

# Gavi Strategic Goal 4

*Ensure healthy markets for  
vaccines and related products*

## **Market Shaping Roadmap Mpox Vaccines**

Public Summary, December 2025

## Introduction

### Epidemiological context

Mpox disease is caused by the transmission of the monkeypox virus to humans through contact with infected animals and is subsequently transmitted human to human through close contact (e.g. touching, kissing, sex). People considered at highest risk of infection include health and frontline workers; sex workers; people with multiple sexual partners, including men who have sex with men (MSM); and other close contacts. Mpox causes skin rashes and mucosal lesions often accompanied by fever, headache and muscle aches – and it can be fatal in up to 10% of cases.

Mpox is endemic in Africa, with different regions typically being affected by different clades of the virus: Clade I is endemic across Central Africa; and Clade II is endemic across West Africa. Historically, most mpox outbreaks were sporadic and linked to zoonotic spillovers in rural areas.

However, in recent years, there have been two significant spreads of mpox to non-endemic regions, each of which led the World Health Organization (WHO) to declare a Public Health Emergency of International Concern (PHEIC). The first, in 2022, was driven by Clade II and affected 110 countries globally. The outbreak predominantly affected MSM, with most of the 88,000 cases linked to sexual networks. The second outbreak, in 2024, was driven largely by Clade I, with the majority of the 77,000 cases identified in Africa. In many countries, these outbreaks led to the repurposing of smallpox vaccines for mpox vaccination, including the first widespread roll-out of mpox vaccines in Africa.

### Context on Gavi engagement

Gavi, the Vaccine Alliance has closely monitored mpox since the 2022 outbreak and assessed the need for intervention through its Vaccine Investment Strategy (VIS). In June 2024, the Gavi Board approved a three-pronged approach to mpox, including: (i) establishing a global stockpile of mpox vaccines in Gavi's 2026–2030 strategic period (Gavi 6.0); (ii) launching a learning agenda to fill evidence gaps and inform future vaccination efforts; and (iii) facilitating vaccine donations prior to Gavi 6.0, in light of the growing outbreak in Central and West Africa.

Following the worsening of the outbreak and WHO's declaration of mpox as a PHEIC in August 2024, Gavi intensified its response. The Gavi Secretariat signed an Advance Purchase Agreement (APA) to secure 500,000 doses of MVA-BN vaccine, which ensured rapid access to the only WHO-prequalified mpox vaccine. This deal represented the first use of Gavi's First Response Fund (FRF), which was established after the COVID-19 pandemic to enable early funding for Gavi's response to public health emergencies. This direct source of vaccines, which were delivered to countries via UNICEF, were complemented by a supply of donated vaccines from donors including Bavarian Nordic, Canada, the European Union and its member states, Japan, United Arab Emirates and the United States of America. A cross-partner group, called the Access and Allocation Mechanism (AAM), was established to operationalise a response and distribute these vaccines to affected countries, bringing together partners from across the vaccine value chain: Africa Centres for Disease Control and Prevention (Africa CDC), Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, UNICEF and WHO. By the end of the PHEIC in September 2025, nearly 5 million doses had been delivered to 15 countries; and nearly 1.7 million doses had been administered. As of December 2025, several affected countries continue to administer vaccines.

In July 2025, the Gavi Board approved the final investment case for the mpox vaccine programme – with a funding envelope of US\$ 35 million for Gavi 6.0. Work is now ongoing to operationalise the stockpile through the International Coordinating Group on Vaccine Provision (ICG), which also manages operations for the Gavi-funded stockpiles for cholera, Ebola, meningococcal and yellow fever vaccines. In December 2025, the Gavi Board designated mpox a Priority Vaccine under the African Vaccine Manufacturing Accelerator (AVMA), which means eligible manufacturers of mpox vaccines in Africa can access higher incentive payments than for non-Priority, Gavi-supported vaccines.

### Purpose, scope and roadmap timelines

Roadmaps are a foundational tool of Gavi's Market Shaping strategy. They assess the current health of a specific vaccine market; articulate a long-term vision for a healthier market; define a set of objectives, outcomes and interventions across partners to make progress towards this vision; and are used to inform future procurement strategies and decisions related to Gavi's programmes.

