payments level that would allow manufacturers to pay back a significant part of their high start-up investment costs, including initial capital expenditure and cost of capital. Modelling has demonstrated the significance of AVMA as an instrument that will reduce barriers to entry for African countries by providing support early on and throughout the AVMA's lifespan.	• AVMA Modelling: The modelling approach was detailed in the modelling appendix submitted to PPC in October 2023
2. AVMA design has been thoroughly tested and presented in stakeholder consultations. Indeed, if an African manufacturer successfully obtains the WHO PQ and competes effectively to win a UNICEF tender, it is reasonable to consider that overcoming these hurdles is a testament to the manufacturer's viability.	*Please note the following list of stakeholder consultations is not exhaustive.* • Roundtable with DCVMN: Strategy to support African regional manufacturing • Working session with Africa CDC: AMC design choices, AMC technical design • Roundtable with IFPMA: Gavi's regional manufacturing strategy, AMC design, collaboration • Consultation with CSOs: Gavi's regional society strategy, breakout discussions • Consultation with AVMI: Summary of AVMI feedback to AVMA, modelling approach • Working session with CEPI: Gavi's regional manufacturing strategy, AMC design, Gavi-CEPI collaboration • Consultation with CHAI: Collaboration on African vaccine manufacturing, Baseline market report outline, USAID collaboration
3. In the long term, manufacturers consolidate their position on the African continent, they benefit from increasing production scale, strengthening local talent, learning curve effects, and blue-collar efficiency, which can contribute to cost improvements and competitiveness in vaccine manufacturing.	• BMGF: Factors contributing to cost-competitiveness in regional manufacturing

2.4.2 Building capacities and capabilities that improve PPPR

Table 3: Key assumptions for outcomes related to building capacities and capabilities that improve PPPR

Mid-term outcomes	
Assumption 1	
Various stakeholder commitments are bolstering the African vaccine manufacturing ecosystem and addressing key potential challenges along the vaccine manfacturing value chain e.g. by supporting the development of regulatory landscapes and the enhancement of technological and operational capacities of manufacturing plants across the African continent	
Evidence supporting assumption	Supporting document(s) / consultations
1. Commitments to develop African vaccine manufacturing have been made across the ecosystem (billion dollar budgets) (i) PHAHM, the African Union. (ii) the European Commission and the Bill & Melinda Gates Foundation investing over 100 million from 2022-2027. (iii) Several European governments including Germany, France, Belgium supporting the funding for the African Medicines Agency (AMA). (iv) Establishment of the African Pharmaceutical Technology Foundation, which amongst other efforts will support upgrading of manufacturing plant capacities and regulatory quality to meet World Health Organization standards. (v) Team Europe supports Development Agency (AUDA-NEPAD) on regulatory strengthening; WHO's mRNA technology transfer hub in South Africa; Skill development for create the right ecosystem for vaccine manufacturing at a national level; Other initiatives to help strengthening health systems and pandemic preparedness. (vi) Development of local R&D capabilities in Africa in partnership with Africa CDC, including both BMGF and CEPI.	• PHAHM: Partnership for African Vaccine Manufacturing (PAVM) From Aspiration To Action • MAV+: Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa • EU-Africa Global Gateway Investment Package • BMGF: Ahead of EU–AU Summit, African Medicines Regulators Receive Boost of More Than 100 Million Euros from Team Europe and The Bill & Melinda Gates Foundation • Dependency mapping: Details on other actors' commitments to key dependencies can be found in the dependency mapping for submission to the Gavi board

(vii) July 2023, Institute Pasteur Dakar announced a US$ 45 million partnership with the Mastercard Foundation on workforce development for the vaccine manufacturing industry.	
Long-term outcomes	
Assumption 2	
Greater localised capacity for Drug Substance accross diverse platforms and Fill & Finish manufacturing on the African continent will allow for a quicker pandemic outbreak response.	
Evidence supporting assumption	Supporting document(s) / consultations
1. Research has shown that having greater capacity for Drug Substance and Fill & Finish manufacturing enables a faster pandemic outbreak response, as existing infrastructure, operations, and a trained workforce can be utilised for outbreak vaccine production. As global manufacturing capacity is finite, it is crucial to create plans for adequate and thoughtful vaccine production during a pandemic outbreak. To address this constraint, it is necessary to invest in greater drug substance manufacturing capacity, which can also lead to the development of a solid base of diverse vaccine technology platforms. These platforms allow for the development of new vaccines without customizing the process, enabling rapid production of multiple vaccines from a single system. Additionally, another bottleneck, happening more downstream of the vaccine manufacturing stage, is Fill & Finish capacity, which can lack capacity in case of a pandemic outbreak. Finally, to further enhance outbreak manufacturing capacity, it is important to consider supporting new manufacturers in producing vaccines that are needed on a routine basis worldwide, even if there are higher costs early on. These new facilities can be leveraged as a reliable source of production capacity in a future pandemic if they are sustained over time.	• Scientific paper: Williams, B.A., Jones, C.H., Welch, V. et al. Outlook of pandemic preparedness in a post-COVID-19 world. npj Vaccines 8, 178 (2023) • Scientific paper: Monrad, J.T., Sandbrink, J.B. & Cherian, N.G. Promoting versatile vaccine development for emerging pandemics. npj Vaccines 6, 26 (2021) • Scientific paper: Feddema, J. J., Fernald, K. D. S., Schikan, H. G. C. P., & van de Burgwal, L. H. M. (2023). Upscaling vaccine manufacturing capacity - key bottlenecks and lessons learned. Vaccine, 41(30), 4359-4368 • CHAI: Current and planned vaccine manufacturing in Africa • WEF Forum: Ramping up Africa's vaccine manufacturing capability is good for everyone. Here's why. • McKinsey: Building greater resilience in vaccine manufacturing

Furthermore, as logistics are often complicated and strained during a pandemic outbreak, having localized manufacturing and aligning processes like active substance production and fill-and-finish operations to take place closer together would reduce logistical complexity and could increase pandemic outbreak response time. By streamlining the manufacturing and distribution processes, it becomes easier to ensure timely and efficient delivery of vaccines to affected areas. In summary, increasing drug substance and fill & finish manufacturing capacity, supporting new manufacturers, and optimizing logistical processes are all crucial steps in developing outbreak manufacturing capacity and improving pandemic outbreak response. These measures can help ensure that vaccines are produced and distributed efficiently during times of crisis, ultimately saving lives and mitigating the impact of pandemics.	

