# Gavi Strategic Goal 4

***Ensure healthy markets for vaccines and related products***

## Market Shaping Roadmap
## Ebola Vaccines

Public Summary, September 2025

# Introduction

## Context

Ebola diseases are caused by the transmission of *Orthoebolavirus* to humans through contact with infected animals, and spread through human-to-human transmission. The animal reservoir for Ebola is thought to be fruit bats, with non-human primates as potential intermediate hosts. People most at risk include health workers, family members of the infected and mourners in contact with bodies during burials. Early diagnosis is essential for treatment and infection control. Access to therapeutics remains limited, and the average Ebola disease case fatality rate is around 50%.

The *filoviridae* virus family covers eight genera, including *Orthoebolavirus* and Marburg virus. Of the six known *Orthoebolavirus* species, three – Zaire (EBOV[1]), Sudan (SUDV) and Bundibugyo (BDBV) – have caused large outbreaks in Africa, with fatality rates between 25–90%. Historically, Ebola was confined to small outbreaks in rural Africa, but the 2014–2016 West African outbreak spread to urban areas, resulting in over 28,000 cases and 11,000 deaths, prompting the World Health Organization (WHO) to declare the outbreak a Public Health Emergency of International Concern (PHEIC). When the outbreak started, there were no vaccines ready to be tested.

Gavi's engagement began in September 2014, with the endorsement of a US$ 390 million 'Ebola Envelope' for vaccine procurement and health system recovery. In 2015, Gavi executed an Advance Purchase Commitment with Merck, providing US$ 5 million as a prepayment on a future stockpile of licensed vaccine, contingent on the manufacturer making available 300,000 doses of experimental vaccine for use prior to licensure (which were subsequently used in the second largest EVD outbreak, which took place in the Democratic Republic of the Congo from 2018–2020). Subsequently, in 2021, Gavi helped launch and continues to support a global 500,000-dose stockpile of licensed vaccines managed by the International Coordinating Group (ICG) on Vaccine Provision to respond to EVD outbreaks.

In 2024, WHO recommended two licensed Ebola vaccines for preventive use among high-risk groups such as health care workers (HCWs) and frontline workers (FLWs). Gavi has since opened a funding window for preventive vaccination, supplementing the global emergency stockpile and formalising the support to preventive vaccination beyond the repurposing of doses close to expiry from the stockpile. Gavi's Ebola funding envelope covers all *Orthoebolavirus* species, although licensed vaccines and WHO Strategic Advisory Group of Experts on Immunization (SAGE) recommendations are only available for EBOV at the moment. Considering the vaccine pipeline combining EBOV and other filoviruses (e.g. SUDV, Marburg virus), and the similarity of Marburg and Ebola diseases in terms of clinical symptoms, epidemiology and recommended outbreak control measures, this roadmap covers such pipeline vaccines as well, recognising that their inclusion in the Gavi menu may require additional approvals by the Gavi Board.

[1] EBOV refers to the specie *Orthoebolavirus zairense* and causes Ebola virus disease (EVD).

### Purpose, scope and roadmap timelines

The roadmap is a foundational tool of Gavi's 2021–2025 Market Shaping Strategy. Its purpose is to articulate a medium- and long-term strategy designed to align market shaping objectives and target outcomes across Vaccine Alliance partners; define a set of interventions to reach these objectives and target outcomes; and inform procurement strategies and decisions.

The objectives, target outcomes and interventions articulated in the market shaping action plan focus on the currently Gavi-eligible country market, while including global market considerations to highlight interdependencies and their impact on overall market health.

