

SUBJECT: COVAX UPDATE

Agenda item: 06

Category: For Decision

Section A: Summary

Context

Since the Board approved the Gavi Secretariat's role in administering the COVAX Facility, it has, in collaboration with partners in the COVAX Pillar, successfully delivered more than 80 million doses of COVID-19 vaccine to 129 participants¹ and efforts are underway to prepare for substantial increase in vaccine supply towards the latter part of this year. Further to the Secretariat's commitment to the Board one year ago, this update is intended to seek input on the programme's future direction, including on the core question of Gavi's role in the administration the COVAX Facility. Whilst acknowledging ongoing challenges such as continued supply constraints and global inequity in access to COVID-19 vaccines, it is timely to look towards the longer term evolution of COVAX, taking into consideration the parallel development of the WHO Global Vaccination Strategy, and discuss several urgent questions relevant to Gavi's continued engagement in the COVID-19 pandemic response.

Questions this paper addresses

This paper examines how the context and global goals have evolved since the COVAX Pillar and Facility were established and puts forward an updated value proposition for 2022, as well as addressing the following questions:

- Should Gavi continue to administer the COVAX Facility beyond 2021? Based on experience to date and the future outlook, what considerations should inform the renewed objective of the COVAX Facility?
- Looking at the question of participation beyond 2021, which of the options outlined would ensure access to COVID-19 vaccine for participants without alternative sources of secure supply whilst reducing operational complexity and financial risk for Gavi?
- How could Gavi's engagement in COVID-19 vaccines mitigate risks and contribute to achieving Gavi 5.0 goals and objectives going forward?
- How should delivery support be designed to ensure rapid, near term support for COVID-19 vaccine delivery while in the medium term also strengthening immunisation programmes for both delivery of COVID-19 vaccines and routine immunisation in line with Gavi 5.0?

¹ As of 7 June 2021

Conclusions

Despite COVAX's progress to-date, the sharp inequities in global COVID-19 vaccine access that have emerged only underscore the importance of Gavi's continued role in the pandemic response. The continued engagement of the COVAX Facility is necessary to course-correct and bring about a more equitable distribution of vaccines.

This paper reflects input received from the Programme and Policy Committee (PPC), Audi and Finance Committee (AFC), and consultations with partners, participants and other stakeholders. It is intended to address time-sensitive questions related to COVAX operations whilst discussing the future direction of Gavi's engagement in COVID-19 vaccines in 2022, and investigating contributions of Gavi's role in COVID-19 vaccine procurement and delivery to mitigating risk and furthering the strategic goals of Gavi 5.0 where possible.

During the critical months ahead, COVAX expects to deliver hundreds of millions of doses of COVID-19 vaccine globally, learning much more about the disease (variants, need for boosters etc.) and the use of vaccines in a variety of contexts to counter it. The Secretariat will continue to engage with the Board throughout and plans updates in September and December 2021 on the future direction of the COVAX Facility.

Section B: Gavi's engagement in COVID-19 to date and the broader context

- 1. Re-assessment of Gavi's role in administering the COVAX Facility**
 - 1.1 Since the COVAX Facility and Pillar were established in the first half of 2020, the global context and operating environment have shifted significantly.** Over 172 million cases and close to 4 million deaths attributed to COVID-19 have been reported globally, with countries experiencing very different levels of disease burden and associated health and socioeconomic impacts. Whilst the timelines for development of safe and effective vaccines against the ancestral strain has been unprecedented in terms of speed, the emergence of variants of concern poses scientific and programmatic challenges. Supply has ramped up significantly, but is still insufficient, over-reliant on a few manufacturers and highly sensitive to shifts in the external environment. While COVAX remains the only global mechanism to secure and deliver vaccines, the African Union (AU) has emerged as an important regional procurement mechanism and many countries in all income brackets have established bilateral deals. Looking forward to the prospect of increased supply in the latter half of 2021, in-country delivery is a topic of growing importance in light of challenges related to operational complexity and vaccine hesitancy. The COVAX Reporting Framework (Paragraph 1.8) provides further insights into how COVAX has fared to date against selected topline metrics.
 - 1.2 The COVAX pillar has been pivotal in bringing accelerated access to the 92 participants eligible to receive doses funded by the Gavi COVAX AMC** (the first COVAX shipments to Ghana and Côte d'Ivoire were within

