African Vaccine Manufacturing Accelerator (AVMA) Guidance for Manufacturers

This version of the AVMA Guidance for Manufacturers represents the most current description of how Gavi operates AVMA. It was last updated on 20 June 2024. The AVMA Guidance for Manufacturers may be updated from time to time.

The AVMA Guidance for Manufacturers is not a comprehensive description of all aspects of AVMA, and receipt of any AVMA incentives by manufacturers is subject to contract. The publishing of the AVMA Guidance for Manufacturers by Gavi is not a commitment to enter into any transaction or contractual relationship.

Introduction

This document is intended as guidance for manufacturers who are seeking more information on AVMA. It outlines key elements of relevance for manufacturers and steps a manufacturer must go through to receive financial incentives through AVMA. This document is publicly available on the Gavi website and will be updated periodically with additional information.

The AVMA end-to-end flow shown (see Figure 1) is composed of: (i) Expression of Interest; (ii) the application for AVMA in-principle eligibility; (iii) Milestone payment; and (iv) Accelerator payment.

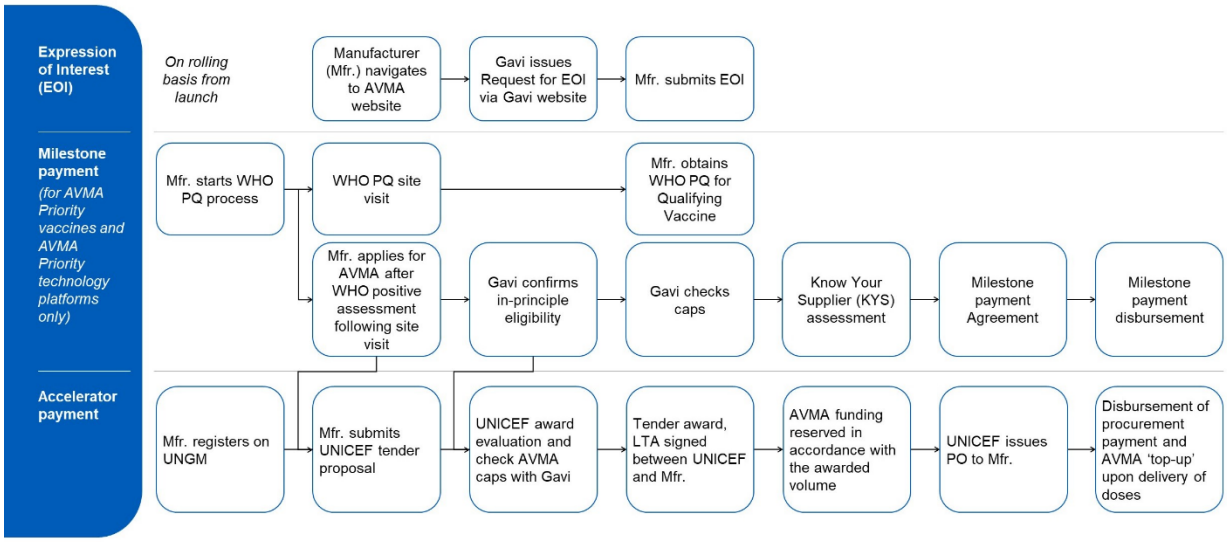

Figure 1: Overview of the end-to-end AVMA flow

This document provides details of the steps in Figure 1 and is structured in the following sections:

1. **AVMA Key Terms:** an overview of the key details of AVMA
2. **Expression of Interest (EOI):** a voluntary submission of manufacturers' plans to Gavi
3. **Application for AVMA in-principle eligibility:** the process steps and documentation needed for manufacturers to confirm with Gavi that they are, in principle, eligible to receive payments
4. **KYS assessment:** a description of the due diligence check manufacturers will undergo prior to payments to manufacturers
5. **Milestone payment:** the process steps and documentation needed for manufacturers to receive a Milestone payment
6. **Accelerator payment:** the process steps and documentation needed for manufacturers to receive an Accelerator payment
7. **AVMA caps:** an overview of AVMA's caps and their implementation
8. **Course correction:** an overview of the process to review and potentially update AVMA's key terms
9. **Further information**

Additional information can be found on the AVMA webpage of the Gavi website (https://www.gavi.org/programmes-impact/types-support/regional-manufacturing-strategy/avma).