2.4.3 Sustaining a healthy global market

Table 4: Key assumptions for outcomes related to sustaining a healthy global market

Immediate outcomes	
Assumption 1	
AVMA responds to targeted African ecosystem needs to develop a stable vaccine manufacturers base and ensures to maximise positive externalities	
Evidence supporting assumption	Supporting document(s) / consultations
1. AVMA would form part of broader momentum to develop vaccine manufacturing in Africa, and there are multiple initiatives already underway. As a result, multiple stakeholder, in particular Africa CDC's Platform for Harmonized African Health Products Manufacturing (PHAHM), have pointed to the need for financial support to help manufacturers become financially viable. Additionally, key actors and donors (including the AU, EC and the G7 Development Ministers in their	• Gavi: Expanding sustainable vaccine manufacturing in Africa Priorities for Support • African CDC: What will it take to develop a sustainable vaccine manufacturing ecosystem in Africa? • MAV+: Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa

10-point plan for the expansion of sustainable vaccine manufacturing in Africa) have welcomed AVMA as a way of supporting business cases for African vaccine manufacturers, thus derisking investments.	• G7 Development Minister: Achieving the Sustainable Development Goals in times of multiple crises • CHAI: Current and planned vaccine manufacturing in Africa • WEF Forum: Ramping up Africa's vaccine manufacturing capability is good for everyone. Here's why. • McKinsey: Building greater resilience in vaccine manufacturing
Assumption 2	
AVMA instrument design choices are based on informed decisions on the most suitable course of action to sustain healthy vaccine markets e.g., vaccine platforms, antigen scope and prioritization (Pillar 1 & 2).	
Evidence supporting assumption	Supporting document(s) / consultations
1. The specific priority antigens and platforms proposed at AVMA's launch were extensively consulted with key partners to draw on expertise from the ecosystem	*Please note the following list of stakeholder consultations is not exhaustive.* • Roundtable with DCVMN: Strategy to support African regional manufacturing • Working session with Africa CDC: AMC design choices, AMC technical design • Roundtable with IFPMA: Gavi's regional manufacturing strategy, AMC design, collaboration • Consultation with CSOs: Gavi's regional society strategy, breakout discussions • Consultation with AVMI: Summary of AVMI feedback to AVMA, modelling approach • Working session with CEPI: Gavi's regional manufacturing strategy, AMC design, Gavi-CEPI collaboration • Consultation with CHAI: Collaboration on African vaccine manufacturing, Baseline market report outline, USAID collaboration
2. Gavi has recognised vaccine market expertise through Pillar 1 & 2, access to confidential market forecasting data, and a track record in identifying and assessing market needs in collaboration with African governments. Therefore, AMVA will be able	• AMVA Framework Report: The approach to developing the antigen scope and priorities is detailed in the Framework Report

to benefit from the monitoring of the vaccine market environment and implement adjustments to its instruments through course correction as defined by governance processes.	
Assumption 3	
Sufficient capacity (financing and human resource) is dedicated to establishing and running AVMA's governance and operations.	
Evidence supporting assumption	Supporting document(s) / consultations
Operating cost estimates taking into account the operating costs associated with running the AVMA will be kept below a 3% target, and are expected to be kept under approximately US$ 3 million annualised.	• AVMA AFC-2024-Mtg-01-Doc 07- Main paper
Mid-term outcomes	
Assumption 4	
Manufacturers' investment decisions are shaped by the incentives set in AVMA and Gavi's market health assessment (Pillar 1 & 2).	
Evidence supporting assumption	Supporting document(s) / consultations
1. Gavi, through its Pillar 1 & 2, has developed a strong expertise in the African vaccine market environment, allowing it to assess which vaccine markets make the most sense for manufacturers to enter due to latent demand. Additionally, the incentive structure of AVMA has been carefully designed and tested through stakeholder consultations to ensure that AVMA's support is sufficient for new vaccine manufacturers to operate efficiently in the vaccine markets that have been prioritised.	• AMVA Framework Report: The approach to developing the antigen scope and priorities is detailed in the Framework Report
2. Gavi through it Pillar 1 offers manufacturers and investors structured insights on the vaccine market environment, primarily through the publication of detailed market intelligence reports.	
Long-term outcomes	
Assumption 5	

Overall, the market entries and other changes associated with the AVMA have proven beneficial for the health of the vaccine market, leading to a more adequate vaccine supply and balanced competitive dynamics. These changes have resulted in a diversified vaccine procurement landscape in Africa and the development of buffer capacity directly on the continent.	
Evidence supporting assumption	Supporting document(s) / consultations
1. Manufacturer eligibility and incentive structure design are based on Gavi's expertise and consultation with stakeholders to ensure the greatest impact on vaccine market health by encouraging the entry of manufacturers into antigen markets where they are most needed.	• AVMA Modelling: The modelling approach was detailed in the modelling appendix submitted to PPC in October 2023
2. Market distortions due to substantial overpayments are highly unlikely to occur as the incentive structure has been carefully designed (substantial modelling backing this).	

3. AVMA reporting and review cycles

The monitoring and review cycles for the AVMA are designed with multiple considerations in mind. 1) Collection of timely data on key operational metrics. 2) Internal reporting for Gavi governance to give guidance and if need be, inform course correction. 3) Reporting for external accountability and transparency to partners, donors and broader stakeholders. 4) Evaluation and evidence-gathering to inform future instruments or similar initiatives.

The proposed review cycles reflect these objectives and are detailed in Figure 2. They include biannual reporting of key operational metrics, annual board updates, larger-scale triennial reviews with external reviewers (also to inform potential course correction) and a fully independent final evaluation.

