
Subject **Gavi’s role in a future COVID-19 Vaccine Programme**

Agenda item **10**

Category **For Decision**

Section A: Executive Summary

Context

COVAX, the Alliance’s emergency vaccine response to COVID-19 is set to sunset in 2023. This paper considers Gavi’s potential role in providing countries with access to COVID-19 vaccines starting in 2024. The Gavi COVID-19 Vaccine Investment Approach, part of Gavi 5.1, considers how a future Gavi-supported COVID-19 vaccine programme could be designed and implemented considering target populations and scope of country support. The investment approach takes into account modelling on the estimated impact of future COVID-19 programmes and potential implications for the broader immunisation landscape while building on key learnings to date.

The Secretariat is proposing an up-to-investment figure of US\$ 1.8 billion for the first phase of the programme (2024-2025). This would ensure timely ongoing procurement of vaccines for higher risk groups in AMC countries, with differentiated support for the Gavi54 - those countries eligible for Gavi support - and the AMC37 - the never- and former-Gavi eligible countries which received COVAX support.

The approval requested of the Board at this meeting is ‘in principle’ reflecting the inherent uncertainty in underlying assumptions, and yet the need to start planning. The Secretariat will return to the Board by June 2023 for approval of the financial envelope, with updated country demand estimates to inform supply volumes, and an updated delivery approach based on continued learnings from COVID-19 vaccine Delivery Support (CDS) deployment. The Secretariat will also return to the Board and relevant committees should WHO SAGE (Strategic Advisory Group of Experts on Immunization) guidance and/or the assumptions on which this investment approach is based deviate significantly from current status. Finally, the Secretariat will return to the Board in June 2024 as part of the Gavi 6.0 strategy development process to assess the case for the continuation of the programme informed by the experience of the first phase, trade-offs with other Gavi 6.0 priorities, and up to date epidemiological considerations for a longer-term COVID-19 vaccine programme as part of the 2024 Vaccine Investment Strategy (VIS).

Key inputs were collected from across the Secretariat and partners (including WHO, UNICEF, CEPI (Coalition for Epidemic Preparedness Innovations)) and through country consultations. Additionally, the investment approach reflects the steer provided by Board and Programme and Policy Committee (PPC) members

at the Gavi 5.1 deep dive consultation on 26 September 2022 and the PPC meeting on 31 October 2022.

Questions this paper addresses

- Should Gavi continue to support a COVID-19 vaccine programme, and if so, how should it be designed?
- What countries would be eligible for a future COVID-19 programme?
- What are the financial implications of a future COVID-19 vaccine programme for Gavi? How should co-financing and delivery cost-sharing be applied?
- What are the risks and trade-offs of Gavi's continued support of COVID-19 programmes, including the potential impact on countries' routine immunisation and Gavi core programmes?

Section B: Content

1. Introduction

- 1.1 WHO estimates that nearly 15 million excess deaths due to COVID-19 occurred globally in 2020 and 2021. While over 12.9 billion vaccine doses have been administered, there continue to be great disparities in vaccination coverage between countries and regions.¹ Recent modelling estimates that COVAX-supported COVID-19 vaccines have averted over 1.7 million deaths among AMC participants.² Many AMC participants have relied on COVAX to supply a large proportion of their COVID-19 doses, approximately 75% for low-income countries in particular, providing continued access for the global fight against COVID-19.
- 1.2 The investment approach reflects the goals outlined in the WHO Strategy to Achieve Global COVID-19 Vaccination³ and the latest guidance from SAGE on additional boosters⁴. Looking forward, **if the pandemic trajectory continues as per the WHO base case⁵, the Alliance would shift from an emergency response focused on global health security through COVAX to a programme focused on protecting the most vulnerable through a COVID-19 vaccine programme, while retaining an ability to quickly shift and mobilise in a worst-case scenario.** The anticipated timeline for transitioning from COVAX to a routine programme is by the beginning of 2024.

¹ <https://covid19.who.int/>

² Based on impact modelling generated by Imperial College, London. Estimates generated from first COVAX doses in 2021 through till end June 2022.