1. AVMA Key Terms

1.1 Basic Description

Instrument Name	African Vaccine Manufacturing Accelerator (AVMA)
Proposed duration	To be launched in 2024 with a proposed duration of 10 years[1]
Objectives	A. A sustainable African manufacturing base that contributes to healthy global vaccine markets B. Improved African pandemic and outbreak vaccine supply resilience
Size	US$ 750–1,000 million
Incentive structure	AVMA provides Milestone payments available for AVMA priority vaccine category upon WHO PQ and per dose Accelerator payments paid for all Gavi-supported vaccines upon delivery of purchased doses under UNICEF tender.

1.2 Eligibility

Eligibility criteria

The requirements for AVMA eligibility are:

Vaccine Type: Qualifying Vaccine that is WHO prequalified

Manufacturing Type:

- The Qualifying Vaccine is Fully Manufactured on the African continent;
  or
- Fill & Finish of the Qualifying Vaccine is carried out in a manufacturing facility on the African continent that is Controlled by the holder of the WHO prequalification of the Qualifying Vaccine.

Where capitalised terms have the following meanings:

AVMA Drug Substance Manufacture: the process of manufacturing every constituent antigen of a vaccine, with the exception of manufacturing of the polio antigen or any other antigen designated by the WHO as necessitating a Containment Certification Scheme (or similar). For the avoidance of doubt, manufacture of adjuvants, conjugate carrier proteins, preservatives and excipients as well as lyophilization and

[1] AVMA disbursement will continue until delivery of all doses from tenders that were awarded within the 10-year timespan (subject to Caps). Tenders *awarded* within the 10-years may extend beyond that timespan, doses from which that are delivered will receive payment

formulation of bulk vaccine are not considered under this definition.

Fill & Finish: The process of filling vials (or equivalent final container) with formulated drug substance with or without subsequent intermediate and final packaging. For the avoidance of doubt, packaging of intermediate or final product alone without the process of filling will not constitute Fill & Finish.

Fully Manufactured: both (i) AVMA Drug Substance Manufacture; and (ii) Fill & Finish.

Qualifying Vaccine: A Qualifying Vaccine is defined as all vaccines in Gavi's vaccine portfolio. A Qualifying Vaccine is also considered an AVMA priority (and therefore eligible for Milestone payment and higher Accelerator payments) if it is identified as an AVMA Priority vaccine and/or manufactured on an AVMA Priority technology platform (see below).

Controlled: The decision-making executives of the WHO prequalification holder of the Qualifying Vaccine are authorised to make final decisions with respect to the operations and strategic planning of the facility.

AVMA Priority vaccines and AVMA Priority technology platforms

All vaccines in the Gavi portfolio are included in scope and may be eligible for Accelerator payments. Vaccines described as "AVMA Priority" are further eligible for Milestone payment and higher Accelerator payments from the AVMA. The vaccine is considered an AVMA Priority if:

- The vaccine is an AVMA Priority vaccine (see list below) and/or
- The vaccine is a Gavi portfolio vaccine manufactured on an AVMA Priority technology platform (see list below)

AVMA Priority vaccines:

- Oral Cholera Vaccine
- Malaria
- Measles-Rubella
- Hexavalent (wP),
- Yellow Fever
- Ebola (required profile: indication against at least 2 Ebola species and improved thermostability as from -20°C)
- Rotavirus (required profile: single-dose blow-fill-seal presentation)
- Pneumococcal (required profile: minimum 13 valent)

AVMA Priority technology platforms ('rapid response platforms'):

- mRNA
- Viral Vector

Procurement Pathway	Vaccines which are procured via successful UNICEF tenders (and fulfil all other eligibility criteria) are eligible for Accelerator payments (see below for details). A future pooled procurement mechanism established on the African continent could also be considered at a later stage, with the process and decision subject to determination in line with AVMA's governance arrangements.
Further requirements	Vaccines meeting the two criteria listed under "Eligibility criteria" and procured under an eligible Procurement Pathway are in principle eligible for AVMA incentive payments, conditional on entering into the appropriate binding contracts and passing relevant due diligence checks.

