

HEXAVALENT INVESTMENT CASE

BOARD MEETING

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26-27 June 2023, Geneva, Switzerland



Governance pathway and key decisions

2018

Board approved:

- **In-principle support for wP-Hexavalent**, subject to a vaccine being licensed, recommended for use by WHO, WHO prequalified, and with market attributes met that support the successful implementation
- **Support for IPV** - based on the rationale that polio eradication is a global public health good, and routine vaccination with IPV plays a fundamental role in the polio eradication strategy

2019

Gavi joined GPEI as an official core partner

2022

Board approved: continuation of its 2019 IPV support decision - countries are exempt from Gavi eligibility and co-financing policies until polio eradication and the withdrawal of bivalent oral polio vaccine (bOPV) from routine immunisation

Gavi Alliance partners assessed Hexavalent support conditions, using price and supply information → 4/5 conditions met, price condition to be confirmed by MSDC

2023

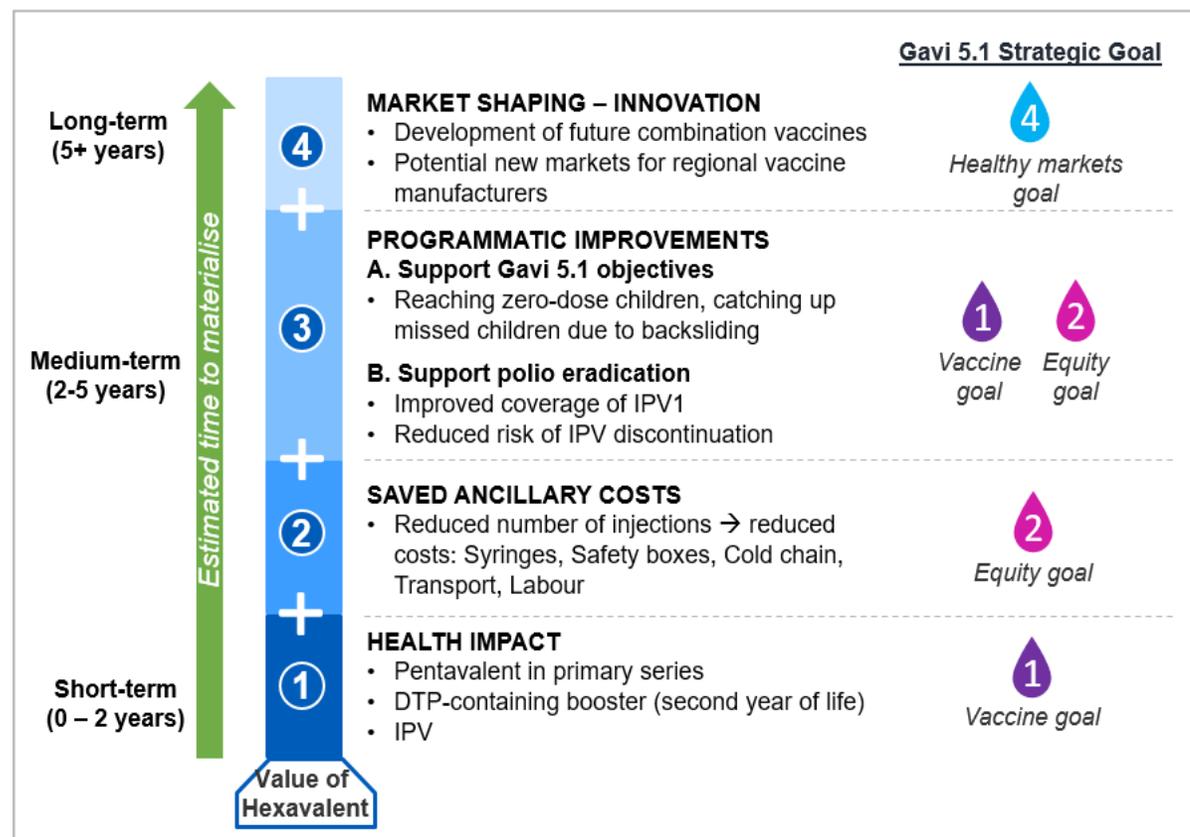
MSDC (February 2023) confirmed that the price aligns with Hexavalent's expected benefits → **5/5 support conditions are met**

PPC (May 2023) recommended to the Board to open a funding window for Hexavalent in Q3 2023

Board (June 2023) to decide on opening a funding window for Hexavalent in Q3 2023

Value of Hexavalent and financial implications

Value of Hexavalent



Additional costs: Hexavalent vs 3Pentavalent + 2IPV

	Gavi 5.1	Gavi 6.0
Gavi	US\$ 29 million [US\$ 62 million]	US\$ 357 million [US\$ 430 million]
Countries	US\$ 0.2 million [US\$ 2 million]	US\$ 34 million [US\$ 60 million]

- Cost range reflects the base and high demand scenarios (in brackets).
- Figures include the saved ancillary costs to Gavi, and a one-time switch grant based on US\$ 0.25/child.
- Figures include the cost of two additional doses of IPV currently not Gavi-supported and a DTP-containing booster dose.

Risks related to the Hexavalent investment case

▶ RISKS OF APPROVING A FUNDING WINDOW



- **Future funds** to cover financial implications in Gavi 6.0 not secured for now



- **Low demand:** Slower production scale-up if demand materialisation lower than expected
- **High demand:** Limited country access to Hexavalent if demand materialisation higher than supply [scenario not reflected in the forecast]
- **Delayed IPV2 introduction**



- **Low competition period (2023-2026):** Increased impact of potential supply disruptions
- **Competitive period (2027+):** Potential Pentavalent / IPV price increase and supply reduction



Gavi Alliance partners will use targeted market shaping interventions, including procurement strategies for UNICEF tenders, to mitigate demand and supply-related risks.

▶ RISKS OF DELAYING A DECISION



- **Risk of deprioritisation or discontinuation of Hexavalent development plans** and production scale-up, and investments in vaccine manufacturing in Africa



- **Missed programmatic benefits,** including support for Gavi 5.1 and polio eradication objectives; convenience; saved costs; second year of life (2YL) platform strengthening



- Potential **negative impact to Gavi's market shaping model** impacting other antigens that Gavi signalled to manufacturers to develop/produce

Recommendation

The Gavi Alliance Programme and Policy Committee **recommends** to the Gavi Alliance Board that it:

- a) **Approve** the opening of a funding window for Hexavalent vaccine for the administration of diphtheria, tetanus, whole-cell pertussis, hepatitis B, Haemophilus influenza b, and IPV antigens;
- b) **Note** that the initial estimates of the financial implications associated with the above approval for 2023-2025 are expected to be up to US\$ 62 million, and the US\$ 29 million estimated costs associated with base demand has been taken into account in the financial forecast to be presented to the Board in June 2023; and
- c) **Note** that the initial estimates of the financial implications associated with the above approval for 2023-2025 for additional operational cost support and Secretariat and partner resources will be accounted for in the financial forecast to be presented to the Board in December 2023, following consultations with partners and countries; and
- d) **Note** that the initial estimates of the financial implications associated with the above approval for the strategic period 2026-2030 are expected to be up to US\$ 430 million and contingent on financial resources being made available for the next strategic period; and
- e) **Note** that the initial estimates of the financial implications for both time periods are based on a fully loaded vaccine price and include saved ancillary costs and a one-time switch grant.

Thank you