This Mpox Vaccine Market Shaping Roadmap covers a period of ten years, from 2025 through 2034. It was developed in collaboration with Vaccine Alliance founding partners WHO, UNICEF and the Gates Foundation; and with other stakeholders, including CEPI.

## Market health, market shaping vision and strategic objectives

### Market overview

Three vaccines are currently licensed for the prevention of mpox:

- i) **MVA-BN** manufactured by Bavarian Nordic. The vaccine was granted WHO prequalification (PQ) in 2024 and is indicated as a two-dose regimen for individuals aged 12 years and older.
- ii) **LC16m8** manufactured by KM Biologics. The vaccine was granted WHO Emergency Use Listing (EUL) in 2024 and is under evaluation for PQ. It is indicated as a single-dose regimen for individuals aged 1 year and older.
- iii) **ACAM2000** manufactured by Emergent. The vaccine has not yet been granted WHO PQ but is approved for use against mpox in the USA under an emergency use authorisation. It is indicated as a single-dose regimen for individuals aged 1 year and older.

Several trials are ongoing to generate data that could lead to expanded indications for these licensed vaccines including to additional age groups and special populations, with the support of funders including CEPI.

Several mpox vaccine candidates are in clinical development but are not expected to be available until at least the late 2020s. The speed at which these programmes move forward will be partially influenced by the strength of global demand signals.

It should be noted that, currently, there are no approved therapeutics for mpox.

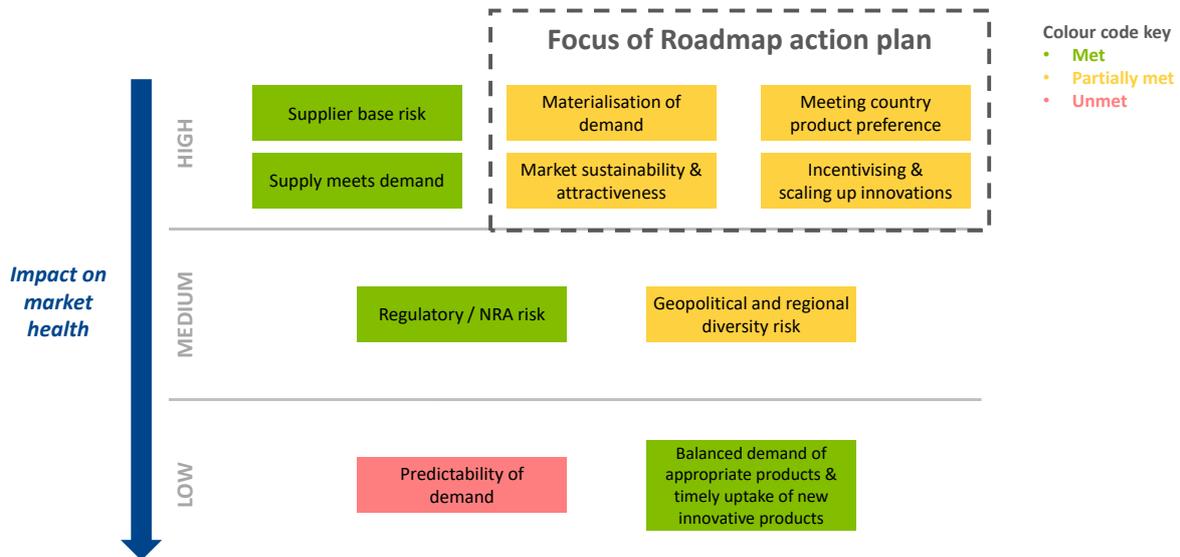
**Market health assessment**

The mpox vaccine market is characterised by relatively small and unpredictable demand, given that demand is closely linked to the occurrence of outbreaks. This limits the commercial attractiveness of the market and puts at risk the sustainability of current suppliers, as well as the successful development of pipeline vaccines and innovations. There is currently a heavy reliance on a single supplier – Bavarian Nordic – due to the programmatically challenging profiles of other licensed vaccines; both LC16m8 and ACAM2000 are administered using a bifurcated needle and are not recommended for use in immunocompromised or pregnant populations.<sup>1</sup>

In 2025, the mpox vaccine market is assessed as ‘Acceptable with risks’, as per Gavi’s Healthy Market Framework (see Figure 1 below for details). This rating reflects the specific market dynamics for rare outbreak diseases and the greater tolerance for some attributes to not be fully met.

