Gavi The Vaccine Alliance

Report to the Board
28 September 2021

SUBJECT:	**COVAX: KEY STRATEGIC ISSUES**
Agenda item:	04a
Category:	For Guidance

Section A: Executive Summary

Context

At its June 2021 meeting, the Gavi Alliance Board approved: a) the continued administration of the COVAX Facility by Gavi in 2022; b) the proposed future participation model for Self-Financing Participants (SFPs); and c) Gavi taking an active role in the provision of fast, responsive and flexible funding through the creation of a COVID-19 Delivery Support (CDS) envelope and cross-cutting delivery elements. These decisions were taken in the context of growing inequities in access to COVID-19 vaccines and affirmed the COVAX Facility's continued central role in the global vaccine response.

To date, COVAX Pillar partners have supplied a total of 261 million doses, of which 204 million have gone to AMC countries (including 10 million for India) and 58 million to Self-Financing Participants (SFPs). It is the main or only source of vaccine for an estimated 57 countries. In the face of supply challenges, the COVAX Facility has worked hard to adapt and build resilience, including through the establishment of a dose sharing programme that has supplied 110 million donated doses (of over 660 million that have been pledged to date) and through portfolio diversification across vaccines platforms, geographies and manufacturers. Based on the latest COVAX Facility Supply Forecast most likely supply scenario, close to 1 billion doses will be available for supply between now and the end of 2021, and the 2 billion mark will be met before the end of Q1 2022. For AMC Participants, the COVAX Facility can provide access to ~2.5 billion doses through donor funds and vaccine donations, enough to fully vaccinate ~37% of the AMC population[1].

In light of the WHO COVID-19 Global Vaccination Strategic Vision, the ongoing COVAX Pillar Strategy effort, and a continuously evolving external environment, the Facility is updating its strategy for 2022 and beyond, while maintaining focus on core operations and working across Gavi and Alliance partners and countries to prepare for the significant increases in deliveries over the coming quarter.

Questions this paper addresses

What should the COVAX Facility contribution to global vaccine supply in 2022 be?

How is the delivery of COVAX vaccines progressing and what should Gavi's role in COVID-19 vaccine delivery in 2022 for AMC92 be?

[1] Average excludes India, who gets 20% of COVAX APA doses

Should additional mechanisms – Brokerage, Resell to the Facility and Exchange – be implemented?

Is the proposed SFP country participation model in line with the Board-endorsed principles of simplifying operations, mitigating financial risk to Gavi and inclusivity?

Conclusions

The COVAX Facility is the backbone of the global COVID-19 vaccine response, marshalling US$ 10 billion+ of funding (procurement and delivery), constructing a diverse vaccine portfolio containing 11 products, forecasting 2 billion doses supplied before the end of Q1 2022, and assembling 195 Participants. Looking towards the end of 2021 and into 2022, the COVAX AMC and COVAX Facility are examining scenarios to secure additional resources and supply to cover ~60% or ~70% of AMC populations plus an additional 500 million doses contingency pool to manage risk of e.g., paediatric use, variants and boosters. Furthermore, efforts are focusing on ensuring successful in-country delivery of the increasing supply of COVID-19 vaccines, with COVAX partners working in close collaboration with countries to identify and mitigate key delivery risks. In addition to the delivery funding being made available directly to countries, the Alliance is providing dedicated support in specific areas which have been identified as particular risks, including vaccine confidence, stock management, management capacity and ultra-cold chain (UCC) capacity.

Following examination of potential options, the Secretariat has provisionally concluded that a brokerage (countries reselling doses to each other through the Facility) entails substantial legal and operational complexity as well as unclear fit with Gavi's core mission and as such should not be pursued further; however, a resell to the Facility (countries reselling doses to the Facility) could be considered on a case-by-case basis. The Facility is looking into ways to integrate the benefits of an exchange (countries exchanging COVAX-allocated doses with each other) into existing mechanisms.

Finally, the Facility is operationalising the SFP2.0 design based on the Board decision in June 2021 and follow-up consultations with SFPs.

Topics concerning the future of the COVAX Facility (organisational considerations and integration with routine immunisation) and Gavi 5.0 (priorities, progress and links to COVAX) will be addressed at the next Gavi Board meeting in December, as they are highly linked to the dynamic evolution of the pandemic landscape.

Section B: Facts and Data

1. COVAX Facility status update and looking into 2022

1.1 Globally, as of 13 September 2021, there have been at least 223 million cases and 4.6 million confirmed deaths resulting from COVID-19 disease. **Beyond direct health impacts, the pandemic has had profound economic and social impacts, disproportionately affecting the most vulnerable**. Alongside non-pharmaceutical measures, vaccines are making

a growing contribution to reducing and mitigating the impacts of COVID-19 disease. Since the first vaccinations in December 2020, more than 5.3 billion vaccine doses have been administered and more than 1.2 billion people have been fully vaccinated, which is meaningful progress towards fulfilling the roughly 11 billion total doses of vaccine needed to achieve 70% global coverage as estimated by WHO. The update to the Gavi Board in June highlighted the challenges related to insufficient and volatile supply and disparities in access to COVID-19 vaccines; currently, there remains an urgent need for doses to protect the most vulnerable. While in HICs, total doses administered per 100 population is at 120, this number goes down by income bracket: 69 for UMICs excl. China (148 in China), 26 for LMICs excl. India (53 in India) and 3 for LICs[2].

