

# Request for Expressions of Interest (REoI) Gavi Regional Manufacturing Strategy EOI-GAVI-RMS-2024

## 1. Purpose

The purpose of this **Request for Expressions of Interest (REoI)** is for Gavi, the Vaccine Alliance to collect information from manufacturers on their plans to produce vaccines suitable for Gavi-supported programmes that could potentially be eligible for incentive payments through the African Vaccine Manufacturing Accelerator (AVMA), as part of Gavi's Regional Manufacturing Strategy (RMS). The information submitted through the Expression of Interest (EoI) will contribute to Gavi's understanding of potential applicants' plans for manufacturing in Africa.

Manufacturers are encouraged to provide a response to this request if they are currently developing, or planning to develop, capacity to manufacture vaccines on the African continent and consider it likely that they may be within the scope of AVMA.

It is expected that a significant portion of the information submitted will be considered strategic, confidential and/or proprietary. Please see Section 7 below in relation to confidentiality.

Gavi will provide periodic updates on AVMA for manufacturers via the African Vaccine Manufacturing Initiative (AVMI), on the [AVMA website](#), and at the annual joint Gavi and Africa CDC African Vaccine Manufacturing Forum. Manufacturers are encouraged to seek up-to-date information on AVMA through these exchange platforms.

## 2. Background

Diversity across the supplier base has long been a key tenet of Gavi's approach to shaping sustainable vaccine markets. This brings advantages in terms of supply security and buffers, healthy competition, and innovation. In recent years, it has become evident that **geographical diversity** across this supplier base is also desirable across several dimensions, chief among which is the desire for equity in manufacturing opportunity, self-determination and regional/local health security – not to mention the financial and climate-related advantages of having production occur closer to consumption.

Gavi, as the largest vaccine financier in Africa, is well positioned to leverage its market shaping and innovative financing expertise to facilitate this initiative. In December 2022, the Gavi Board approved a **Regional Manufacturing Strategy (RMS)** to support strengthening vaccine supply resilience at regional levels. The strategy was developed to respond to the challenge surrounding equitable access to vaccines during the COVID-19 pandemic, and to the African Union's call to action on building regional manufacturing capacity in Africa.

The fourth pillar of Gavi's regional vaccine manufacturing strategy, the African Vaccine Manufacturing Accelerator (AVMA) is a financing mechanism designed to make up to US\$ 1 billion available over ten years (2024–2034) to support eligible manufacturers through provision of financial incentives. The instrument has two objectives. The first is to support a sustainable African vaccine manufacturing base that contributes to healthy global vaccine markets. The second is to improve pandemic and outbreak vaccine supply resilience in Africa. AVMA aims to provide a pathway to financial sustainability for eligible manufacturers by disbursing two types of incentives/payments (Milestone payment and Accelerator payment) at specified trigger points. Through these payments, AVMA seeks to level the playing field for African-based manufacturing, helping African-manufactured vaccines to better compete in the global market.

For further information, please refer to the [AVMA website](#) and [AVMA Guidance for Manufacturers](#).

Manufacturers not familiar with the UNICEF vaccine procurement process are strongly encouraged to read the information on the UNICEF website relevant to potential suppliers that intend to participate in a UNICEF tender.<sup>1</sup>

### **3. Request for Expressions of Interest (REoI)**

This document describes the Expression of Interest (EoI) process and aims to encourage manufacturers of potentially AVMA-eligible vaccines to engage early with Gavi. The REoI is neither a request for quotation or proposal, nor an invitation to apply for AVMA payments.

Through this REoI, Gavi is requesting interested vaccine developers and manufacturers who believe they may be within AVMA's scope to provide input on their existing and potential plans to manufacture vaccines in Africa. The REoI will help Gavi to ensure that manufacturers' products and plans are signalled in advance of being potentially eligible for Milestone or Accelerator payments.

Each submission and any updates thereto will hereafter be referred to as an 'Indication'. While it is important that information provided in each Indication is as accurate as possible, the information provided by each manufacturer will not be considered by Gavi to be in any way binding.

The publishing of this REoI by Gavi is not a commitment to enter into any transaction or contractual relationship. The receipt of any AVMA incentives by manufacturers is subject to contract.

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<sup>1</sup> [http://www.unicef.org/supply/index\\_procurement\\_policies.html](http://www.unicef.org/supply/index_procurement_policies.html)

#### **4. Potential AVMA-supported products**

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 AVMA, subject to all applicable terms and conditions. The vaccine is considered an AVMA Priority if:

- the vaccine is listed as AVMA Priority vaccine; and/or
- the vaccine is a Gavi portfolio vaccine manufactured on an AVMA Priority technology platform

For the list of AVMA Priorities, please refer to [AVMA Guidance for Manufacturers](#).

#### **5. Response format**

Responses to the REoI are to be provided in the AVMA EoI Indication sheet – Form A or B (document in Excel format).

##### **5.1 Response forms**

- **EOI-GAVI-RMS-2024 Indication sheet - Late Stage - Form A:** Manufacturers with a technology transfer supply agreement signed and facility construction complete or underway are encouraged to fill out Indication sheet A (<https://www.gavi.org/news/document-library/Gavi-RMS-Expressions-of-Interest-Form-A>).
- **EOI-GAVI-RMS-2024 Indication sheet - Early Stage - Form B:** Manufacturers not meeting the Form A criteria are encouraged to fill out Indication sheet B (<https://www.gavi.org/news/document-library/Gavi-RMS-Expressions-of-Interest-Form-B>).