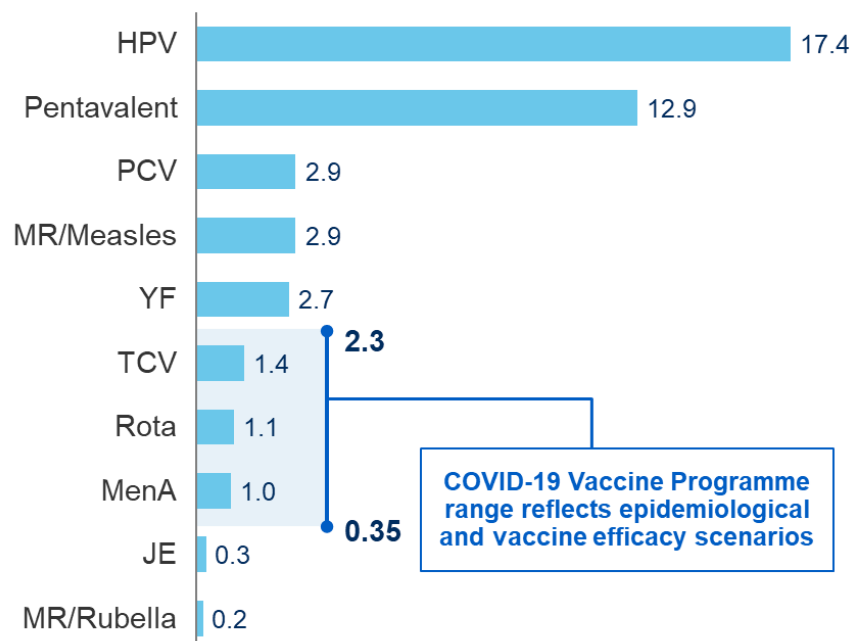
³ <https://www.who.int/publications/m/item/global-covid-19-vaccination-strategy-in-a-changing-world-july-2022-update>

⁴ <https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-good-practice-statement-second-booster>

⁵ <https://www.who.int/publications/i/item/WHO-WHE-SPP-2022.1>

1.3 Initial impact estimates for a COVID-19 programme show that 0.35-2.3 deaths could be averted per 1,000 fully vaccinated persons⁶ based on annual boosting of people over 60 years old across AMC91. This is within the range of impact estimates for other Gavi-supported routine immunisation programmes (Figure 1). Annex A provides a more comprehensive summary of impact estimates generated to date, including cases, hospitalisations, deaths, years of life lost (YLL) averted as well as cost-effectiveness. Given that disease burden is particularly high amongst the elderly, it would be beneficial to compare disability adjusted life years (DALYs) for COVID-19 vaccines versus other vaccines. Unfortunately, this was unable to be done given current uncertainties. Instead, YLL was used, which constitutes the largest portion of the DALYs lost.

Figure 1: Deaths averted per 1000 FVPs of the COVID-19 Vaccine Programme in comparison with other Gavi-supported routine immunisation programmes⁵



1.4 The following **principles and objectives** will guide Gavi's approach to designing the programme:

- Focus on maximising health impact to protect the most vulnerable against COVID-19
- Ensure no detrimental impact on other routine immunisation programmes

⁶ Based on impact modelling generated by Imperial College, London. Range reflects differences in vaccine efficacy assumptions across different vaccine products and incorporates both baseline and moderate epidemiological scenario (see Annex B). The Institute for Disease Modelling (The Bill & Melinda Gates Foundation (BMGF)) generated a range of 1.59-4.8 of for estimated deaths averted per 1,000 full vaccinated persons (FVP) across similar baseline and moderate epidemiological scenarios