1.2 **The COVAX Pillar has been the backbone of the global vaccine response for AMC participants and has been pivotal in providing early access** to many participants, both AMC and SFP, who face major access barriers. Since February 2021, based on the secured doses from the COVAX Facility, the COVAX Partnership has supplied 261 million doses, of which 204 million to AMC92 participants. COVAX Facility doses accounts for more than two thirds of doses supplied to LICs and one third of doses supplied to L(M)ICs (excluding India) (Figure 1). As of early September 2021, it is estimated that 57 countries (4 SFP, 53 AMC) rely on the COVAX Facility as their primary or only source of COVID-19 vaccines. To date, based on pledges for the AMC amounting to US$ 9.8 billion, the Facility is expected to procure up to 1.9 billion doses[3]. In addition, around 660 million doses have been announced as donations to the COVAX Facility of which 110 million doses have already been supplied, most of them to AMC countries. Combining donated doses and those funded by COVAX AMC, the COVAX Facility can provide enough vaccines to cover ~37% of AMC92 populations (excl. India[4]). Multiple innovations – the No-Fault Compensation (NFC) scheme for AMC countries, the model Indemnity & Liability (I&L) agreement, the WHO global Emergency Use Listing (EUL) for vaccines and the pandemic labelling – are cornerstones of a global procurement and delivery mechanism. The COVAX Facility has diversified its portfolio and with 11 vaccines, now has the largest portfolio of vaccines in the world.

[2] Source: Our World in Data
[3] Of which 1.7 billion have been committed to date through Advance Purchase Agreements
[4] Average excludes India, who gets 20% of COVAX APA doses

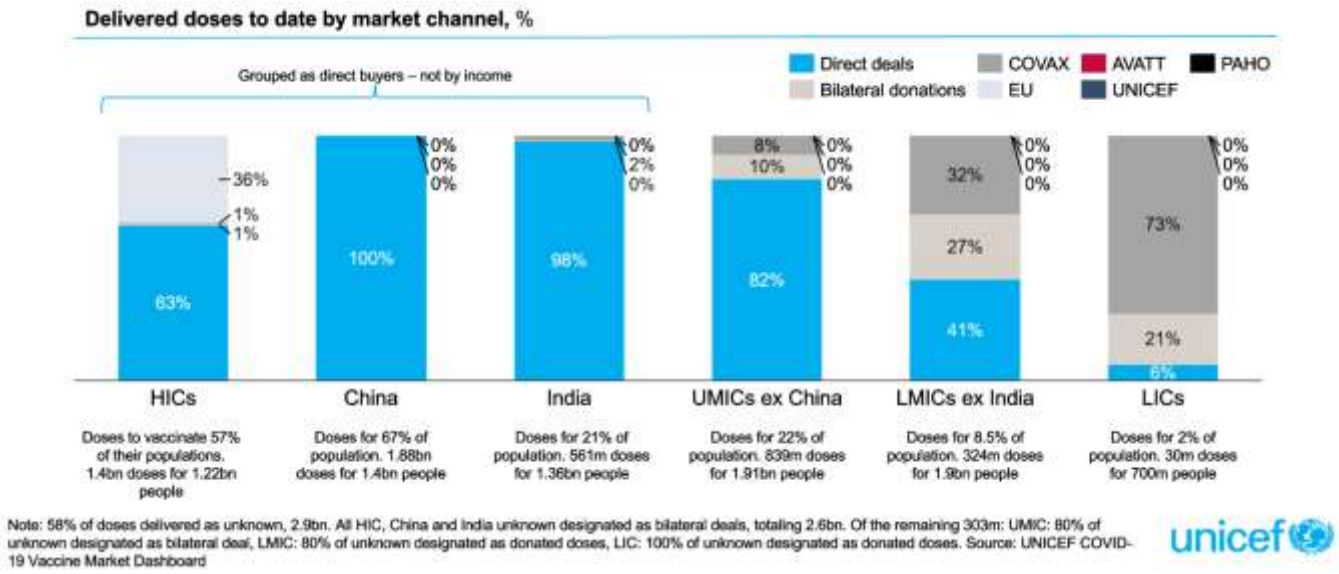


Figure 1. Delivered doses to date by market channel. Source: UNICEF, COVID-19 Vaccine Market Shaping Strategy, Advisory Group materials, as of August 2021

1.3 During 2021, export restrictions and technical difficulties in manufacturing scale up have resulted in significant delays in supply of the COVAX Facility doses. A large portion of the doses originally forecasted to arrive throughout 2021 have been pushed into Q4 2021 and early 2022. The COVAX Facility experience has not been unique, and many countries and other procurement mechanisms have been affected by a highly unpredictable market. **The COVAX Facility has launched multiple efforts to adapt to the volatile context of COVID-19 vaccine supply including through increased diversification of its portfolio across manufacturers, vaccine technology platforms, and geographies** (Figure 2). This diversification is already yielding results, with new deals signed and options exercised in the past months to bolster supply in Q3 and Q4 2021. We have recently seen the pace of supply significantly accelerate and expect Q4 2021 to outpace the first three quarters of the year combined. **The key COVAX Facility milestone of 2 billion doses released for delivery is now expected to be reached before the end of Q1 2022** (Figure 3).

