Subject	Vaccine Investment Strategy 2024 – Investment Cases					
Agenda item	10					
Category	For Decision					

# **Executive Summary**

This paper presents for Gavi Board decision the Vaccine Investment Strategy (VIS) 2024 investment cases for tuberculosis, group B streptococcus and dengue as routine/preventive vaccine programmes, and hepatitis E as a stockpile; note the non-extension of the current COVID-19 programme post 2025; and a recommendation on the investment case for an mpox stockpile and response to the current mpox outbreak. The actions have been informed by recommendations from the Programme and Policy Committee (PPC), guidance from the VIS Steering Committee, input from countries, as well as consultations with civil society organisations (CSOs), technical partners, disease experts, academics, practitioners, and vaccine manufacturers. This decision represents the third and final decision point on VIS 2024, aligned with a decision on the Gavi 6.0 strategy.

#### **Action Requested of the Board**

The Gavi Alliance Programme and Policy Committee (PPC) recognised that this Vaccine Investment Strategy (VIS) is taking place in a different global health and fiscal landscape with significant pressures on health systems, vaccination schedules and changing epidemiology due to climate change and urbanisation.

As the menu of vaccines available across the life course increases, countries may require technical support to strengthen decision-making capacities on vaccine prioritisation and optimisation, and support to strengthen their health systems to deliver them.

The PPC also recognised the importance of the VIS for long-term market signalling to manufacturers despite the many unknowns.

Considering this, the Gavi Programme and Policy Committee <u>recommended</u> to the Gavi Alliance Board, subject to the availability of funding for the 2026-2030 period following Gavi's replenishment for that period, that it:

a) <u>Approve</u> in principle, support for a <u>tuberculosis</u> (TB) vaccine programme, contingent on the availability of a licensed product for adults/adolescents, outcomes of regulatory and technical review processes (including WHO prequalification and SAGE recommendation), and meeting the financial assumptions used as the basis for the TB investment case set out in Annex B to Doc 10;

- b) <u>Approve</u> in principle, support for a dengue vaccine programme, contingent on outcomes of regulatory and technical review processes and the availability and application of disease burden data in Gavi supported countries to inform the design of a vaccine programme, and meeting the financial assumptions used as the basis for the dengue investment case set out in Annex B to Doc 10;
- c) <a href="Approve">Approve</a> in principle, support for a group B streptococcus (GBS) vaccine programme, contingent on the availability of a licensed product, outcomes of regulatory and technical review processes (including WHO prequalification and SAGE recommendation), and meeting the financial assumptions used as the basis for the GBS investment case set out in Annex B to Doc 10;
- d) <u>Note</u> continued exploration by the Secretariat of the need for, and design of, timely market shaping interventions aimed at ensuring that TB vaccine supply matches anticipated demand with minimal lag;
- e) <u>Note</u> the expected public health impact of a future shigella vaccine programme in Gavi-supported countries and that continued vaccine development is important, and request the Secretariat to revert to the PPC with an updated investment case for a shigella vaccine programme when there is further information on country product preferences and timelines for technical guidance, policy and regulatory review processes;
- f) <u>Approve</u> the VIS learning agendas for 2026-2030 for shigella, GBS, dengue and tuberculosis as described in Annex B to Doc 10;
- g) <a href="Approve">Approve</a> in principle, support for a global stockpile of hepatitis E vaccines, contingent on outcomes of regulatory and technical review processes (WHO prequalification), and meeting the financial assumptions used as the basis for the hepatitis E investment case set out in Annex B to Doc 10;
- h) **Approve** in principle, support for a global stockpile of mpox vaccines, contingent on outcomes of regulatory and technical review processes, and meeting the financial assumptions used as the basis for the mpox investment case set out in Annex B to Doc 10;
- Note the financial implications associated with the above approvals (taken as a whole) for 2026-2030 are expected to be approximately US\$ 56.7 million, comprised of approximately US\$ 32.9 million for vaccine and operational cost support and approximately US\$ 23.8 million for learning agenda and reporting activities;
- j) <u>Note</u> that the routine COVID-19 programme will be discontinued following the completion of the current 2024-2025 programme, and that support for COVID-19 in the event of a worst-case scenario would be considered through Gavi's pandemic preparedness, prevention and response activities;

- k) <u>Approve</u> the VIS learning agendas starting from 2024 for hepatitis E and mpox vaccines, as described in Annex B to Doc 10 and note that the financial implications associated with the above approvals for 2024-2025 are expected to be approximately US\$ 0.5 million, which the Secretariat will seek to absorb from the Board-approved budget for the 2021-2025 Strategic Period; and
- I) Approve from 2024, a role for the Gavi Alliance in responding to the ongoing mpox outbreak, including coordinating mpox dose donations in response to the ongoing outbreak in the Democratic Republic of the Congo and further potential outbreaks in surrounding countries. Building on lessons learnt from the COVAX Facility, this coordination role will be contingent upon favourable conditions, including the availability of resources, clear demand from countries, regulatory compliance, and reaching agreements that are actionable by all parties involved.