- Support global public health objectives and equity, given uncertainties as we shift out of the acute phase of the pandemic
 - Promote country ownership and sustainability
 - Focus on programmatic integration to achieve mutual sustainable benefits for COVID-19 and routine immunisation
 - Generate learnings in view of a potential life course approach to immunisation in Gavi 6.0
 - Leverage Gavi's comparative advantage and learnings from COVAX, including the importance of agility to deal with uncertainties
- 1.5 **There are many uncertainties around the future of COVID-19**, including presence of sustained and predictable demand for continued vaccination; emergence of new variants that could be more severe and/or transmissible; how vaccine products may evolve and implications on efficacy, durability, programmatic feasibility and market dynamics; and predictability of surges and seasonality (Annex B). Recognising the need to start planning, the Alliance is moving forward with scenario-based planning for phase one with humility, using the best information available, and understanding assumptions may change with new information, and countries could access doses through other sources.
- 1.6 **In considering how a new vaccine programme may be designed, the Alliance had to make several assumptions** (Annex C), including estimating the number of doses per year, what vaccine product types might be available, cost per dose, and coverage targets. With these assumptions, we reached a ranged financial envelope to be deployed for phase one depending on how the pandemic and disease evolve. The Secretariat will review the assumptions to inform any updates to the proposal ahead of the June 2023 Board meeting.
- 1.7 **The Secretariat will continue to work through the established Gavi Alliance approach for routine immunisation, which includes partners in defined roles and responsibilities to leverage their comparative strengths, technical expertise, and business acumen for the future COVID-19 vaccination programme.** Established Alliance demand planning processes will be used for portfolio planning, and supply management will shift from advanced purchase agreements used within COVAX to the standard UNICEF-led tendering process which will allow increased flexibility to tackle uncertain demand.
- 2. Strategic Choices**
- 2.1 Use cases: Emerging impact analyses show that higher priority groups would account for the largest cohort of deaths averted with continued vaccination. Through COVAX in 2023, countries will be able to continue vaccinating broader populations with their primary series, but with an increased focus on the high and highest priority use groups to ensure

protection for the most vulnerable. **Therefore, we are assuming increased primary series coverage rates in these populations by 2024 and propose a programme focusing on the higher priority group from 2024 onwards as long as the WHO base-case scenario holds.**

- 2.2 **Population cohorts: It is critical to understand which populations to target our finite resources to have the greatest impact.** In the guidance released on 11 August 2022, SAGE recommended a second booster for the higher priority user groups, comprising the following (without any relative prioritisation): older persons; healthcare workers; immunocompromised persons; pregnant persons; and adults with comorbidities.
- 2.3 **The proposed programme would support countries in vaccinating the user groups outlined in the SAGE recommendation.** Initial impact modelling estimates support the hypothesis that continuing to extend protection for those most at risk of severe disease, death, and hospitalisations would likely have the greatest direct health impact and value for money compared to expanding the programme to broader age groups. However, the programme would initially only be able to provide sufficient supply for approximately 35% of the recommended user groups, which is the lower end of the projections for primary vaccination coverage and would amount to approximately 7% of total population coverage in the supported countries. Of course, demand is unknown, but given the reduced demand we have been seeing, this may align well with country demand. The PPC highlighted the importance of retaining the flexibility to account for new entrants into the cohort and, depending on demand, providing continued support for primary series vaccination.
- 2.4 **Country scope:** In addition to Gavi-eligible countries (Gavi54)⁷, there were 37 other never- or former Gavi-eligible countries^{8,9} that received COVAX-funded doses, collectively the AMC37. **It is necessary to consider how to continue supporting these countries in the first phase of the COVID-19 vaccine programme to achieve global COVID-19 objectives.** Initial impact modelling suggests an additional 77,000 – 158,000 deaths could be averted in the AMC37 over 2024-2025 if they were to introduce a routine booster programme for high-priority groups in the base case scenario.
- 2.5 **The Secretariat recommends providing support to AMC37 only in phase one to ease the transition from emergency COVAX support and enable the introduction of COVID-19 vaccines into the country's immunisation programme.** Continued support would help provide equitable access during the transition from 2023 to 2024-2025 as well as offer support in line with the existing MICs Approach. The expectation is that

⁷ Countries eligible for Gavi support at end-2023 would be eligible for this programme in phase one (2024-2025)

⁸ Separate proposal for India to be considered as done with previous Gavi Board tailored strategy for COVAX in 2020

⁹ 22 never Gavi-eligible; 15 former-Gavi eligible

support would not be continued in Gavi 6.0 under the WHO base-case scenario.