This Roadmap prioritises three areas that are expected to have the greatest impact on market health: (i) demand – the need for demand to materialise as expected to give credible market signals and reduce the risk of vaccine wastage; (ii) supply – the need for a sustainable and reliable supplier base with the capabilities to meet potential demand spikes; and (iii) innovations – the need for a sufficiently attractive market that can incentivise improvements in product characteristics to better meet country product preferences.

**Figure 1: Healthy Market Framework assessment for mpox vaccine market (2025)**



<sup>1</sup> See WHO SAGE recommendations for more details: <https://www.who.int/publications/i/item/who-wer-9934-429-456>

## Market shaping vision and strategic objectives

Based on an assessment of mpox vaccine market health, and underpinned by Gavi's healthy markets goal, the Mpox Vaccine Market Shaping Roadmap outlines three strategic objectives:

- **Objective 1:** Improve characterisation of demand for both reactive and preventive vaccination to clarify supplier base needs and optimise supply management.
- **Objective 2:** Improve security of supply and sustain the market presence of at least one manufacturer of WHO-prequalified mpox vaccine with sufficient supply performance and capacity.
- **Objective 3:** Incentivise vaccine innovations to better meet country needs through improved product characteristics.

Each strategic objective is underpinned by target outcomes that the Vaccine Alliance aims to achieve through a set of concerted interventions among Gavi's market shaping partners.

### Objective 1: Improve characterisation of demand for both reactive and preventive vaccination to clarify supplier base needs and optimise supply management.

Demand for mpox vaccines has been difficult to forecast. Beyond national vaccine stockpiles, demand mainly stems from active outbreak response needs. However, the unpredictable timing and size of outbreaks drives demand uncertainties which are further compounded by the heterogenous response of affected countries to mpox outbreaks, including how mpox is prioritised against other health priorities and which population groups should be vaccinated. In the 2024–2025 outbreak, uptake among affected and at-risk countries was lower and slower than expected. Policy guidance on preventive vaccination, as a basis for more predictable demand, is currently limited to laboratory personnel working with orthopoxviruses only, although in late 2026 the WHO Strategic Advisory Group of Experts on Immunization (SAGE) will discuss potential changes based on the latest data. The small, and largely unpredictable, nature of demand beyond national stockpiles reduces market attractiveness. Therefore, it will be critical to better characterise potential demand for mpox vaccines to ensure that appropriate supply needs can be signalled to suppliers in a timely manner.

#### Target outcomes and interventions

**Outcome 1:** Transparent strategy for building up to, and refining size of, Gavi-funded stockpile.

- Define annual procurement volumes over Gavi 6.0 to achieve target stockpile size.
- Reassess stockpile requirements (size and vaccine composition) on a two-yearly basis under the ICG based on evolving epidemiology and risk modelling, updated policy recommendations (e.g. on preventive vaccination, expanded risk groups, data on durability of protection) and changes to available vaccines.
- In case of more expansive WHO SAGE recommendations on preventive vaccination, develop policies for repurposing stockpile vaccines that are at risk of expiry to minimise wastage, as per Gavi Board approval.

**Outcome 2:** Country-level mpox vaccination strategies that are evidence-based such that demand materialises as forecasted.

- Generate and disseminate evidence to countries, including as a result of Gavi's learning agenda, on the health and economic impact of mpox vaccination.
- Ensure countries have access to relevant evidence, including on vaccination strategies and latest recommendations, learning from recent outbreaks.
- Support evidence generation that can inform potential future WHO SAGE recommendations on preventive vaccination, building on learnings from recent outbreaks.

**Objective 2: Improve security of supply and sustain the market presence of at least one manufacturer of WHO-prequalified mpox vaccine with sufficient supply performance and capacity.**

Following Gavi Board approval, the Vaccine Alliance is now mandated to establish a vaccine stockpile that will ensure rapid equitable access to mpox vaccines in the event of outbreaks. The goal is to launch the stockpile in 2026 following programme planning and tendering.

