

Annex A: Risk and impact

A.1. Key risks and mitigations associated with the Gavi Secretariat's current response to mpox outbreak

Key risks and challenges	Risk rating pre mitigation	Proposed mitigations	Risk rating post mitigation
Delivery funding: Timelines for disbursement of delivery funding from Gavi have been longer than desired for an outbreak (for a mix of reasons – some linked to Gavi disbursement processes and others linked to delays in country acceptance of doses / development of national plans/submission of requests for funding to Gavi)	High	WHO and Africa CDC are providing technical assistance to countries for the development of national plans / preparation for delivery funding applications. The Secretariat has a tracker in place to identify process delays, and country teams are prioritising mpox applications as well as permitting the use of available in-country funds where feasible. While mpox delivery funding has gone out quicker compared to routine disbursements from Gavi (and in some cases, faster than COVID-19 delivery funding), learnings from mpox are being integrated into grant management transformation workstreams in preparation for Gavi 6.0 to further identify improvements in disbursement processes. No further delivery funding applications are now expected – which means focus will be on disbursing as swiftly as possible over coming weeks.	Low
Supply and funding gaps: There will likely be gaps in supply / funding between current support (funded by Gavi FRF and others) and the global mpox stockpile (subject to Board approval). This may reduce the overall impact / sustainability of	Very high	Dose sparing / fractional dose strategies, approved for use by WHO SAGE are being discussed by partners and countries. Targeted redeployment of doses from certain countries may also take place to ensure stock availability in countries of greatest need and there is close scrutiny on the	High

Gavi's acute phase support to mpox, and presents challenges for the overarching goal towards outbreak control.		appropriate allocation of remaining secured doses given limited supply. UNICEF is fundraising for 500,000 doses secured via its emergency tender – of which funding has already been secured for 23,000. Efforts are ongoing by Africa CDC and others towards mobilisation of additional resources for mpox response (recognising the current challenges in the global health and development sector). Gavi remains ready to facilitate future donations if they become available, building on the expertise built during COVAX and the current mpox response.	
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**A.2. Key risks and mitigations associated with Scenario assessed:
Investment in a Global Mpox Stockpile for outbreak response**

Risk of Inaction

Strategic	- Gavi's mission is to expand access to life-saving vaccines. Not investing in a global mpox stockpile would create a significant gap in epidemic preparedness, limiting the ability to respond rapidly to mpox outbreaks.	High
Programmatic	- Access to vaccines during future mpox outbreaks will remain a risk without a stockpile. Lack of timely vaccine access could result in prolonged outbreaks, especially in high-risk countries with limited resources, with risk of spread to other countries.	Very High
	- Without Gavi's support through a stockpile, many countries, particularly those where mpox is endemic, may face delays in access, procurement and distribution due to limited market supply. The stockpile would provide a long-term mechanism beyond future donations for existing and future outbreak response.	High
Financial	- Without a Gavi-funded stockpile, countries may need to divert limited resources from other critical health priorities in order to respond to outbreaks due to the high cost of the	Very High

	<p>commonly used mpox vaccine (MVA-BN by Bavarian Nordic).</p> <ul style="list-style-type: none"> - In some cases, the high procurement cost of MVA-BN may prevent countries from being able to respond to outbreaks at all, leaving them without timely and equitable access to vaccines. 	
Market	<ul style="list-style-type: none"> - Lack of investment by Gavi may reduce manufacturers' incentives to invest in new vaccine platforms (e.g. mRNA) and mpox vaccines with suitable product characteristics for low- and middle-income countries, delaying the availability of vaccines for future outbreaks. 	High
Reputational	<ul style="list-style-type: none"> - Gavi has been a key player in the current mpox PHEIC response; failing to act in providing a long-term solution may impact its reputation as a global health security player, especially after signalling a commitment to it with the Vaccine Investment Strategy 2024 Board in-principle approval 	High

Risk & mitigations if Global Mpox stockpile is approved

Strategic	<ul style="list-style-type: none"> - While the current mpox outbreak is currently classified as a public health emergency of international concern (PHEIC) and public health emergency of continental security (PHECS), its lower-case fatality ratio compared to other diseases (e.g., yellow fever, cholera, meningitis) may result in a lower prioritisation compared to more urgent health needs. This can result in a low-demand programme. Strong communication and engagement with affected countries are needed to support vaccine prioritisation and delivery. 	Medium
Programmatic	<ul style="list-style-type: none"> - Introducing the mpox stockpile will place additional demand on Gavi's operational capacity, potentially delaying support for other vaccines and programmes. An early decision by the Board would enable timely co-design with partners and countries to allow for proactive planning to address programmatic and human resourcing challenges. 	Medium
	<ul style="list-style-type: none"> - Countries will require support to plan, request, and implement vaccination activities, particularly for hard-to-reach, at-risk populations. Without sufficient operational funding and tailored technical assistance, vaccine 	High

	deployment may be delayed or ineffective, limiting the public health impact of the stockpile.	
Financial	- Fluctuations in donor funding could lead to financial risks, impacting the sustainability of the stockpile and the ability to procure additional doses if needed.	Very High
	- The procurement cost of the only WHO-prequalified mpox vaccine is high, and fluctuations in stockpile size may increase financial risk. To mitigate this, close engagement with manufacturers and the development of a robust vaccine demand forecast are essential.	High
Market	- Gavi Secretariat's ability to shape the market will be limited by the size of the stockpile investment; a relatively small stockpile may limit Gavi's ability to incentivise products that are better suited to the needs of low- and middle-income countries.	Medium
Reputational	- The proposed stockpile size may underestimate the full public health need, since its focus is on outbreak response. To mitigate this, close collaboration with donors and other partners is essential to ensure that Gavi's efforts complement and build upon the initiatives of other organisations and countries.	Medium