The PPC member representing the donor constituency cluster anchored by Norway asked that it be noted that her constituency cluster was not in agreement with the decision to go forward with the recommendation to approve in-principle investment cases for dengue and GBS. The PPC was therefore unable to reach consensus on recommendations b) and c) and parts of f) above and the minority position expressed by Hannah Haaij on behalf of her constituency cluster is being reported to the Board in line with the PPC Charter.

# **Next steps/timeline**

Implementation of the new routine/preventive vaccination programmes and stockpiles, outlined in the investment cases will be subject to conditions outlined in the decision and contingent on availability of funding. The Secretariat will continue to monitor the vaccine pipelines and progress of these products along regulatory and policy pathways to inform updated investment cases for PPC/Board decision, as well as planning and design of future vaccine programmes/stockpiles.

### Previous Board Committee or Board deliberations related to this topic

In May 2024 PPC meeting book: Doc 09 Vaccine Investment Strategy 2024 – Investment Cases

**In December 2023 Board meeting book**: Doc 11 Vaccine Investment Strategy 2024 - Proposed shortlist

**In June 2023 Board meeting book**: Doc 9 *Vaccine Investment Strategy 2024 - Longlist and evaluation frameworks* 

# **Report**

## 1. Background

- 1.1 The VIS is Gavi's prioritisation process to evaluate vaccines and immunisation products for possible inclusion into the future portfolio. Every five years, through this rigorous, consultative, and transparent process, the Secretariat reviews evidence to identify and assess new and/or under-used vaccines of high public health relevance for Gavi-eligible countries. VIS 2024, Gavi's fourth VIS, has evaluated eight vaccines as investments in routine/preventive immunisation programmes or global vaccine stockpiles.
- 1.2 This paper presents the outcomes of the third and final phase of the VIS 2024. In Phase 1, the Board approved a longlist of vaccines and frameworks to evaluate them against, and in Phase 2 a shortlist of vaccines for investment case development. In Phase 3, the Secretariat has developed investment cases and proposed learning agendas that Gavi can support to provide evidence for the launch, implementation and effective scale up of a vaccine programme/ stockpile.
- 1.3 The VIS Steering Committee<sup>1</sup> reviewed and provided guidance on draft investment cases in March 2024, commending the Secretariat's work and highlighting the completeness and rigour of the assessments. Extensive country consultation has taken place<sup>2</sup> as with other stakeholders, including CSOs, technical partners, disease experts, academics, practitioners, and vaccine manufacturers.
- VIS 2024 investments would begin from 2026, contingent upon funding being available for the 2026-2030 strategic period (Gavi 6.0). However, the bulk of VIS 2024 introductions would be in Gavi 7.0 (Annex B). Despite the time lag in expected vaccine availability, it is important to signal to manufacturers Gavi's interest in pursuing these programmes early, or risk discontinuation of certain programmes. This signal may also prove important in accelerating development and regulatory timelines and provides a mandate for the Secretariat to begin preparatory activities via learning agendas, technical assistance to countries planning to introduce or engagement with partners to agree roles and responsibilities for new programmes.
- 1.5 The PPC recognised the quality of the investment cases, highlighting the rigour of the guidance provided by the VIS Steering Committee and the work of the Secretariat during the last 18 months. The PPC recommended in-principle

<sup>&</sup>lt;sup>1</sup> Provides independent external expert advice to the Secretariat on the strategic questions, methodology and process for the VIS. Chaired by Prof. Helen Rees, it includes 10 independent members with complementary skills selected from an open competitive call and 8 *ex officio* members representing partners and stakeholders, including a PPC member.

