

## Annex K: Implications and Anticipated Impact

### 1. Overview of risks and implications

- **Gavi Secretariat and Alliance partners resources:** anticipated workload for the expansion of the meningococcal programme is expected to be covered for the most part with the current resources allocated for the meningococcal programme implementation within the Secretariat, while incremental support is requested for the initial programme design and implementation. Competing priorities of multiple programmes being supported by partners also have a risk to limit their bandwidth; resources currently supporting MenACV rollout are anticipated to also support the implementation of MMCV, with incremental resources allocated through PEF for the period 2024-2025 (See Table 5).
- **Reputational risk:** Gavi is one of the key partners for the *Defeating Meningitis by 2030* global road map which includes the rollout of a MMCV to mitigate the risk of meningococcal serogroups predominantly causing epidemics. If there is a slower pace of introductions due to operational complexity or fund availability, there is a risk that these objectives would not be met. To mitigate this, there is a close collaboration with partners which will continue through a dedicated working group to support the programme design and monitor the implementation and consider further changes which could be reflected in future forecasts.
- **Countries uptake:** given the increased cost per dose for MMCV compared to MenACV and the competing priorities including outbreaks and expanded menu of vaccines available for countries in the African meningitis belt, there is a risk that MMCV introduction would be deprioritised. To partially mitigate this there have been regional consultations for the *Defeating Meningitis by 2030* road map which include advocacy for the upcoming MMCV, in addition to workshops planned with highest risk countries in 2024-2025 (See Table 5 under Foundational Support and Strategic Focus Areas support) as well as continued work with priority countries to support their plans for introduction of meningococcal vaccines.
- **Epidemiological risk:** the inherent unpredictability of the meningococcal meningitis epidemiology and additional impact due to climate change<sup>1</sup> might shift the risk profile of the countries in the African meningitis belt, changing the need and eligibility for campaigns and overall prioritisation of MMCV introduction. To mitigate this there is the continued availability of the meningococcal vaccines through a stockpile, in addition to the expectation of countries carrying out risk assessments to inform their strategies for MMCV implementation and continued engagement with identified high risk countries to support their efforts to address emerging meningococcal risks.

<sup>1</sup> As meningitis is considered a climate-sensitive disease, changes in rainfall patterns, heatwaves, dry season and population movements would have an impact in its risk profile.

- **Market health and supply availability:** reliance on a single manufacturer for the start of the MMCV programme could pose a risk to market health. Current expected production capacity of the supplier is expected to meet demand, while a second supplier is anticipated to enter the market towards 2028. If supply limitations materialise the Alliance partners would review implications and adjust programmatic priorities informed by epidemiological context and risk assessments.

**Financial risk:** if there is a change in the underlying assumptions from the demand scenarios proposed in the MMCV investment case (i.e. selection of countries, geographic scope of campaigns and/or pace of introductions), then the financial implications could surpass the costs currently outlined. As more evidence is available the programme parameters could be adjusted to reflect additional cost-effectiveness considerations in Gavi 6.0, if this is the case, changes will be reflected in upcoming financial forecasts for approval as more information becomes available, while current financial implications for 2026-2030 are contingent on resources being available.

## 2. Demand scenarios for MMCV and corresponding implications

### 2.1 Underlying assumptions for demand scenarios

Current risk classification groups the 26 meningitis belt countries in sub-Saharan Africa as 7 high-burden, 9 medium-burden and 10 low-burden countries.

The long term forecast for MMCV<sup>2</sup> assumes that most countries in the African meningitis belt will introduce this vaccine in the routine schedule while high burden countries will also implement campaigns<sup>3</sup>. Although introductions are expected to continue beyond 2030, for the purpose of this investment case we have outlined two scenarios for the Gavi strategic period 5.1 and 6.0, based on assumed pace of introductions given the multiple competing priorities at country level:

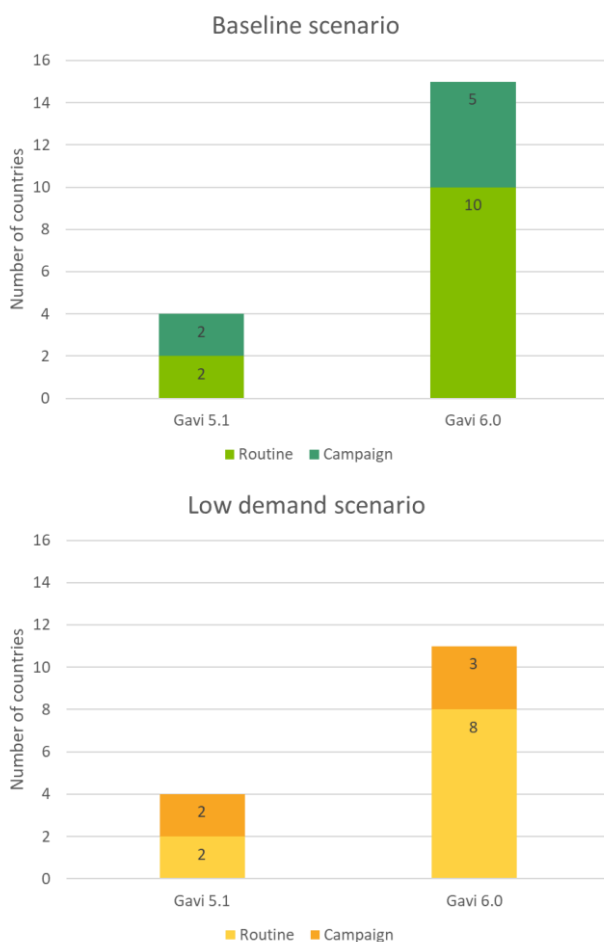
- 1) Baseline scenario: Assumes 12 switches from MenACV to MMCV in the routine in 6 years (2025-2030) and 7 campaign launches with an average pace of 2 introductions per year. Introduction of MMCV in the routine is prioritised for countries at highest risk, so it is assumed that countries that have yet to introduce MenACV in their routine (3 from the 12) will do so before switching to MMCV up to 2030.
- 2) Low demand scenario: Assumes 10 switches from MenACV to MMCV in the routine in 6 years (2025-2030) and 5 campaign launches with reduced subnational campaign targets for Nigeria. Introduction of MMCV in the routine is prioritised for countries at highest risk, so it is assumed that

