

VACCINE INVESTMENT STRATEGY 2024 – INVESTMENT CASES

BOARD MEETING

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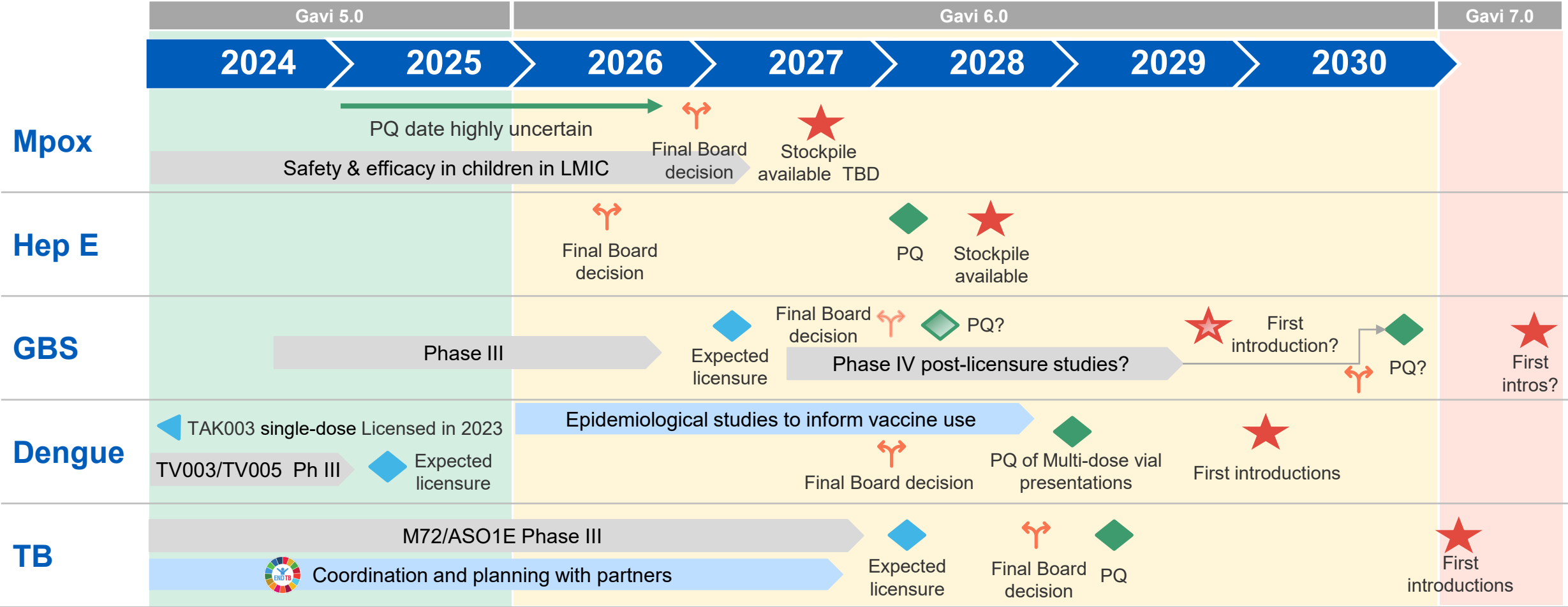
6-7 June 2024, Geneva, Switzerland