<sup>&</sup>lt;sup>2</sup> In Phase 1 input was obtained through a high-level, non-representative survey and phase 2 in-depth consultations took place with a sub-set of 16 Gavi-supported countries. In this final phase, an online survey to countries showed highest demand for a TB vaccine, while for epidemic diseases a need for better surveillance data and improved community awareness of vaccines to support effective decision-making and use of stockpiles. There was uncertainty on COVID-19, with only seven out of 26 countries reporting a national plan in place post 2025.

approval for the TB, GBS and dengue investment cases, stockpile investments for mpox and hepatitis E, and learning agendas for TB, GBS, dengue, shigella from 2026. Learning agendas for mpox and hepatitis E were also recommended for support with activities starting earlier in 2024 given the learning opportunities provided by the ongoing outbreak in the Democratic Republic of Congo (DRC) for mpox and the pilot stockpile being set-up for hepatitis E. In addition, the PPC noted the recommendation to discontinue the COVID-19 programme from 2026, considering decreased demand from countries and trade-offs for the 6.0 strategic period, and agreed with the recommendation that the Alliance coordinate dose donations to address the ongoing mpox outbreak in DRC, building on experience and learnings from COVAX.

- 1.6 For TB and GBS investment cases, the PPC recognised the high public health impact of the vaccines, and for dengue the importance of the changing epidemiology and increased number of outbreaks as highlighted by country representatives, but agreed that availability of burden data from Gavi countries should be a condition for any investment. For shigella, the PPC acknowledged the public health importance of a future vaccine programme and the importance of a market signal from Gavi at this time to maintain the vaccine pipeline, but discussed the uncertainty of country demand in the context of other vaccine introductions and a crowded vaccination schedule as well as potential preference for combination products. Thus, they requested the Secretariat provide an updated investment case when further information on country product preferences, and timelines for technical guidance, policy and regulatory review pathways is available.
- 1.7 The PPC recognised that this iteration of the VIS was taking place in a different landscape with significant fiscal constraints and challenges related to weak health systems, expanding vaccine portfolios across the life-course, and changing epidemiology with an increased risk of outbreaks. In this context, the PPC highlighted the importance of providing support to countries to strengthen their health systems to deliver vaccines, particularly those targeting non-infant populations, as well as supporting countries to make evidence-based vaccine prioritisation and optimisation decisions. Gavi will consider efforts to build country capacity for vaccine prioritisation and optimisation as part of the health system strategy being developed for 6.0.

### 2. Health impact, cost and value for money

2.1 The projected health impact of VIS 2024 vaccines (Table 1) is within range of the current portfolio (Annex B), however, projected health impact for vaccines administered outside infant touchpoints (TB, GBS, dengue) is likely only achievable if additional investments are made to strengthen immunisation for the relevant population.

Table 1: Overview of health impact and value for money, Gavi-eligible countries only, 2026-20403

		Dengue	GBS	TB	Нер Е	Shigella
Health impact	Total future deaths averted	388 – 447	193K – 376K	201K – 230K	1K – 6K	17K – 44K
	Total future DALYs averted	29K – 33K	14M – 26M	64M – 73M	62K – 308K	1M – 3M
Value for money	Total cost per death averted	\$67K – 134K	\$6K – 7K	\$10K – 19K	-	\$45K – 58K
	Total cost per DALY averted	\$896 – 1.8K	\$81 – 103	\$33 – 61	-	\$667 - 989

2.2 Forecast of Gavi costs for VIS 2024 in Gavi 6.0 (Table 2) are associated with learning agendas and an mpox stockpile. No procurement or delivery costs have been forecast for GBS and TB, even with possible availability in Gavi 6.0, considering the uncertainties regarding product availability, regulatory and policy pathways.

Table 2: Gavi costs (US\$ million) for VIS 2024 vaccines in 6.0 for Gavi-eligible countries\*

Gavi 6.0 (2026-2030)	Procurement	VIGs/Ops	Learning agenda	Reporting/ Monitoring	Totals by Vaccine
Shigella	0	0	2.0		2.0
GBS	0 – likely to be av	ailable in early 7.0	5.6	Modelling for	5.6
Dengue	0.8	0.5	3.5		10.9
+ campaigns	5.7	0.4	3.5		
Tuberculosis	0 – funding needs to be further assessed during the cycle		5.0	new vaccines	5.0
Hepatitis E	1.2	0.2	3.5		4.9
Мрох	24	0.06	3.5		27.6
COVID-19	0	0	0	0	0
Total	31.8	1.1	23.1	0.7	56.7

<sup>\*</sup>Partners' Engagement Framework (PEF) and Secretariat opex costs to be absorbed within the overall Gavi 6.0 envelope. HSS costs not shown and will be absorbed by existing forecast or may require forecast revisions at time of final Board decisions to launch specific vaccines in line with ambition.