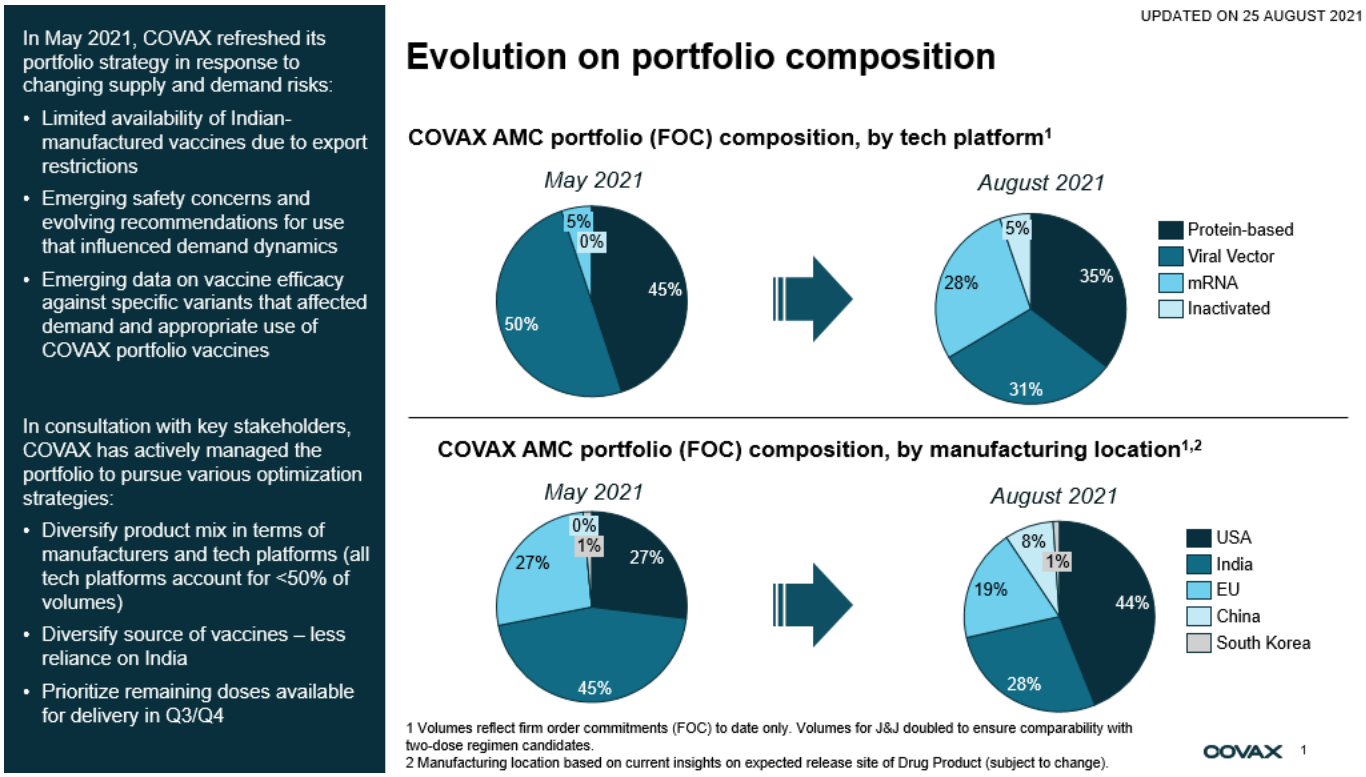


Figure 2. Evolution of COVAX portfolio composition

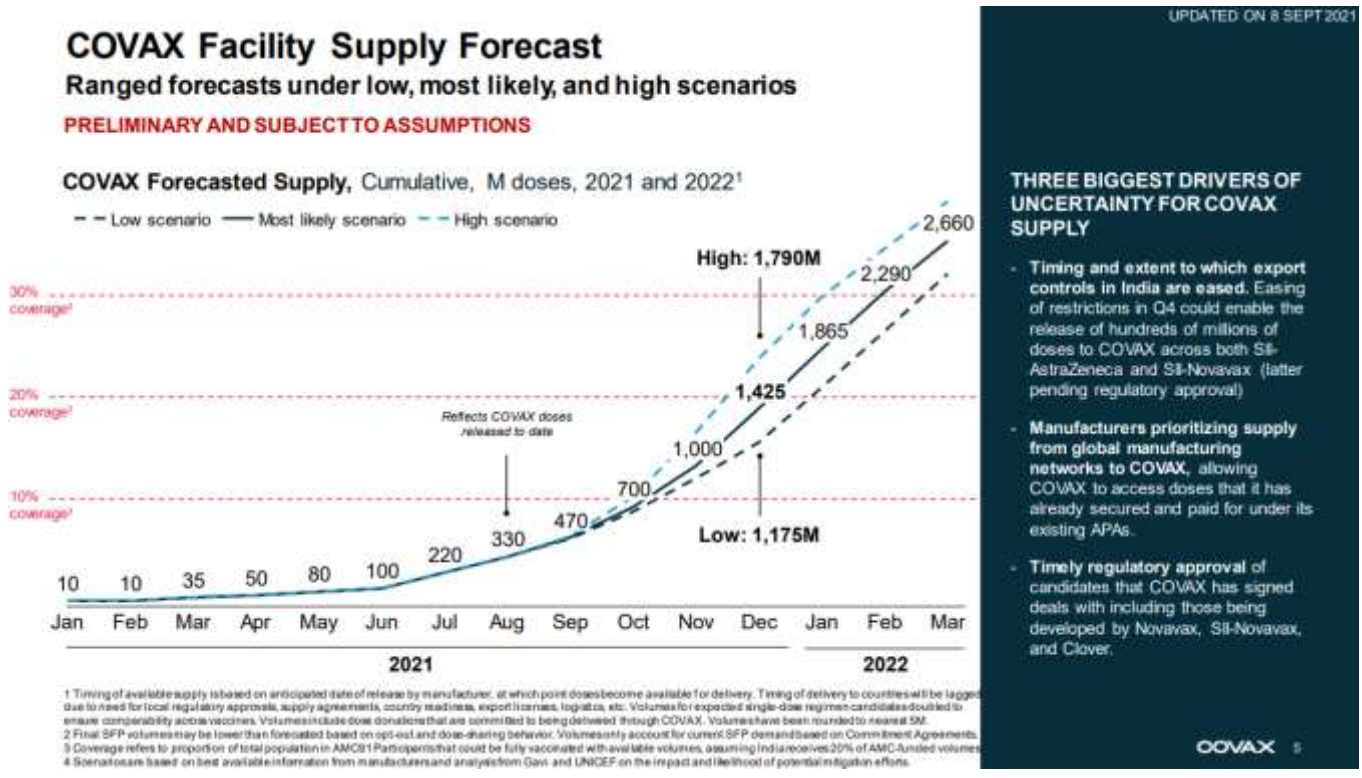


Figure 3. COVAX Facility Supply Forecast as of 8 September 2021

1.4 **The delivery on Gavi´s role in COVID-19 vaccination requires engagement across various departments across the Gavi Secretariat**. Funds and resources in kind are raised by the Resource Mobilisation team through mechanisms such as the AMC, cost-sharing and dose donations for COVID-19 Vaccination. Based on this funding the COVAX Facility secures and supplies the required doses as well as builds mechanisms such as the No-Fault Compensation, the Humanitarian Buffer etc. In-country delivery is supported by the Secretariat and the Alliance Partners and led by the Country Programmes team. Other critical functions such as financial management, risk assurance, and monitoring and evaluation etc are supported through Gavi Secretariat teams and the 3 Lines of Defence model.

