

SUBJECT: COVAX: KEY STRATEGIC ISSUES

Agenda item: 07a

Category: For Decision

Section A: Executive Summary

Context

In the context of evolving epidemiological, supply and demand uncertainties, and of COVAX supply ramping up over the end of 2021 and into 2022, this paper presents an update of the COVAX Facility's approach to procurement and the Alliance's role in COVID-19 vaccine delivery through to the end of 2021 and into 2022. This paper builds on previous Board discussions and on two Programme and Policy Committee (PPC) discussions in October 2021 and November 2021, and presents recommendations to the Board for approval.

Questions this paper addresses

What is the scope of Gavi's support to AMC countries in achieving their COVID-19 vaccination goals, in view of the WHO Global Vaccination Target of 70% by mid-2022 and taking into account sources of supply beyond COVAX?

What is the COVAX Facility's approach to procurement of COVID-19 vaccine for 2022?

What are the key delivery challenges faced by AMC countries? What has been the Alliance's role so far in the delivery space and how would it evolve going forward?

What are the risks and trade-offs of Gavi's continued involvement in COVID-19 vaccination?

How is Gavi engaging in ongoing discussions in pandemic preparedness, response and financing?

Conclusions

Given the global goal, set by WHO, to achieve 70% COVID-19 vaccination coverage in all countries by mid-2022, as well as the tight fiscal space and weak health systems in many AMC countries, the Gavi Alliance has been providing vital supply of COVID-19 vaccines and support for their delivery to meet countries' vaccination ambitions. Basing ourselves on the lessons learned from 2021, Gavi will sharpen its focus in 2022 on lower income countries who urgently need support, while also putting in place solutions such as the Pandemic Vaccine Pool to strengthen resilience in the face of potential supply and demand shocks. The COVAX Facility is securing supply through Advance Purchase Agreements, which enable flexibility in response to changing circumstances through the use of options and make efficient use of both donor funding and cost-sharing from countries. The COVAX Facility will also continue to use dose-sharing as required. Overall, the

portfolio strategy will prioritise a flexible and adaptive approach to account for the uncertainties that lie ahead in 2022 (e.g. emergence of new variants, need for boosters or additional doses) and work in collaboration with non-COVAX sources to support countries' vaccination strategies and goals. Furthermore, whilst countries shoulder the primary responsibility of financing effective COVID-19 vaccine delivery, the Alliance proposes supporting AMC countries with supplemental financing, technical assistance, innovative delivery interventions, enhanced coordination at global, regional and country levels and to further enhance monitoring and rapid response to country needs to rapidly increase throughput of COVID-19 vaccines. This support also helps ensure that resources and capacities are not diverted from routine immunisation, which is a growing risk.

Section B: Content

1. Context

1.1 This paper aims to answer a series of questions relating to Gavi's role in COVID-19 vaccination asked at the September 2021 Board and the October 2021 and November 2021 PPC meetings.

1.2 **As a priority, the imminent question is what is required for COVAX to succeed or make meaningful progress by the end of this year.** There are two major sources of supply that are critical to success: Advance Purchase Agreements (APAs) and dose donations.¹ Combined, these sources are expected to yield approximately 1.3 billion doses in available supply from manufacturers by the end of 2021,² which are forecasted to translate to approximately 0.8-1.0 billion doses to be received in country:³

- **Supply through Advance Purchase Agreements (APAs):** Procurement and supply are the core remit of the COVAX Facility. COVAX supply in 2021 has faced numerous challenges (export bans, technical delays, prioritisation of other bilateral customers by manufacturers). In this difficult context, the COVAX Facility has continued to actively manage the composition of its portfolio to enhance resilience and flexibility. COVAX has signed deals with manufacturers for 2.3 billion doses in firm order commitments to satisfy AMC demand (donor-funded and cost-shared) and Self-Financing Participant (SFP) demand.⁴ To date, 350 million of COVAX's APA doses have been made available for supply. Given the challenges above, COVAX now expects a total of ~620 million APA doses to be available by end 2021 in the most likely scenario with the rest available in 2022. Of these 620 million doses, approx. 490 million are expected to be available to AMC and 130 million to SFPs. Remaining uncertainties on the extent to which export

¹ Advanced Purchase Agreements include both COVAX AMC-funded doses and cost-share doses. See Doc 07b for more information on cost-sharing

² Includes some quantities of yet-to-be confirmed dose-sharing supply

³ Expressed in actual doses expected to be received in country without doubling J&J volumes. The 1.3 billion doses available for supply included doubling of J&J supply, which would equate to 0.9-1.1 billion doses expected to be received in country.

⁴ Volumes includes 200 million doses of J&J, of which approximately 10 million are expected to be available for supply by end 2021. These volumes have been doubled for effective comparability with two-dose regimens.

restrictions are eased in India and ongoing scale-up challenges at manufacturing sites that supply COVAX could lead to these volumes changing by +/- 10%.

Summary of available APA supply through COVAX by recipient (million doses)⁵

COVAX supply	Total by end 2021	Total by end 2022
AMC ⁶	490	1,920
SFP ⁷	130	380
Total	620	2,300

- Supply from dose-donations:** Supplementing supply from APAs, dose donations have become a substantial contributor of supply to AMC countries. COVAX has already shipped or has confirmations from donors of 470 million doses for shipment to countries within 2021, with further supply being clarified. Of these, 430 million are expected to be for AMC countries. An additional 570 million doses of donations have been pledged for supply by mid-2022, but it is not yet confirmed what proportion of these doses will be supplied via COVAX, and of those that are, which will be for self-financing countries and which for AMC countries. Gavi is urgently working with donors and manufacturers to improve visibility on forthcoming dose donations and shelf-life and has also shifted to a more regular allocation cycle that supports longer planning horizons. Countries need greater predictability and visibility on supply to be able to plan and deliver vaccination. It is envisaged that over time COVAX would seek to decrease dependence on dose donations in favour of doses procured via standard means.
- Doses to be received in country:** Across all sources of supply, COVAX has as of 17 November shipped ~508 million doses of vaccine to 144 participants (of which ~408 million doses to 86 AMC participants) across all regions⁸. COVAX remains a major contributor of vaccine to the AMC92 with 45 AMC participants who depend on COVAX as the source of >50% of their supply. Whilst global coverage remains starkly inequitable, the recent uptick in doses received in country from COVAX is making a meaningful contribution to participants’ efforts to protect their populations. Dose donations have contributed ~207 million shipped doses of which ~185 million have gone to AMC participants. Looking ahead, COVAX expects a significant ramp up in doses to be received by countries. Forecasts for doses estimated to be received by participants are currently

⁵ Timing of available supply is based on anticipated date of release by manufacturer under the most likely scenario – based on best available information from manufacturers and analysis from Gavi and UNICEF. Volumes rounded to nearest 10 million. Distribution between AMC and SFPs has been estimated but may change based on future SFP behaviour (e.g. opt-outs, transfer of COVAX volumes, additional demand through SFP 2.0). Volumes for all doses of J&J’s single-dose vaccine have been doubled for effective comparability with two-dose regimens.

⁶ Includes 135 million doses financed by the cost-sharing programme

⁷ Total SFP values reflect requested volumes as confirmed in SFP Commitment Agreements. Final values subject to change.

⁸ It should be noted here that these include J&J that are one dose courses, and they have not been doubled for the purpose of reporting on delivery.

being refined, but are expected to land in a range between 0.8-1.0 billion doses by the end of 2021⁹ though these are subject to a high degree of uncertainty related to final supply availability, country preparedness, manufacturer readiness, and logistical delays. It is important to note the divergence between available supply and supply received in country, which results from necessary administrative, regulatory, legal and logistical steps undertaken by countries, manufacturers, and COVAX partners.