2.3 Estimated overall procurement and delivery costs for Gavi and Gavi-eligible countries for the period 2026-2040 and by strategic period are summarised in Annex B. The Secretariat has incorporated the VIS forecast for middle-income countries into the vaccine introduction costing analysis to inform the development of the 'catalytic phase' of the eligibility and transition policy that was presented at the Board Retreat in April, estimated to cost US\$ 250 million in 6.0 (see Doc 06a).

#### 3. Investment cases – recommended by PPC

3.1 The Board is requested to make in-principle decisions, meaning that when the vaccine and related regulatory and policy recommendations become available, the Secretariat would review the relevant investment case, assess whether the assumptions still sufficiently hold and bring it back to the PPC and Board for a decision to move forward with the design of the vaccine programme or

<sup>&</sup>lt;sup>3</sup> Values do not reflect the additional impact if vaccines were introduced in MICs, nor do they reflect the additional impact of one-off catch up campaigns for TB. Values do reflect a one-off catch up campaign for dengue. COVID- 19 is not included as the health impact modelling and demand forecasting currently have different underlying assumptions. Mpox is not included due to lack of modelling data at this time.

stockpile. In-principle decisions allow Gavi to include the vaccine in the design of Gavi 6.0 (see Doc 06), identify estimated costs for resource mobilisation and provide a signal to manufacturers and countries regarding level of interest (see Annex A). Vaccines with in-principle decisions would not be brought back into a new VIS process for 7.0.

- 3.2 Group B streptococcus (GBS) is the leading cause of neonatal/infant sepsis and meningitis globally, accounting for ~91K deaths and ~57K stillbirths per year, concentrated among poor and vulnerable populations, with burden of disease highest in Sub-Saharan Africa (half of all deaths). A GBS vaccine for pregnant women has the potential to reduce neonatal mortality and has high health impact and value for money relative to other VIS vaccines. There is uncertainty on vaccine availability timelines, as regulatory approval will likely be based on immune correlates of protection (efficacy trials not feasible for this disease) whereas a global policy recommendation may require real world efficacy data. When the conditions of the in-principle decision are met, the updated investment case will take into consideration the available funding and appetite to include support to strengthen the maternal immunisation touchpoint. Prioritised questions for a learning agenda include identifying programmatic and financial requirements for a strong maternal immunisation touchpoint, and surveillance strengthening activities to improve understanding of the burden of disease.
- 3.3 **Dengue** is transmitted to humans by mosquitoes, causing ~100 million cases per year which result in ~36,000 deaths. The global incidence of dengue has grown dramatically in recent decades with outbreaks occurring in multiple geographic areas putting over half the world's population at risk.<sup>4</sup> Important epidemiological data gaps remain in Gavi eligible countries, an investment in dengue vaccines (targeting children 2-16 yrs.) would need to be informed by data on burden of disease in Africa. However, evidence of increased outbreaks due to climate change and urbanisation have highlighted the epidemic potential of the disease in Africa. A conditional in-principle decision from Gavi would signal a recognition of the growing burden of dengue in lowand-middle income countries, as well as interest in and acknowledgement of the importance and utility of dengue vaccines in addressing the burden. Prioritised learning agenda questions with a focus on Africa include: a) clinical characterisation, b) burden of disease (including seroprevalence and integration of diagnostics), and c) safety and acceptability.
- 3.4 <u>Tuberculosis</u> data from 2022 showed that ~10.6 million people developed active TB disease and 1.3 million died. About a quarter of the global population is estimated to be infected with TB, with adults and adolescents accounting for almost 90% of disease transmission. Developing new safe, affordable, and

<sup>&</sup>lt;sup>4</sup> Two vaccines are licensed with a third in Phase 3, and two vaccines are expected to be available in multi-dose vial formulations ~2028.

effective TB vaccines for adults and adolescents<sup>5</sup> is considered essential for eliminating TB by supplementing existing TB interventions and aligns with the global agenda to end TB by 2030. Gavi's in-principle support would include routine immunisation at an adolescent time point (~15 year olds) and whilst recommended vaccination strategy is not yet known, a one-off catch-up campaign for a narrow age range (16-18 year olds) is assumed in this analysis. Gavi is engaging with WHO's TB Vaccine Accelerator Council and other key stakeholders such as the Global Fund with the aim of accelerating vaccine availability and ensuring rapid vaccine access. The high level of uncertainty associated with the product availability date, recommended vaccination strategy and realistic demand scenarios create challenges for anticipating market shaping opportunity/risk and developing realistic costings. Further work will be needed to clarify these. A potential market shaping intervention in 6.0 to ensure that initial supply volumes are adequate for launch will be considered. Funding may be required for preparedness activities in 6.0 before launch of a TB vaccine programme window. Learning agenda priorities include integration of TB vaccines with other health services, acceptability and uptake by older adolescents, identification of priority groups and cost-effectiveness.