1.5 **The operating context has evolved significantly since the launch of the COVAX Facility,** and we anticipate further shifts to come, due to several factors which are listed below:

- Access to doses, including vaccines outside of the COVAX Facility portfolio, e.g. from bilateral deals and/or regional mechanisms
- Growing importance of preference for specific products
- Many HICs will have (or have already) vaccinated a large portion of their population and are seeing benefits in terms of socio-economic recovery
- Many countries are changing their vaccination strategies, targeting different populations and introducing boosters
- Widespread vaccine misinformation and fluctuating vaccine confidence

1.6 **At the same time, there are many fundamental scientific uncertainties** which will impact the use of COVID-19 vaccines in the future. These are being closely monitored by COVAX Pillar partners and include the need for boosters; the public health case for paediatric vaccination strategies; the emergence, transmission and impacts of new variants of concern on vaccine efficacy; the role of mix and match strategies in the context of supply constraints and potential benefits in terms of population coverage; and the potential feasibility and impact of dose-sparing strategies in the context of supply constraints (particularly the role of fractional/single dosing in the context with high rates of disease transmission where these approaches may have a boosting effect). Given scientific uncertainties and supply constraints, it is important to maintain a diversified portfolio for now but when the supply situation eases and there is more scientific certainty, it will likely be necessary to narrow the number of products gradually to optimise the products for countries and reduce complexity in delivery. Monitoring the market and active signalling to manufacturers will be important to ensure reliable supply through sustainable competition.

1.7 The COVAX Pillar continues to work together to develop a common vision for the next phase, building on experience to date and understanding of partners individual and collective comparative advantages. **The COVAX**

Facility's approach to 2022 will be anchored in and aligned with the WHO COVID-19 Global Strategic Vision and the COVAX Pillar Strategy for 2022.

- The WHO Global Vaccination Strategic Vision intends to i) inform countries, policy makers and investors on decisions related to target vaccination in 2021-2022 and ii) promote an equitable approach to COVID-19 vaccination globally. The WHO Global Vaccination Strategic Vision outlines relative levels of coverage required to meet both health and socio-economic goals of recovery. The Strategic Vision establishes that the pandemic trajectory and the most complete recovery goals require addressing not only COVID disease, but also transmission. That ambition results in an ever-broadening scope of vaccination, toward a universal vaccination strategy, for all age groups contingent on evidence for vaccine authorisation and policies, and deployed stepwise through age strata. **The Strategic Vision is in a finalization process and is converging on a high-level aspirational coverage objective of 70% of the global population, with country specific coverage targets aligned to the 70% goal, recognising country-specific flexibilities resulting from age demographics are needed.**

- An effort to refresh the COVAX Pillar Strategy for 2022 and beyond has been undertaken with the goals of **clarifying the Pillar's objective, role and value proposition, helping delineate the roles of each partner and providing a cohesive foundation** upon which each of the partner organisations can structure their own approaches. The effort brought together core COVAX Pillar partners and other key stakeholders. Work-in-progress is outlined in Annex A.

1.8 The Facility is committed to working with countries toward their own coverage goals and the aspirational target of 70% population coverage called for by WHO in the context of continued health and socio-economic impact of the pandemic. Recognising the challenge of achieving 100% coverage in any age stratum, this ambitious goal sets a trajectory toward vaccinating children under 12 years of age, notably in AMC countries (average population percentages by age group are outlined in table 1). Global regulatory authorizations and vaccine policies regarding paediatric vaccination strategies (i.e., under 12s) will depend on the evidence from ongoing scientific studies and the disease epidemiology over the coming months. The COVAX Facility will continue to monitor the policy landscape, quantify the number of doses that would need to be secured to contribute to any eventual target as part of a stepwise approach to expanding coverage, and monitor any implications for COVAX AMC Fundraising (Resource Mobilisation agenda item).

	% of total population aged 50+	% of total population aged 18+	% of total population aged 12+
AMC91	15%	60%	72%
AMC92	17%	63%	75%
India	20%	69%	80%

Table 1. Population percentage by age group in AMC countries.

1.9 There is a long road ahead before we see the end of the COVID-19 pandemic, and **the COVAX Facility will continue to play a central role in the response.** In the face of glaring inequities, many countries continue to depend upon the COVAX Facility for access to supply. At the same time, countries who have already achieved high coverage levels are moving quickly to secure supply for potential booster or other downside scenarios. These developments make a clear case for the COVAX Facility to act now in order to ensure it and the countries it supports (both AMC and SFP) are not left behind in 2022 whilst also underscoring the importance of flexibility to meet emerging evidence (e.g. on boosters, paediatric use) and face unexpected market and other shocks. **Recognising huge outstanding vaccine needs, pending evidence gaps and the Global Vaccination Target, the Facility is aiming to secure a significant contribution of supply for all participants, AMC and SFP alike**.

