

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.

In October 2023, the Programme and Policy Committee (PPC) recommended a shortlist of vaccines. With Board approval, investment options will be developed for final consideration in May/June 2024. The quantitative and qualitative analyses, guidance from the VIS Steering Committee and consultations with other stakeholders that inform the shortlist of vaccines are meant to guide decisions and shortlist vaccines for potential investment that could have the highest public health impact in Gavi countries.

To provide quantitative and other qualitative measures, the VIS depends on collecting up-to-date data and making informed assumptions to arrive at accurate assessments. The Secretariat carries out a rigorous and consultative process to ensure that the latest evidence is gathered and that any assumptions are informed and aligned with disease experts and public health practitioners.

Shortlisted vaccines will include vaccines against endemic and epidemic diseases. As the data to evaluate the risk of epidemic diseases and outbreaks has a higher level of uncertainty, the Secretariat monitors these potential risks through living-assessments of pathogens prioritised by WHO's R&D Blueprint team that have a pipeline vaccine with preliminary data at Phase 2 or where there has been a public health event. Living assessments monitor emerging data, highlight data gaps and are updated regularly to facilitate timely decision-making upon epidemic and/or market triggers in between VIS cycles if needed.

Adding vaccines to the Gavi portfolio through the VIS poses risks to countries and the Alliance:

Impact on countries:

- The vaccines under consideration as part of VIS 2024 are expected to have an important public health impact and avert deaths, morbidity and disability in Gavi-eligible countries. The Secretariat has sought to quantify this impact for vaccines against endemic diseases (shigella, TB, dengue and group B streptococcus). Whilst further details are available in Annex B, it has been estimated that these vaccines have the potential to avert in total, between 239-1,237 future deaths per 100K vaccinated over the period 2026-2040. Not shortlisting for further consideration means that disease related deaths and disability will not be averted.
- As part of the in-depth consultations with countries and feedback received from NITAG¹ members at the Global NITAG Network meeting in June 2023, in-country

¹ National Immunisation Technical Advisory Group

partners have highlighted their limited capacity to prioritise and implement already available vaccines along with any new vaccines in a sustainable and timely manner. Furthermore, the VIS Steering Committee indicated that supporting countries in an evidence-informed vaccine prioritisation process that considers countries' unique epidemiological contexts was a critical role for Alliance partners. The Secretariat is collaborating with WHO and other partners to align on assumptions, approaches and support to countries as well as assess realistic demand. As the design of 6.0 progresses and Gavi considers its operationalisation, the Alliance's role in supporting countries in the prioritisation of an expanding number of vaccine programmes available to Gavi countries and their potential financing (e.g. fiscal space analyses to unlock additional domestic financing) will be an important consideration moving forward.

Impact on vaccine development:

- Shortlisting sends a signal to vaccine developers and manufacturers that Gavi is considering the vaccine for potential future investment, whereas not shortlisting a vaccine indicates that the vaccine will not be considered further for potential investment at this point in time. Shortlisting sends a positive signal to manufacturers and while manufacturers will make their own risk-based decisions considering multiple factors beyond VIS, in some instances not shortlisting a vaccine could disincentivise a manufacturer from continuing development of the vaccine, especially if the disease is confined to low-and-middle-income countries (LMICs), or to scale up or ensure supply capacity to accommodate potential future LMICs needs. As such, providing clear rationales as to why a vaccine is recommended not to be shortlisted is particularly important to ensure subsequent manufacturer decisions are optimally informed.
- With regards to vaccines under evaluation for prevention of epidemic diseases (hepatitis E, chikungunya, mpox), not recommending for further analysis at this time does not preclude Gavi from monitoring and further developing living assessments and presenting an ad hoc investment case in response to a trigger such as an R&D milestone or a public health event.

Impact on Alliance:

- The increased number of vaccines available for different target age groups and potential addition of new vaccines to the Gavi portfolio, has been recognised by the VIS Steering Committee and other experts and stakeholders as adding complexity as well as prioritisation and delivery challenges at country level. There is a need for broader consideration on how the Alliance can support countries to embed immunisation infrastructure across multiple age groups into an integrated primary health system for greater sustainability.