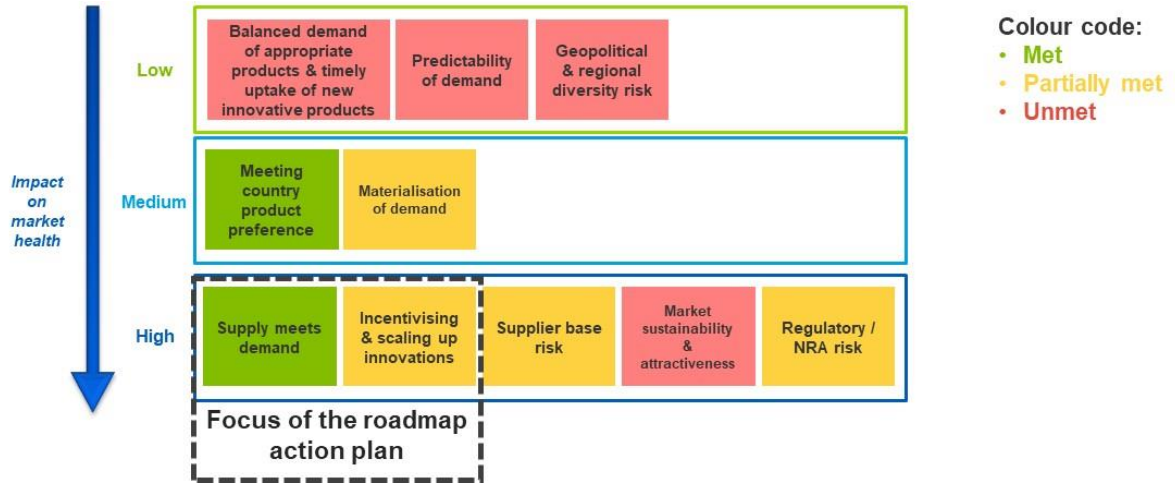
This Ebola Vaccines Market Shaping Roadmap covers a period of ten years (2025–2034), with high-level strategic objectives designed to provide a long-term view.

## Market health, market shaping vision and strategic objectives

### Market health assessment

The Ebola vaccine market is driven by the occurrence of outbreaks, and therefore is characterised by low and uncertain demand, limiting commercial attractiveness. There is currently heavy reliance on a single supplier. These factors pose significant risks to the sustainability of current vaccine supply and to the progress of pipeline vaccines and innovations. The Ebola Healthy Market Framework (HMF) assessment as shown in Figure 1 (below) is a reflection of the Ebola vaccine market's health in 2024. Despite several attributes not being met, the Ebola vaccine market was assessed as 'Acceptable with risks', reflecting the unique challenges of vaccines for rare outbreak diseases. This roadmap action plan prioritises two attributes deemed to have the highest impact on global health security, 'Supply meets demand' and 'Incentivising and scaling up innovations', with greater tolerance for other attributes being 'unmet' or 'partially met'.

***Figure 1: 2024 Healthy Market Framework assessment for Ebola vaccine market***




Demand for Ebola vaccines is inherently volatile due to the sporadic and unpredictable nature of outbreaks; relatively small preventive vaccination demand based on existing policy recommendations; and uncertainties linked to scope of implementation, given the recency of SAGE recommendations on preventive vaccination. In affected countries, low awareness of the availability of Ebola vaccines, low risk perception in the absence of outbreaks and competing priorities (e.g. mpox vaccination) bring further uncertainty with regards to future vaccine uptake. Furthermore, the overwhelming preference for

a single WHO-prequalified Ebola vaccine, the only one recommended for holistic outbreak response vaccination activities, contributes to an unbalanced uptake of vaccines currently available.

On the supply side, the situation has improved since the establishment of the global stockpile in 2021, with ample supply availability for outbreak response. The stockpile is fully stocked at approximately 500,000 doses. Fewer than 10,000 stockpile doses have been used to control three outbreaks in 2021 and two in 2022. (There were no reported outbreaks in 2023 or 2024.) However, the stockpile contains only one vaccine, despite the existence of two WHO-prequalified options – due to differences in product profiles and usage recommendations, with preference for the single-dose rVSVΔG-ZEBOV-GP vaccine. Although the single supplier's experience and reliance on a WHO-listed regulatory authority help to mitigate some risks, the lack of supplier diversity remains a concern. Overall, the market exhibits low sustainability and attractiveness considering the small volumes and unpredictable nature, which require financial incentives to retain existing suppliers and attract new entrants.