- 2.6 **Procurement Financing:** Currently, COVID-19 vaccines are provided as a global public good through COVAX and are not subject to any co-financing. **For Gavi54, the Secretariat recommends waiving co-financing requirements in phase one**, with the intent to introduce it in subsequent phases of the programme. This is in line with past approaches of treating vaccinations in response to public health emergencies of international concern as global public goods and can help incentivise countries to continue COVID-19 vaccinations to protect higher priority groups. Further, it would help limit any potential diversion of country funds from other routine immunisation programmes to COVID-19. Lastly, implementing the Gavi co-financing policy could invoke other elements of this policy that would be counter-productive based on the principles underpinning the programme, e.g. if a country defaults on its COVID-19 co-financing obligation, support across all antigens would be suspended.
- 2.7 However, lack of co-financing may result in uncertain true demand and increase the risk of potential dose expiries. There could be distorted incentives for countries to prioritise COVID-19 if the COVID-19 programme is not subject to co-financing as other Gavi-supported programmes are. Gavi processes can help mitigate these risks. Demand planning processes remain integral to understand future trends and offer continued support. Additionally, countries can leverage their National Immunisation Technical Advisory Groups to help prioritise their vaccine investments informed by evidence and country needs. The PPC agreed that despite the risks of waiving co-financing, it will be critical to limit the cost to countries given the global economic situation and the high cost of COVID-19 vaccines.
- 2.8 **For the AMC37**, the Secretariat proposes vaccine catalytic financing in line with the principles of Gavi’s Middle-Income-Countries (MICs) Approach¹⁰. This would offer countries one-off vaccine financing to cover the dose cost for half of the first target cohort to ‘catalyse’ a new vaccine programme. The Secretariat initially proposed a tapered approach whereby the AMC37 would have access to procurement support for 50% of the doses in 2024 and 25% in 2025; however, members of the PPC and Board, at the September 2022 Gavi 5.1 deep dive consultation and the PPC at its October 2022 meeting, requested to transition to standard Gavi policies and processes as quickly as possible. Thus, this proposal would continue supporting the AMC37 while swiftly transitioning to standard Gavi policies.

3. Considerations and Key Inputs

- 3.1 **Supply:** As part of transitioning to established Alliance processes, UNICEF and PAHO would establish a comprehensive procurement approach. **Through UNICEF/PAHO tender(s) designed to elicit explicit price competition between suppliers, Alliance Partners will monitor price dynamics and understand the impact on preferences to ensure price**

¹⁰ <https://www.gavi.org/types-support/sustainability/gavi-mics-approach>

trends do not become prohibitive to Gavi and countries. Tenders offer flexibility to adapt supply levels to movements in demand as it manifests.

- 3.2 **COVAX has benefited from generous dose donations; however, uncertainty on future donated supply means a COVID-19 vaccine programme based primarily on potential future dose donations may not be a reliable base for supply. Instead, any future dose donations would complement the overall outlay.** Further, if there arises a need to expand the programme beyond Gavi's projected budget for 2024-2025, i.e. in the event of increased demand or a worst-case scenario, dose donations could be critical to meet the need.
- 3.3 **Delivery: Gavi proposes to support the delivery of COVID-19 vaccines for Gavi54 only by making additional resources available within its Health System and Immunisation Strengthening (HSIS) grants. This would ensure countries can continue to reach high-risk groups,** either through established immunisation delivery strategies or supplementary immunisation approaches, begin to strengthen health systems' capacities to sustainably deliver COVID-19 vaccination to some high-risk groups, and learn how countries can routinely reach adult target populations.
- 3.4 **Integrating delivery support into HSIS¹¹ and Partners' Engagement Framework (PEF) grants** would streamline Gavi support by reducing complexity and transaction costs arising with fragmented funding envelopes and entail a gradual pivot towards delivery through more regular Primary Health Care (PHC) services. It will help countries to capture synergies between investments in infant, adolescent (including for HPV) and adult immunisation to enhance service delivery, community engagement, demand generation, and data systems. Of note, through the recently launched third-round COVID-19 Delivery Support funding envelope, the Alliance has already started to pivot in that direction, putting an increased focus on a stronger immunisation delivery mechanism through COVID-19 integration. The Secretariat will share additional details on the delivery approach with the PPC and Board by June 2023.
- 3.5 **The Secretariat proposes Gavi54 be provided 70% of the estimated total delivery cost plus technical assistance through the PEF.** Many countries have relatively well-established delivery platforms for routine infant vaccines in the Gavi portfolio. Therefore, Gavi does not typically fund the full cost of delivery of the routine vaccines, instead providing specific investments to strengthen and expand the existing platforms through the Gavi HSIS envelope and PEF TCA. The 70% contribution reflects the fact that the delivery platforms needed to reach the priority target groups for COVID-19 are yet to be established in many countries. While some high-risk groups will likely continue to be reached through campaign-like delivery

