

Annex A: Implications/Anticipated impact**Risk implication and mitigation, including information on the risks of inaction**

- A stronger focus on affordability of vaccine programme costs will most likely bring trade-offs on several market health dimensions, notably supply dynamics and geopolitical and health security exposure, with increased exposure to vaccine supply shortages in the near and long terms. These risks will be managed through market shaping roadmaps where minimally acceptable conditions for each vaccine market (including a more granular treatment of supply security concepts within the Healthy Market Framework) and accompanying risk mitigating actions will be established, followed by systematic monitoring to ensure conditions remain acceptable. Future Supplier Base (FSB) assessments are an important process to identify and track individual supplier and portfolio-level risks, such as over-reliance on individual suppliers. These assessments involve periodic reviews of the status of each supplier, evaluating both their business sustainability and their criticality to the overall health of the Gavi market, as well as consideration for potential impact of market strategies on suppliers, ensuring that any changes do not inadvertently undermine supply security. The insights gained from these reviews directly inform roadmap strategies and risk mitigation actions, supporting a more resilient and balanced vaccine supplier base. In the absence of stronger focus on affordability, fewer lives will be saved with the available vaccine procurement funding.
- Prioritising country leadership in the approach to realising target savings brings the risk of failing to achieve the full value of the target savings and not maximising health impact per dollar. This risk is mitigated through a multi-faceted approach to achieving the target savings including the design of the country vaccine budget framework and improved evidence for countries to make cost-conscious product choices, in tandem with procurement strategies bringing an increased emphasis on affordability. Taking a “top down” approach that does not prioritise country leadership would be misaligned with Alliance principles. Only in cases where minimum levels of supply security would be compromised would the Alliance propose this approach, implemented as part of VPOP.
- The country vaccine budget framework will be designed to support countries make cost conscious product choices yet there will be scenarios where countries may make trade-offs within their budgets to use higher priced products that may not fully maximise health impact per dollar according to external evaluations. VPOP will monitor this.
- Countries may not choose to switch to use of lower priced products due to the logistical and resource requirements of physically planning, organising and implementing a switch from one vaccine product to another that may have different programmatic requirements. This risk is mitigated through ensuring that countries have access to the evidence that provides a balanced view of the benefits of switching to a lower priced product.

- The Market Shaping team will update individual vaccine roadmaps to determine the market-specific actions required to balance affordability and market health. There is a risk that even if these actions successfully ensure sustainable access to low priced products for countries, the entirety of the SG4 savings are not realised due to co-dependencies with other parts of the Alliance (e.g. country vaccine budgets, VPOP operationalisation, Secretariat and Alliance partners, etc.). This risk is mitigated through a coordinated approach to incorporating market shaping considerations in the design of country vaccine budgets, the design and operationalisation of VPOP to support cost conscious product choices, and alignment with Secretariat and Alliance partners on the market shaping imperatives during the Gavi 6.0 strategic period.
- There is a risk of eroding the goodwill, confidence and sustainability/viability of vaccine suppliers due to simultaneous decrease in volumes, decreased predictability of demand due to the country vaccine budget model and campaign co-financing requirements, focus on lower pricing and less support for innovation. This risk will be mitigated through proactive and transparent communication with suppliers, combined with raising awareness among Gavi governance bodies on the short- and long-term implications of the risk of degraded goodwill that can inform Alliance decisions such as those proposed to be brought to a mechanism to be developed as part of MSS6.0 for guidance on proposed strategies.
- There is a risk that incentive levels set at the launch of the African Vaccine Manufacturing Accelerator (AVMA) may insufficiently account for what might be a more cost focused global procurement environment in Gavi 6.0. This risk is mitigated through AVMA's governance mechanism in which a planned review will occur in 2026 for potential course corrections in 2027 to ensure fitness for purpose against its original objectives.

Impact on countries

- A stronger focus on affordability and price-reducing procurement strategies is expected to offer countries more affordable choices for vaccine procurement and allow them to procure more vaccine doses within finite country vaccine budgets.
- Country use of lower priced products will, in many cases, involve a resource and time intensive country process of planning for and implementing the physical product "switch" at country level.
- Systematic management of market health risks (e.g. supply security) may in some instances require countries to use a higher priced product than their preference, eroding their budget available for other vaccine procurement. This risk is mitigated by proposing a financial contingency for supply security & market health, to make manual adjustments to country vaccine budgets where a country is required to use a more expensive product than their first choice. Failure to manage market health in such ways would lead to unacceptable supply security outcomes, possibly leading to interrupted vaccination due to lack of vaccine supply. The overall

contingency amount is being calculated as part of CVBs design, and the processes will be developed through CVBs/VPOP.

- Maintaining a focus on market health, including supply security, will benefit countries in the long term through continued access to sustainable vaccine supply. This focus may require additional spending on some vaccine programmes to ensure sufficient market health can be achieved.
- There is a risk that the advent of innovative products occurs at a slower rate than in previous periods due to lack of focused resources, information and investments. This risk is mitigated through maintaining some activity encouraging innovation and allowing procurement of innovative next generation vaccines through a defined governance pathway and the Product Portfolio Management principles.

Impact on Alliance

- Failure to achieve the target savings will lower the overall health impact and future lives saved of the country vaccine budget.
- Failure to maintain supply security or meet vaccine demand may result in loss of confidence in the core Market Shaping actors and ability of the Alliance model to meet public health needs.
- Development of an approach to making financial adjustments to country vaccine budgets to support management of market health risks and associated details such as updated criteria for market health in each market will be a considerable use of human resources across multiple Secretariat teams and Alliance partners.
- Implementing new procurement strategies responding to new affordability and supply security objectives may require more complex and time-consuming procurement activities beyond those previously planned.

Legal and governance implications

- Pursuit of procurement strategies focused on affordability and increased risks of supply security may entail new approaches that require governance resources for approval. Specifically, guidance from an Alliance governance mechanism to be defined as part of MSS6.0 will require additional time from Secretariat teams, especially Market Shaping, involved stakeholders and associated governance processes, when required.