Innovation in the Ebola vaccine market is critical to address some of the shortcomings of existing vaccines. There are promising second-generation candidates in development that aim to improve thermostability, reduce production costs and expand coverage to multiple species/filoviruses (e.g. SUDV, Marburg virus). Despite this, the factors impacting market attractiveness and sustainability pose a high risk of market exits and pipeline discontinuations. Furthermore, regulatory pathways for these new vaccines, especially those using novel platforms or targeting non-EBOV species, are challenged by the rarity and rapid containment of outbreaks. This prolongs the time needed to generate efficacy data required for licensure, further complicating innovation efforts.

Current supply is entirely dependent on a single manufacturer located outside of Africa, even though the disease burden is concentrated on the African continent. This mismatch introduces geopolitical and regional diversity risk, even if the supply from the incumbent manufacturer is expected to remain reliable, in the absence of outbreaks impacting high-income countries. Barriers to market entry linked to the demand outlook also challenge the opportunities for future African production.

## Market outlook

The Ebola vaccine market's evolution over the next ten years is highly dependent on the Vaccine Alliance's ability to shape global health security (GHS) markets characterised by highly uncertain and volatile demand. Broader trends such as deforestation, climate change, rising urbanisation and human mobility are expected to increase the frequency and scale of outbreaks, further driving demand unpredictability.

In such a context, the 'healthy market' target for GHS markets requires adjustment with a conscious deprioritisation of certain attributes, accepting they will remain unmet and 'unacceptable' from a more established routine market perspective, in favour of attributes more pertinent to meeting GHS needs. This ensures critical vaccines remain available against deadly pathogens with large public health impact such as Ebola. Although unpredictable and constrained country demand may not support market sustainability, ensuring global supply availability through the stockpile for global health emergencies such as Ebola outbreaks is an indispensable insurance mechanism. As such, maintaining an acceptable level of health for the Ebola vaccine market may require accepting certain trade-offs, such as:

- Reliance on a single supplier to avoid demand fragmentation and further reducing the market's attractiveness, in order to increase supply security.
- Prioritising innovation rather than market expansion to support sustainability, and potentially maximise cost-effectiveness, by incentivising vaccines with improved product characteristics, reduced production costs, multi-species coverage, etc.
- Choosing between incentivising the development of new monovalent vaccines with associated use case uncertainties versus multivalent vaccines – *Note: This may be more challenging technically (and more costly for use against single-pathogen outbreaks), but it may provide a*

*multifaceted tool for outbreak response and contribute to the sustainability of vaccine protection against multiple diseases*.

- Recognising that demand predictability will continue to be a challenge despite the expansion of Gavi's Ebola vaccine programme to preventive vaccination, and ensuring the maintenance of an appropriately-sized stockpile to serve both reactive and preventive vaccination needs – *Note: Although this approach carries a higher risk of wastage and requires greater financial risk appetite, it is a necessary insurance mechanism – given that the Gavi-funded emergency stockpile is the only source of Ebola vaccines globally*.
- Exploring opportunities for international procurement coordination to consolidate demand and facilitate production planning, while limiting over-reliance on sovereign sources of supply, which can be at the expense of geopolitical and regional diversity risk.
- Reducing regional diversity risk by expanding Ebola vaccine manufacturing to Africa, while ensuring sustainable investment models can support business viability.

### Ebola vaccine market shaping vision and strategic market objectives

Gavi's Ebola vaccine market shaping strategy translates into the following three strategic objectives:

- **Objective 1**: Global health security needs, outbreak response and preventive vaccination demand are sufficiently characterised to clarify supplier base needs, with supply management and vaccine use optimised.
- **Objective 2**: Supply of WHO-prequalified vaccines is sufficient to cover outbreak response and preventive vaccination needs, with cost-effectiveness maximised.
- **Objective 3**: Pipeline Ebola candidate vaccines that respond to country needs, global health security risks and market sustainability imperatives are incentivised.

Each objective is underpinned by target outcomes that the Vaccine Alliance aims to achieve by implementing a set of concerted interventions among Gavi market shaping partners to tackle risks and challenges.