1.3 Incentives, payments and caps

Incentive structure	Two incentive types: • Milestone payment, available upon WHO PQ for AVMA Priority vaccines and/or AVMA Priority technology platforms only (subject to additional requirements mentioned above). • Per dose Accelerator payment, paid upon delivery of vaccines purchased via UNICEF tenders.	
Incentive values	**Milestone payment**	• US$ 25 million: Qualifying Vaccines where AVMA Drug Substance is manufactured on an AVMA Priority technology platform • US$ 20 million: AVMA Priority vaccine where AVMA Drug Substance is manufactured on African soil • US$ 10 million: AVMA Priority vaccines for which only the Fill & Finish takes place on African soil (Note: Manufacturers performing both drug substance and fill finish steps will only receive the drug substance incentive payment.)
	Accelerator payment	• US$ 0.50 per dose: Qualifying Vaccines where AVMA Drug Substance is manufactured on an AVMA Priority technology platform • US$ 0.50 per dose: AVMA Priority vaccine where AVMA Drug Substance is manufactured on African soil • US$ 0.40 per dose: all other Qualifying Vaccines where AVMA Drug Substance is manufactured on African soil

	• US$ 0.30 per dose: Qualifying Vaccines for which only the Fill & Finish takes place on African soil, up to a cap of US$ 1 per vial (Note: Manufacturers performing both drug substance and fill finish steps will only receive the drug substance incentive payment.)
Manufacturer caps	The total disbursement (Milestone and Accelerator payments) per manufacturer is capped at: • US$ 250 million • *(of which)* US$ 50 million for "fill and finish only"
Instrument wide caps	The total disbursement across the entire instrument is capped at: • Net funds raised for the AVMA initiative, deducting operational costs incurred[2] • US$ 300 million per vaccine (pathogen) category / market • US$ 250 million for total Milestone payments across the life of the AVMA • US$ 250 million for "fill and finish only"

1.4 Access and payment modalities

Expressions of Interest	A Request for Expressions of Interest will be issued subsequent to AVMA launch. Manufacturers are invited to submit Expressions of Interest, indicating key information on their plans, timelines, and products for which they expect to submit applications for AVMA payments (Milestone or Accelerator). Expressions of Interest are voluntary and do not constitute an application for AVMA support, nor will they receive at that stage an assessment of eligibility.
Milestone Payments	**Applications** After the manufacturing site inspection as part of the WHO PQ process, and subject to WHO PQ positive assessment, manufacturers may submit an application for a Milestone payment. Eligibility will be assessed in relation to applicable caps as well as conditions specified in Section II. Eligibility.

[2] Operating costs to be estimated by end of 2024, as determined by operating design elements

	Contract and Disbursement If the manufacturer is deemed eligible for a Milestone payment and achieves WHO PQ for an AVMA Priority vaccine with no applicable caps having been reached, then Milestone payment funds will be disbursed by UNICEF, subject to entering into the appropriate binding contracts specified in Section II. Eligibility.
Accelerator Payments	**Applications** Prior to submission of UNICEF tender bids, manufacturers may submit an application for confirmation that they are in principle eligible for Accelerator payments on vaccines tendered by UNICEF. Provided that manufacturers submit their applications in accordance with the AVMA eligibility application processes, manufacturers' compliance with eligibility criteria will be assessed, and manufacturers will be informed of the outcome prior to the UNICEF tender submission deadline allowing due time for manufacturers to consider this in the development of their offers. **Contract and Disbursement** If awarded by UNICEF and provided funding is available within the relevant caps, the AVMA Accelerator payment amount will be reserved in accordance with the volume of UNICEF award[3]. The Accelerator payments will be paid in addition to the awarded price on UNICEF contract per each dose of vaccine, included in each Purchase Order issued by UNICEF. Payments will be made after the manufacturer has fulfilled the delivery terms of the UNICEF contract and Purchase Order and upon successful delivery of doses.

1.5 Governance

Decision-Making Structure and Bodies	The AVMA instrument is overseen by Gavi, the Vaccine Alliance, its Board, relevant committees and forums.
Course Correction	Gavi is committed to offering support which balances stability of market signals with responding to the evolving needs of the African continent over AVMA's 10-year lifetime. To achieve this, principles are set out under which periodic adjustments to the instrument may be made.

[3] AVMA Accelerator payment amount is reserved at the point of the tender award and paid out per doses delivered. Information on AVMA disbursements and caps monitoring will be made available publicly on AVMA's webpage and accessible to manufacturers.

Principles for course correction

- **Stability of market signals:** Commitments made at launch should remain throughout AVMA's duration except where changed in accordance with the course correction principles.
- **Transparent communication:** Modifications to the instrument should be based on a consultative approach with industry and stakeholders and transparently communicated to all stakeholders to ensure timely market signals.
- **Legal integrity:** Binding contractual obligations made during AVMA's duration will not be revoked outside of the provisions stated in the relevant contracts.
- **Funding constraints:** Adjustments will need to consider the available funds limiting the flexibility to expand the scheme (e.g. to include new priorities).
- **React to exceptional circumstances:** In circumstances assessed as exceptional by Gavi, Gavi may also launch an ad hoc course correction process.