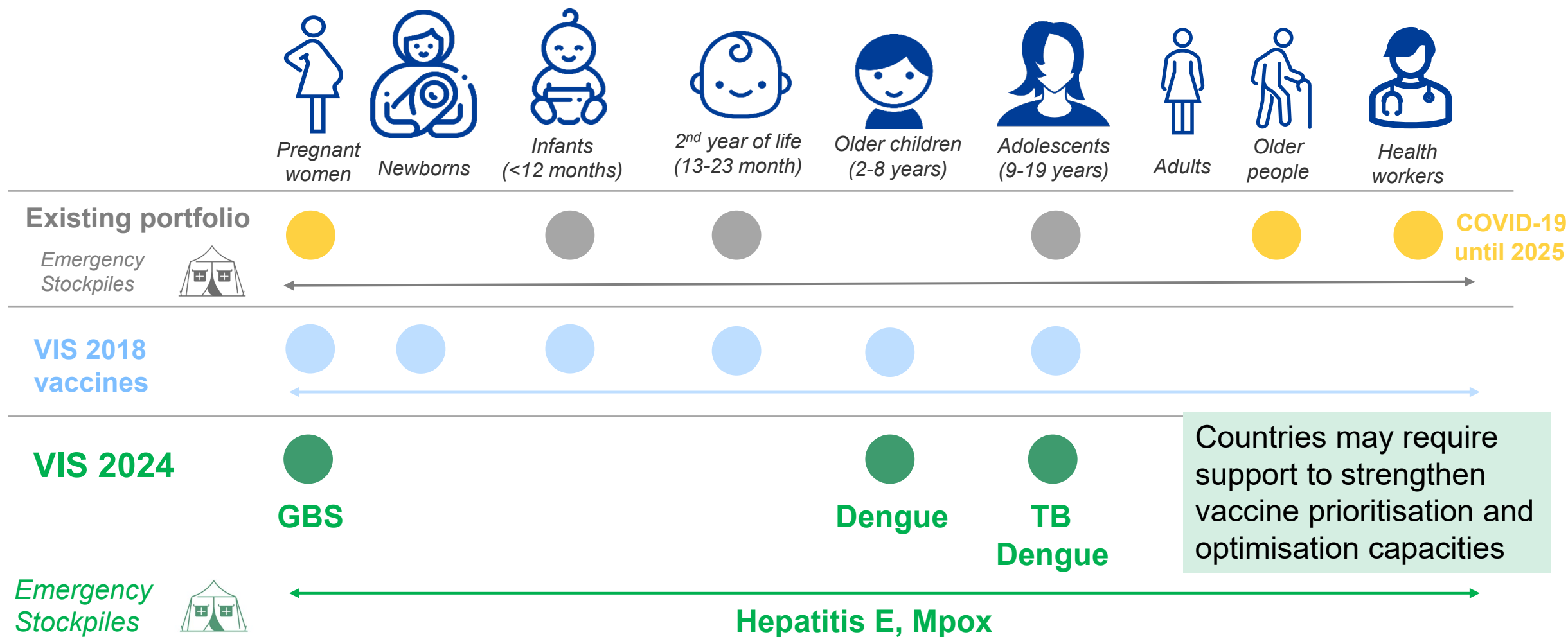
PPC Recommendation: Support for learning agendas and in-principle investments

Vaccine	Population	In-principle investment	Learning Agenda
Tuberculosis	Adolescents/ Adults	✓	✓
Group B Streptococcus	Pregnant women	✓	✓
Dengue	2-16 years	Conditional on burden data in Africa	✓
Hepatitis E	High-risk in outbreak response	✓	✓ from 5.1
Mpox		✓	✓ from 5.1
Shigella	Infants	✗	✓
COVID-19	High-risk populations	No continued investment post-2025	

VIS 2024 vaccines may only be available later in Gavi 6.0 – market signaling and preparedness activities required earlier



VIS vaccines represent an expansion to the current portfolio



Tuberculosis



- A future TB vaccine **programme requires advanced close coordination with partners**
- Potential **market shaping mechanism** to be considered in Gavi 6.0

Mpox



- **Ongoing severe Mpox outbreak in Democratic Republic of Congo (DRC)** requires a rapid and coordinated response

Proposal:

- **Learning agenda** from Gavi 5.1
- Explore **donation coordination mechanism**
- **Vaccine stockpile** once regulatory approvals in place

COVID-19



- **No continued programme post-2025** recommended by PPC
- Gavi's **Global Health Security investments** will be able to respond to worst-case scenarios

Implications:

- Loss of delivery platforms
- Decreased market shaping leverage
- Prices likely to increase

Recommendation (1/4)

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 lifecourse 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.

Recommendation (2/4)

Considering this, the Gavi Alliance Programme and Policy Committee **recommended** 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) **Approve** in principle, support for a **tuberculosis (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) **Approve** 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) **Approve** 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) **Note** 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;

Recommendation (3/4)

- e) **Note** 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) **Approve** the VIS learning agendas for 2026-2030 for **shigella, GBS, dengue and tuberculosis** as described in Annex B to Doc 10;
- g) **Approve** 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;
- i) **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;

Recommendation (4/4)

- j) **Note** 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) **Approve** 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
- l) **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 favorable conditions, including the availability of resources, clear demand from countries, regulatory compliance, and reaching agreements that are actionable by all parties involved.

Thank you