## Objective 1 – Global health security needs, outbreak response and preventive vaccination demand are sufficiently characterised to clarify supplier base needs, and supply management and vaccine use optimised.

To date, Ebola vaccine demand has been confined to outbreak response in Africa and government stockpiles, with limited preventive use. Gavi's new preventive vaccination programme may increase uptake, but demand remains uncertain due to countries' competing priorities. The Ebola vaccine market is expected to remain small (unless there are large urban or multi-country outbreaks) and commercially unattractive for manufacturers, rendering the articulation of demand supporting vaccine supply sustainability continuously challenging. This will require accounting for global health security objectives and approaching the sufficient availability of Ebola vaccine supply as an insurance mechanism against the unknown risk of majorly disruptive outbreaks. While the Ebola vaccine emergency stockpile is now fully stocked at 500,000 doses, ongoing modelling and cost-effectiveness analyses should help clarify whether it remains at the same level. In parallel, the preventive vaccination programme offers an opportunity to optimise vaccine use and reduce wastage by sourcing supply from the stockpile.

If left unaddressed, lack of visibility over a sufficient level of contracting for Ebola vaccines may result in insufficient levels of supply, further leading to market exits and pipeline development discontinuations, significantly compromising countries' ability to respond to Ebola epidemics and increasing the risk of PHEICs.

### TARGET OUTCOMES

1. Emergency stockpile requirements are clearly established and articulated to support outbreak response, mitigate global health security risk and define supply needs in the third quarter of 2025 (pre-UNICEF tender), followed by annual updates, in line with evolution of the preventive programme and country needs.
2. Timely updated annual Gavi/UNICEF demand forecast for Ebola preventive vaccination programme rooted in country engagement activities, including technical support and guidance.

### INTERVENTIONS

- Annual ICG reassessment of stockpile requirements for outbreak response based on evolving epidemiology and risk modelling, updated policy recommendations, and vaccine characteristics/ability to control outbreaks, building on Imperial College London's work to update the transmission modelling, project outbreak scenarios and inform stockpile sizing.
- Ensure complementarity of outbreak response activities with preventive campaigns by defining the overall Ebola vaccine supply requirements to ensure adequate supply management, allowing rotation of stocks, optimising vaccine use, limiting the risk of vaccine expiry and considering supplier sustainability risks.
- Develop a preventive demand forecast to inform the next UNICEF tender, reflecting findings from country engagement aimed at socialising new recommendations, supporting preventive campaign planning and encouraging applications to Gavi.
- Update preventive demand forecast on annual basis, reflecting updated implementation guidance and/or newly released policy recommendations.
- Estimate non-Gavi demand for preventive vaccination from countries at risk of EVD outbreaks (specifically middle-income countries).

## Objective 2 – Supply of WHO-prequalified vaccines is sufficient to cover outbreak response and preventive vaccination needs, and cost-effectiveness is maximised.

The current preventive demand forecast and global health security risk modelling indicate that current supply capacity, and a single supplier, of a vaccine indicated for use for both outbreak and preventive vaccination should be sufficient to cover demand and the large majority of outbreak situations. A single-supplier market is typically not desirable from a market health perspective, but aiming for supplier diversification in the EBOV vaccine market would mean fragmenting an already small demand base and further reducing commercial attractiveness, potentially leading to price increases and, in a worst-case scenario, undesired market exit. This is exacerbated by the fact that the ICG has not recommended inclusion of the prime-boost vaccine regimen in the stockpile, rendering its uptake dependent on country demand for preventive vaccination.

Efforts should focus on sustaining the market presence of at least one supplier of Ebola vaccine that meets countries' preferences while minimising costs where possible, especially if a high level of wastage remains acceptable to support sustainability. Long-term reliance on a single supplier will require appropriate risk mitigation measures such as close collaboration with the manufacturer and key global procurers.

### TARGET OUTCOMES

1. Minimum of one supplier of WHO-prequalified EBOV vaccine with indication for use for both reactive and preventive vaccination.
2. Minimised Gavi Ebola programme costs while maintaining market sustainability and minimising country plan disruptions.