- 1.3 **Beyond addressing the immediate priority of delivering as much supply as possible before the close of 2021, this paper also further clarifies Gavi’s continued role in the COVID-19 pandemic response in 2022 as outlined in Section 2.** The decisions for the Board to approve are being brought by the Secretariat following review by Gavi governance bodies and stakeholders. In particular, the Programme and Policy Committee (PPC) has been engaged on matters and risks regarding COVAX Facility’s procurement strategy, mechanisms, participation model and delivery, the Audit and Finance Committee (AFC) has been engaged on matters and risks regarding COVAX Facility finances and operations, the Market-Sensitive Decisions Committee (MSDC) on its portfolio and transactions and related risks, and the Governance Committee on COVAX governance structures and risks. The Board is directly engaged on matters of resource mobilisation strategy and organisation.
- 1.4 Gavi’s efforts are an integral part of the wider COVID-19 response in 2022 and are shaped by a set of strategies that have been developed by and with partners. The strategic context is primarily informed by three documents:
- **The Access to COVID-19 Tools Accelerator’s (ACT-A) “Strategic Plan and Budget: October 2021 to September 2022”** which provides an overview of the plans of the vaccines, therapeutics, and diagnostics pillars as well as the health systems & response connector, bringing together a holistic view of the ACT-A priorities and funding requirements for the next year.¹⁰ The vaccine requirements for the COVAX Facility and approach to supporting country delivery are outlined in pages 19-23 of the ACT-A document.
 - WHO has released a **“Strategy to Achieve Global Covid-19 Vaccination by mid-2022”** which outlines the actions required by the global community to vaccinate 70% of the world’s population against COVID-19 by mid-2022.¹¹ This ambitious coverage target informs the approach to supporting countries’ vaccine requirements being brought to the Board in Section 3 of this paper.

⁹ Expressed in actual doses expected to be received in country without doubling J&J volumes. The 1.3 billion doses available for supply include doubling of J&J supply, which would equate to 0.9-1.1 billion doses estimated to be received in country.

¹⁰ <https://www.who.int/publications/m/item/act-accelerator-strategic-plan-budget-october-2021-to-september-2022>

¹¹ https://cdn.who.int/media/docs/default-source/immunization/covid-19/strategy-to-achieve-global-covid-19-vaccination-by-mid-2022.pdf?sfvrsn=5a68433c_5

- **The draft COVAX Pillar strategy** (See Appendix 1) lays out the overall vision and priorities for the COVAX Pillar partners, covering the contributions of all COVAX partners, CEPI (Coalition for Epidemic Preparedness Innovations), Gavi, WHO and UNICEF, including Gavi's efforts in procurement, financing, and delivery (pages 10-16 of Appendix 1). The Pillar Strategy has been brought to relevant COVAX Pillar coordination bodies for review and is in final stages of the consultation process. This document also provides further context on how the COVAX Pillar partners currently work together and will strengthen ways of working together to offer a holistic response to the pandemic, including by reflecting on collaboration with other players active in the space such as regional mechanisms like the African Vaccine Acquisition Trust (AVAT).

2. Gavi's role in COVID-19 vaccination in 2022

2.1 In response to feedback from the PPC and Board, the Secretariat has prepared a consolidated and simplified vision for Gavi's role in COVID-19 vaccination in 2022, which is to be a **flexible global instrument, urgently meeting the immediate needs of countries and providing resilience as the pandemic evolves**. This vision has three elements:

- **Urgently building the foundations of COVID-19 protection, with a focus on lower income countries and the most in need** – Recognising the continued global toll of the pandemic, persistent inequitable access, and the emergence of other procurement mechanisms, Gavi continues to provide critical supply of COVID-19 vaccine to support countries' coverage ambitions on an urgent timeline and is sharpening its focus on those who most need supply. This element is elaborated further in Section 3.
- **Deploying a flexible, reliable portfolio of COVID-19 vaccine to manage uncertainty and anticipate risk** – As seen in 2021, a diverse, actively-managed portfolio is important in the context of the rapidly evolving pandemic and global environment. Looking ahead, this flexibility remains critical in light of continued uncertainties (e.g. need for boosters, emergence of new variants). This element is described further in Section 4.
- **Providing support for delivery at-scale** – The Alliance will continue to support countries to roll-out COVID-19 immunisation programmes and expand protection in line with global normative guidance. This element is described further in section 5.

2.2 Gavi's vision as articulated above is highly complementary and closely connected to the COVAX Pillar Vision for 2022 that has been shared previously with the PPC and Board and is presented in detail in Appendix 1. Key contributions of Gavi across the COVAX Pillar are illustrated in the figure below.

Gavi's contribution to the COVAX Pillar 2022 Vision

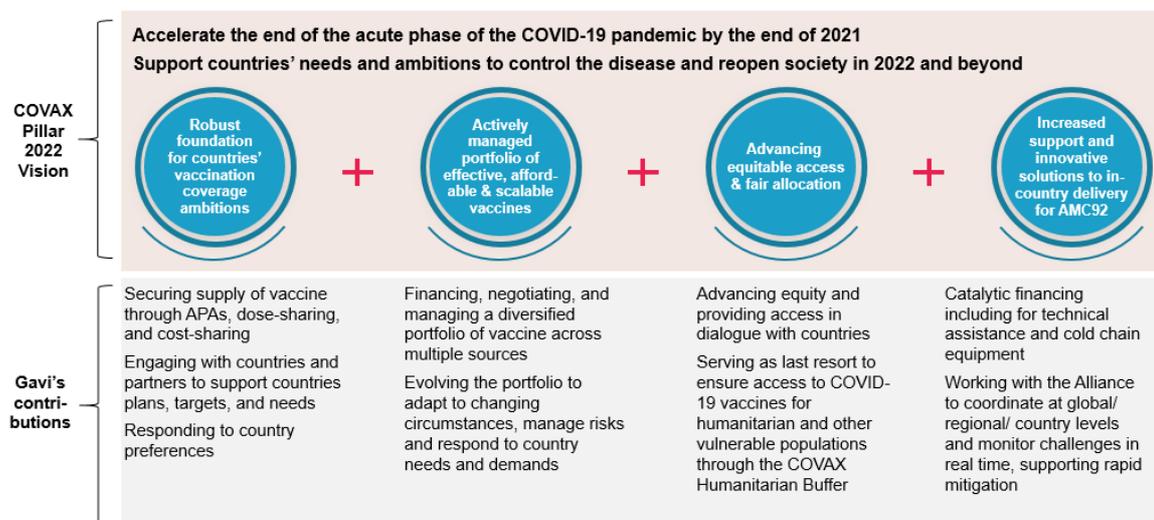


Figure 1: Gavi's contribution to the COVAX Pillar 2022 Vision

3. The COVAX Facility role and ambition in vaccine procurement in 2022

- 3.1 To-date, one of the most important aspects of the COVAX Pillar 2022 Vision has been the COVAX Facility's procurement of COVID-19 vaccine supply. The WHO has set the global vaccination coverage target at 70%. Whilst this goal offers global guidance, adaptation to different contexts is required, based on demographics, economic structure, programme reach and competing public health priorities. Across AMC¹² countries, the adult population represents 60%, implying that to reach 70%, vaccination programmes would need to expand to adolescents and children. Furthermore, depending on the local importance of different economic sectors (e.g. agriculture versus tourism), different vaccination goals may be sufficient to re-open societies. Finally, COVID-19 vaccination might compete with routine immunisation programmes and other public health priorities more broadly in terms of funding, workforce, infrastructure, etc. To mitigate against this the Secretariat is working with Alliance partners to support countries to take a synergistic approach to COVID-19 vaccination and routine immunisation.
- 3.2 In line with Gavi's traditional support for the principle of country ownership, the COVAX Facility believes that countries should take the lead in defining their own vaccination goals, taking into consideration global normative guidance as well as their unique circumstances. Thus, the Secretariat is seeking the Board's endorsement for the COVAX Facility to support countries in their own vaccination goals and individual situations, in light of the 70% global vaccination target and sources of supply beyond COVAX. While some countries have specific vaccination goals used for planning their programmes, many countries are continuously shaping their vaccination targets and plans based on visibility of supply, emerging evidence and evolving epidemiology. The Secretariat and partners will be continually

¹² excluding India

engaging with countries as targets and vaccination strategies are set and refined.