For AMC countries, the scenarios being explored include providing sufficient vaccines to contribute to 60% or 70% coverage of AMC populations as further discussed in the COVAX Resource Mobilisation Update paper. Total population coverage of 60% corresponds to vaccinating the entire adult population in AMC91 countries (table 1). The baseline coverage upon which the Facility is building amounts to ~45% and accounts for the COVAX Facility donor-funded supply (including dose donations) representing ~37% coverage (see paragraph 1.2), cost sharing, and already delivered doses from non-COVAX Facility sources. COVAX Facility doses would be complemented by supply from other sources, including regional mechanisms notably AVATT. In addition, the COVAX Facility will see to establish a contingency pool of 500 million doses to manage risk, including the need for boosters, variants, and paediatric populations. For example, 500 million doses is sufficient to provide boosters for all high-risk groups in the AMC91 or to fully vaccinate an additional ~10% of AMC91 populations, potentially for under 18-year-olds or as a first layer of protection in the event of an escape variant. Further thinking, including on cost-sharing, is provided in the Resource Mobilisation agenda item. **The COVAX Facility will adopt a step-wise approach as more evidence becomes available, notably on vaccination strategies in paediatric populations, as well as keep the necessary flexibility to manage risks related to new variants and need for boosters.**

The COVAX Facility will also continue to support SFPs who will be able to continue to procure through the Facility under the SFP 2.0 Model (paragraphs 3.6-3.13).

1.10 Work is ongoing to quantify the potential public health and broader socioeconomic impacts of COVID-19 vaccination across different scenarios and levels of ambition for the COVAX Facility. This includes work with Imperial College and Harvard, and coordinating with the Impact Modelling Subgroup of the WHO SAGE Working Group on COVID-19 Vaccines, which is investigating 18 policy questions ranging from strategies to maximise in-person schooling to assessing the extent to which vaccination can allow non-pharmaceutical interventions to be reduced[5]. Precisely projecting the impacts of COVID-19 vaccination is challenging given the sensitivity of projections to the choice of counterfactual and evolving uncertainties associated with vaccine efficacy, waning immunity, new variants and population demand for vaccines. **While modelling refinements continue, current projections suggest** providing vaccines that could enable scale up of coverage to vaccinate at least 60% of the total population in 2022 could avert up to 3.5 million deaths in AMC countries. In terms of GDP effects, initial modelling results for the six largest AMC countries suggest that while vaccinating those aged 50+ could reduce GDP disruptions anticipated without vaccination by 20 to 33% across those countries, **vaccinating 18+ could limit GDP disruptions by much as 50%** in some countries[6]**.**

1.11 The COVAX Facility strategy is centred around promoting equity by ensuring those countries in greatest need are guaranteed a foundational layer of coverage. However, the **COVAX Facility also recognises the critical role of partners and regional mechanisms, notably AVATT,** to complement the Facility and help countries build off this foundational layer in pursuit of their individual targets including to reopen their economies by further reducing disease and transmission. Estimates of non-COVAX Facility supply available to AMC92 participants (excl. India) range up to an additional ~30% population coverage. However, these figures are highly uncertain (e.g., data sourced from press releases), and there is limited visibility as to when and in what quantity these volumes might materialise. Further, these volumes would largely be domestically financed representing a significant burden on countries already hard-hit by the health and economic consequences of the pandemic.

1.12 As the COVAX Facility works towards delivering on its 2021 objectives, the vision for 2022 is becoming clearer. Some elements remain unchanged – a core belief that a global mechanism is required to tackle a global challenge leveraging existing infrastructure wherever possible, that a diversified

[5] Work underway. SAGE questions are outlined in https://www.ungm.org/Public/Notice/120376

[6] Initial deaths averted projections based on modeling from Imperial College, which considered different scenarios with respect to public health and social measures and assuming scale up from Sept 2021 to December 2022. Initial GDP results from Harvard University, which used an epidemiological-economic model to assess the potential impacts of vaccine scale up on population health and GDP in Bangladesh, Ethiopia, India Indonesia, Nigeria, and Pakistan across different scenarios of virus transmissibility and public health and social measures.

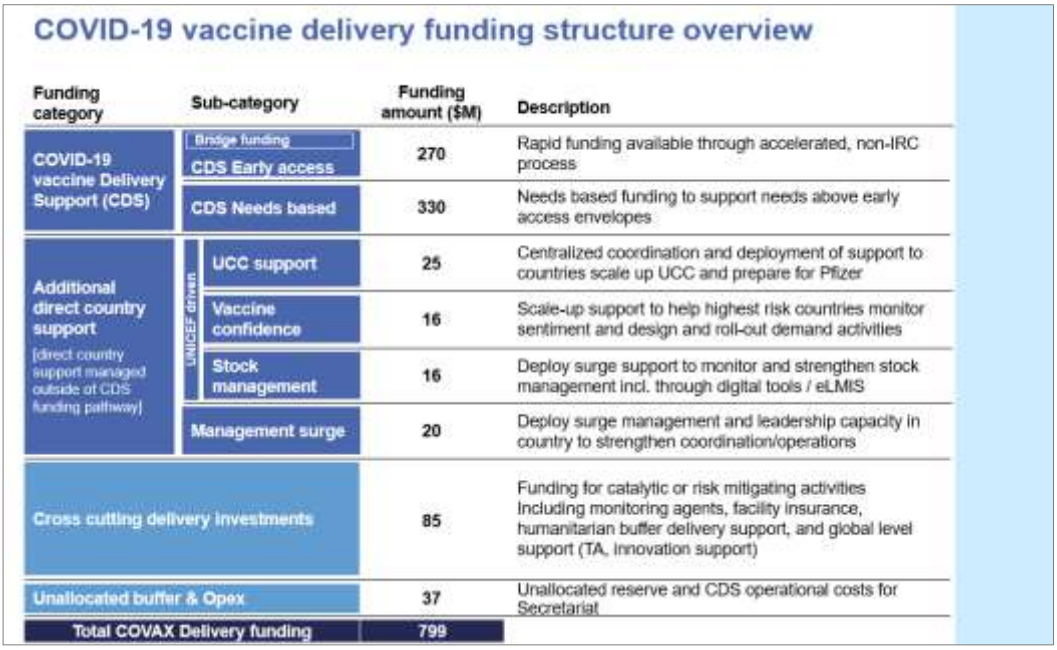
portfolio is critical to managing supply risk, and that moving early is the only way to protect the most vulnerable from being left behind. In 2022, we seek to build off these elements as well as drawing from the accumulated experience and systems established over the last year in our mission to save lives and address stark inequities. With its renewed ambition, the COVAX Facility reaffirms its central role in the pandemic response in support of countries in greatest need. The COVAX Facility seeks the Board's guidance on the vision for 2022 outlined in this section.