### INTERVENTIONS

- Close engagement with lead supplier and global procurers to monitor supplier-specific risks, including understanding business sustainability thresholds in context of changing demand patterns; and undertake relevant interventions in response to identified risks.
- Monitor progress of EBOV vaccine pipeline (i.e. non-WHO-prequalified vaccines licensed domestically, or candidates in earlier stages of development), and assess potential role of candidate or locally licensed vaccines in support of Ebola vaccine market health to inform supplier engagement and UNICEF procurement strategy.
- Through continuous supplier engagement, including through the UNICEF tender process, evaluate the role of potential new suppliers based on supply security, as well as cost and sustainability criteria; and identify what relevant manufacturers require in order to become viable suppliers.
- Explore opportunities to reduce vaccine price and/or Gavi Ebola vaccine programme costs through innovations such as improved product characteristics, more efficient production processes (e.g. flexible manufacturing) or new product market entries (e.g. platform vaccine, multivalent vaccine, technology transfers), optimised supply management or regional stockpiling impacting transport costs, while maintaining supply sustainability – *This intervention also contributes to Objective 3 (see below).*
- In case of new product uptake and new preventive vaccination programmes, monitor country product registrations to support timely outbreak response, and provide the relevant manufacturer with visibility over country applications and Gavi approvals to support timely campaigns.

## Objective 3 – Pipeline Ebola candidate vaccines that respond to country needs, global health security risks and market sustainability imperatives are incentivised.

Current WHO-prequalified vaccines only protect against EBOV, highlighting the public health risks linked to other Ebola species and filoviruses (e.g. SUDV, Marburg virus). As such, more emphasis should be placed on incentivising innovations for next-generation vaccines that will better meet country and global health security needs against these diseases with similar clinical manifestations, high case fatality rates and significant epidemic potential.

Based on current epidemiology and historical outbreak occurrence, these vaccines will face the same, if not greater, demand challenges as for EBOV, offering little leverage to build market attractiveness. This means an even greater need to define an investment and procurement model that is sustainable, offering business viability to sustain supply availability while remaining acceptable from a financial perspective in a context of increasing fiscal constraints. Such a model may consider technical and manufacturing innovations (e.g. modular manufacturing, vaccine platforms more adapted to epidemic and pandemic needs, manufacturing networks), as well as new commercial and contracting practices (e.g. bulk contracting).

## TARGET OUTCOMES

3. An established, well-defined role for next-generation vaccines in support of global health security needs and sustainability.
4. Facilitated generation of evidence for vaccine efficacy, safety, duration of protection, boosting effect of re-vaccination, cross-protection between virus species and vaccination strategies, including feasibility.

## INTERVENTIONS

- Drive the development of framework policy recommendations for future vaccines (both monovalent and multivalent) based on potential use cases, country interest and estimates of country uptake, including modelling considering global health security needs.
- Based on developers' and manufacturers' funding and technical support needs, as well as business sustainability thresholds and fiscal constraints, define new investment models considering new manufacturing and commercial practices that will ensure supply sustainability once candidates reach licensure, despite constrained demand.
- If viable use cases and investment models are identified, develop pull interventions/investment cases for Gavi's Board – e.g. leveraging Gavi Vaccine Investment Strategy (VIS) epidemics framework to expand Ebola funding envelope to all filoviruses – that would complement activities from push funders and further incentivise the market entry of candidate vaccines.
- Support stakeholder engagement – e.g. facilitated discussions between marketing authorisation holders, regulatory authorities of reference and at-risk countries' national regulatory authority (NRA) – to facilitate regulatory approvals based on non-standard data for relevant candidate vaccines, in the context of rare outbreaks, where generating clinical efficacy data under randomised controlled trials may take prolonged periods of time.
- Support relevant stakeholders (e.g. Ebola Vaccine Programme Coordination Team partners, countries) to identify gaps and coordinate the collection of required clinical data for licensed vaccines, ensuring partner alignment on a learning agenda.