- 3.3 The COVAX Facility has worked to translate this approach to supporting countries' coverage targets into an estimate of the total number of doses needed by AMC countries. This estimate accounts for the volumes required to achieve 70% coverage (3.56 billion doses), an allowance for 10% wastage¹³ (0.36 billion doses), currently approved doses for India (240 million doses), and estimated additional volumes to allow for management of risks related to boosters, additional doses to complete the primary series, further vaccination needs in case of a potential variant escaping immunity, or supply-side risks (point estimate of 500 million doses). In aggregate this indicates a total need of 4.65 billion doses.
- 3.4 The total dose requirement of 4.65 billion doses is to be met by supply from COVAX and non-COVAX sources. While much of this supply has already been contracted, or pledged as donations by donors, these volumes are subject to substantial levels of risks – including regulatory delays and failures, ongoing manufacturer scale-up, and export controls, among others. Many of the supply challenges experienced in 2021 are likely to continue into 2022 - and non-COVAX sources of supply are likely to be equally affected given the generic nature of some of these risks (for example, export controls and regulatory approval delays). As such, a substantial proportion of these volumes may not materialise or may only materialise in the second half of 2022 or into 2023. Current estimates show COVAX secured supply of 2.68 billion doses (equivalent to 43% coverage across AMC91 countries) across donor-funded and cost-shared APA doses, donated doses, and as well as an estimated contribution from AVAT and non-COVAX sources of 1.3 billion doses by mid-2022. This leaves an outstanding dose requirement of approximately 0.68 billion doses. To note, these figures shown in Figure 2 are indicative and being continuously validated through the Global Market Assessment Working Group which includes representatives from the Bill & Melinda Gates Foundation (BMGF), CEPI, Gavi, International Monetary Fund (IMF), UNICEF, and WHO, among other organisations. **Importantly, the 0.68 billion dose gap is a point estimate that will shift due to both supply and demand factors.** For further discussion of illustrative scenarios related to supply and demand risk, please refer to Doc 07b.

¹³ COVAX will aim to minimise wastage and so far has seen less wastage of COVID-19 vaccines than with routine vaccines. For the purpose of these projections and to be in line with other partners, it has been decided to use 10% as the general assumption of wastage.

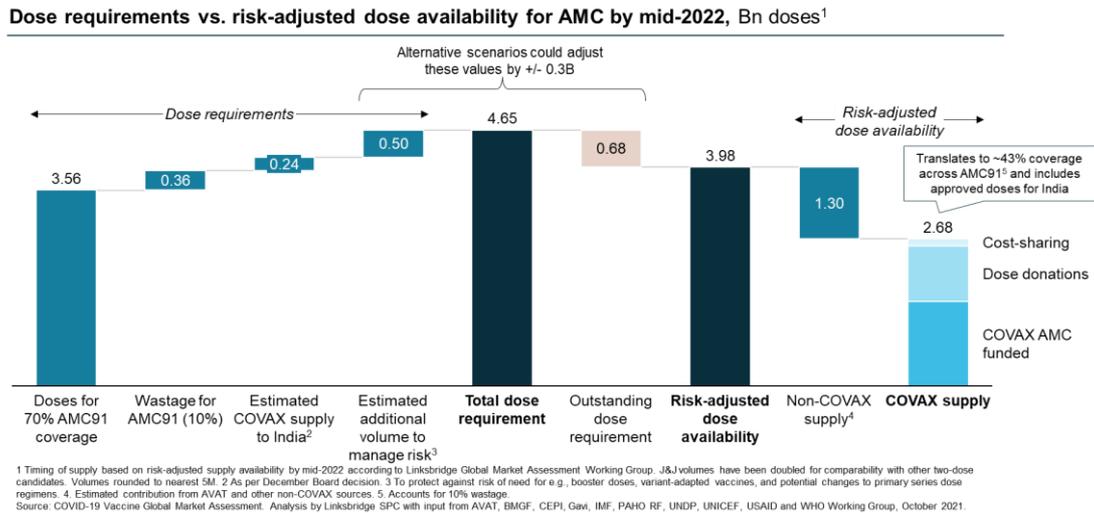


Figure 2: Highly preliminary estimates of AMC dose requirements vs. risk-adjusted supply available by mid-2022

- 3.5 Whilst non-COVAX supply is significant, there are additional uncertainties about this supply. For example, financing of these deals is generally not specified in publicly available data, and in many instances likely relies on loans, putting fragile economies under further fiscal burden. Also, the timing of their supply is usually not publicly known but is anticipated to be subject to the abovementioned generic risks that COVAX's and other bilateral supply have to manage. Finally, countries' portfolios are rarely diverse, exposing them to supply shocks.
- 3.6 On the demand side the total dose requirement may be increased by forthcoming evidence related to the need for boosters, target populations, and booster frequency; SAGE (WHO Strategic Advisory Group of Experts on Immunization) guidance on the number of doses required to complete the primary series of specific vaccines; and emerging evidence on the efficacy of specific vaccines. If several of these demand risks are realised, the estimated gap has the potential to more than double. Furthermore, vaccine-specific demand risks include country preferences based on efficacy and safety profiles, greater familiarity with existing vaccines over pipeline vaccine candidates, availability of appropriate cold chain equipment and manufacturer-specific legal requirements; this might result in demand concentrated towards just a few vaccines.
- 3.7 These supply and demand risks come in the context of an evolving landscape for COVID-19 procurement. Large purchasers, notably high-income countries, had started 2021 with deals across a large number of products, but towards the end of the year have gradually refined their portfolio towards typically two vaccines of interest. Therefore, the supply landscape is anticipated to move away from overall constraint to differential availability by product (for example, there is the potential for relative supply constraints for the most preferred vaccines, but greater relative supply of others), with implications on COVAX's sources of supply, both APA and dose donations. As part of actively managing its portfolio, the Facility is

continuously monitoring the evolving supply and demand landscape across the whole market (COVAX and non-COVAX) and responding by adapting the portfolio's composition and volumes to these risks. The COVAX APAs provide for options, which can be selectively exercised as needed to mitigate or address the supply or demand risks. In addition, new APAs for specific vaccines that are not currently in the portfolio, or to secure additional doses of preferred vaccines beyond what has already been contracted, can be entered into if required. Sections 4.5-4.7 describe how such portfolio decisions are made by the Facility in response to needs.

4. Management of uncertainties in 2022

4.1 Despite the high coverage anticipated to be provided from COVAX and non-COVAX sources, a substantial amount of supply and demand risk remains in 2022, notably due to:

- Potential need for additional doses to complete the primary series or for booster doses
- Potential need for further vaccination in case a variant escapes vaccine-conferred immunity
- Potential expansion of vaccination strategy to include paediatric vaccination
- Challenges with manufacturing scale-up or regulatory approval
- Further unexpected epidemiological, programmatic, supply events

4.2 The Secretariat proposes a COVID-19 Pandemic Vaccine Pool to cover these risks. This pool is specifically intended to manage risk including increasing coverage if it is indicated. A particular emphasis will be placed on using this supply increasing primary coverage in highest need countries such as low-income countries (LICs), which generally lack alternative sources of supply and to date have relied on COVAX for more than 70% of their supply on average (source: UNICEF Covid-19 Vaccine Market Dashboard). The base case calls for 600 million doses of incremental supply. However this value is a point estimate, and the actual requirements will continue to evolve due to the uncertainties mentioned above. The currently estimated impact of these risks generates high and low case scenarios of 900M and 300M doses respectively. The higher end of this range reflects a larger degree of risk materialising, including for example recommendations around population-wide use of boosters on the demand side or renewed export controls on the supply side. **Thus, in total, the Secretariat intends to secure 600 million doses to help mitigate risk and meet the gap described in Section 3.4.** Based on estimated pricing, the 600 million doses could cost between US\$ 3.2-4.3 billion¹⁴. An estimated US\$ 545 million are also required for ancillary costs to secure supplies, e.g. syringes, for supply from dose donations. Doc 07b indicates details on the costing and financing of these doses, including considerations on cost sharing.

¹⁴ As discussed on page 37 of the ACT-A's "Strategic Plan and Budget: October 2021 to September 2022."