For submission of information for multiple vaccines, please fill out one Excel sheet per vaccine.

##### **Form A requests the following information:**

1. Product Profile
  - Vaccine
  - Presentation
  - Formulation
  - Expected Market Authorisation holder
  - Expected WHO prequalification holder
  - Technology transfer partner(s)
  - Product dependencies

2. Manufacturing Locations

- Manufacturing site location
- Drug Substance manufacture (Yes/No)
- Fill & Finish manufacture (Yes/No)

2.a If Drug Substance manufacture is planned

- Manufacturing steps performed
- Owner of the Drug Substance production site
- Location of the Drug Substance production site
- Drug Substance technology platform used
- Anticipated capacity (doses)

2.b If Fill & Finish manufacture is planned

- Manufacturing steps performed
- Owner of the Drug Product production site
- Location of the Drug Product production site
- Please indicate the anticipated capacity for this product
- Percentage of line capacity dedicated to the Qualifying Vaccine
- Filling machine speed (vials per minute)

3. Anticipated Timelines

3.a Please indicate the anticipated timelines for the facility relevant to this product, including:

- Expected date for facility completion
- Facility operational commissioning started
- Final first product process performance qualification completed

3.b Product filing and commercialisation

- Expected date to submit product filing with the relevant national regulatory authority
- Expected date to receive local registration
- Expected date to submit an application to WHO for prequalification
- Anticipated market for the specific product

**Form B requests the following information:**

1. Anticipated Products

- Vaccine
- Technology transfer partner(s)
- Agreement Status

2. Manufacturing Locations

- Manufacturing site location

3. Anticipated Timelines

3.a Please indicate the anticipated timelines for the facility relevant to this product, including:

- Expected date for facility ground-breaking
- Facility operating commissioning started
- Final first product process performance qualification completed

### 3.b Product filing and commercialisation

- Expected date to submit product filing with the relevant national regulatory authority
- Expected date to receive local registration
- Expected date to submit an application to WHO for prequalification
- Anticipated market for the specific product

## **6. Procedure and instructions to participating developers/manufacturers**

### **6.1 Invitee list**

This REoI has been sent electronically to the African Vaccine Manufacturing Initiative (AVMI) Secretariat and Africa CDC; and is available on the [Gavi Regional Manufacturing, AVMA website](#).

The target invitees are vaccine developers and manufacturers. Indications from other entities will not be considered.

### **6.2 Submission dates and updates to Indications**

Unless announced otherwise by Gavi, submissions may be made at any time within the instrument duration. Indications should be submitted electronically via email to: [avma@gavi.org](mailto:avma@gavi.org). The Subject line of the email should be marked with **EOI-GAVI-RMS-2024-Manufacturer's name**.

Manufacturers are invited to update their Indication for material progress updates. Examples for updates could be (but are not limited to):

- Changes to planned partnerships for technology transfers
- Completion of relevant technology transfers
- Achievement of national regulatory approval
- Submission of letter of intent for WHO prequalification

## **7. Confidential environment**

It is understood that certain information may be considered confidential to parties submitting the Indication. At the same time, visibility and understanding of the information in the Indication will help optimise Gavi's regional vaccine manufacturing strategy and for planning AVMA activities in a way that is beneficial to potential eligible manufacturers and the functioning of AVMA. In light of this, Gavi may share certain information received in response to this REoI, including on an aggregated and anonymised basis. When doing so, Gavi will put in place reasonable precautions designed to protect the confidential information of a manufacturer.

For any queries relating to the REoI, please email “Gavi, Regional Manufacturing, Senior Manager, Market Shaping – [avma@gavi.org](mailto:avma@gavi.org)”.

Gavi will periodically provide updates to manufacturers/developers through the AVMA website, and other regular engagements with industry networks (i.e. AVMI, DCVMN, IFPMA).

Please follow the following links for more information on Gavi Regional Manufacturing, Gavi, the Vaccine Alliance, UNICEF immunisation programmes and UNICEF procurement of vaccines.

- **Gavi, the Vaccine Alliance:** <https://www.gavi.org/>
- **Gavi’s Regional Manufacturing Strategy:** <https://www.gavi.org/programmes-impact/types-support/regional-manufacturing-strategy>
- **Gavi’s African Vaccine Manufacturing Accelerator (AVMA):** <https://www.gavi.org/programmes-impact/types-support/regional-manufacturing-strategy/avma>
- **UNICEF – Immunization:** <https://www.unicef.org/immunization>
- **UNICEF – Strategic vaccine public procurement processes:** <https://www.unicef.org/supply/strategic-vaccine-public-procurement-processes>

## 8. Annexes

**Annex A:** EOI-GAVI-RMS-2024 Indication sheet - Late Stage - Form A

(<https://www.gavi.org/news/document-library/Gavi-RMS-Expressions-of-Interest-Form-A>)

**Annex B:** EOI-GAVI-RMS-2024 Indication sheet - Early Stage - Form B

(<https://www.gavi.org/news/document-library/Gavi-RMS-Expressions-of-Interest-Form-B>)

**Annex C:** AVMA Guidance for Manufacturers (<https://www.gavi.org/news/document-library/AVMA-Guidance-for-Manufacturers>)

**Annex D:** AVMA Frequently Asked Questions (<https://www.gavi.org/programmes-impact/types-support/regional-manufacturing-strategy/avma/faqs>)