80 days of the start of vaccination in High-Income Countries) and contributing to greater global equity of vaccine introductions. As of 6 June 2021, the Facility has secured deals for 2.155 billion doses in 2021 against the target of 2 billion. In response to countries' needs, the Facility has revised its initial plan to send 50% of supply to self-financing participants (SFPs) and 50% to AMC participants and now expects at least three quarters to go to AMC participants. To date, over 80 million doses from COVAX have been delivered to 129 participants of which 53 million doses have gone to 78 AMC participants. Globally, the COVAX pillar has contributed to streamlined processes and reduced barriers for countries to receive vaccines, through mechanisms such as the WHO global vaccine Emergency Use Listing (EUL) procedure, the no-fault compensation scheme and the introduction of a standard Indemnification & Liability agreement. **However, there are large – and growing – disparities in coverage which exemplify the major challenge facing COVAX today:** while many high-income countries have vaccinated on average 1/3 of their population, many lower-income countries still have coverage levels below 1%. **If sustained, these disparities will likely lead to divergent trajectories in health system, social and economic recovery between countries (and economies) based on access to vaccination, with profound global implications,** including for global health security. Thus, continued engagement of the COVAX Facility is needed in 2022 to minimise disparities.

- 1.3 In July 2020, the Gavi Alliance Board approved Gavi as the legal entity to administer the COVAX Facility and requested an assessment of the continued role of Gavi in administering the Facility by July 2021. This paper recommends that the Gavi Alliance Board **approves Gavi's continued role in the administration of the Facility**. Two major observations guide this recommendation: (1) there is a continued need for COVAX (both Pillar and Facility) in 2022 whilst much of the world works to end the acute phase of the pandemic and (2) there is accumulated know-how and experience of the Gavi Secretariat in running the COVAX Facility that would be extremely difficult to transfer.
- 1.4 **As the pandemic evolves, the WHO (with the Gavi Secretariat and other partners and stakeholders) is developing a Global COVID-19 Vaccination Strategy, aiming to define a disease goal and associated epidemiological, supply and demand scenarios** (Annex A). The goal will reflect both health and socio-economic considerations. The specific vaccination coverage targets needed are yet to be defined and will likely be tailored to country and population characteristics. While the WHO work is ongoing and will be presented to SAGE (Strategic Advisory Group of Experts on Immunization) in June 2021, indicative scenarios are provided to frame the potential parameters of COVAX's role in 2022:
 - In an upside case, there continues to be some global transmission of COVID-19 but existing measures, including vaccines, remain highly effective, including against Variants of Concern (VoCs)

- In a base case, there continues to be widespread global transmission of COVID-19, in part resulting from the emergence of new VoCs, but vaccines and technologies remain effective in preventing severe disease and death
- In a downside case, there continues to be widespread ongoing global transmission of COVID-19 driven by the emergence and widespread transmission of VoCs. Efficacy of existing measures varies and regular reformulation of vaccines and/or boosters may be required to maintain efficacy

1.5 When the COVAX pillar was established several assumptions were defined of which some (e.g. severe supply constraints in 2021) have materialised as anticipated while others have diverged, both positively (e.g. success rates of vaccine R&D) and negatively (e.g. emergence of variants of concern). Given the current environment in 2021 and upcoming expectations for 2022, **the different elements of the COVAX Pillar's role and objectives articulated in 2020 were updated to reflect experience to date and the forward view:**

- Shift from emphasis on portfolio diversity in the context of uncertain vaccine efficacy to an **actively managed portfolio of effective and scalable vaccines**
- Shift from pooling of demand, supply and resources to a **complementary procurement mechanism, pooling demand, supply, expertise and resources**
- An updated definition of **fair and equitable access** in the context of growing disparities (e.g., in coverage, risk & epidemiology, demand)
- An enhanced focus on delivery at scale as supply ramps up, towards **increased support and innovative solutions to in-country delivery**