- 3.5 Hepatitis E accounted for ~44,000 deaths in 2015, concentrated in poor and vulnerable populations (e.g. pregnant women) with limited access to clean water. Burden of disease is highest in India and Sub-Saharan Africa with ~88% concentrated in Gavi countries and outbreaks frequently noted in internally displaced populations in Africa. Gavi's in-principle support for a stockpile would provide a positive signal for the manufacturer to prequalify the vaccine as the investment would be contingent on this (~2028).<sup>6</sup> A Hep E stockpile represents a relatively small investment for Gavi with high associated value for money and impact on equity. The vaccine stockpile would be informed by outbreak response activities implemented by Médecins Sans Frontiers (MSF) and a Bill & Melinda Gates Foundation-funded proof-of-concept stockpile. Prioritised questions for a learning agenda include effectiveness and duration of protection in different population groups, integration of diagnostics to identify outbreaks as well as costs and feasibility of vaccine delivery.
- 3.6 Mpox caused a multi-country outbreak in 2022 with ~1.2 deaths per 1k cases worldwide and countries in West and Central Africa experience continuous and growing outbreaks. The Democratic Republic of Congo (DRC) is currently experiencing an outbreak of a more severe clade of the virus with the casefatality ratio (CFR) at 6% (331 deaths from 5,743 diagnosed cases in Jan-Apr

<sup>&</sup>lt;sup>5</sup> The phase 3 clinical trial of M72/ASO1E has just started, with results, PQ and availability estimated by ~2028. This vaccine is expected to target adolescents (≥ 15 years) and may include one-off catch-up campaigns to reach a broader group. Two other pipeline vaccines being considered with reservation for this analysis: 1) VPM1002, a mycobacterial live attenuated vaccine with an intended primary indication for disease prevention, with an ongoing household study targeting adults and adolescents. The study is not collecting information on PLHIV (an ECVP key priority group), and their study design might hinder global policy recommendations; and 2) MTBVAC, another mycobacterial live attenuated vaccine primarily indicated for disease prevention undergoing Phase 3 in infants but Phase 2a for adolescents and adults, with an expected study completion in 2024, and its phase 3 is deemed unlikely to meet the 2030 timeline.

<sup>&</sup>lt;sup>6</sup> WHO has a permissive recommendation of the currently licensed vaccine, Hecolin, for use in outbreaks. The vaccine is undergoing reformulation for global use and prequalification (PQ) is expected in 2028.

2024). Children <15 years are the most affected group accounting for the majority of cases (68%) and deaths (85%) observed. In infants <1 year of age and children aged 1-5 years, CFR is reported at almost 11% and 9%, respectively. In December 2023, the Gavi Board de-prioritised mpox for the development of an investment case due to poor availability of burden data and lack of demand from countries, requesting the Secretariat to develop options for a learning agenda. However, due to the ongoing outbreak in DRC, and in accordance with the 2018 Board-approved approach for developing living assessments for vaccines for epidemic preparedness and response, the Secretariat, supported by the VIS Steering Committee, has developed investment options that address the current and future outbreaks. DRC has since signalled that it will submit a request for support. A three-pronged approach is proposed:

#### 3.6.1 **In the immediate term** (beginning in 2024, as part of 5.1):

- a) A learning agenda to complement country and partner investments to better understand the epidemiology and burden of disease in endemic contexts, as well as exploring vaccine impact through modelling studies by leveraging new data from DRC.
- b) Given current vaccine supply challenges and donation offers, Gavi has been asked by some Gavi-supported countries and donors to explore facilitating access by establishing a mechanism to coordinate dose donations. This would build on lessons learnt during COVAX and would be dependent on available resources, articulated country demand, national regulatory approval, and ability to reach implementable agreements with all parties (e.g. sufficient shelf-life for effective roll-out, easily deployable).
- 3.6.2 **In the longer term**: Gavi would invest in a stockpile of 100k doses per year to address outbreaks. This would be contingent on the availability of a vaccine with the necessary regulatory approvals.
- 3.7 As a Protracted Grade 2 Emergency, and until such a time as a stockpile is operational, an mpox response could also be assessed for eligibility of funding from the First Response Fund being proposed in Doc 11a, if the proposed programmatic parameters and eligibility criteria are approved by the Board.

