

Annex A: Implications/Anticipated impact

The Vaccine Investment Strategy (VIS) facilitates strategic decision-making and is a fundamental tool in fulfilling Gavi's equity objectives. The rigorous process estimates health and economic impact of the vaccines under consideration in Gavi-eligible countries from 2026-2040 and compares them to the expected impact of vaccines in the current portfolio, thus providing a quantitative measure of comparable anticipated impact. The VIS process is meant to guide decisions for investment that could have the highest public health impact in Gavi countries.

In this Governance cycle (PPC/Board in May/June 2024), final investment decisions will be requested to be implemented from Gavi 6.0 subject to replenishment. Investment cases include vaccines against endemic and epidemic diseases leading to investments in routine/preventive programmes or stockpiles, respectively.

According to estimated timelines, the vaccines included in the investment cases would be available for use by Gavi towards the end of the 6.0 period (Figure 1, Doc 10), thus the recommendations presented to the PPC are for in-principle support. These in-principle decisions allow Gavi to include the vaccine in the design of Gavi 6.0, identify estimated costs for resource mobilisation and to provide a signal to manufacturers and countries regarding level of interest. The risks associated with these in-principle decisions include the level of uncertainty regarding timelines, product characteristics, supply and regulatory/policy recommendations. To mitigate these risks, the Secretariat will continue to monitor the vaccine pipelines, potential demand and progress of these products along regulatory and policy pathways to inform updated investment cases that will go back to the PPC/Board for a final approval to start planning and designing the vaccine programme/stockpile. Although Gavi could consider deferring these investment decisions until information is more readily available, this poses risks around funding not being available at the time of a future decision, as well as negative impact on manufacturers' continued investment in development of new products and production scale-up that would impact the timeliness and scale of supply availability and future market health.

Furthermore, the VIS recommendations from the PPC pose risks to countries, the Alliance and vaccine development:

Impact on countries – Non-infant vaccines

- As more and more countries consider the introduction and sustainability of additional vaccines outside the infant immunisation timepoint, it is important that countries have sufficient financial support for their successful delivery. Vaccines for dengue, tuberculosis and group B streptococcus target non-infant populations (2yrs, 15yrs and pregnant women, respectively) and thus are expected to require additional support to strengthen or develop additional immunisation touchpoints. As products become available and updated investment cases are developed and presented to the PPC/Board, this additional support provided either by Gavi or other stakeholders will need to be considered and weighed against other vaccines and health interventions. If there is limited funding and appetite for this additional support when these updated investment cases are reviewed there is a risk that

programmes will not achieve the estimated health impact and will have limited uptake and coverage, as well as contributing to intra-country inequity.

Impact on countries and Alliance – discontinuation of COVID-19 programme

- The discontinuation of the COVID-19 programme post-2025 includes risks such as loss of associated health impact, loss of delivery platforms created to reach high priority populations (elderly, health care workers), decreased market shaping leverage, i.e. prices are likely to increase for those countries that choose to continue self-funded purchasing, or some product options may disappear altogether as viable commercial volumes cannot be achieved. In some cases, loss of “live” mRNA manufacturing platform may represent a loss to overall pandemic preparedness.

Impact on countries and Alliance – Vaccine prioritisation

- Informed by the VIS, Gavi countries are grappling with an ever-expanding portfolio of vaccines in a context where there is a scarcity of global guidance on how countries should decide which vaccines to introduce and in what sequence. Countries may require technical support to strengthen their decision-making capacities and address evidence gaps and access global and regional guidance.
- In response, Alliance partners (WHO, the Bill & Melinda Gates Foundation, Gavi) have started to develop coordinated mechanisms to proactively align at global level to engage and support countries across prioritising and optimising this wide range of options. Alliance partners are proposing a three-pronged approach: **a) data, evidence and guidance** – facilitating Gavi country access to a curated repository of data, evidence and SAGE & RITAG guidance, leveraging existing resources; **b) tools and dedicated support** – providing frameworks and examples of tools used in other countries, providing support for country review, including through dedicated staff/unit if possible; and **c) country capacity and systems** – strengthen the capacity of NITAGs¹, promoting engagement between Ministries of Health and Finance, as well as proactive and regular decision-making processes. In the remaining months of 2024, partners will further develop this approach, exploring further linkages with regional offices (e.g. AFRO, EMRO, SEARO), and building on experiences to date with the objective of presenting an update on this work to SAGE in March 2025. As Gavi develops its health systems strategy and considers the operationalisation of Gavi 6.0, Gavi would plan to integrate this work into their regular programming and support and consider any associated costs.

Impact on vaccine development – Shigella

- The PPC considered an in-principle investment in a shigella vaccine programme to be premature in the context of multiple uncertainties including policy and regulatory pathways as well as country demand. However, the Committee acknowledged the importance of a Gavi market signal to maintain the shigella vaccine pipeline and sustain progress of stand-alone vaccine candidates to allow the development of potentially more attractive combination vaccines in the future and wanted to ensure this was captured in the recommendations.

¹ National Immunisation Technical Advisory Group