1.6 In mid-2020, the COVAX Facility was set up with the objective of vaccinating populations at highest risk such as healthcare workers, people over 65 and populations with comorbidities; globally this population represents ~20% of total population. Although – as expected – supply has been severely restricted in the first half of 2021, current projections suggest that availability of doses for the COVAX Facility will ramp up significantly towards the end of 2021². The vaccines, to be delivered in 2021 and early 2022, will enable the COVAX Pillar to protect almost 30% of the population in 91 AMC economies. The broader context has however evolved. Many countries, as well as regional groupings, such as the AU, have stated coverage objectives well above 20-30%. New goals and aspirations, including coverage, will be informed by the WHO Global Vaccination Strategy and consideration of how best to use available resources (both vaccines and funding) for public health impact. In light of the scenarios outlined in paragraph 1.4, and pending

² Based on current supply projections

further information on likely duration of protection and the role of boosters, there is a need to define indicative goals and re-evaluate the required level of coverage to achieve these for planning purposes into 2022. **The COVAX Facility will continue to support countries' needs and ambitions to control the disease and lift socioeconomic restrictions, with supply from the COVAX Facility complemented by other sources (bilateral, multilateral, domestic).**

- 1.7 The Secretariat will continue to update and engage with the Board (at its meetings in September and December 2021) and with relevant committees on the development of the forward-looking strategy.
- **A re-evaluated goal for the COVAX Facility based on supply, funding and demand considerations will be proposed in September** which will be based upon the expected WHO guidance. The Secretariat also plans to provide greater visibility into technical elements of the COVAX mechanism (such as allocation, delivery and supply).
 - **Further considerations on the future of the COVAX Facility will be brought to the Board in December 2021.** In line with initial thinking when establishing the COVAX Facility, several options for its integration are to be explored. The Board will continue to be engaged on Gavi's role in pandemic preparedness and global health security.
 - Critical inputs in considering the future of the Facility are notably the WHO Global COVID-19 Vaccination Strategy (which will provide an indication of the goals and types of vaccine programmes, and the implications for the required resources and the portfolio); decisions taken by the Board now and the outcome of further engagement with participants (providing greater visibility into the participation scope and model) and the unfolding pandemic evolution (notably implications of variants and the need for boosters/routine vaccinations).
- 1.8 **This paper focuses on a subset of urgent topics, including scope and model of country participation, opportunities for contributing to Gavi 5.0 and COVID-19 Delivery and Systems Strengthening (CDSS) (as discussed at the PPC in May 2021 and revised to incorporate feedback provided by the PPC) as well as an update on the COVAX Resource Mobilisation strategy.** In addition, this paper describes **the implementation of a holistic monitoring, evaluation and learning (MEL) linked to the COVAX Facility and COVAX Advance Market Commitment (AMC), including a COVAX Reporting Framework with actuals against topline metrics reported for the first time (see Annex B).** The COVAX MEL, as well as the COVAX Reporting Framework will continue to adapt as both the pandemic and the COVAX pillar's vision and goals evolve. Finally, this paper shares **an updated COVAX risk report** describing the most critical risks that could potentially have an impact on the ability of the COVAX Facility to achieve its mission and goals (see Annex C).