- 4.3 It is important to account for coverage and risk contingency together, and not in isolation. **Indeed, some countries will be increasing primary coverage, some will be focusing on boosters for high-risk populations, and others yet will be advancing on both fronts in parallel.** WHO SAGE will deliberate on the evidence for booster doses in December 2021. The Pandemic Vaccine Pool needs to be flexible to respond according to countries' needs. Hence, in order to support countries' vaccination strategies and to ensure that no doses are idle, the Pandemic Vaccine Pool would complement needs to increase coverage, supply boosters or manage other risks simultaneously. It would also be informed by country preferences, absorptive capacity, and coverage achieved through all sources (COVAX and non-COVAX).
- 4.4 A key challenge for COVAX has been to provide visibility and security of supply for countries. **The Pandemic Vaccine Pool would be an essential element within the COVAX Facility to provide visibility and security, which is particularly important for fragile and lower-income countries, many of which currently have the lowest rates of coverage.** This would allow for these countries and COVAX partners to plan for steady increases in coverage (alongside continuous efforts to increase country readiness and absorptive capacity and to adapt to changing policy guidance).
- 4.5 **The COVAX Facility will manage demand and supply risk by applying a flexible approach to procurement, involving continual active management of the portfolio's composition and volumes to respond with agility to these risks.** Under its existing APAs, COVAX has further optional doses that could be exercised to meet this 600 million dose gap. If required, additional COVAX APAs may also be considered.
- 4.6 The COVAX Facility has a **portfolio strategy** for 2022 based on five principles to guide the strategic prioritisation of deals to be signed and/or options to be exercised. The principles have been derived from lessons learned in 2021 and are set in response to the anticipated changing risks and needs – for example, increasing country preferences, such as a desire for early and reliable supply of specific vaccines, certain classes of vaccines that offer relatively higher quality of protection. The key principles are:
- Optimising for price and value for money in order to maximise volumes for the portfolio.
 - Prioritising earlier supply to achieve coverage targets as early as possible.
 - Optimising quality of protection by prioritising relatively more efficacious or effective vaccines, and/or manufacturers with variant-adapted vaccines under development.
 - Prioritising manufacturers that are expected, or have shown, to be reliable in delivering on supply commitments.

- Maintaining a diversified geographic footprint of COVAX's manufacturing network.
- 4.7 Depending on which criteria are prioritised and the market environment, COVAX can build a portfolio that optimises for those criteria to close the base case of a 600 million gap. Such decisions are guided by the Market Sensitive Decisions Committee (MSDC), which provides input on these principles and the considerations that underpin the active management of the COVAX portfolio, and which approves manufacturer transactions. Other sources of supply such as AVAT options, new bilateral deals, or additional dose donations not directed through COVAX may also contribute to closing this supply gap for AMC Participants and will be actively monitored. The role of cost-sharing as a funding mechanism for overall supply is discussed in more detail in Doc 07b. As part of this approach, the Secretariat will also monitor the risks and incentives for countries to procure doses through alternative routes as well as the impact of other developments, e.g. the availability of therapeutics. A broader risk update is available to the Board in Doc 09, which includes a description of COVAX-specific risks.
- 4.8 **The Secretariat seeks the Board's endorsement, subject to funding availability for the COVAX AMC, of the COVAX Facility's approach to procurement of COVID-19 vaccine for 2022, focusing on supporting lower income countries dependent on the COVAX Facility to assure supply, and through the establishment of a Pandemic Vaccine Pool to manage risks given the significant uncertainties (e.g. variants, need for boosters, need for additional doses for primary series).**
5. **Delivery**
- 5.1 This section provides an overview of current context, the Alliance's delivery support so far and how its role is proposed to evolve to best support countries in 2022. **The Board is asked to endorse the Alliance's role in the delivery of COVID-19 vaccines in 2022 and delegate** to the Secretariat the authority to allot the full US\$ 799 million¹⁵ of COVID-19 delivery funding without an independent review to rapidly meet urgent funding needs from countries.

Context

- 5.2 **The last months of 2021 and the first half of 2022 will see an unprecedented volume of COVID-19 vaccine doses rolled out in AMC countries.** So far, countries have largely been able to absorb and roll out vaccines received from COVAX and other sources with very low rates of dose expiry. However, as supply increases in the coming months, country absorption rates will also need to increase significantly to utilise all available

¹⁵ Proposed decision language agreed at PPC on US\$ 799 million which corresponds to amount broken down in Figure 3, excluding initial US\$ 150 million core resource for TA and CCE as well as new US\$ 23 million pledged by France expected to be received soon by Gavi.

doses. Although the situation varies across countries, key delivery challenges include limited predictability of supply, short shelf-life, multiple products to manage, in-country inequities, overstretched management capacity, gaps in cold chain and service delivery or vaccine confidence issues. A number of players beyond COVAX including the multilateral development banks (e.g. the World Bank), bilateral donors (e.g. USAID) as well as regional mechanisms (e.g. AVAT) are providing support to countries, requiring close coordination across a wide range of partners to limit fragmentation.

The Alliance's role in COVID-19 vaccine delivery so far

- 5.3 **Acknowledging that countries shoulder primary responsibility to organise and finance delivery of COVID-19 vaccines, the Alliance's role in COVID-19 vaccination has so far focused on providing guidance, catalytic financing and technical assistance (TA) for in-country delivery of COVID-19 vaccines, coordinating shipments and delivery of COVAX doses at global, regional and country level, monitoring progress and mitigating delivery risks as they emerge.** WHO, UNICEF and other Alliance partners have surged staff on the ground, leveraged emergency mechanisms, streamlined decision-making and administrative processes to rapidly scale-up support to countries in areas including microplanning, surge of Human Resources, mass vaccination sites, in-country logistics and vaccine management. The following paragraphs describe the Alliance's role in more detail.
- 5.4 **Catalytic Financing and Technical Assistance: To date, Gavi has mobilised nearly US\$ 1 billion for COVID-19 vaccine delivery in addition to US\$ 262 million mobilised directly by UNICEF. WHO has also raised additional funding to support work on delivery.** In September 2020, the Gavi Board approved an envelope of US\$ 150 million for Technical Assistance ('COVAX TA') and Cold Chain Equipment (CCE) support to countries, which to date has supported >400 UNICEF and WHO in-country short-term positions and has provided 5,900 vaccine fridges and freezers, 180 walk-in cold rooms and 150,000 passive transport devices. Following Board approval in June 2021, additional substantial delivery support – US\$ 822 million¹⁶ – has been added which includes dedicated support in specific areas identified as particular risks such as vaccine confidence, management capacity, and stock management; and support for ultra-cold chain (UCC) expansion which allowed 41 AMC countries to receive UCC equipment (representing over 90% of the storage volumes planned for this first wave of investment) and absorb the large influx of donated and purchased Pfizer vaccines. It also includes a COVID-19 Delivery Support (CDS) early access window of approximately US\$ 270 million which was launched on 5 July 2021. As of 15 November

¹⁶ Gavi COVID-19 delivery funding envelope now includes an additional EUR 20 million (US\$ 23 million) from France for targeted delivery scale-up support through UNICEF – Envelope as of 15 November 2021 is of US\$ 822 million compared to US\$ 799 million described at October 2021 PPC

2021, 83 of AMC 92 countries have requested CDS early access support, totalling US\$ 225 million of which, US\$ 168 million has been disbursed to countries and the rest is to be disbursed by end of November. **A detailed breakdown of the Alliance’s COVID-19 delivery funding through Gavi to date is included in the figure below¹⁷.**

COVID-19 vaccine delivery funding structure overview			
Funding category	Sub-category	Funding amount (\$M)	Description
COVAX TA and CCE (launched in 2020)		150	TA: >400 WHO & UNICEF country-level staff supporting planning & delivery CCE: >5,900 refrigerators and freezers and >161,120 passive devices
COVID-19 vaccine Delivery Support (CDS)	Bridge funding	270	\$225M requested and \$127M disbursed in early access funds for delivery costs including vaccinators, service delivery, demand generation)
	CDS Early access		
	CDS Needs based	330	Needs based funding to support needs above early access envelopes
Additional direct country support (direct country support managed outside of CDS funding pathway]	UNICEF driven		
	UCC support	25	41 of 62 AMC countries choosing Pfizer will have UCC at end of October Capacity sufficient to store >65M doses at one time
	Vaccine confidence	16	Scale-up support to help ~20 highest risk countries monitor sentiment and design and roll-out demand activities
	Stock management	16	Deploy surge support - ~75 UNICEF surge capacity positions in ~40 countries - to monitor & strengthen stock management incl. through digital tools/ eLMIS
	Targeted delivery scale up support	23	Provide intensified end-to-end urgent support to delivery in a subset of higher risk countries
	Management surge	20	Deploy surge management and leadership capacity in country to strengthen coordination/operations in high-risk countries
Cross cutting delivery investments		85	Funding for catalytic or risk mitigating activities Including monitoring agents, facility insurance, humanitarian buffer delivery support, and global level support (TA, innovation support)
Unallocated buffer & Opex		37	Unallocated reserve and CDS operational costs for Secretariat
Total COVAX Delivery funding		972	