Approach to course correction

Gavi will undertake planned course correction exercises in 2027, 2030, and 2033 to enable AVMA to respond to evolving needs and circumstances. The course correction exercises will follow a transparent, consultative and evidence-based process.

Accountability Mechanisms	AVMA operations and impact are monitored through five main monitoring mechanisms: • **Regular Reports to the Gavi Board:** Updates on AVMA's performance and progress against its Theory of Change and associated indicators are submitted as part of standard Gavi reporting procedures. • **Stakeholder forums:** Annual forums will be convened by Gavi and/or partners including jointly with Africa CDC, to inform and consult stakeholders; • **Periodic Review:** An evaluation of AVMA against its objectives will be commissioned to an external evaluator in 2027, 2030 and 2033. Here the Theory of Change and instrument outcomes are tested in the context of the evolving landscape, to inform course correction proposals. • **Final Evaluation:** A final evaluation of AVMA for Gavi, stakeholders and investors will be conducted by an external evaluator that will produce a synthesis of all indicators and reporting over time as well as an overall evaluation of the instrument at the close of AVMA; • **Ongoing public information:** Data on key operational AVMA metrics will be reported on the Gavi website and updated as appropriate (e.g. number of Milestone payments, disbursement volumes)

	Annual, periodic, and final reports will be made public in accordance with Gavi's guidelines on the dissemination of documents.

This version of the AVMA Term Sheet represents the most current description of how Gavi intends to operate AVMA. The AVMA Term Sheet is not a comprehensive description of all aspects of AVMA and a manufacturer's ability to receive any payment of incentives under AVMA is subject to contract. The publishing of the AVMA Term Sheet by Gavi is not a commitment to enter into any transaction or contractual relationship.

2. Expression of Interest (EOI)

Gavi has published a Request for Expressions of Interest (EOI) on the Gavi website, inviting interested manufacturers to submit an EOI. Expressions of Interest are voluntary and do not constitute an application for AVMA support, nor will they receive an assessment of eligibility as an outcome. Manufacturers are encouraged to provide a response to the Request for EOI if they are currently developing, or planning to develop, capacity to manufacture products on the African continent and consider it likely that they will be within AVMA's scope.
Gavi will assess incoming responses to the Request for EOI on an ongoing basis and acknowledge receipt to manufacturers, without any commitment to further engagement.

3. Application for AVMA in-principle eligibility

After the manufacturing site inspection as part of the WHO PQ process, and subject to WHO PQ positive assessment, manufacturers may submit an application to Gavi for AVMA in-principle eligibility. The criteria and process are outlined in the following sections. The legal entity submitting the application must be the entity which holds, or has applied for, the WHO prequalification of the Qualifying Vaccine.

3.1 AVMA eligibility criteria

The eligibility criteria to determine whether a manufacturer's product is eligible to participate in AVMA and receive AVMA incentives are set out in *Section 1.2 of the AVMA Key Terms*. The determination as to whether a manufacturer's product is in-principle eligible will be made by Gavi.

For Milestone payments, vaccines meeting the eligibility criteria are in-principle eligible for a Milestone payment, conditional on the caps set out in Section 7 and on passing relevant due diligence checks and entering into the relevant binding contracts. Milestone payments are disbursed to the WHO prequalification holder of the Qualifying Vaccine.

For Accelerator payments, vaccines meeting the eligibility criteria and procured under an eligible Procurement Pathway are in-principle eligible for Accelerator payments conditional on the caps set out in Section 7. Accelerator payments are disbursed to the entity that contracts with UNICEF for the supply of a Qualifying Vaccine following a UNICEF tender.

3.2 Application process for AVMA in-principle eligibility

3.2.1 Link to WHO prequalification process

WHO prequalification (PQ) is a condition of eligibility for AVMA, and therefore, a prerequisite for a product to receive both Milestone payments and Accelerator payments.

The WHO PQ process is managed by WHO. Manufacturers that wish to obtain WHO PQ for a vaccine must apply for assessment from the WHO in accordance with the WHO's then current

guidelines and procedures. More information about the WHO PQ process can be found on this website: Prequalification of Medical Products: Vaccines.

Once the WHO has conducted a manufacturing site visit and given a positive assessment, a manufacturer may apply to Gavi for an assessment of in-principle eligibility of the candidate vaccine. The process for making such application is set out in *Section 3.2.2*.