In pursuit of improving supply security, it will be critical to maintain the market presence of at least one manufacturer of a WHO-prequalified vaccine that has the capacity to supply the vaccine stockpile, potentially with surge capacity for rare but very large outbreaks.

In the event of very large outbreaks, there is a risk that the Gavi-funded stockpile is depleted. In these scenarios, it will be prudent to have procedures in place to rapidly facilitate access to additional and complementary supply of donated vaccines, as was the case in the 2024–2025 outbreak. However, during this outbreak, access to some donated vaccines was slow, given the need to agree on contractual arrangements, among other things, and so undertaking this work in advance will be critical to supporting rapid outbreak response. Some donations also proved unsuitable for affected countries, for example due to relatively short shelf lives and product inserts in different languages.

*Target outcomes and interventions*

**Outcome 3:** Gavi-funded stockpile of mpox vaccines is established in 2026.

- Ensure ICG mechanisms, policies and resources are in place in early 2026 to enable operationalisation of mpox stockpile.
- Develop UNICEF procurement strategy and conduct UNICEF tender in early 2026, informed by the Market Shaping Roadmap and potential timelines for licensure of pipeline vaccines.
- Understand, and align with, strategies for other potential mpox vaccine stockpiles to ensure they are complementary and not competitive.

**Outcome 4:** Minimum of one supplier of WHO-prequalified mpox vaccine with sufficient capacity to supply the Gavi-funded stockpile, with surge capacity for rare but very large outbreaks.

- Monitor supplier-specific risks and strategies for future manufacturing through close engagement with manufacturers.
- Monitor progress of and challenges with pipeline vaccines, including timelines for licensure and therefore potential eligibility for the stockpile.

**Outcome 5:** Policies and procedures are in place to enable rapid access to vaccine donations if the Gavi-funded stockpile risks depletion.

- Develop generic contractual documents and procedures with potential donors through which Gavi can facilitate vaccine donations.
- Update and align on principles and preferred product characteristics for mpox vaccine donations.

### **Objective 3: Incentivise vaccine innovations to better meet country needs through improved product characteristics.**

Currently licensed mpox vaccines meet some, but not all, of the needs of countries. MVA-BN can only be stored at 2–8°C for eight weeks, and it is currently indicated by WHO PQ as a two-dose regimen and for use in individuals aged 12 years and over only (although most countries have used it as a single-dose regimen in the 2024–2025 outbreak, in line with WHO SAGE recommendations; and trials are ongoing to collect data in younger age groups). Both LC16m8 and ACAM2000 are programmatically challenging to administer, requiring administration using a bifurcated needle; and are not recommended for use in immunocompromised or pregnant populations.

Pipeline vaccines may provide some advantages; but based on current knowledge, they would still not fully meet WHO's target product profile (TPP) for mpox vaccines.<sup>2</sup>

While the shortcomings relative to WHO's TPP are numerous, there are certain product characteristics that would make a substantial difference if improved: age indications, dosing regimen, administration method and thermostability.

#### *Target outcomes and interventions*

**Outcome 6:** Vaccines with improved product characteristics are available via the Gavi-funded stockpile.

- Advocate for extended age indications for vaccines, building on CEPI's forthcoming clinical trial data and real-world evidence from the 2024–2025 outbreak.
- Ensure countries are informed of WHO SAGE's recommendation for off-label dose-sparing use of vaccines and, if sufficient data is available, support SAGE to issue broader recommendations on dose-sparing strategies.
- If data is insufficient, encourage research & development (R&D) funders to fund studies on safety and efficacy of dose-sparing strategies (e.g. one-dose regimen, fractional dosing), including in immunocompromised populations.
- Advocate to manufacturers and R&D funders for continued stability studies on licensed and pipeline vaccines to ensure longer shelf lives at 2–8°C temperatures, thereby reducing the risk of vaccine wastage.

---

<sup>2</sup> WHO Target Product Profile for Mpox Vaccines, October 2024: <https://www.who.int/publications/m/item/who-target-product-profiles-for-mpox-vaccines>