

Annex B: Risks, potential implications, and mitigations

The Health Systems Strategy is designed to provide greater clarity on Gavi's role in health systems, increase the impact of its investments and allow better measurement of progress. However, there are significant strategic and operational risks to its implementation. In addition to the risks related to constrained funding and required changes to the partnership model which are described in the main body of the paper, several additional risks will need to be managed as the HS strategy is operationalised:

Risk that shifts in Gavi's investment approach have an adverse effect on immunisation programme performance:

A key proposed shift in the health systems strategy is to more systematically differentiate Gavi investments by country context including through greater focus on catalytic health systems investments and a reduction in funding for operational or recurrent costs as countries approach transition¹. While this approach will contribute to long-term programmatic sustainability and will be phased over time to prevent abrupt changes at country level, **there remain significant risks that reduction in Gavi support for operational activities could have a negative impact on programme performance**. The risks may be most acute in settings and programmes that are more highly dependent on outreach and campaign strategies (and thus require support for per diems, fuel, etc.), including remote settings with high number of zero-dose, or school-based outreaches to delivery HPV vaccines. This reflects a tension in the two strategic goals of the HS Strategy as equity and sustainability may be at odds in particular contexts. The differentiation framework with the HS Strategy intends to identify the relative prioritisation of these goals across different country contexts, recognising that achieving one may require trade-offs with the other. This risk will be further mitigated through Gavi's broader approach to programmatic sustainability and emphasis on aligned financing and budget advocacy with countries to increase domestic commitment for PHC.

Risk that shifts to Gavi's funding architecture and approach may impact programme outcomes

The consolidation of funding levers and greater alignment of Gavi funding to National Immunisation Strategies or other PHC strategies represent a positive step towards greater country ownership, simplicity, and alignment to the principles of the Lusaka Agenda². Consolidated funding and planning and greater programmatic collaboration with other health system funders also provides an important opportunity to more closely align Gavi's historic HSS programming and support for campaigns and new vaccine introductions and identify efficiencies. This will be important to better target and reach zero-dose communities, who may be reached through campaigns funded across different initiatives (e.g. polio campaigns by GPEI) but are not always referred to and followed-up through routine immunisation or reached by other PHC

¹ Support for operational activities in fragile/conflict settings and initial self-financing countries will still be allowable and necessary.

² Funding against national immunisation strategies is aligned to the Lusaka Agenda priorities but may be in tension with other efforts to align processes, application materials, and approaches with other funding institutions (e.g. Global Fund).

programmes. At the same time, these shifts also represent a departure from Gavi's current funding architecture and approach which is more directive in nature and aligned with very specific Board priorities (e.g. innovation, zero-dose, HPV revitalisation). With greater fungibility across cash funding, countries will have more agency to determine the relative split of funding across different priorities which means Gavi will have less direct control on how resources are allocated across different strategic priorities. The final HS Strategy, HSIS Policy, and forthcoming 6.0 programme funding guidelines, application materials, and monitoring tools will be key resources to inform how countries can and cannot use Gavi funding and mitigate this risk.

In addition, robust technical support from partners to strengthen the capacity of governments to develop, cost, implement, and monitor robust national strategies, and to determine priorities across vaccine introductions, campaigns and health system strengthening investments within a constrained financial envelope, will be essential. As part of EVOLVE, Gavi is currently launching pilots to test the feasibility of consolidated planning (across all cash funding levers) and funding against National Immunisation Strategies to inform operationalisation of Gavi 6.0 (see doc 7) to test and learn from these approaches before scaling them up. Similarly, the outcome of work of the Health Campaign Effectiveness Coalition Collaborative Action Strategy, and ongoing pilots in two countries, is expected to inform further integration and refinement of the needed support and changes in Gavi's guidelines. Other grant management changes envisioned under EVOLVE, including more robust annual planning and implementation monitoring will also be important enablers and mitigation factors.

Risk that delays or shifts to other 6.0 operationalisation efforts impact implementation of the HS Strategy

Finally, given the many interdependencies between the HS Strategy and other 6.0 operationalisation efforts, there is a risk that delays or issues within those workstreams (e.g. funding policy review, partnership model redesign, fragile and conflict approach) will impact the successful finalisation and implementation of the HS Strategy.

Risk that countries, Alliance, and Secretariat struggle to understand and adopt 6.0-related shifts, including those proposed within and linked to the HS Strategy

Gavi 6.0 will represent a period of significant change for the Secretariat, Alliance, and most importantly countries. While changes are intended to ultimately benefit countries, there is also a risk that the Secretariat and Alliance face bandwidth constraints in trying to implement the many, interdependent changes being made for Gavi 6.0 in parallel and that this could also increase complexity for countries in the near term. To mitigate this risk, the Secretariat's Strategy team is carefully project managing 6.0 operationalisation, identifying key interdependencies and helping to sequence implementation steps. Careful consideration for change management, including broad socialisation across global, regional, and country stakeholders will be essential, as will ongoing monitoring to inform potential course corrections.