

Annex A: Implications and Anticipated impact

Scenario assessed: Investment in a maternal vaccine to protect infants against RSV.

Risk of Inaction

Strategic	<ul style="list-style-type: none"> - Gavi's core mission is to expand access to life-saving vaccines. Not investing in RSV immunisation would result in a significant gap in addressing one of the major causes of severe respiratory illness and deaths in infants. This inaction may weaken Gavi's ability to achieve its strategic goals related to child mortality reduction. 	High
Programmatic	<ul style="list-style-type: none"> - RSV is the leading cause of acute lower respiratory infections (ALRI) in infants, leading to hospitalisations and deaths. Without investment, RSV-related mortality will remain high, particularly in Lower Middle-Income Countries (LMICs) where access to advanced care is limited. 	Very High
	<ul style="list-style-type: none"> - Without Gavi support, RSV vaccines will not be widely introduced in LMICs, exacerbating health inequities. Countries may face challenges in independently procuring RSV immunisation products at comparable prices and potentially resulting in delays to implementation. 	High
Financial	<ul style="list-style-type: none"> - RSV hospitalisations generate substantial costs for countries, including inpatient care, oxygen therapy, and intensive care unit admissions. Without prevention efforts, these costs will remain high, diverting already limited resources away from other health priorities. 	Very High
Market	<ul style="list-style-type: none"> - Without Gavi's investment, manufacturers may focus on high-income country markets, reducing incentives for the development of affordable, scalable RSV products tailored to LMIC needs. There is an important need to clarify the magnitude of the potential Gavi demand as soon as possible to ensure the manufacturer can plan capacity to align with the expected materialisation of demand. This could slow innovation and hinder access to lower-cost options. 	High
Reputational	<ul style="list-style-type: none"> - Gavi has been instrumental in shaping global vaccine markets and expanding equitable access. A failure to act on RSV - despite prior signaling to manufacturers, an in-principle Board decision, the known RSV burden, and the availability of effective interventions—could not only weaken Gavi's reputation as a global health organisation, but also undermine the effectiveness of its market shaping approach enabling 	High

	access to vaccines, potentially impacting future engagements with partners and manufacturers.	
	<ul style="list-style-type: none"> - Gavi-supported countries, partners, and donors expect Gavi to respond to high-burden diseases with timely access to available interventions. Inaction on RSV following the VIS process could undermine confidence in Gavi's commitment to equitable access to new vaccines as soon as they are available — a cornerstone of Gavi's approach — and weaken trust in its role as a leader in addressing emerging health threats. 	High

Risk & Mitigations if RSV is approved

Strategic	<ul style="list-style-type: none"> - While RSV prevention aligns with Gavi's child health objectives, its lower epidemic potential compared to other vaccine-preventable diseases (e.g. measles) may lead to its deprioritisation by countries. 	Medium
	<ul style="list-style-type: none"> - Gavi, but not countries, has limited experience in maternal immunisation programmes compared to traditional infant vaccines. Effective implementation will require strong coordination between EPI and maternal and newborn health (MNH) services, increasing operational complexity. 	Medium
Programmatic	<ul style="list-style-type: none"> - Given constrained resources, investing in the RSV vaccine could reduce flexibility for vaccines for higher-burden or epidemic-prone diseases, however the risk is low given the low expected procurement cost to Gavi and countries co-financing share. 	Low
	<ul style="list-style-type: none"> - Limited awareness of RSV's burden at the community level could minimise demand, leading to slow uptake. Tailored demand generation strategies are needed, addressing potential hesitancy challenges. 	Medium
	<ul style="list-style-type: none"> - While country consultations suggest Gavi can leverage existing ANC platforms to integrate RSV vaccination with minimal changes to service delivery, some Gavi-supported countries may lack the programmatic capacity to integrate RSV immunisation into ANC or EPI services effectively, leading to delayed or uneven rollout. Continued investment in ANC is needed. Notably, Gavi's Board did not prioritise cash investments in ANC platform strengthening during the Gavi 6.0 design phase (prioritising infants and the second 	High

	year of life), and potential reductions in HSS funding may further constrain progress. In the current context of funding cuts, addressing this potential gap and the need for continued investment will require additional external support, innovative public-private partnerships, or increased domestic financing for reaching high coverage levels beyond what is expected through ANC.	
Financial	- Donor funding cuts (e.g. USAID reductions in ANC funding) may increase financial risks for RSV vaccine successful implementation.	High
	- Operational costs for integrating RSV into maternal immunisation programs may be underestimated, particularly given gaps in ANC funding and the need for additional health worker training and logistics support.	Medium
Market	- Although this market is expected to be “single supplier” for the near to mid-term, no market shaping challenge has been identified as the supplier is well-established with a reliable track record and has offered an access commitment for the product in LMICs. There is a pressing need to clarify the magnitude of the potential Gavi demand as soon as possible to ensure supply is aligned with expected materialisation of demand	Low
Reputational	- Any adverse events following immunisation (AEFIs) - even if rare - could trigger public resistance, negatively impacting RSV uptake and broader maternal immunisation efforts.	Medium