Figure 3: Overview of Gavi’s COVID-19 vaccine delivery funding structure

5.5 **Following the closure of the early access window, the Secretariat launched the needs-based CDS window of US\$ 330-400 million¹⁸ on 7 October 2021.** This is designed to support countries to fill critical funding gaps in their National Deployment and Vaccination Plans, recognising the highly heterogenous availability of delivery funding across countries. In addition to a standard, significantly accelerated approval pathway, the Secretariat will also maintain a fast-track approval mechanism for urgent needs that put scale-up of vaccine delivery at immediate risk. The Country Readiness & Delivery (CRD) implementation monitoring review (IMR) mechanism will be one important way to surface critical funding gaps (See Section 5.7), which could trigger fast track support. All applications and approvals of CDS funding are also shared with the Country Readiness & Delivery (CRD) Funders’ Forum to facilitate a coordinated response to country needs and to ensure transparency around any residual funding gaps that may remain after Gavi support has been exhausted. In order to respond with maximum agility to country needs, the PPC recommended that the Board **delegate to the Secretariat the authority to allot up to US\$ 799 million of COVID-19 delivery funding without requiring independent review.** The PPC acknowledged the higher risk of this approach yet considered it was required given the emergency context and urgent country needs.

¹⁷ Not including funding mobilised separately by UNICEF and WHO

¹⁸ Final amount will depend on the amount of funding rolled over from early access CDS

- 5.6 **Guidance, coordination, monitoring and mitigating:** Since the launch of COVAX, **Gavi Secretariat Senior Country Managers (SCMs) have played a critical operational role as the primary interface between COVAX supply (including for vaccine donations) and countries, working closely with WHO and UNICEF country and regional teams on the ground.** This has included a significant amount of time to help countries understand and execute on all readiness requirements (e.g., Indemnity & Liabilities agreement, regulatory clearance, import/export licenses), providing and clarifying communications on supply and delivery support available. Partners and Secretariat country teams have also been closely engaged in helping country governments develop their COVID-19 vaccination scale up plans and articulating corresponding funding needs in their CDS requests. As COVID-19 vaccination scales up, **SCMs and partners also have an important role in monitoring progress on delivery, identifying new bottlenecks early on and supporting countries to identify solutions** (e.g. through additional TA, CDS funding, or supplemental Multilateral Development Bank (MDB) financing). SCMs together with partners also have a critical function in monitoring the impact of COVID-19 vaccine roll-out on routine immunisation (incl. the Alliance’s key objectives to maintain and restore immunisation and reach zero-dose children and missed communities), working with countries to prevent further disruption and accelerate progress.
- 5.7 **Lastly, the Alliance also provides guidance and coordinates support to countries through the Country Readiness and Delivery (CRD) workstream, co-led by WHO, UNICEF and the Secretariat.** Partners’ and SCM country intelligence regularly feed into the CRD IMR, which collates cross-partner intelligence and data on country delivery performance and rapidly identifies implementation risks requiring special attention and targeted interventions. Repeatedly “flagged” countries, a group of ~25 countries known as ‘deep dive’ countries, are then noted for dedicated sessions. These sessions, coordinated by Gavi SCMs, who bring UNICEF, WHO country/regional teams along with other partners are conducted on a weekly basis to develop a cross-partner view on root causes of low delivery capacity, a targeted country support plan to address, and to follow up on implementation of the country plans. Where acute funding needs are presenting a bottleneck to vaccine roll-out, CDS needs-based support is being made available in a rapid manner for technical assistance and direct delivery support. **Beyond country-specific engagement, CRD plays a key role providing guidance through WHO and UNICEF normative roles.**

COVAX Pillar ambition for delivery for 2022 and the Alliance’s role

- 5.8 **The refreshed COVAX Pillar Strategy for 2022 (Appendix 1) recognises the variability of countries’ context and the fact that many partners are providing support to countries to scale up delivery. It has the following key dimensions:**

- A greater emphasis on strengthening in-country deployment of vaccines in AMC countries, especially higher-risk countries, through guidance, TA, advocacy support, operational coordination, and funding to establish delivery infrastructure and operational support;
- A clearer role as delivery funder for COVAX in close coordination with other funders to meet delivery funding gaps; and
- A more deliberate and systematic approach to a joint operational posture with other partners supporting AMC countries including AVAT. This includes supporting real-time planning and management of shipments from various channels, monitoring country issues and initiating rapid regional or global response for countries with urgent needs.

5.9 The Alliance’s role in the scale up of COVID-19 vaccination in 2022 will build on its comparative advantages and experience of operating for more than two decades under the Gavi umbrella to scale vaccines.

These advantages include the Alliance’s ability, coordinated by the Secretariat, to bundle funding that would otherwise be provided to countries and agencies across a more fragmented landscape, leveraging proven mechanisms for coordination across Alliance partners and other delivery partners. Acknowledging limited control on funding streams beyond the Alliance (i.e., from multilateral banks or bilateral donors), the Alliance is providing one ‘go-to’ point for country needs and significantly reducing transaction costs, providing aligned financial and technical support and ensuring funding is allocated to those partners best placed to provide impact. In addition, the Alliance can build on its voice, advocacy power and technical expertise, leveraging WHO and UNICEF’s footprint across AMC countries as well as the Secretariat SCMs to closely monitor progress on the ground, provide country intelligence and rapidly help countries troubleshoot together with all partners as needed. With the CRD, the Alliance is also uniquely positioned to provide normative guidance to countries, ensure coordination across partners, real-time monitoring of key challenges across countries and targeted technical and financial support as needed. Lastly, the Alliance has a responsibility and is uniquely placed to collectively minimise the threat posed by COVID-19 vaccine delivery to routine immunisation programmes and explore opportunities for COVID-19 vaccination to be integrated into routine immunisation and to contribute to the Alliance’s core mission of restoring routine immunisation and reaching zero-dose children and missed communities.

5.10 The role envisioned for the Alliance in COVID-19 vaccine delivery in 2022 will build on current functions described above and shift as follows:

- **More systematic collaboration with other funders at global, regional and country levels.** This pivot is being driven primarily through CRD via the development of active country monitoring and targeted country action plans and follow up (as described in Section 5.7). The Alliance, working together through CRD, will work to enhance coordination across, and transparency between, all delivery partners,

including the African Union (AU) and World Bank, to share country intelligence and to ensure countries are receiving aligned support. CRD will also continue to support countries with normative guidance.

- **More targeted financial support and enhanced technical support to AMC countries with a heightened focus on ~25 highest risk countries¹⁹** facing the most significant challenges and financing gaps. Concretely, this will translate into ensuring continuity of technical assistance provided so far, with flexibility to add/pivot support where needed, filling remaining gaps in cold chain equipment capacity and especially ultra-cold chain given the large increase in the share of COVAX supply which will require UCC, expanding financial support to countries for both long-term and urgent needs and ensuring the humanitarian buffer delivery is fully funded. Moreover, to successfully support countries with the delivery of COVID-19 vaccines in 2022, the Secretariat, coordinating through CRD, will further **help countries go beyond ‘business as usual’ through innovative approaches**. For example, Gavi support scaling new delivery approaches for rapid throughput, including through mass vaccination sites and by broadening implementation partners, e.g. to the private sector. Such approaches would build on existing engagement with high-risk countries to assess their needs and to identify new local and international partners able to deploy specific support rapidly.
- **Enhanced monitoring of delivery progress and risks** as well as stronger role of SCMs and WHO and UNICEF at country and regional level to support countries manage, e.g. new readiness requirements, and mitigate delivery risks (e.g. by facilitating access to funding and to technical assistance, as described in Section 5.6).