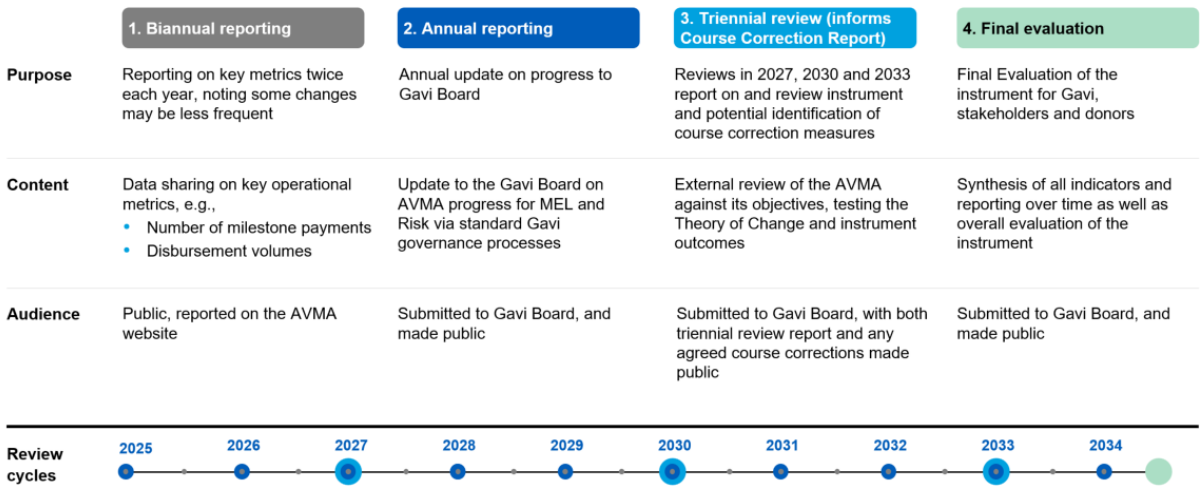


Figure 2: AVMA Reporting and review cycles

1. *Biannual reporting:* The Secretariat reports on operational key metrics twice a year, such as milestone payments and disbursement volumes, and makes this information publicly available on its website. It is important to note that these reports do not provide a complete overview of the entire MEL logframe and will be subject to data availability. Additionally, many metrics may change less than twice per year, especially during the initial years of the instrument before disbursements begin.

2. *Annual reporting:* The Secretariat will submit an annual report covering all metrics in the AVMA logframe to the Gavi Board, in line with established Gavi governance processes.

3. *Triennial review*: Every three years, the AVMA undergoes external review against its objectives, including testing the Theory of Change and instrument outcomes. It is proposed that these external reviews are decentralized, i.e., commissioned directly by the AVMA team. Based on the findings of the external reviews, the Secretariat prepares a Course Correction Report, formulating any proposals for instrument adjustments in line with the scope for course correction set out in the PPC-2024-Mtg-01-Doc 12 Main Paper as well as PPC-2024-Mtg-01-Doc 12-Appendix 1. Reviews will be conducted in 2027, 2030, as 2033 to assess the instrument and identify potential course correction measures.

4. *Final evaluation:* The final evaluation is not expected to occur before 2035, since the exact timeframe for commissioning the evaluation will be determined by taking into account other key considerations such as the UNICEF tender timelines. It is proposed that the evaluation is conducted with oversight from Gavi's Evaluation Advisory Committee in the form of a centralised evaluation, and in line with the standard Gavi evaluation practice. Evaluators will be expected to build upon and fully utilise all MEL associated work done to date – inclusive of triennial reviews.

4. AVMA monitoring and evaluation metrics

The AVMA Theory of Change (ToC), approved by the Board in December 2023, outlines four outcome targets for its two objectives, as detailed under 4.1 and illustrated in Figure 3. To effectively monitor and evaluate these targets, the AVMA Monitoring, Evaluation and Learning (MEL) Framework includes a "logframe" that links MEL indicators as well as interim targets to the ToC's immediate, mid-term and long-term outcomes. These indicators and targets will be used to measure the AVMA's progress across review cycles (2027, 2030, 2033) and its final evaluation. In this section, the outcome metrics, the logframe and the underlying methodology are examined.

4.1 Outcome metrics

As illustrated in the AVMA ToC in section 2.3, the AVMA has two key objectives:

- **Objective A**: A sustainable, African vaccine manufacturing base that is contributory to healthy global vaccine markets (in alignment with Pillar 1)
- **Objective B**: Improved African pandemic and outbreak vaccine supply resilience (inclusive of platform technologies that support coronaviruses response)

4.1.1 Outcome metrics on Objective A

The modelling, simulation and scenario analysis conducted to date provides confidence in meeting AVMA's specific objectives, whilst also contributing to those of Gavi's broader market-shaping and pandemic prevention, preparedness and response (PPPR) objectives, and those

of the AU partners. Specifically, the AVMA is expected to support the commercial viability of at least four manufacturers who secure at least one United Nations Children's fund (UNICEF) tender each with AVMA support and set on the path to long-term sustainability by 2035[3].

In addition, the AVMA is expected to incentivize the production of over 0.8 billion cumulative vaccine doses over 10 years, including drug product and DS (with Africa meeting 15-20% of Gavi-eligible African demand by 2035) and thus, ensuring that manufacturers reach sustainable business operations, supported by both AVMA financed demand, and that of the wider continent. Therefore, the AVMA will support substantial and sustainable vaccine production capacity, as a necessary and foundational contribution to reach the AU target to manufacture over 60% of the doses required for Africa's immunisation needs on the continent by 2040. This target requires ~1.1 billion annual doses by 2040[4], indicating at least 4-6 manufacturers producing 150-350 million doses p.a. (to ensure diversity and avoid monopoly).

4.1.2 Outcome metrics on Objective B

In a future pandemic, vaccine production capacity may well need to pivot to pandemic-related vaccines. By 2035, the maximum drug product capacity of the AVMA-supported supply base could reach 0.7 billion doses that may be repurposed in a potential outbreak scenario. The AVMA will therefore make a critical contribution to continental pandemic preparedness and ability to ramp up production for coverage.

As CEPI has noted, vaccine platform diversity is a critical component of an effective vaccine-led pandemic response, due to the unpredictability of the required response unknown pathogens. Via the AVMA, at least three major DS platform technologies are expected to be supported until 2035.

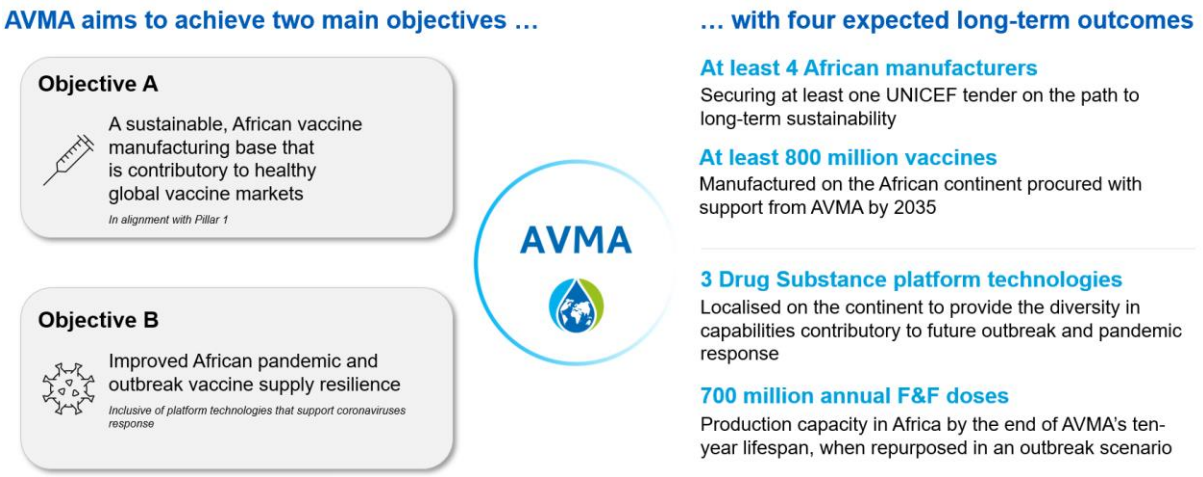


Figure 3: AVMA Objectives and expected long-term outcomes

[3] Inclusive of both F&F and DS manufacturers. DS platform technologies are the focus of the outcome metric for objective B.
[4] Total estimated African vaccine demand is 1.8 billion doses in 2040, CHAI/PATH Vaccine Manufacturing in Africa – Current State Supply Map, 2023