2. Country participation model

- 2.1 In 2020 the Board approved the establishment of **two separate and independent sources of funding for the Facility: COVAX AMC and self-financing participants (SFPs)**. SFPs had the opportunity to choose between two models: the Committed Purchase and Optional Purchase arrangements.
- 2.2 At its informal April 2021 meeting, **the Board suggested that these models should be reviewed focusing on addressing the needs of those countries requiring support from the COVAX Facility in 2022 to meet vaccination coverage goals**. This proposition has been reinforced through extensive consultation with SFPs, partners and key stakeholders, including the multilateral development banks. Participant feedback shows demand for continued engagement with the Facility, including in managing uncertainties related to variants of concern and the potential need for boosters. Feedback has also highlighted a need to simplify the current operational model and to reduce the financial risk to Gavi presented by this model. Further detail can be found in Annex D.
- 2.3 After fulfilling the current obligations and informed by the considerations outlined in paragraph 2.2, the offer to SFPs will be for future doses on top of their current 2021 requirements. The PPC was presented with three options for a country participation model for 2022 (after fulfilling the current commitments to SFPs): **Option 1)** would retain the **Status Quo** of AMC-92 and SFPs using the current model, with its operational complexity and financial risk. SFPs would procure future doses under the same model they are currently using; **Option 2)** would focus on AMC-92 countries whilst offering all SFPs the opportunity to rejoin to procure future doses under revised terms. This **AMC+** model would simplify operations and mitigate Gavi's financial risks. Participants themselves would define their need and all SFPs would be welcome to join if they wished to procure vaccines under the new revised terms and conditions. **Option 3)** would engage with **AMC-92 countries only**, thereby excluding SFPs from procuring future doses through the Facility. This would potentially leave some countries who struggle to source supply through bilateral deals without access to vaccines and would represent a sudden change in scope that countries may not be prepared for.
- 2.4 In the current phase of the COVAX Facility's operations, Gavi has implemented a fully global solution with 192 confirmed and/or eligible participants and donors. If it is decided to move forward with Option 2, the COVAX Facility would transition into a time-limited second phase retaining the full scope of the AMC-92 whilst likely seeing a reduction in the number of SFPs procuring vaccine via the Facility given the focus on those most in need and the revised terms. Once the COVID-19 vaccine market stabilises (e.g. end of 2022), the Facility could subsequently enter a third phase where it supports AMC-92 participants only. This three-phase approach represents **a measured transition back to Gavi's traditional scope, in line with routine Gavi programmes and Gavi 5.0**.

- 2.5 Consultations with multilateral development banks highlighted that it would be extremely difficult to define eligibility criteria to restrict access to only those SFPs in need of COVAX support. Therefore, **the proposal under Option 2) is instead to offer all SFPs the opportunity to procure vaccine through the COVAX Facility in 2022 but under revised terms and conditions and a new Commitment Agreement.** The goal of these revisions would be to simplify operations, minimise financial risk to Gavi, and design terms suitable to those SFPs most in need. Emerging thinking is that this could be achieved through a single model with one window to opt into deals, and by streamlining the contracting process through the mandatory use of a pooled procurement agency (e.g. UNICEF Supply Division or PAHO Revolving Fund). Financial risk to Gavi would be minimised by introducing a new payment structure: on opting into a product, participants would need to transfer the full payment for their doses into escrow or similar assurance from a reputable development or commercial bank prior to Gavi entering Advance Purchase Agreements. This proposal was presented to the AFC and our financial advisors who indicated support for the proposal and suggested comfort with the level of financial risk. Upon Board approval of one of the options, the Facility would convert the principles into the new Commitment Agreement.
- 2.6 The **PPC recommended that the Board consider Option 2 for the future participation model for Self-Financing Participants (SFPs) and the proposal to unify terms and conditions** as set out in Annex E subject to additional information including risk considerations requested by the PPC being made available to the Board and subject to the analysis of the three models as reviewed by the AFC.
- 2.7 The PPC requested further information on the risk considerations of the three proposed models. The analysis, which can be found in Annex D, considered the financial, reputational, operational, governance and pandemic response risks. Introducing the AMC-92 only model would lower the financial, operational and governance risks in comparison to the status quo. However, it would increase Gavi's reputational risk by moving away from a global equity-based approach and increase the pandemic response risk by excluding some participants that may need the COVAX Facility's support. The AMC-92+ model would have a higher operational and governance risk than AMC-92 only (medium vs low) and the same low financial risk given the adjustments in the model. However, it would have a lower reputational and pandemic response risk as it would allow countries to self-select their participation and would include those that rely on COVAX as their primary source of vaccines. **This analysis indicates that the AMC-92+ model tends to mitigate the most risks of the three models.** The PPC also requested that the Secretariat more thoroughly examine whether the three proposed options would have any positive or negative impact on AMC participants. The assessment, also to be found in Annex D, looked at supply, speed of deal-making process and manufacturer's vaccine pricing structure. While an AMC-92 only model would simplify and potentially speed up the deal making process in comparison to the status quo and AMC-92+ models, there is unlikely to be any advantage or disadvantage to moving to