Delivery funding gap in 2022 and implications for COVAX contribution

- 5.11 **Availability of delivery funding is highly variable across countries.** For example, there are about 25 AMC countries with more than US\$ 10 per capita in external funding for delivery and another 25 countries with less than US\$ 2 per person.²⁰ As of 29 October 2021, there were still 35 AMC countries without World Bank support approved. In countries where World Bank funding has been approved, the level of delivery funding is highly uncertain as funding is fungible, can be shifted between vaccine procurement and delivery and can take time to deploy (e.g. requiring parliamentary decisions). Even when funding has been provided to countries, it can sometimes take time for it to be made available to Ministries of Health, disbursed to subnational levels, and spent.

¹⁹ Includes the following countries as of 15/11/2021 (list is dynamic and regularly updated): Countries with fragile, conflict, chronic or systemic circumstances: Afghanistan, CAR, Chad, Djibouti, Haiti, Mali, Niger, PNG, Somalia, South Sudan, Sudan, Syria, Yemen; Countries with time-limited problems or discrete event: Burkina Faso, Burundi, Cameroon, Eswatini, Ghana, Guinea, Guinea-Bissau, Madagascar, Mauritania, Senegal; High population/impact countries: DRC, Ethiopia, Nigeria

²⁰ Figures based on countries targeting coverage of 30% of their population. Numbers would scale proportionately at higher coverage levels.

- 5.12 **With limited AMC country experience in delivering COVID-19 vaccines at scale, the heterogenous contexts, systems and strategies countries are using, and the complexity of the donor landscape, estimating total delivery funding needs and gaps remains a challenge.** Latest delivery funding gap estimates to reach 70% coverage in AMC countries by end of 2022 range from **US\$ 1.5 billion to US\$ 3.8 billion.**²¹ **The range is driven by several key variables including** the uncertain needs in humanitarian settings, levels of Human Resource (HR) surge required, the use of fixed sites or outreach approaches for delivery, the time countries take to reach the 70% WHO coverage target and how funding from the multilateral development banks is used. These ranges represent the net additional funding needed accounting for already available and pledged funding from various donors (i.e. from CDS, World Bank projects disbursed or allocated, UNICEF ACT-A).
- 5.13 **Current estimates have already been tested and continue to be refined by a better understanding of bottom-up, actual delivery costs** in countries that are scaling up vaccination. **Initial inputs from countries on some of the key hypotheses show variable situations but seem to confirm current assumptions.** For instance, bottom-up data from Mongolia and Sri Lanka on delivery modalities tallies with the assumed split between fixed-site and outreach approaches. However, data collected from countries on HR surge varied; more datapoints are currently being collected from additional countries and CRD will continue to refine costing estimates and triangulate them against the latest country budgets and expenditure data from a representative set of AMC countries.
- 5.14 **To support country scale-up in 2022, COVAX partners plan to contribute approximately US\$ 1 billion of the 2022 delivery funding gap beyond their currently secured financing, broken down as follows:** The Secretariat, on behalf of the Alliance, will aim to contribute an additional US\$ 600 million which indicatively includes US\$ 500 million for CDS and approximately US\$ 100 million for technical assistance and additional UCC capacity for the increased supply of Pfizer doses. The design of this extended CDS will evolve based on lessons learned so far including on how needs are identified, funding is allocated, and disbursed rapidly. Channeling of CDS funds will either go directly to governments or to existing or new partners that are best placed to support/implement activities, leveraging existing partnership agreements as much as possible. In addition, UNICEF will seek to contribute US\$ 400 million in complementary funding to support countries including approximately US\$ 130 million in funding for targeted emergency needs through its UNICEF country offices as well as US\$ 270 million delivery costs needed for the humanitarian buffer and humanitarian settings. By doing so, UNICEF would leverage its existing role and expertise in emergency settings and build on its ability to move smaller funding amounts quickly to country level through its country offices. WHO will also seek to contribute support to

²¹ Including delivery funding need for the Humanitarian Buffer

country delivery similar as for 2021 through its Emergency Funding processes.

6. COVAX Facility: Risks and trade-offs to Gavi

- 6.1 As described in the latest Risk and Assurance report (Annex A to Doc 09) **large-scale COVID-19 vaccine delivery is affecting and may continue to pose risks to routine immunisation and to Gavi, largely through diversion of capacity and supplies as well as potential reputational damage.** It is however also acknowledged that not addressing the pandemic would equally continue to disrupt routine immunisation programmes and thus Gavi's core mission. Furthermore, **there are also opportunities to exploit synergies and leverage momentum from the COVID-19 vaccine rollout** for routine immunisation programmes and Gavi 5.0 objectives such as extending immunisation services to missed communities.
- 6.2 **The COVID-19 pandemic has had an immense impact and continues to pose risks to the capacity of the Gavi Secretariat, partners, and countries** by diverting focus and attention from routine immunisation. Whilst the Secretariat, WHO and UNICEF have benefited from a surge in staff specific to COVAX, this capacity has taken time to ramp up. Many of the staff meant to focus on routine immunisation programmes, in the Secretariat and partner organisations, have been pulled into COVAX related work and continue to bear a very heavy burden of work. At the country level, many aspects have been shifted towards COVID-19 including management attention, workforce capacity, resources (e.g. funding, but also materials, such as syringes) – sometimes at the expense of routine immunisation programmes. Going forward, an unprecedented scale up of COVID-19 vaccine delivery (countries will be delivering up to 8x the number of usual doses in early 2022) poses a real risk of disruption of RI and essential health services.
- 6.3 **The risk to supply of Gavi-supported vaccines posed by COVID-19 is receding, but still exists.** The impact of a 2020 pneumococcal conjugate vaccine (PCV) disruption was successfully managed with partners into 2021, and the risk has not materialised beyond this so far. Some repurposing of primary and secondary production lines for COVID-19 vaccines is inevitable, but this has not resulted in any material trade-off with non-COVID-19 vaccine processes. Additionally, Gavi is also monitoring COVID-19's impact on development timelines of pipeline vaccines in Gavi-supported categories; some delays have been reported by manufacturers, which in two cases resulted in revisions to supply and procurement roadmap assumptions. At present, there are no pipeline delays considered to be critical to long-term market health outcomes or could result in delaying programmes in country.
- 6.4 As countries scale up the rollout of COVID-19 vaccines, vaccination **supply chains and service delivery capacity may get overwhelmed by the volume of COVID-19 vaccines, resulting in wastage or interrupting**

replenishment of RI stocks. Furthermore, **rumours and misinformation associated with COVID-19 vaccines could spill over to routine immunisation and affect broader vaccine confidence.** The Alliance is also still monitoring and actively mitigating the **risk of diversion of routine immunisation syringes** and postponement of campaigns linked to a short supply of COVID-19 vaccine syringes. Furthermore, the fiscal impact of the COVID-19 pandemic and response is putting huge strain on government budgets and may result in **reductions in expenditure on routine health services.** The **fragmented delivery financing landscape** (e.g. World Bank, MDBs, COVAX, AVAT) poses another risk to scaling-up COVID-19 vaccine delivery as it significantly increases transaction cost for countries and limits the ability of stakeholders to efficiently allocate resources. COVAX mitigates this by coordination across partners and where possible bundling delivery funding in the Secretariat, that would otherwise be provided to countries and agencies across a more fragmented landscape.