4.2 AVMA Logframe

The AVMA's monitoring and reporting activities are essential for assessing the effectiveness and impact of the instrument throughout its lifespan. To ensure accurate tracking, a logframe has been developed, attaching MEL indicators and associated targets on to most elements of the AVMA's Theory of Change (ToC).

The entire AVMA logframe, includingToC elements, their associated MEL indicators and targets, can be found at the end of this document (AVMA MEL Logframe). For assessing progress of ToC elements, which do not have an indicator, see section 5, Learning Agenda.

4.2.1 MEL Indicators

MEL indicators serve as measurements to determine if specific elements or stages in the AVMA ToC have been successfully implemented or achieved. A total of 19 MEL indicators, were identified and are shown in Figure 4. A detailed assessment of each indicator can be found at the end of this document (AVMA MEL Indicator Reference Sheets). Note that not all indicators have an associated target, as explained below.

4.2.2 Targets

The interim targets for the identified MEL indicators have been defined in alignment with Gavi's Board-approved outcome targets and extensive AVMA modelling. These targets and indicators are mapped to AVMA's review cycles, specifically in 2027, 2030, 2033, and aim to assess AVMA's performance and progress towards the desired outcomes outlined in the Theory of Change (ToC). By regularly reviewing and assessing performance against these targets, the AVMA can track its progress, identify areas for improvement, and make informed decisions to optimize its impact.

4.2.2.1 MEL indicators with targets

For most MEL indicators, each mapping to specific ToC element(s), targets were established to coincide with and inform each of the triennial review points. These targets serve as an indication of whether this part of the ToC has materialised as planned, and whether the AVMA is therefore on track.

4.2.2.2 MEL indicators without targets

Certain MEL indicators, again each mapping to specific ToC element(s), do not have targets due to methodological constraints. An example of this is target-setting linked to manufacturing capacity - which is methodologically challenging to accurately measure in a high-quality manner. Additionally, targets are not set for AVMA's broader contribution to ecosystem-related changes, such as developing a more skilled workforce in Africa, since it is not a direct objective of the AVMA and therefore falls outside of Gavi's mandate. Given not all indicators or aspects of the broad ToC lend themselves well to measurable quantitative indicators and targets, the Secretariat will seek to complement quantitative reporting with qualitative reporting where necessary. A key example here is work linked to the ecosystem (see below).

Figure 4: AVMA MEL Indicators

AVMA MEL Indicators

Indicator with target | Indicator without target

1	Number of AVMA-eligible manufacturers having secured competitively at least one UNICEF tender	11	AVMA priority markets with an improved assessment of the "Geopolitical and regional diversity risk" HMF attribute (i.e., from "Unmet" to "Partially met", from "Partially met" to "Met")
2	Number of vaccine doses that have received accelerator payments and are being supplied through long-term agreements (LTAs), won by AVMA-supported manufacturers, via the UNICEF tender process	12	Qualitative updates as and when changes are made to the AVMA design via course correction procedure in the AVMA governance (e.g., other antigens, platforms, manufacturers) setting out nature and rationale
3	Existing African F&F capacity (doses) which can be repurposed to manufacture vaccines in case of a future pandemic	13	Number of AVMA eligible manufacturers who formally engaged with Gavi on the AVMA (e.g., through submission of an Expression of Interest (EoI))
4	Total outbreak scenario capacity (doses) of the AVMA-supported supply base	14	Planned maximum manufacturing capacity (doses) of AVMA-eligible manufacturers who formally engaged with Gavi on the AVMA (e.g., through submission of an Expression of Interest (EoI)) - based on annual forecasts
5	Number of different drug substance platform technologies supported by the AVMA (through milestone payments, accelerator payments, or both)	15	Governance processes have been adhered to (Yes / No)
6	Number of milestone payments	16	Qualitative assessment of governance, its implementation and alignment with broader ecosystem insights collected from Pillar 1, 2 and 3
7	Number of UNICEF tenders won competitively by manufacturers supported by the AVMA	17	Formal stakeholder engagements on AVMA topics have happened (Yes / No)
8	Number of LOIs submitted by AVMA-eligible manufacturers to begin the WHO PQ process (incl. both priority and non-priority vaccines)	18	Qualitative assessment of broader stakeholder engagement on AVMA topics in terms of perception and satisfaction - (with focus on support from Pillar 3)
9	Total existing capacity (doses) of the AVMA-supported supply base	19	Monitoring of caps reached
10	Number of national regulatory authorities (NRAs) with maturity level 3 (ML3) producing status on the African continent		

4.2.2.3 Methodology for target-setting

The pipeline of manufacturer forecasts from the AVMA Model, developed over 10 months and in collaboration with deep technical and landscape knowledge from Gavi Market Shaping, UNICEF, CHAI, BMGF, and individual experts, serves as the baseline for setting these targets. Forecasts on the manufacturers expected to produce eligible vaccines, when they achieve WHO Prequalification (PQ), and when and at what volume they achieve a UNICEF tender, form the basis of a solid foundation for understanding the current landscape and projecting payment of milestone and accelerator payments, as well as setting related targets.

Vaccine manufacturing is technically complex and subject to significant regulatory considerations. This entails a significant amount of uncertainty surrounding manufacturers' plans. Adjustments have been made to ensure that the interim targets reflect a conservatively realistic risk appetite. One key adjustment involves delaying the potential WHO PQ date of a manufacturer or the date when they would be expected to win the UNICEF tender. By doing so, AVMA avoids committing too early on ambitious interim targets at the 1st and 2nd AVMA review cycles. Additionally, adjustments have been extensively aligned with market shaping to ensure that the interim targets are feasible and achievable. This results in targets, including the board approved objective of 800 million doses, being derived at a high level from the anticipated minimal output of at least 4 manufacturers, representing what is expected to be minimally needed for the stable functioning of a sustainable vaccine manufacturing industry. There is an expectation that successful manufacturers produce more relative to what they

minimally need in order to be sustainable, which is why a higher funding commitment is needed.

