

Annex A: Implications/Anticipated impact

Risk implication and mitigation

- Should the Board choose not to support the VIS vaccines, it would be a missed opportunity to potentially avert ~0.2-0.8 million deaths over the 2021-2030 timeframe, to close crucial equity gaps and protect marginalised populations and to shape markets for improved supply and price. For cholera and meningococcal vaccines, lack of support for preventive programmes would also result in continued reliance on stockpiles for outbreak response, which carries significant cost (in terms of mortality and disruption due to outbreaks, as well as the cost of response). For rabies and cholera vaccines, there would also be a missed opportunity to leverage vaccine to potentially incentivise development of comprehensive disease control strategies. For RSV, lack of support for demand and evidence generation activities would result in continued lack of understanding of the true burden of RSV in contributing to paediatric morbidity and reduced likelihood that manufacturers would account for Gavi-eligible countries in their supply plans. Finally, for hepatitis B and D, T, & P-containing boosters, Gavi could miss an opportunity to achieve the additional impact of strengthening and establishing new immunisation platforms, in addition to preventing morbidity and mortality.
- Given the different nature of some of these vaccines, there is a risk that Gavi's current policies might not be fit for purpose. This could be mitigated through a future review of Gavi's support model (for both the current portfolio and VIS vaccines). There is also a risk that replenishment efforts might not result in the financing required to establish successful programmes and Gavi might need to deprioritise some of the approved vaccines. On a vaccine specific basis, some additional risks associated with investment include:
 - For RSV and meningococcal vaccines, there is a risk that timelines are delayed and new products come to market later than expected; there is also a risk that they do not meet the financial parameters indicated in the investment cases. An 'in principle' decision for support would allow Gavi to re-evaluate these vaccines when the products are made available and the other conditions are met.
 - For cholera and rabies vaccines, there is a risk that requiring commitment to broader disease control strategies could delay the use of the vaccine. However, this commitment would itself mitigate the risk that programmes are poorly planned and do not achieve impact. It would be important to ensure that partners engaged in these broader efforts can support countries to meet the conditions for support.
 - For D, T, & P-containing boosters and hepatitis B birth dose, there is a risk that the proposed support might not be sufficient to catalyse development of the immunisation delivery platform. This risk can be mitigated by ensuring that platform strengthening activities are appropriately identified

and supported via the process of reviewing and updating Gavi's Health Systems and Immunisation Strengthening Support Framework.

- Further risks are detailed in the individual investment cases in Appendix 2.

Impact on countries

- Support for these VIS vaccines has implications for countries. While countries would not be expected to take up all of the vaccines, there is some risk that programmatic capacity to add new vaccines might be weak in some countries. Some countries might also lack the financial capacity to incur the additional recurrent costs needed to deliver vaccines. In addition, countries will need to develop their decision-making capacity, which will require time, attention and resources, both domestic and donor-supported. Finally, for some vaccines (e.g., cholera and rabies), countries will also need to invest additional time and resources to develop disease control strategies to access vaccine support.

Impact on Alliance

- Alliance partners will need to ensure they have the requisite capabilities and resources to ensure country readiness to take up relevant vaccines. This would include ensuring that at global, regional and national levels, partners can provide technical guidance on choosing the appropriate vaccines for local and regional context and designing national plans and programmes.