2. Delivery

2.1 **The latter part of 2021 will see an unprecedented volume of COVID-19 vaccine doses to be rolled out in AMC92 countries**. The absorption of such volumes of vaccines is expected to represent a significant challenge for many countries. COVAX Pillar partners' priorities and efforts are increasingly targeted at supporting countries to administer these vaccines at scale.

2.2 **So far, countries have largely been able to absorb and successfully rollout vaccines received from the COVAX Partnership**. Although the situation varies across countries, most countries have been able to increase delivery as supply scales up and mitigate risk of dose expiry. COVAX Pillar partners have identified several key delivery risks and are actively monitoring and mitigating them through weekly 'implementation monitoring reviews'. In these weekly reviews, partners assess key delivery risks across countries, identify those needing special attention and define targeted interventions (e.g. adjust future shipments, consider redeployment of doses, provide specific technical assistance). Risks monitored are linked to country delivery challenges which vary significantly from one country to another. Delivery challenges can include difficult or fragmented access to available delivery funding, limited predictability of short- and medium-term supply, insufficient workforce capacity, gaps in cold chain, supply chain and service delivery or issues with demand and vaccine confidence in some countries. **Significant funding is being made available by funders including UN partners, bilateral donors, private sector partners and the multilateral development banks to try and help mitigate these risks, and Gavi is also providing substantial delivery support – US$ 799 million[7] – as approved by the Board in June 2021** (on top of the US$ 150 million of funding for technical assistance and cold chain equipment approved in September 2020, which is already being implemented). The structure of this funding is recapped in Figure 4 below.

[7] With the additional US$ 30 million contribution from the Bill & Melinda Gates Foundation (currently unallocated) and exchange rate adjustments, the funding is now of US$ 799 million instead of US$ 775 million



COVID-19 vaccine delivery funding structure overview

Funding category	Sub-category	Funding amount ($M)	Description
COVID-19 vaccine Delivery Support (CDS)	Bridge funding CDS Early access	270	Rapid funding available through accelerated, non-IRC process
	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	Centralized coordination and deployment of support to countries scale up UCC and prepare for Pfizer
	UNICEF driven: Vaccine confidence	16	Scale-up support to help highest risk countries monitor sentiment and design and roll-out demand activities
	UNICEF driven: Stock management	16	Deploy surge support to monitor and strengthen stock management incl. through digital tools / eLMIS
	Management surge	20	Deploy surge management and leadership capacity in country to strengthen coordination/operations
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		799	

Figure 4 – COVID-19 vaccine delivery funding structure

2.3 **Following the Board decision, a CDS early access window of ~US$ 270 million was launched on 5 July 2021. As of 13 September 2021, 80[8] of AMC 92 countries have requested support, totalling US$ 207 million, of which US$ 21 million has already been disbursed**. After a slow start, countries' requests for this funding have peaked in the second part of August. Key drivers for the relatively slow early uptake include a limited sense of urgency for countries to access this funding as the major increase in doses has not reached them yet and funding for delivery from the World Bank and other donors was in negotiation and has now started to flow. Countries have also been dealing with competing priorities such as mitigating COVID-19 disruption to their health systems, trying to procure COVID-19 vaccine doses outside of the COVAX Facility or maintaining routine immunisation.

2.4 **As presented to the Board in June 2021, following the closing of the early access window, Gavi is making a further US$ 330-400 million[9] available to countries to target their greatest unmet delivery support needs**. As requested by the Board, the Secretariat worked with Alliance partners and CDS donors on fleshing out the design of this window through a dedicated workshop in July and ongoing discussions with CRD. Funding will not be an entitlement for countries but instead designed to target greatest unmet needs. The funding window has been designed to support both medium-term plans from countries, based on robust analysis of funding needs and gaps, as well as responding to urgent needs that put scale-up of vaccine delivery at immediate risk through a light-touch request process. The process for accessing funding will build on already strengthened collaboration with other funders and leverage existing COVAX Pillar mechanisms: e.g. using the current 'Implementation Monitoring Review' to

[8] Including 26 AMC countries where CDS funding is directly managed by UNICEF
[9] final amount will depend on the amount of funding rolled over from early access CDS

identify urgent country needs and building on the process used for CDS early access window to review urgent requests. While all countries will be able to request this funding based on needs, CRD partners will identify 10 to 12 high-risk countries which would receive particular focus to help them access additional CDS based on updated and robust NDVPs. This funding window will open before the end of September, and include rolled over funds from early access CDS.

2.5 As shown in Figure 4, i**n addition to the funding being made available directly to countries, the Alliance is providing dedicated support in specific areas which have been identified as particular risks, including vaccine confidence, stock management, management capacity and ultra-cold chain (UCC) capacity.** This will result in a significant scale-up of support to the highest-risk countries in these areas, primarily through UNICEF. UCC has become a particularly urgent priority since the US Government announced in June 2021 that it would support the COVAX Facility to provide 500 million doses of Pfizer vaccine, with first doses becoming available already in August 2021. Very few AMC countries had existing UCC capacity, requiring a rapid and intense effort to deploy UCC equipment and help countries prepare to handle the vaccine. This has been led by a special task team within the Country Readiness & Delivery workstream of the COVAX Pillar, supported by US$ 25 million in dedicated funding. This support, managed by UNICEF, is being used to rapidly scale up UCC capacity and provide countries with technical support. This should enable all countries who have been allocated Pfizer vaccine to be able to do receive and safely store it. So far, 22 countries have already received UCC equipment since this effort was launched in June 2021, and 20 more countries should receive UCC freezers by the end of September 2021. Collectively, this support will be sufficient to store more than 67 million doses of Pfizer vaccines.