5. Learning agenda

The M&E Framework set out above provides clearly defined indicators which regularly assess the AVMA's progress and impact against its objectives. However, understanding AVMA's influence, effectiveness and impact cannot be understood nor unpacked sufficiently with indicators alone. One clear limitation is that robust and regular data is not always available, e.g., on total planned manufacturing capacity, where highly differing approaches from manufacturers prevent comparable or cumulative quantification. The other key limitation is that for such a complex ecosystem, evaluating causal connections between the AVMA's incentives and second-order effects (e.g., on local availability of talent, on infrastructure, or on pandemic response) must be done with great care. A simple connection between single indicators and ecosystem is not sufficient and cannot unpack potential intended or unintended consequences of AVMA over its implementation.

For these topics, over the AVMA's lifetime, a more detailed investigation of specific questions and / or dedicated data generation and analysis may be required (detailed next). The AVMA learning agenda will continue to be developed as the instrument is launched and begins operating.

5.1 Ecosystem learnings

The notion of the AVMA as part of a wider ecosystem is integral to the instrument's design, its governance, risk, and monitoring. Ecosystem mobilisation is key as an input to help operationalise the instruments, as well as an output for the Learning Agenda to regularly assess the broader vaccine manufacturing landscape as it pertains to the AVMA. Indeed, AVMA will rely on collaboration and engagement with stakeholders and partners.

To monitor changes in the broader ecosystem, an analysis of ecosystem dependencies will be conducted as a component of the triennial review (Table 5). This review will contextualise the AVMA's progress and impact within the broader ecosystem. Gavi will commission and engage external partners to review the ecosystem to provide the in-depth analysis and mapping required for the Ecosystem Dependencies Review.
The Manufacturing Forum, an annual event co-convened by Gavi and the Africa CDC, offers participants the opportunity to explore key dependencies and share insights that critically inform both the quantitative and qualitative understanding of the AVMA's ecosystem. While the forum does not hold decision-making authority, its consultative role enables a collective examination of ecosystem health and interdependencies. The insights garnered here inform the indicators and broader qualitative assessment used in the Ecosystem Dependencies Review.

Table 5: AVMA ecosystem learnings[5]

Dependency	Description	Proposed Analysis

[5] These can be further refined, adapted or revisited as AVMA evolves

Market design & demand intelligence	One of the main challenges for the AVMA revolves around ensuring sufficient demand for new manufacturers in Africa to establish economies of scale.	Analysis on the change in market health, including tracking the "Geopolitical and regional diversity risk" attribute of Gavi's Healthy market Framework for improvement or deterioration. Collaboration with PAVM and other partners on demand intelligence and analyses.
Access to finance	Financing is a crucial challenge for African vaccine manufacturing, with perceptions of high risk and unclear business cases hindering investment. Funds are committed by a wide variety of programmes for the African vaccine manufacturing agenda.	Landscaping of the financing for African vaccine manufacturing, including assessing the total funds committed (in US$ million) and nature of the financing.
Regulatory strengthening	Achieving WHO Prequalification is a requirement for AVMA eligibility, but only South Africa and Egypt currently have WHO-qualified National Regulatory Authorities (NRAs) at the requisite ML3 status for vaccine production.	Mapping of national regulatory authorities (NRAs) maturity levels for vaccines, for progress towards ML3 which serves as an indicator of the continent-wide level of sophistication in the pharmaceutical regulatory environment.
R&D and talent development	Insufficient local talent, compounded by brain drain and lack of funding, poses a significant challenge to vaccine manufacturing in Africa. While talent development and retention is beyond Gavi's primary focus, it does form part of the upstream ecosystem that will ultimately drive the AVMA's success.	Review of progress in talent development and R&D pipeline, including the number of full-time employees (FTEs) working for AVMA supported manufacturers.
Technology transfer and IP	The AVMA's success hinges on an increase in technology transfers, which it indirectly encourages by generating new incentives for IP owners to partner with African manufacturers.	Mapping of tech-transfers which AVMA manufacturers receive and plans underway
Infrastructure development	Access to infrastructure e.g., water, electricity and transport networks may be insufficient for industry use. Soft trade enablers such as regulatory harmonization and trade of vaccine-specific inputs and outputs also form part of the	Mapping of specific blocks and initiatives aimed as African vaccine manufacturing monitor wider progress than AVMA underway in this dependency. Landscaping and analysis of manufacturers & products

	necessary framework infrastructure for the industry	considered ineligible for AVMA e.g. CMOs in Africa

5.2 Operational learnings

Beyond specific ecosystem learnings, several operational aspects of the AVMA, such as market health and the impact of diversified regional vaccine manufacturing, likely require dedicated work beyond the M&E framework (Table 6). They could be externally commissioned as part of the triennial reviews and as a complement to the core monitoring and evaluation set out above.

Table 6: AVMA operational learnings[6]

Operational learning	Initial reflections
To what extent is the AVMA impacting market health either positively or negatively?	• Explore a more in-depth causality assessment approach between AVMA results and timelines and evolution of market health over time
To what extent have manufacturers' decisions been influenced by the AVMA?	• Impact on choice of F&F or DS platforms • Access, utility and influence of Gavi's healthy market assessments on manufacturer decision-making • Impact on acquisition of regulatory compliance requirements • Impact on UNICEF tender applications
What have been the potential impacts of diversified regional vaccine manufacturing from a public health or economic impact perspective?	• Modelling to explore impact on deaths averted and other key health metrics • Economic impact on public health, e.g., as reduction in loss of income resulting from vaccine-preventable diseases (due to increased vaccination rates) • Review of Sustainable Development Goal (SDG4) metrics from a market health perspective, e.g., impact of vaccines on specific diseases such as Cholera • Economic benefit on local industry, e.g., through creation of job opportunities in the region
What have been the potential impacts of diversified regional vaccine manufacturing on pandemic preparedness?	• Impact on vaccine production efficiency, diversity and scale • Infectious disease modelling (e.g., number of lives saved if assumptions for manufacturing capacity were different)

[6] These can be further refined, adapted or revisited as AVMA evolves

6. Definitions for Indicator Reference Sheets and Logframe

Table 7: Parameters of the MEL indicators

Level of disaggregation	Level of detail at which data is collected and reported for AVMA MEL indicators. Each level has different (interim) targets associated with it	Overall	Summary of data across all levels of disaggregation
		F&F	Fill and finish
		DS	Drug substance
		DS platforms	All drug substance platforms
		DS priority platforms	Only mRNA and Viral Vector platforms
Frequency of reporting	Lowest feasible data collection and reporting frequency (if triggered by changes)	Biannual	Twice per year
		Annual	Once per year
		Triennial	Every three years
Data type	Classification specifying the nature of information utilized as indicators	Internal indicator	Metrics derived from internal processes or data sources of the AVMA
		External indicator	Metrics derived from outside stakeholders or environments of the AVMA
Data source	Origin from which information is gathered to measure indicators		
Data handling	Gavi team responsible for managing and processing indicator data		