3.2.2 AVMA in-principle eligibility application and assessment

Application

To apply for AVMA in-principle eligibility, manufacturers must submit to Gavi an **AVMA Application Form**, which is available at the following link: https://www.gavi.org/news/document-library/AVMA-Application-Form. Manufacturers may apply for in-principle eligibility for both Milestone and Accelerator payments after the manufacturing site inspection as part of the WHO PQ process, subject to WHO PQ positive assessment.

Unless decided otherwise by AVMA governance, Gavi will accept applications until the end of the duration of AVMA, until the caps described in Section 7 are reached, or until funds are exhausted (whichever comes first). Any and all communications, correspondence and queries relating to any current or prospective applications for AVMA in-principle eligibility shall be made in writing to Gavi at the following address:

Attn: Gavi Regional Manufacturing, Senior Manager – Market Shaping

Email: avma@gavi.org

Gavi will send an acknowledgement of receipt by email after the receipt of a complete application and all required documents. Gavi may respond to incomplete applications to solicit further information if required, to enable Gavi to make a full assessment of a manufacturer's application. Gavi aims to respond to complete applications within four weeks, upon receipt of a complete application and all required documentation.

In addition to the information provided in the AVMA Application Form, manufacturers who receive a positive assessment of in-principle eligibility may be requested from time to time to participate in monitoring, learning and evaluation exercises over the lifespan of AVMA and contribute information, learning and perspectives through these exercises.

Assessment

Once Gavi has completed its assessment of the in-principle eligibility of a manufacturer's product, Gavi will communicate the outcome of its assessment in the form of an **In-principle Eligibility Statement**, which will provide:

i. confirmation that the vaccine is in-principle eligible for AVMA Milestone payment or, if not, the rationale why the vaccine is not eligible; and

ii. confirmation that the vaccine is in-principle eligible for AVMA Accelerator payment or, if not, the rationale why the vaccine is not eligible.

At the time of UNICEF tender, a manufacturer whose product has previously been assessed by Gavi as in-principle eligible will be required to submit a confirmation that no change has occurred to the information submitted in its original AVMA Application Form for the relevant vaccine. Where changes have occurred to information provided in a manufacturer's in-principle eligibility application, the manufacturer is required to inform Gavi with a clear indication of the changes, and Gavi will re-assess the in-principle eligibility.

4. KYS assessment

Following successful confirmation of in-principle eligibility, manufacturers seeking a Milestone payment will be requested to undergo a due diligence review relating to the following areas, including: (i) corporate structure, (ii) compliance with sanctions legislation, anti-bribery and corruption, anti-money laundering and similar laws and regulations, and (iii) financial condition. More detail will be provided to manufacturers at the time of application as to the scope of the "Know Your Supplier" (KYS) assessment and the specific information required.

Manufacturers intending to apply for Accelerator payments only (as specified in their completed AVMA Application Form) are exempted from the KYS assessment for Milestone payment and will undergo UNICEF standard due diligence practices as part of the UNICEF tender process.

5. Milestone payment

Once a manufacturer has received WHO prequalification for a Qualifying Vaccine, as well as an In-principle Eligibility Statement from Gavi confirming that the vaccine it produces is in-principle eligible for Milestone payment, then subject to (i) successful completion of the KYS assessment noted under Section 4 and (ii) applicable caps not having been reached (see Section 7), the manufacturer will be required to enter a Milestone Payment Agreement for the disbursement of the Milestone payment.

The Milestone Payment Agreement will set out the basis and terms on which the Milestone payment will be made to a manufacturer. The terms of the agreement are standardised (non-negotiable) and the Milestone payment will only be disbursed once there is a validly executed agreement. The information that a manufacturer has received an AVMA Milestone payment will be made public.

The terms of the Milestone Payment Agreement will be made available to a manufacturer upon request, following submission of a valid AVMA Application Form.

6. Accelerator payment

Accelerator payments are disbursed as a top-up to the awarded price per dose under UNICEF procurement. A manufacturer may apply for in-principle eligibility for Accelerator payment at any time after the WHO issues a positive assessment following a manufacturing site visit (see

Section 3). Gavi encourages manufacturers intending to participate in future UNICEF tenders to apply for AVMA in-principle eligibility as early as possible to reduce the risk of any delays in receiving an In-principle Eligibility Statement once a UNICEF tender is launched.