<sup>&</sup>lt;sup>7</sup> There is currently no prequalified vaccine for mpox and although there are vaccines licensed for smallpox and mpox in several countries, vaccine access through the existing regulatory (Emergency Use Listing (EUL), PQ, etc.) and policy pathway is hindered due to the grading of mpox (e.g. not a Public Health Emergency of International Concern (PHEIC), and not a priority pathogen for WHO PQ). Furthermore, there is a recognised lack of vaccine safety data and no effectiveness data in children limiting potential response.

# 4. Investment cases – not recommended by PPC

- 4.1 COVID-19: In December 2022, the Board approved a continued COVID-19 programme for 2024-2025,8 once COVAX concluded in December 2023. The Board also requested that through VIS, the Secretariat evaluate a continued vaccine programme from 2026. Consultations with countries, Alliance partners, guidance from the VIS Steering Committee and steer from Gavi Board (April Board retreat) all endorsed not extending the current COVID-19 programme post-2025 given country demand is likely to continue to decrease as countries make trade-off decisions on how to best use their resources. Countries could continue procuring COVID-19 vaccines themselves via UNICEF and a worst-case scenario response would be possible through Gavi's pandemic prevention, preparedness and response activities. Notable risks include loss of platforms to reach high priority populations and likely manufacturer withdrawals from the market/ increased prices.
- 4.2 <u>Shigella</u> caused ~150k deaths in 2019 and is the second leading cause of diarrhoea globally, with an important impact on stunting and AMR. Most of the burden of disease concentrated in Sub-Saharan Africa and ~90% in Gavi countries. Whilst expressing that it is too early to make decisions on investments in a shigella vaccine programme, the PPC did recommend a learning agenda to assess country product preference, demand and burden of disease.
- 4.3 <u>Chikungunya:</u> In December 2023, the Board requested the Secretariat propose a learning agenda for chikungunya. However, the VIS Steering Committee's guidance did not prioritise an investment in a learning agenda but indicated the Secretariat should continue to monitor and update the living assessment, thus it was not included in the recommendations presented to the PPC.

# 5. Future considerations of the VIS and next steps

5.1 Over time, Gavi's vaccine portfolio has evolved from a focus on vaccines for routine infant immunisation to include vaccines that target other age groups, such as HPV, as well as vaccines that support outbreak and epidemic preparedness and response providing countries with a growing number of options and the need to prioritise. The VIS has informed these options and outcomes from this current process are expected to continue this trend, which is aligned with the Immunisation Agenda 2030's life-course approach. There is also recognition of the increasing regional context of some vaccines and the need to ensure that Gavi countries have access to them, as well as the need for the global health community, Gavi, donors and countries to call for combination vaccines to help ease the overcrowded infant immunisation schedule. However, as more and more countries consider the introduction and

<sup>&</sup>lt;sup>8</sup> The 2024-2025 COVID-19 programmes shifts from an emergency response to one focused on continued vaccination support for the 91 COVAX participants. A total of 58 countries will receive 68 million doses in 2024. This includes a 50% reduction of doses for the 37 Advance Market Commitment (AMC) countries and estimates for 2025 are further reduced.

sustainability of additional vaccines, particularly those targeting non-infant populations, additional challenges emerge. The PPC highlighted the importance of strengthening countries' capacities to prioritise vaccine introductions and optimise their portfolios effectively, considering country or regional-level priorities, as well as the need for longer-term health system support to ensure that countries can reach and sustain equitable coverage of vaccines. It was noted that the emerging Gavi 6.0 strategy prioritises health systems investments for the infant touchpoint as per guidance from the April 2024 Board Retreat.

VIS decisions will form part of the deliberations for Gavi's 6.0 strategy to ensure alignment and coordination. The Board's decisions on investment cases are contingent on availability of funding for the Gavi 6.0 strategic period. In the interim, the Secretariat will continue to engage internally and externally to monitor the availability of products and progress of policy recommendations to inform updated investment cases and facilitate the design and ultimate launch of vaccine programmes, when appropriate in Gavi 6.0 or beyond.

### **Annexes**

**Annex A**: Implications/Anticipated impact

**Annex B**: Summary of VIS recommendations and costs