<sup>2</sup> Strategic Demand Scenarios (SDS)

<sup>3</sup> Aligned to the current risk classification, although this might change as per the recommended risk assessments from relevant countries in the African meningitis belt.

countries that have yet to introduce MenACV in their routine (3 from the 10) will do so before switching to MMCV up to 2030.

Figure 1. Demand scenarios for MMCV introduction



The associated costs from the two demand scenarios are driven by the volumes required for campaigns targeting 1-19 year olds, taking into account subnational targets in those countries that implemented subnational MenACV campaigns. The below tables summarise the associated costs for the two MMCV demand scenarios.

Table 1: Baseline scenario Cost to Gavi (all costs are in US\$, millions)

MMCV	Gavi costs	Gavi 5.1	Gavi 6.0	Total
	Vaccine Costs (US\$ M)	112	519	631
	Cash Costs (US\$ M)	20	58	78
	<b>Baseline total costs (US\$ M)</b>			<b>709</b>

Table 2: Low demand Scenario Cost to Gavi (all costs are in US\$, millions)

MMCV	Gavi costs	Gavi 5.1	Gavi 6.0	Total
	Vaccine Costs (US\$ M)	112	298	410

	Cash Costs (US\$ M)	20	28	48
	<b>Low demand scenario total costs (US\$ M)</b>			<b>458</b>

Note: Vaccine costs represent fully loaded vaccine procurement costs (including costs of freight, syringes, and safety boxes). Cash costs includes only costs associated with vaccine introduction grants (VIGs), switch grants, and operational cost grants (Ops).

## 2.2 Linkages between MenACV and MMCV programme

Currently Gavi supports the meningococcal A vaccine (MenACV) with an initial mass preventive campaign, followed by routine introduction alongside a catch-up campaign. The approval of a MMCV programme will imply that some of the countries currently being supported with MenACV will switch to MMCV in their routine immunisation, while a subset of these will implement an MMCV campaign.

The version of the financial forecast for Dec. 2023 Board approval (v.21) includes US\$ 79 million for MenACV during Gavi 5.1 period, and US\$ 150 million for Gavi 6.0 period, assuming a baseline scenario for MMCV; cost implications for MenACV would change depending on the approval and demand scenario for MMCV (Table 3).

Table 3. Cost implications for Gavi on MenACV and MMCV (all costs are in US\$, millions) excluding stockpile

	MenACV Only scenario		MMCV Baseline demand scenario		MMCV Low demand scenario	
	Gavi 5.1	Gavi 6.0	Gavi 5.1	Gavi 6.0	Gavi 5.1	Gavi 6.0
<b>MMCV</b>						
Vaccine costs	0	0	112	519	112	298
Cash costs	0	0	20	58	20	28
<b>MMCV Subtotal</b>	<b>0</b>	<b>0</b>	<b>132</b>	<b>577</b>	<b>132</b>	<b>326</b>
<b>MenACV</b>						
Vaccine costs	76	138	71	110	71	116
Cash costs	10	41	8	40	8	41
<b>MenACV Subtotal</b>	<b>86</b>	<b>179</b>	<b>79</b>	<b>150</b>	<b>79</b>	<b>158</b>
<b>TOTAL</b>	<b>86</b>	<b>179</b>	<b>211</b>	<b>727</b>	<b>211</b>	<b>484</b>

Note: Approval of the Baseline demand scenario for MMCV will result in an adjustment of +US\$ 4 million for MenACV in Gavi 6.0 to align with updated subnational targets. Approval of the Low demand scenario for MMCV will result in an adjustment of +US\$ 8 million for MenACV in Gavi 6.0 to align with updated subnational targets and for more countries remaining on MenACV due to lower pace of MMCV rollout.

### 2.3 Cost to countries

Similar to the current MenACV programme, countries are expected to co-finance routine vaccine procurement costs for MMCV, while Gavi fully funds the cost of campaign doses.