¹¹ This could include HSS grants, operational costs for campaigns, and vaccine introduction grants. The precise funding modality will be determined as the overall programme design is refined over the coming months, with an update provided to the PPC and Board as part of the final COVID-19 programme proposal by June 2023.

modalities in 2024-2025, the investments needed for these and to enable health systems to deliver COVID-19 vaccines through more routine-like approaches will be higher than for most existing vaccines. A 70% share will also help to ensure that lack of financing for delivery cost does not become an impediment to countries sustaining their COVID-19 vaccination programmes. Funding support will be provided to only the Gavi54 countries recognising that the AMC37 is better able to mobilise their own resources to pay for delivery.

4. Recommendation and Funding Envelope

4.1 **The recommendations sum to a total funding envelope of up to US\$ 1.8 billion for Gavi in the 2024-2025 period^{12,13}** as shown in Table 1 below:

Table 1: Approximate breakdown of 2024-2025 funding envelope for the COVID-19 programme

	Gavi54	AMC37
Procurement	~1,200M	~300M
HSS	~220M	Nil
PEF†	~47M	Nil
Secretariat Opex	TBD-part of US\$ 60 million provision under COVAX budget as per AFC forecast.*	
Total	~1,800M	

* To be noted that this funding will also cover targeted additional investments into PPR

† Including Targeted Country Assistance (~27.9M), Foundational Support (~12.7M), and special investments in Strategic Focus Areas (~6M)

Section C: Actions requested of the Board

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

- a) **Approve**, in principle, a new programme for COVID-19 vaccination, phase one of which will be implemented in 2024-2025, contingent on:
 - a. Continuation of the WHO base-case scenario for the pandemic evolution requiring continued focus on the higher priority user groups as per SAGE recommendation;
 - b. Sufficient funding as confirmed by the Board by June 2023
 - c. Updated country demand estimates informing volume requirements; and

¹² Availability of funding for the COVID-19 routine programme will be confirmed by the Board by June 2023 for the 2024-2025 period, and hence are not included in current COVAX financial forecast.

¹³ The total funding envelope would be sufficient to finance 190-240 million doses, as per current estimations. This estimation is subject to change and will be reviewed by June 2023.

- d. Further information from country experience and use of COVID-19 Delivery Support (CDS) to date.
- b) **Approve**, in principle, the following country scope and extent of support for phase one of the new COVID-19 programme:
 - a. Country scope: AMC91 (Gavi54 and AMC37)
 - b. Extent of support:
 - i. Gavi54: Eligible for full vaccine procurement support without co-financing obligations and delivery support (consisting of the provision of 70% of estimated total delivery costs for the vaccines).
 - ii. AMC37: Eligible for vaccine catalytic financing in line with the MICs Approach for vaccine procurement and not eligible for delivery support.
- c) **Acknowledge** that planning for phase one, including engagement with countries, for a COVID-19 programme would commence prior to funding commitments coming for approval by June 2023 to ensure the feasibility of a timely launch by 2024.

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

- a) **Note** that the Secretariat will update programme assumptions and the approach for phase one of the COVID-19 programme, incorporating the latest demand estimates and the latest information on delivery, as informed by the implementation of CDS3;
- b) **Note** that the Secretariat will return to the Board by June 2023 for approval of the final programme design and the financial envelope for 2024-2025;
- c) **Note** that the Secretariat will update the Board at each meeting and will return to the Board formally, through the PPC, if future SAGE guidance evolves such that this programme is no longer aligned with technical guidance and/or assumptions outlined in Annex C to Doc 10 vary significantly as to affect the implementation feasibility of the programme; and
- d) **Note** that the Secretariat will return to the Board as part of the Gavi 6.0 strategy development with proposed updates to the COVID-19 vaccination programme to account for changes in disease epidemiology as well as consideration of Gavi 6.0 priorities.

Annexes

Annex A: Impact Modelling

Annex B: Looking Ahead and Uncertainties

Annex C: Modelling Assumptions