2.6 **As we plan for 2022, the COVAX Pillar needs to redefine what its role in delivery support should be**. Under a refreshed COVAX Pillar Strategy for 2022, the Pillar has started to frame its future role. Annex A provides an overview of thinking to date. The COVAX Pillar Strategy for delivery is grounded in WHO's Global COVID-19 Vaccination Strategic Vision for 2022 and COVAX Pillar contribution as described in section 1 above. WHO's Strategic Vision for 2022 also acknowledges the developing evidence around the potential need for booster doses in specific cases (e.g. for populations at risk) which may increase demand on systems in the future and could also result in the integration of COVID-19 vaccines in routine programmes over time. Initial thinking on the delivery role of COVAX pillar partners for 2022 is also based on an understanding of key delivery challenges, including those seen in country as well as challenges at global level which include limited coordination of vaccine shipments and delivery support from multiple sources, a dynamic funding landscape with an imperfect common understanding of existing funding needs and gaps and limited visibility to total supply volume, as well of timing of supply, in countries.

2.7 COVAX Pillar's role in delivery going forward could be summarised across following key dimensions:

- **A greater emphasis on strengthening in-country deployment of vaccines in AMC countries** through guidance, technical assistance, advocacy support, operational coordination, and funding to establish delivery infrastructure, benefiting COVAX Facility and non-COVAX Facility procured doses as maintaining the distinction between the two can be difficult in practice.

- **A heightened effort to coordinate with other delivery funders to close the immediate and long-term delivery funding gaps. COVAX partners would** continue to closely monitor the funding landscape, assess country needs for delivery funding, and advocate for increased delivery funding**. COVAX** partners will continually **re-evaluate the need** for additional fundraising and if needed COVAX will continue to raise funding for delivery. COVAX will work with countries to allocate domestic funding for delivery.

- **A more operational posture with a more deliberate and systematic approach to coordinate with other partners supporting AMC countries** (e.g. the African Union). This could include 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, and promoting sharing of best practices and lessons learnt between countries.

2.8 **Beyond ensuring successful delivery of COVID-19 vaccines, in 2022, the Alliance will have a responsibility in ensuring it contributes to the broader immunisation agenda (e.g. Gavi 5.0 equity ambition, IA 2030, epidemic and pandemic preparedness).** At a minimum, the COVAX Pillar would need to focus on the principle of protecting routine immunisation programmes, to explore opportunities for integration and shine a light on missed communities (e.g. through prioritisation of marginalised populations, refugees and migrants and through the Humanitarian Buffer when governments are not able to cover those populations). Ultimately, the Alliance should play a role in supporting the integration of COVID-19 vaccination into routine immunisation programmes, ensuring processes, tools, guidelines, delivery innovations and lessons learned can be leveraged for the wider immunisation agenda, putting a deliberate focus on extending the reach of immunisation programmes to marginalised communities, a life course approach and strengthening the links between routine immunisation and pandemic preparedness.

2.9 We welcome any guidance from the Board on the initial thinking on Gavi's role in delivery as part of the COVAX Pillar Strategy for 2022 and beyond. An update will be presented to the Board in December 2021.

3. Further developments in the COVAX Facility

Update on Brokerage, Resell and Exchange

3.1 The exchange mechanism has been under discussion since late 2020. Given the evolving supply context, this mechanism has led to a series of discussions to best determine its potential contribution. More recently, through various fora, COVAX Participants have asked the COVAX Facility to investigate a series of cases, notably the possibility to resell doses from bilateral deals to other countries through the Facility (or to the Facility) or to "lend" doses to other countries through the Facility. A major theme has been the role of the COVAX partnership in fair and equitable access and fit with Gavi mission. The Facility has undergone extensive analysis on the implications and potential design for new mechanisms and broadly consulted COVAX partners, COVAX participants and manufacturers to outline the recommendations below.

3.2 **Brokerage refers to a potential new mechanism whereby countries with excess bilateral doses resell them to other countries through the COVAX Facility.** The Facility recognises that a bilateral secondary market for COVID-19 vaccines will emerge, and that lack of regulation may contribute to inequitable access. However, a brokerage mechanism implies significant consequences – legal burden (multipartite agreements between Seller, Buyer, Manufacturer, Gavi), potential financial liability, operational burden, with limited clarity and added value on the role for the COVAX Facility as a "broker" - and thus reputational risk. In its consultations with participants, the Facility did not receive a high level of interest in buying excess doses from HICs through a COVAX brokerage mechanism. Outreach to manufacturers highlighted significant administrative and transparency challenges for all parties. **In summary, the Facility has provisionally concluded that it will not lead in the set-up of a brokerage mechanism** but remains open to cooperate with other constructs to advocate for equitable access.

3.3 **Resell to the Facility refers to reselling of excess bilateral deals to the COVAX Facility.** This could allow for quick access to doses in the short-term as well as allocation of doses through the fair & equitable allocation framework while avoiding wastage. **The Facility is looking to engage with potentially interested countries in negotiations and according to the following principles**:

- All deals will be considered on a case-by-case basis. Major factors are type of vaccine, volume and availability
- Pricing would be informed by the COVAX Facility APA
- Further conditions might apply (e.g. bundling with donations, only doses still at the manufacturer, vaccines targeted for further procurement as part of the COVAX Facility portfolio strategy, not taking down-payments etc.)