Once a UNICEF tender is launched, a manufacturer who has received an In-principle Eligibility Statement for the relevant vaccine is required to confirm to Gavi that no information submitted in its previous application has changed. If any information has changed, manufacturers are required to provide complete and accurate updated information, and request re-assessment of in-principle eligibility by Gavi. A manufacturer who has not previously made an application will need to submit the AVMA Application Form (see Section 3). Gavi will aim to provide a response as soon as reasonably practicable to allow the manufacturer to have a clear view on its eligibility for Accelerator payments prior to submitting its response to the UNICEF tender. However, where new applications are made on short notice (or where updated information is submitted on short notice in relation to a vaccine for which an In-principle Eligibility Statement was previously issued), Gavi cannot guarantee timely response ahead of the deadline for submission of response to the UNICEF tender. Accordingly, manufacturers should allow sufficient time for Gavi to conduct this evaluation when planning to submit their response to the UNICEF tender.

If a manufacturer is issued an In-principle Eligibility Statement and is awarded under a UNICEF tender, Accelerator payments will be paid following delivery of doses under applicable UNICEF terms and conditions. Following UNICEF tender award, Gavi will publish the information that the manufacturer has achieved eligibility to receive AVMA Accelerator payments on the AVMA website. Gavi will not include details of the tender award volume as part of this website publication. For detailed information related to the outcomes of UNICEF tenders and awards, please refer to UNICEF Supply Division's official website.

7. AVMA caps

To ensure diversification of the funds disbursed by AVMA, a set of "caps" has been established as part of AVMA's design. The caps set the maximum amount that can be disbursed by AVMA per manufacturer, per vaccine category, as Milestone payments, and across total incentives paid in relation to Fill & Finish-only vaccines.

Manufacturers may check the status of the instrument-wide caps (including the amounts remaining under each) by checking the AVMA website. The website will be updated biannually. Manufacturers that have received an In-principle Eligibility Statement confirming in-principle eligibility may contact Gavi for current cap information at avma@gavi.org.

The disbursement caps are set at the amounts specified in Figure 2. With respect to the manufacturer caps, manufacturing entities under common control will be counted as one manufacturer for the purposes of the manufacturer cap. Gavi nevertheless retains the discretion to treat two or more manufacturers under common control as separate manufacturers for the purposes of administering the manufacturer cap, if Gavi determines that in so doing it would

further AVMA's stated objectives, while taking into account the range of potential AVMA manufacturers and the current and projected market demand for the Qualifying Vaccine.

Figure 2: Overview of AVMA caps

Manufacturer caps	The total disbursement (Milestone and Accelerator payments) per manufacturer is capped at: • US$ 250 million • *(of which)* US$ 50 million for "fill and finish only"
Instrument-wide caps	**The total disbursement** across the entire instrument is capped at: • Net funds raised for the AVMA initiative, deducting operational costs incurred[4] • US$ 300 million per vaccine (pathogen) category / market • US$ 250 million for total Milestone payments across the life of the AVMA • US$ 250 million for "fill and finish only"

8. Course correction

Over the lifespan of the instrument, Gavi may make certain changes (known as 'course corrections') to the design of AVMA in recognition of the need to respond to evolving needs and circumstances. This section sets out both when course corrections may be made and the principles which will apply to such course corrections.

Gavi is committed to offering support which balances stability of market signals with responding to the evolving needs of the African continent over AVMA's 10-year lifetime. To achieve this, principles are set out under which periodic adjustments to the instrument may be made.

Principles for course correction

- **Stability of market signals:** Commitments made at launch should remain throughout AVMA's duration except where changed in accordance with the course correction principles.
- **Transparent communication:** Modifications to the instrument should be based on a consultative approach with industry and stakeholders and transparently communicated to all stakeholders to ensure timely market signals.
- **Legal integrity:** Binding contractual obligations made during AVMA's duration will not be revoked outside of the provisions stated in the relevant contracts.
- **Funding constraints:** Adjustments will need to consider the available funds limiting the flexibility to expand the scheme (e.g. to include new priorities).

[4] Operating costs to be estimated by end of 2024, as determined by operating design elements

- **React to exceptional circumstances:** In circumstances assessed as exceptional by Gavi, Gavi may also launch an ad hoc course correction process.

Approach to course correction

Gavi will undertake planned course correction exercises in 2027, 2030, and 2033 to enable AVMA to respond to evolving needs and circumstances. The course correction exercises will follow a transparent, consultative and evidence-based process.

9. Further Information

For further information, or clarification on any part of the process please contact Gavi at:

Attn: Gavi, Regional Manufacturing, Senior Manager, Market Shaping
Email: avma@gavi.org