7. AVMA MEL Indicator Reference Sheets (short-hand version)

Indicator I.D. / Name	1. Number of AVMA-eligible manufacturers having secured competitively at least one UNICEF tender
Unit	# of manufacturers
Count	Cumulative
Level of disaggregation	Overall, F&F, DS
Frequency of reporting	Biannual
Data type	Internal indicator
Data source	AVMA (recorded when receiving payment notice from UNICEF)
Data handling	Market Shaping

Indicator I.D. / Name	2. Number of vaccine doses that have received accelerator payments and are being supplied through long-term agreements (LTAs), won by AVMA-supported manufacturers, via the UNICEF tender process
Unit	# of doses (million)
Count	Cumulative
Level of disaggregation	Overall, F&F, DS
Frequency of reporting	Biannual
Data type	Internal indicator
Data source	AVMA (recorded when receiving payment notice from UNICEF)
Data handling	Market Shaping

Indicator I.D. / Name	3. Existing African F&F capacity (doses) which can be repurposed to manufacture vaccines in case of a future pandemic
Unit	# of doses (million)
Count	Cumulative
Level of disaggregation	F&F
Frequency of reporting	Annual
Data type	External indicator
Data source	Internal Gavi calculation of outbreak capacity based on capacity of AVMA-supported supply base
Data handling	Market Shaping

Indicator I.D. / Name	4. Total outbreak scenario capacity (doses) of the AVMA-supported supply base
Unit	# of doses (million)
Count	Cumulative
Level of disaggregation	DS
Frequency of reporting	Annual
Data type	External indicator
Data source	Internal Gavi calculation of outbreak capacity based on capacity of the AVMA-supported supply base
Data handling	Market Shaping

Indicator I.D. / Name	5. Number of different drug substance platform technologies supported by the AVMA (through milestone payments, accelerator payments, or both)
Unit	# of DS platform technologies
Count	Cumulative
Level of disaggregation	DS, DS priority platforms (only mRNA, Viral Vector)
Frequency of reporting	Biannual
Data type	Internal indicator
Data source	AVMA (recorded when disbursing milestone and accelerator payments)
Data handling	Market Shaping

Indicator I.D. / Name	6. Number of milestone payments
Unit	# of payments
Count	Cumulative
Level of disaggregation	DS, DS priority platforms (only mRNA, Viral Vector), F&F
Frequency of reporting	Biannual
Data type	Internal indicator
Data source	AVMA (recorded when manufacturer receives WHO PQ and Gavi approves milestone payment and transfers it to UNICEF)
Data handling	Market Shaping

Indicator I.D. / Name	7. Number of UNICEF tenders won competitively by manufacturers supported by the AVMA
Unit	# of tenders
Count	Cumulative
Level of disaggregation	DS, F&F
Frequency of reporting	Biannual
Data type	External indicator
Data source	UNICEF (when UNICEF communicates that AVMA-supported manufacturer won the tender process)
Data handling	Market Shaping

Indicator I.D. / Name	8. Number of LOIs submitted by AVMA-eligible manufacturers to begin the WHO PQ process (incl. both priority and non-priority vaccines)
Unit	# of LOIs
Count	Cumulative
Level of disaggregation	Overall, F&F, DS, DS priority platforms (only mRNA, Viral Vector)
Frequency of reporting	Biannual
Data type	External indicator
Data source	WHO (LOI submitted by manufacturer)
Data handling	Market Shaping

Indicator I.D. / Name	9. Total existing capacity (doses) of AVMA-supported supply base
Unit	# of doses (million)
Count	N/A
Level of disaggregation	F&F, DS, DS platforms, DS priority platforms (only mRNA, Viral Vector), Vaccine market
Frequency of reporting	Annual
Data type	External indicator
Data source	Internal Gavi assessment
Data handling	Market Shaping

Indicator I.D. / Name	10. Number of national regulatory authorities (NRAs) with maturity level 3 (ML3) producing status on the African continent
Unit	# of NRAs
Count	N/A
Level of disaggregation	N/A
Frequency of reporting	Biannual
Data type	External indicator
Data source	WHO website publication
Data handling	VMHS MEL

Indicator I.D. / Name	11. AVMA priority markets with an improved assessment of the "Geopolitical and regional diversity risk" HMF attribute (i.e., from "Unmet" to "Partially met", from "Partially met" to "Met")
Unit	# of markets
Count	N/A
Level of disaggregation	N/A
Frequency of reporting	Annual
Data type	External indicator
Data source	Market Shaping
Data handling	Market Shaping

Indicator I.D. / Name	12. Qualitative updates as and when changes are made to the AVMA design via course correction procedure in the AVMA governance (e.g., other antigens, platforms, manufacturers) setting out nature and rationale
Unit	N/A
Count	N/A
Level of disaggregation	N/A
Frequency of reporting	Triennial
Data type	Internal indicator
Data source	Gavi (Pillar 1) - To provide potential nature and rationale of course correction
Data handling	Market Shaping

Indicator I.D. / Name	13. Number of AVMA-eligible manufacturers who formally engaged with Gavi on the AVMA (e.g., through submission of an Expression of Interest (EoI))
Unit	# of manufacturers
Count	Cumulative
Level of disaggregation	Overall
Frequency of reporting	Biannual
Data type	Internal indicator
Data source	AVMA (recorded when EOI recorded on website)
Data handling	Market Shaping

Indicator I.D. / Name	14. Planned maximum manufacturing capacity (doses) of AVMA-eligible manufacturers who formally engaged with Gavi on the AVMA (e.g., through submission of an Expression of Interest (EoI)) - based on annual forecasts
Unit	# of doses (million)
Count	N/A
Level of disaggregation	F&F, DS, DS priority platforms (only mRNA, Viral Vector)
Frequency of reporting	Biannual
Data type	Internal indicator
Data source	AVMA (recorded when EOI recorded on website)
Data handling	Market Shaping

Indicator I.D. / Name	15. Governance processes have been adhered to (Yes / No)
Unit	N/A
Count	Yes / No
Level of disaggregation	- Annual governance reporting has been completed - AVMA has been discussed at PPC and board meetings
Frequency of reporting	Annual
Data type	Internal indicator
Data source	Governance processes recorded as they occur
Data handling	VMHS MEL