3.4 **The exchange refers to the possibility for countries to exchange doses allocated through COVAX** (no money involved). The Facility understands that some countries would like to be able to defer doses to a later point and that while it ensures equity, the allocation mechanism does not always result in optimal preference matching. The Facility is also mindful of creating an operationally complex mechanism. **The Facility is evaluating alternative ways of incorporating the benefits of an exchange mechanism (intertemporal trades and improved preference matching) through light adjustments to and lean integration with the allocation process.**

3.5 **Separate to these mechanisms, and complementary to dose donations, the Facility is encouraging countries with excess doses available in the near term that they would still want access to longer term to consider queue swapping.** Countries which don't need their doses now (but potentially in the future) can allow the Facility to benefit from earlier production slots for a given product to enable the Facility to procure doses under its APA earlier. This proposal has the advantage of bringing doses earlier to the COVAX Facility, while preserving legal and operational simplicity – and that countries maintain access to doses at a point in time when they might need them.

Update on SFP 2.0: process and current advancements

3.6 **At its June 2021 meeting, the Board tasked the Facility with designing a future model for self-financing participants based on three principles: simplifying operations; mitigating financial risk to Gavi; and inclusivity.** The Facility has been developing the new model in line with these principles, informed by ongoing consultations with participants. The model will incorporate different elements for SFPs to choose to participate in, including sharing of best practice, access to mechanisms such as dose-sharing, and procurement of doses for those who need to continue to rely on the COVAX Facility.

3.7 The revised terms and conditions will **simplify operations** by moving the procurement element to a single model, where participants will have to actively opt in to the vaccine products they want to procure during a single decision window. Participants will be asked to give a non-binding indication of the number of doses they wish to procure; there will be no minimum or maximum. In response to feedback from self-financing participants that the use of a pooled procurement agent would add complexity for them, this requirement will not be mandatory.

3.8 **Financial risk** in the procurement element will be mitigated by participants being required to provide Gavi with a letter of credit or full payment of funds before an offering is finalised with the manufacturer. The financial model will be presented to the Audit and Finance Committee (AFC) at its September 2021 meeting to confirm it mitigates risk to Gavi.

3.9 The model will continue to focus on **inclusivity** by offering different ways for SFPs to continue to engage with the Facility even if an SFP is no longer procuring COVAX Facility doses. SFPs can choose to continue to

participate in meetings, briefings and workshops, and access existing and potential future mechanisms such as dose-sharing and reselling. There will be a subset of SFPs who will continue to need the COVAX Facility to procure doses as they have insufficient access through bilateral deals. By redefining participation to include not just SFPs who are procuring doses, participants will be able to show their solidarity to the Facility without having to commit to purchasing doses they do not need.

3.10 **The revised model simplifies operations, mitigates financial risk and retains inclusivity, in line with the Board's steer.** As a consequence of having a procurement model open to all, there is a chance that some SFPs who do not need the COVAX Facility to procure doses choose to continue to buy through the Facility, which would potentially take focus away from those who need us the most. However, not opening the model to all SFPs risks leaving SFPs in special situations behind as discussed by the Board in June 2021.

3.11 A workshop will be held with SFPs immediately following the 13 September 2021 AFC meeting to finalise the terms and conditions of the procurement element of the model. SFPs will be invited to sign agreements from late September. There will be no deadline for joining, although the sooner participants join, the more Supply Offerings they can take advantage of. The first supply offering is expected to be launched before the end of 2021 for supply in 2022. Existing governance arrangements will continue through 2021, while consultations on how to improve them take place; the Governance Committee will be updated in advance of the Gavi December Board meeting.

3.12 The launch of the revised model will signal a move from the first phase of a fully global procurement offer to a second, time-limited phase focusing procurement only on those SFPs most in need, while retaining the full scope of AMC-92. Once the COVID-19 vaccine market stabilises the Facility could enter a third phase where it offers procurement to AMC-92 countries only. The timing of this is subject a number of factors including the evolution of the pandemic, use of variants and boosters, and the manufacturing landscape. Moving to the second phase for 2022 is a key step in the measured transition back to Gavi's traditional scope.

3.13 Further updates on Allocation, Humanitarian Buffer and Contingency Provision are detailed in Annex B.

4. Topics for future Board meetings

4.1 In December 2021, the Facility plans to bring to the Board's attention topics relating to (1) the future of the COVAX Facility, including organisational and governance considerations and integration with Gavi's core mission and routine immunisation; these will be dependent on and conditional to the evolution of the pandemic; (2) Links to Gavi 5.0; (3) Updates on the COVAX Monitoring, Evaluation and Learning strategy (incl. Reporting against the COVAX reporting framework), Risk, RM strategy and country financing

arrangement, including co-financing. This list of topics could still change based on emerging priorities.

4.2 In 2022, it is expected that the pandemic will shift into a new phase, and thus the Board will be requested to continue to weigh in on the future of the COVAX Facility, as well as some topics beyond COVAX such as Gavi's role in epidemic and pandemic preparedness.

Section C: Actions requested of the Board

The Gavi Alliance Board is requested to **provide guidance** on the COVAX Facility's vision for 2022 and re-affirmed ambition as the global backbone in the COVID-19 vaccine response, seeking progressive integration with Gavi's core mission and routine immunisation.

The Gavi Alliance Board is also requested to **note** the continuing scientific uncertainty relating to the use of vaccines as to the duration of protection, need for booster doses and how best to deal with variants of concern, requiring flexibility in our approaches as more data is obtained.

Annexes

Annex A: Work-in-Progress COVAX pillar strategy

Annex B: Further updates: Allocation, Humanitarian Buffer and Contingency provision

Additional reference materials online

Latest COVAX Facility Supply Forecast (8 September 2021): online

WHO COVID-19 Global Vaccination Strategy (as of July 2021): online