- 6.5 **A further risk to Gavi is COVAX-related reputational damage.** COVAX is a high-profile project with global participation and high expectations and is operating in a dynamic and often politicised external environment – with many factors required for success being outside of its direct control. This makes the COVAX Facility and therefore Gavi vulnerable to reputational backlashes, e.g. in case of failures in execution and meeting (supply) commitments to participants, (perceived) inequitable or sub-optimal allocation of vaccines, delivery issues such as large-scale wastage of vaccines in-country or deliberate misuse of vaccine or cash support, serious adverse events following immunisation, (geo)political tensions (e.g. around Intellectual Property (IP) or perceived vaccine diplomacy regarding dose sharing), anti-vaccine attacks and disinformation being spread about COVAX, or generally mismanagement of, or a lack of transparency about, challenges and risks. Reputational damage would affect the COVAX Facility's and Gavi's ability to deliver on its mission, leverage effective relationships and count on continued donor, participant and public support. The Gavi Secretariat is mitigating this risk through proactive communication on the challenges and successes of COVAX operations in a complex environment as well as regular engagement with countries on supply developments. Communication remains an essential element that we continually seek to improve, but the reputational risk remains high.
- 6.6 **The Alliance can play an important role in mitigating these risks and protecting routine immunisation, as well as seizing the opportunities for routine immunisation programmes and Gavi 5.0 objectives.** The Alliance's financial and technical support, including through CDS funding plays a key role mitigating these risks by expanding countries' capacity and limiting diversion of routine immunisation resources. Ongoing day-to-day support, coordination and real time monitoring and troubleshooting by Gavi SCMs, in-country Alliance partners and CRD (described in Section 5) are additional ways the Alliance is mitigating main risks.
- 6.7 **Key opportunities** include the unprecedented **political focus** on ensuring strong and equitable immunisation programmes, the **many billions of**

dollars being invested to strengthen health systems to deliver COVID-19 vaccines (e.g. health workforce, service delivery, supply chains, community engagement), the **foundation that COVID-19 vaccination provides for adult immunisation platforms** that did not previously exist in many countries, and the fact that many countries are adopting **new innovations, partnerships and ways of working** to manage the COVID-19 vaccine scale-up that can be utilised for routine immunisation. The Alliance has already started to capture these opportunities and will continue to enhance the way in which it takes a joined-up view of COVID-19 vaccine and routine immunisation delivery to further help countries to capture synergies between them. **This will require more joined up planning, alignment of financing and technical assistance and integrated monitoring and operational support.**

7. Gavi's engagement in pandemic preparedness, response and financing

Purpose of this update

7.1 Beyond the immediate focus on controlling the current COVID-19 pandemic, there are growing calls for a new paradigm for global pandemic preparedness, response, and financing, recognising that current mechanisms have fallen short, and there is a limited window of opportunity for global reform. The devastating human, social and economic costs of the COVID-19 pandemic in terms of direct and indirect morbidity and mortality, as well as broader impacts on human development, have been extensively documented. Notwithstanding the cross-cutting efforts of ACT-A and the COVAX Pillar in the area of vaccines, the COVID-19 response has starkly delineated the technical challenges and political failures that have prevented many countries from securing timely access to the critical diagnostics, therapeutics, vaccines and other commodities such as PPE and oxygen which are essential to control the pandemic, save lives and mitigate broader societal and economic impacts. In the medium to longer term, it is projected that ongoing COVID-19 immunisation and pandemic preparedness in LMICs will require significant expenditure by governments, impacting all health programmes. This section is for information and summarises the context of current political and strategic discussions on pandemic preparedness, response and financing and Gavi's engagement to date. It also outlines potential ways in which Gavi could maintain engagement in these discussions over the coming months, drawing from relevant experience in innovative financing, through cross-cutting support to routine immunisation and health system strengthening in Gavi-supported countries as well as through supporting global access to vaccines against epidemic-prone diseases.

Political and strategic context

7.2 Over the last year, several distinguished panels and commissions (Independent Panel for Pandemic Preparedness and Response [IPPPR]; Global Preparedness and Monitoring Board [GPMB]; High Level

Independent Panel on Financing the Commons for Global Preparedness and Response [HLIP]) **have identified critical gaps and opportunities for pandemic preparedness, response and financing.**^{22,23} There has also been **high level political engagement on the topic of pandemic preparedness and financing at G7 and G20** to which Gavi has directly contributed. In June 2021, G7 leaders discussed the 100 Days Mission, aligned with CEPI 2.0 Strategy, which set out how governments, industry, international organisations and other should work together to accelerate the development of safe and effective vaccines, therapeutics, and diagnostics in a pandemic. The G20 Joint Finance and Health Ministers meeting at the end of October resulted in agreement to establish a task force to report back to Joint Finance and Health Ministers under G20 auspices in early 2022. Looking ahead, the US and Indonesian presidency of the G20 will work together on mechanisms and options for financing preparedness which could enable early vaccine R&D investments which are strategic and coordinated, with parallel investment in manufacturing at risk, technology transfer and procurement. Through a multilateral process with WHO Member States, efforts are underway to explore a new instrument to strengthen preparedness and response for health emergencies, with a strong focus on equitable access to medical countermeasures. Following a series of working group meetings, **Member States will consider the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response at a special session of the WHA in November**, with a view towards the establishment of an intergovernmental process for drafting and negotiation.²⁴ In the coming months we anticipate that these actions will provide a clearer pathway forward on coordinated action.

- 7.3 In addition, Alliance and extended partners are beginning to review early lessons learnt and consider their **future strategic engagement across R&D** (through funding platform technologies, and establishing new partnerships or strengthened partnerships with LMICs), **manufacturing** (including financing, technology transfer and sustainable development of regional and local manufacturing capacity), **procurement** (developing new innovative market shaping mechanisms, and regional initiatives) and **delivery** (highlighting the need to build on investments in strengthening

²² For example, e.g. IPPPR (<https://theindependentpanel.org/>), GPMB (<https://www.gpmb.org/annual-reports/annual-report-2021>), G20 High Level Independent Panel (<https://pandemic-financing.org/>). In addition, there is a growing body of analysis produced by independent think tanks and academic groups.

²³ These recommendations vary, but include a common focus on the need to improve global coordination for preparedness and response particularly through access to medical countermeasures and tools as global public goods, including by adapting existing and/or establishing new structures; to enable rapid release of funds at risk through new or repurposed contingent financing mechanisms so as to support an accelerated and equitable pandemic response; and to strengthen epidemic response, protect critical health services and build resilient health systems through targeted investments in essential infrastructure and capacity.

²⁴ The new instrument could address, among other aspects, equitable access to countermeasures such as vaccines, therapeutics, and diagnostics, and sharing of data, samples, technology and benefits in the context of pandemic preparedness and response. Equity, including equitable access to countermeasures and scale up of local and regional manufacturing capacity, is being considered as a key topic that could be addressed under the umbrella of a potential new instrument, which could further enable our mission on equitable access. The same working group will submit a report with proposed actions for consideration by the World Health Assembly in May 2022 based on the findings and recommendations from various panels and commissions.

health systems, and leverage experience from expanded outreach in the context of vaccine delivery, including to groups not previously prioritised for vaccination). As these initiatives progress, Gavi will continue to engage with partners to improve coordination, avoid duplication and achieve complementarity of efforts.

Gavi's historic role in epidemic and pandemic prevention, preparedness and response and learning from COVAX

- 7.4 To date, Gavi's contributions to these discussions have underlined the contribution of Gavi's core work as a foundation for pandemic preparedness and response, for example, through **promoting equitable access and reaching missed communities; building and sustaining health system capacity; increasing human resources for health; strengthening routine immunisation systems; building cold chain capacity; and supporting community engagement and demand generation**. In addition, Gavi has drawn from extensive institutional experience in **innovative financing and market shaping** (through IFFIm (International Finance Facility for Immunisation); Advance Market Commitments and Purchase Agreements); **epidemic preparedness** (for example, through support to addressing diseases of epidemic potential through preventative vaccination and outbreak response; **investment in global vaccine stockpiles; and selective investments in surveillance and diagnostics** as for Yellow Fever, see also Doc 12; in epidemic response (through the 2014 Ebola response and establishment of the global Ebola vaccine stockpile); and in **pandemic response**, through COVAX. While it will be important to continue development of diverse tools for potential pandemic response, it is likely that vaccines will continue to be a critical component of a future response and Gavi would be well positioned to contribute.
- 7.5 Through **COVAX, the Gavi Alliance has gained unprecedented experience in convening, leading, and operationalising a highly networked pandemic emergency structure, with the goal of ensuring that all countries, regardless of income, could access enough timely doses to protect high risk and vulnerable people as well as frontline workers**. Although several of the challenges faced by COVAX such as securing financing at risk, competition for early doses and managing impacts on routine immunisation were identified as potential risks early in the pandemic, other highly complex challenges (e.g. emergence of variants; the need for widespread expansion in ultra cold chain capacity) could not have reasonably been anticipated. As the host of the COVAX Facility, the Gavi Secretariat has gained experience in fund-raising during a pandemic, establishing broadly representative governance bodies, and establishing and delivering a broad portfolio of vaccines against a backdrop of significant scientific and geopolitical uncertainty. Responding to the impacts of manufacturing delays, export restrictions, geopolitical dynamics and programmatic feasibility challenges has required the Facility to rapidly adapt resource allocation and programmatic approaches; communicate openly in the context of information asymmetry and rapidly changing information; establish new ways of working within and beyond the Alliance; and develop

innovative approaches, such as dose sharing, to secure alternative access to timely supply.