Indicator I.D. / Name	16. Qualitative assessment of governance, its implementation and alignment with broader ecosystem insights collected from Pillar 1, 2 and 3
Unit	N/A
Count	N/A
Level of disaggregation	N/A
Frequency of reporting	Annual
Data type	Internal indicator
Data source	Qualitative assessment from AVMA team in the form of a narrative write-up + Potential survey on governance processes if resources allow
Data handling	Resource Mobilisation

Indicator I.D. / Name	17. Formal stakeholder engagements on AVMA topics have happened (Yes / No)
Unit	N/A
Count	Yes / No
Level of disaggregation	- AVMA has been discussed at Investor Forum - AVMA has been discussed at Square Group meeting - AVMA has been discussed at Africa CDC / Gavi Manufacturing Forum - AVMA has commissioned external evaluators for review / evaluation cycle
Frequency of reporting	Annual
Data type	Internal indicator
Data source	Stakeholder engagements recorded as they occur
Data handling	Resource Mobilisation

Indicator I.D. / Name	18. Qualitative assessment of broader stakeholder engagement on AVMA topics in terms of perception and satisfaction – (with focus on support from Pillar 3)
Unit	N/A
Count	N/A
Level of disaggregation	N/A
Frequency of reporting	Annual
Data type	Internal indicator
Data source	Qualitative assessment from AVMA team (narrative on broader stakeholder engagement) + IF FEASIBLE stakeholder survey on perception of engagements
Data handling	Resource Mobilisation

Indicator I.D. / Name	19. Monitoring of caps reached
Unit	N/A
Count	N/A
Level of disaggregation	- Manufacturer Cap: Total - Manufacturer Cap: F&F - Instrument Wide Cap: F&F - Instrument Wide Cap: Antigen - Instrument Wide Cap: Milestone payments
Frequency of reporting	Annual
Data type	Internal Indicator
Data source	AVMA generated data (by milestone and accelerator payments)
Data handling	Market Shaping

8. AVMA MEL Logframe

Element(s) in Theory of Change	Indicator ID	Indicator Name	Level of Disaggregation	Baseline[1]	First Review 2027	Second Review 2030	Third Review 2033	Final Evaluation
					Target 2026[1]	Target 2029[1]	Target 2032[1]	Final Target[1]
1.A A sustainable, African vaccine manufacturing base, that is contributory to healthy global vaccine markets 2.A African vaccine manufacturers operating sustainably and producing commercially viable vaccines 5.E Provides clear pathways towards sustainable business operations with an exit strategy	1	Number of AVMA-eligible manufacturers having secured competitively at least one UNICEF tender	Overall	0	1	3	4	4
			F&F	0	0	1	2	3
			DS	0	1	2	2	2
1.A A sustainable, African vaccine manufacturing base, that is contributory to healthy global vaccine markets 5.B Provides per dose payments when supplying through Gavi-UNICEF tenders	2	Number of vaccine doses that have received accelerator payments and are being supplied through long-term agreements (LTAs), won by AVMA-supported manufacturers, via the UNICEF tender process	Overall	0	0	130	490	800
			F&F	0	0	60	240	420
			DS	0	0	70	250	380
3.B African F&F capacity can be repurposed to manufacture vaccines in case of future pandemic	3	Existing African F&F capacity (doses) which can be repurposed to manufacture vaccines in case of a future pandemic	F&F	0	100	400	500	700
1.B Improved African pandemic and outbreak vaccine supply resilience 2.C Swift response to potential pandemics, through adaptable DS infrastructure and technology (incl. mRNA) to PPPR	4	Total outbreak scenario capacity (doses) of the AVMA-supported supply base	DS	0	0	0	30	30

[1] Targets are cumulative.

Element(s) in Theory of Change	Indicator ID	Indicator Name	Level of Disaggregation	Baseline[1]	First Review 2027	Second Review 2030	Third Review 2033	Final Evaluation
					Target 2026[1]	Target 2029[1]	Target 2032[1]	Final Target[1]
1.B Improved African pandemic and outbreak vaccine supply resilience 2.F Diversified platform portfolio entering the market over time that allow a swift response to potential pandemics 3.C Increased investments in DS AVM with diversified platform portfolio covering routine immunization (e.g., Covid-19) and PPPR priority platforms including manufacturers receiving milestone payment post WHO PQ	5	Number of different drug substance platform technologies supported by the AVMA (through milestone payments, accelerator payments, or both)	DS	0	1	2	3	3
			DS priority platforms (only mRNA, Viral Vector)	0	0	0	1	1
2.B Potential investments in new DS routine platforms, such as mRNA for Malaria 5.A Supports regional F&F and DS manufacturing investments in all antigen categories 5.C Provides early funding through milestone payments at WHO PQ	6	Number of milestone payments	DS	0	1	2	4	4
			DS priority platforms (only mRNA, Viral Vector)	0	0	0	1	1
			F&F	0	1	1	2	2
2.B Potential investments in new DS routine platforms, such as mRNA for Malaria 5.A Supports regional F&F and DS manufacturing investments in all antigen categories 5.C Provides early funding through milestone payments at WHO PQ	7	Number of UNICEF tenders won competitively by manufacturers supported by the AVMA	DS	0	1	2	3	4
			F&F	0	0	2	4	6

[1] Targets are cumulative.

Element(s) in Theory of Change	Indicator ID	Indicator Name	Level of Disaggregation	Baseline[1]	First Review 2027	Second Review 2030	Third Review 2033	Final Evaluation
					Target 2026[1]	Target 2029[1]	Target 2032[1]	Final Target[1]
2.B Potential investments in new DS routine platforms, such as mRNA for Malaria 2.F Diversified platform portfolio entering the market over time that allow a swift response to potential pandemics 3.C Increased investments in DS AVM with diversified platform portfolio covering routine immunization (e.g., Covid-19) and PPPR priority platforms including manufacturers receiving milestone payment post WHO PQ	8	Number of LOIs submitted by AVMA-eligible manufacturers to begin the WHO PQ process (incl. both priority and non-priority vaccines)	Overall	0	3	4	7	7
			F&F	0	1	2	3	3
			DS	0	2	2	4	4
			DS priority platforms (only mRNA, Viral Vector)	0	0	0	1	1
3.A Strengthened viability of planned and 0existing African platform-agnostic F&F AVM capacity across all antigen priority categories	9	Total existing capacity (doses) of the AVMA-supported supply base	F&F	No target set - it is not possible to meaningfully assess the total maximum capacity of manufacturers given the disparate methodologies, technologies and portfolios which determine this indicator. Therefore, no targets are set for this indicator. Technical detail: For Fill and Finish, capacity is a theoretical number determined by the number and speed of installed filling machines, the composition of a manufacturer's portfolio and the presentation of vaccines in the portfolio. Some products may be interchangeable between filling lines, others are not. This results in the theoretical 'maximum capacity' being ultimately highly derived and ultimately not meaningful. For drug substance the vast differences in production technology between (and even within) products results in a theoretical maximum capacity being equally uninformative.				
			DS					
			DS platforms					
			DS priority platforms (only mRNA, Viral Vector)					
			Vaccine market					

[1] Targets are cumulative.