The co-financing amount of the meningococcal programme, without MMCV is estimated at US\$ 62 million in 6.0. Given the higher cost per dose of MMCV, the cost of co-financing for countries is estimated at US\$78 M in the baseline demand scenario vs US\$ 72 million in the low demand scenario.

Table 4. Cost implications for countries on MenACV and MMCV (all costs are in US\$, millions)

	MenACV Only Scenario		MMCV Baseline demand scenario		MMCV Low demand scenario	
	Gavi 5.1 (2023-2025)	Gavi 6.0	Gavi 5.1 (2023-2025)	Gavi 6.0	Gavi 5.1 (2023-2025)	Gavi 6.0
<b>MMCV</b>						
Vaccine co-financed costs	0	0	1	59	1	49
<b>MenACV</b>						
Vaccine co-financed costs	23	62	22	19 <sup>v21</sup>	22	23
<b>Total</b>	<b>23</b>	<b>62</b>	<b>23</b>	<b>78</b>	<b>23</b>	<b>72</b>

Note: Approval of the Baseline demand scenario for MMCV will result in an adjustment of +US\$ 1 million for MenACV in Gavi 6.0 to align with updated subnational targets.  
Approval of the Low demand scenario for MMCV will result in an adjustment of +US\$ 4 million for MenACV in Gavi 6.0 to align with updated subnational targets and for more countries remaining on MenACV due to lower pace of MMCV rollout.

### 3. Initial estimated costs of MMCV in Gavi 5.1

The table below sets out the estimated cost and background assumptions relating to the MMCV programme in Gavi 5.1 strategy period (2023–2025) by budget area.

Table 5. Overview of costs specific to MMCV in Gavi 5.1 (all costs are in US\$, millions)

Budget area	Amount (US\$)	Background assumptions
<b>Vaccine Costs</b>	112	Assumes two countries switching from MenACV to MMCV in their routine alongside a preventive campaign. This assumption remains for the Baseline demand scenario and the Low demand scenario.

<b>Cash Costs</b>	20	Includes switch grants and operational cost support for two countries introducing 2025. This assumption remains for the Baseline demand scenario and the Low demand scenario.
<b>Foundational Support (FS)</b>	1.81	Mainly driven by staff and consultants in WHO at HQ and AFRO to support laboratory for evaluation of vaccine impact, development of risk assessment materials and support a workshop for application development and active safety follow up after MMCV activities. In addition to the above, FS includes FTEs to support multiple antigens in WHO EMRO and UNICEF, where an approximate was estimated for the share of MMCV.
<b>Strategic Focus Areas (SFA)</b>	0.61	Estimated costs for country capacity assessments for seven countries most likely to apply for MMCV, in addition to regional trainings and additional development of WHO guidance on MMCV use.
<b>Targeted Country Assistance (TCA)</b>	1	Estimated costs of US\$250k per country, considering two countries submitting applications in 2024 and implementing a switch and campaign in 2025, in addition to two more countries submitting applications in 2025. This is aligned with the Baseline demand scenario.
<b>Learning agenda</b>	(0.25 already approved)	Included in previously approved budget to conduct costs for modelling studies, inclusive of MMCV; estimated a quarter of the cost for MMCV modelling subject to prioritisation of across different outbreak-prone diseases. Additional needs for a learning agenda will be reassessed after the SAGE recommendation.
<b>Secretariat operational expenses</b>	0.2 (0.1 already approved)	Secretariat support for operationalisation the program.
<b>TOTAL</b>	135.9	
<b>TOTAL for approval</b>	<b>135.5</b>	

In addition to the above, there are other costs related to the overall meningococcal programme such as: MenACV implementation, meningococcal stockpile for outbreak response and investments for meningococcal diagnostics. These costs do not represent an increased funding requirement and are reflected in the forecast v.21 (presented to the Board in December 2023).

Table 6. Overview of costs for meningococcal programme in Gavi 5.1 (all costs are in US\$, millions)

Budget area	Amount (US\$)	Background assumptions
<b>Meningococcal vaccine stockpile – vaccine cost</b>	60.4	Assumes a stockpile of 5md from 2021 to 2023 and a stockpile of 7mds in 2024 and 2025

<b>Meningococcal vaccine stockpile – cash cost</b>	5.2	Assumes operational cost support up to US\$ 0.65 per targeted person for reactive campaigns
<b>Meningococcal vaccine stockpile – Targeted Country Assistance (TCA)</b>	0.1	Assumes the provision of technical country assistance to support outbreak investigations, submission of request, vaccination planning, support to implementation and monitoring and evaluation.
<b>MenACV – vaccine cost</b>	71	Assumes two countries switching from MenACV to MMCV. This assumption remains for the MMCV Baseline demand scenario and the Low demand scenario.
<b>MenACV – cash cost</b>	8	Includes vaccine introduction grants (VIG) and operational cost support (Ops) supporting MenACV routine introductions alongside a catch up campaign.

*Note: There are no specific MenACV funds for PEF. Technical assistance needs are considered within the prioritisation of TCA funds per country.*