- 7.6 **Whilst acknowledging the challenges related to vaccine supply and timely delivery, Gavi's historic investment in RI and health systems strengthening laid the foundation for global delivery of doses of COVID-19 vaccines at scale.** Many of the new approaches and mechanisms developed in response to challenges faced by COVAX could play an important role in both routine immunisation and potentially in future pandemic response (e.g. close engagement with R&D partners and regulators; delivery of vaccines to new target groups, such as HCWs and high-risk individuals; fair and equitable allocation mechanism; accelerated disbursement of funding for health emergencies). Across the COVAX pillar there is shared recognition of the need to sustain and consolidate new tools and mechanisms (legal, insurance, financial, risk mitigation, policy, operational) as well as partnerships (relationships with humanitarian partners, identifying and working with highest risk countries etc.; R&D; regional initiatives) in preparation for the next emergency. Further efforts are underway to collect and analyse lessons learnt to inform future pandemic preparedness and response. These include a COVAX Facility and COVAX AMC multi-stage independent evaluation commissioned by the Secretariat as well as evaluations commissioned by other public health partners such as UNICEF, Global Fund and CEPI which will also review the effectiveness of their COVID-19 pandemic responses. In the coming months these evaluations, and others, will provide an important evidence base on which to build.

Gavi's engagement in global discussions over the coming months

- 7.7 Gavi's experience to date provides relevant context for the upcoming global discussions and lessons to shape the evolving global agenda, and we intend to work closely with the G20 Task Force and engage in multilateral processes, and with countries and other stakeholders, over the coming months, informed by the following reflections. Firstly, it will be important to **maintain focus on the foundational importance of core support to health system strengthening** (which is the work of Gavi and many other Global Health Institutions) and supporting routine immunisation (where Gavi can draw on two decades of relevant experience in different contexts) for effective pandemic preparedness and response. Secondly, Gavi's **experience in innovative partnerships**, notably in the Alliance and as a partner in the broader ACT-A structure, may be relevant to discussions on the G20 Health and Finance Taskforce proposals as it considers a potential structure to lead future response.
- 7.8 Next, in respect of rapid contingent financing, in the current pandemic Gavi has faced challenges in competing on behalf of AMC91 against others with readily available financing. Learning from this experience, it is **vital that a rapidly accessible contingent financing mechanism is readily available for use**, potentially by a standing structure, to support a diversified portfolio for R&D, and enable manufacturing at risk and advance procurement that explicitly secures timely and meaningful supply of

vaccines for lower income economies, IFFIm is one example of a readily available mechanism which could potentially be adapted for pandemic response. In 2018, initial research confirmed IFFIm's in principle ability to allow sovereign donors to make legally binding contingent financing available that would be released rapidly against a predetermined trigger without affecting debt commitments until and unless the funding is triggered. Furthermore, IFFIm's ability to frontload has been used effectively in 2020, notably by the UK and Norway, releasing rapid funding to Gavi for the COVAX AMC. Gavi has also innovated to introduce new donor frontloading capacity via the European Investment Bank (EIB) and country domestic financing via cost sharing with World Bank, Asian Development Bank and EIB. As new models are explored it will be important to consider how financing instruments could be used, alongside market shaping instruments and approaches which support diversified manufacturing and sustainable local or regional production, towards the goal of securing equitable and timely access to vaccines in future pandemics with particular focus on the needs of AMC participants. Finally, **as more detailed proposals are developed, we anticipate discussions on the need for a new international organisation or financing structure.** One option could be to encompass core elements of the COVAX Facility that would then be embedded within the Gavi Secretariat and the Alliance, acting as a node within a broader network of partners as the foundation for an accelerated and coordinated future pandemic response.

- 7.9 Drawing from COVAX's successes and failures and with a view to ensuring complementarity with Gavi's core mission, over the coming months Gavi is well placed to contribute to discussions on evolving multilateral pandemic preparedness and response mechanisms, with a focus on advocating for approaches which would strengthen the Alliance's equity agenda, secure access to contingent financing for future health emergencies, and address the needs of Gavi-supported countries. Future decisions for the Board will be brought forward in line with the policy dialogue, as the various proposals put forward by the G7, G20, and through multilateral and regional processes develop. Considering the evolving discussions and noting the relevance of Gavi's experience to date, the Board is asked to comment on the relevance of these lessons learnt, and to advise whether there are other priorities which should be reflected in ongoing engagement.

8. Further topics and next steps

- 8.1 As noted in Section 1.4, Gavi's role in COVID-19 vaccination is an integral part of the broader COVAX Pillar strategy outlined in Appendix 1. WHO and the Gavi Secretariat are adapting the way doses are allocated to countries, accounting for absorption capacity to ensure no doses remain idle and based on collaboration with countries towards matching their preferences. Focus going forward will be on those least protected and most in need.
- 8.3 As per previous PPC and Board meetings, an updated report against the COVAX Reporting Framework is shared in Annex A. Please note that as data compiled from this report dates from end October/early November

2021, this report does not represent a final report on progress made and results achieved in 2021.

- 8.4 Annex B provides an update on the Humanitarian Buffer, this update is in response to the decision at the Board meeting regarding providing an update on the status of the Buffer. As highlighted in Section 2 and the Pillar Strategy, the Humanitarian Buffer is a crucial mechanism to enable access to COVID-19 vaccination to the most vulnerable.
- 8.5 Topics planned for the Board meeting in June 2022 include an update and, if required, decisions on the role of Gavi in pandemic preparedness and the future of the COVAX Facility and country eligibility for a potential COVID-19 Gavi programme. These will be discussed in the context of the evolving pandemic, lessons learned and linked as relevant to preliminary thinking on strategic topics in COVID-19 for 2023. The topic list will evolve based on the emerging priorities and decisions will be brought forward earlier if required. As was the case in June 2021, the Secretariat will also bring for decision the continued role of Gavi in administering the COVAX Facility for decision in June 2022.

Section C: Actions requested of the Board

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

- a) **Approve** the Gavi Alliance strategic direction for 2022 of supporting AMC91 countries toward achieving their individual COVID-19 vaccination coverage ambitions as set out in their national targets and ambitions, in view of the WHO Global Vaccination Target of 70% by mid-2022 and taking into account sources of supply beyond COVAX;
- b) **Approve**, subject to funding availability for the COVAX AMC, the COVAX Facility's approach to procurement of COVID-19 vaccine for 2022, focusing on supporting lower-income countries dependent upon the COVAX Facility for assurance of supply, and through the establishment of a Pandemic Vaccine Pool to manage risks given the significant uncertainties (e.g. variants, need for boosters, need for additional doses for primary series);
- c) **Approve** the Alliance's role in the delivery of COVID-19 vaccines in 2022 as laid out in Section 5 to Doc 07a;
- d) **Delegate** to the Secretariat the authority to allot the full US\$ 799 million of COVID-19 vaccine delivery funding as per Figure 3 to Doc 07b with flexible application of the Programme Funding policy including waiving the requirement for independent review, utilising existing programmatic and fiduciary risk mitigation mechanisms such as those used in emergency and humanitarian contexts on a no regrets basis;
- e) **Request** the Secretariat and Alliance partners, coordinating through CRD (Country Readiness and Delivery), to work with existing and additional partners

and countries on rapidly enhancing and accelerating vaccination throughput, including through mass vaccination and reaching hard-to-reach populations; and

- f) **Request** that the Secretariat update the PPC and Board before the end of June 2022.

Annexes

Annex A: COVAX Facility and COVAX AMC Monitoring, Evaluation and Learning (MEL) update and COVAX Reporting Framework

Annex B: Update on the Humanitarian Buffer

Additional information available on BoardEffect

Appendix 1: (In November 2021 PPC meeting book) Annex A to Doc 02 COVAX Pillar Strategy Memo

Additional reference materials online:

COVAX Supply Forecast as of 8 Sept 2021:

www.gavi.org/sites/default/files/covid/covax/COVAX-Supply-Forecast.pdf