Element(s) in Theory of Change	Indicator ID	Indicator Name	Level of Disaggregation	Baseline[1]	First Review 2027	Second Review 2030	Third Review 2033	Final Evaluation
					Target 2026[1]	Target 2029[1]	Target 2032[1]	Final Target[1]
2.D Positive externalities towards pandemic response (e.g., strengthened labour and regulatory to support timely scale-up of vaccine production) 3.D Strengthened enabling environment for the vaccine market (e.g., skilled labour, enhanced regulatory capabilities) and beyond (e.g., economic and labour market development)	10	Number of national regulatory authorities (NRAs) with maturity level 3 (ML3) producing status on the African continent	N/A	Progress is tracked to follow Theory of Change, but as this is beyond AVMA scope and Gavi mandate, no targets are set.				
2.E Sustained market health over time 3.E Selected appropriate adjustments of the AVMA design in response to market context	11	AVMA priority markets with an improved assessment of the "Geopolitical and regional diversity risk" HMF attribute (i.e., from "Unmet" to "Partially met", from "Partially met" to "Met")	N/A	Progress is tracked to follow Theory of Change, but as this is beyond AVMA scope and Gavi mandate, no targets are set.				
3.E Selected appropriate adjustments of the AVMA design in response to market context	12	Qualitative updates as and when changes are made to the AVMA design via course correction procedure in the AVMA governance (e.g., other antigens, platforms, manufacturers) setting out nature and rationale	N/A	No target but could be potentially part of an evaluation.				
4.A Signal to investors and manufacturers for compelling investment cases in African manufacturing: 4.A.1: Volume-driven AVMA funding boosting African F&F and DS manufacturing capabilities 4.A.2: Increased financial capacity due to early payments upon attaining WHO PQ certification 4.A.3: Successful acquisition of AVMA funding enabling diverse antigen	13	Number of AVMA eligible manufacturers who formally engaged with Gavi on the AVMA (e.g., through submission of an Expression of Interest (EOI))	Overall	0	5	5	5	5

[1] Targets are cumulative.

Element(s) in Theory of Change	Indicator ID	Indicator Name	Level of Disaggregation	Baseline[1]	First Review 2027	Second Review 2030	Third Review 2033	Final Evaluation
					Target 2026[1]	Target 2029[1]	Target 2032[1]	Final Target[1]
production across multiple platforms for manufacturing within Africa, facilitated through effective Gavi-UNICEF procurement								
4.A Signal to investors and manufacturers for compelling investment cases in African manufacturing: 4.A.1: Volume-driven AVMA funding boosting African F&F and DS manufacturing capabilities 4.A.2: Increased financial capacity due to early payments upon attaining WHO PQ certification 4.A.3: Successful acquisition of AVMA funding enabling diverse antigen production across multiple platforms for manufacturing within Africa, facilitated through effective Gavi-UNICEF procurement	14	Planned maximum manufacturing capacity (doses) of AVMA-eligible manufacturers who formally engaged with Gavi on the AVMA (e.g., through submission of an Expression of Interest (EOI)) - based on annual forecasts	F&F	Given the various methodologies used to assess manufacturing capacity by each manufacturer (e.g., depending on the served vaccine market or assumptions used for assessing manufacturing capacity), it can be challenging to assess the data shared by manufacturers through EOIs against targets. Therefore, no targets are set for this indicator.				
			DS					
			DS priority platforms (only mRNA, Viral Vector)					
4.B Governance that balances flexibility in response to evolving market context with the need for reliable market signals 5.F Governance and steering allows for adjustments of the AVMA over time	15	Governance processes have been adhered to (Yes / No)	Annual governance reporting has been completed	N/A	Yes	Yes	Yes	Yes
			AVMA has been discussed at PPC and board meetings	N/A	Yes	Yes	Yes	Yes
4.B Governance that balances flexibility in response to evolving market context with the need for reliable market signals 5.F Governance and steering allows for adjustments of the AVMA over time	16	Qualitative assessment of governance, its implementation and alignment with broader ecosystem insights collected from Pillar 1, 2 and 3	N/A	No target but could form part of an evaluation.				

[1] Targets are cumulative.

Element(s) in Theory of Change	Indicator ID	Indicator Name	Level of Disaggregation	Baseline[1]	First Review 2027	Second Review 2030	Third Review 2033	Final Evaluation
					Target 2026[1]	Target 2029[1]	Target 2032[1]	Final Target[1]
4.C Enhanced AVMA effectiveness, ensuring transparency, adaptability, and alignment with stakeholders 5.G Regular stakeholder engagement and expanded resources for technical support	17	Formal stakeholder engagements on AVMA topics have happened (Yes / No)	AVMA has been discussed at Investor Forum	N/A	Yes	Yes	Yes	Yes
			AVMA has been discussed at Square Group meetings	N/A	Yes	Yes	Yes	Yes
			AVMA has been discussed at Africa CDC / Gavi Manufacturing Forum	N/A	Yes	Yes	Yes	Yes
			AVMA has commissioned external evaluators for review/ evaluation cycle	N/A	Yes	Yes	Yes	Yes
4.C Enhanced AVMA effectiveness, ensuring transparency, adaptability, and alignment with stakeholders	18	Qualitative assessment of broader stakeholder engagement on AVMA topics in terms of perception and satisfaction - (with focus on support from Pillar 3)	N/A	No target but could potentially form part of an evaluation.				
5.D Minimizes over- and underpayment through clear value caps	19	Monitoring of caps reached	Manufacturer Cap: Total	No targets are set as hitting caps would represent successful disbursement, however caps are monitored for Governance review.				
			Manufacturer Cap: F&F					
			Instrument Wide Cap: F&F					

[1] Targets are cumulative.

Element(s) in Theory of Change	Indicator ID	Indicator Name	Level of Disaggregation	Baseline[1]	First Review 2027	Second Review 2030	Third Review 2033	Final Evaluation
					Target 2026[1]	Target 2029[1]	Target 2032[1]	Final Target[1]
			Instrument Wide Cap: Antigen					
			Instrument Wide Cap: Milestone payments					

[1] Targets are cumulative.