either AMC-92 only or AMC-92+ in terms of pricing structure due to different manufacturers preferences. The ongoing risk of global supply constraints mean that there is no difference between the three models in terms of impact on supply. **In the absence of a clear-cut superior option, the decision hinges on the trade-off between greater inclusivity due to ongoing need and a greater focus on the smaller set of AMC countries.**

- 2.8 Under the current model there are some participants who have opted out of all offers. It is anticipated that there will be many SFPs who will decide they do not need or want to procure doses through the Facility in 2022. At this moment, it is difficult to predict the precise demand but different scenarios analysed showed that it could be up to half of the current number of participants (See Appendix 1). COVAX will also continue to offer **other ways for SFPs who choose not to join as procuring participants to engage with the Facility including through dose sharing, sharing of best practice and information and collaboration on current and future pandemic preparedness and response.**
- 2.9 This paper outlines the rationale for, and implications of, adopting an AMC-92+ model. Based on lessons learned from 2021, a timely decision on the country participation is critical in order to secure deals for 2022 supply. The Board is requested to **consider** Option 2 for the future participation model for Self-Financing Participants (SFPs) and the proposal to unify terms and conditions as set out in Annex E.

3. COVAX and Gavi 5.0 – opportunities and risks

- 3.1 **Equity is the organising principle across both the COVAX Facility and Gavi's core mission of leaving no one behind with immunisation.** Whilst Gavi's engagement in the COVAX Pillar has built on its decades long experience in ensuring access to vaccines, its role in COVID-19 vaccines and the new capabilities that it has developed through COVAX could **provide distinct, potential opportunities to accelerate Gavi 5.0 goals and objectives.** At the same time, there is a **high risk that the focus and capacity diverted to delivery of COVID-19 vaccines (across countries but also partners and Secretariat) will divert attention, slow progress on Gavi 5.0 and impact routine immunisation (RI)** as the delivery of doses rapidly scales up in 2021 and throughout 2022. It is a reality that COVID-19 vaccines will need to be delivered, with or without a future role of Gavi. Hence, the risks will persist regardless of Gavi's engagement and need to be mitigated as much as possible.
- 3.2 **The Alliance has identified several opportunities how COVAX could contribute to Gavi 5.0 goals and objectives** both near-term (2021) and in the medium term (i.e. ~2022 onwards, depending on the evolution of the pandemic):

- The evolution of the COVAX strategies and the potential expansion of priority populations could provide opportunities to **increase focus on the needs of missed communities in the medium term and to strengthen routine immunisation systems**. To deliver COVID vaccines, countries will need strong supply chains, service delivery and community engagement. If COVID-19 vaccines were delivered building on existing immunisation systems in the medium term (e.g. cold chain/logistics, fixed sites), delivery support could serve the dual purpose of strengthening immunisation systems for all routine vaccines. This could be achieved, for example, through scaling up innovations that would both benefit COVID-19 vaccines and RI with a focus on underserved areas, further catalysing the Gavi 5.0 innovation agenda (e.g. Electronic Logistics Management Information Systems (eLMIS) technologies, digital health interventions such as geographic information systems (GIS) to identify and track target populations, management tools such as digital microplanning, new social mobilisation approaches). Countries are also building the capacity to deliver vaccines to adult populations (e.g. by developing microplans to identify these populations, and developing new service delivery strategies to reach them), which can also provide the basis for a life-course immunisation approach to deliver adult vaccines expected in the coming years. In addition, the COVAX Humanitarian Buffer which offers dedicated vaccines and operational support to vulnerable and underserved populations in fragile settings, could potentially play a role in identifying other immunisation needs of these marginalised communities in the short term.
- The proposed **new COVID-19 Delivery and System Strengthening funding envelope (CDSS, see section 4) is being designed with the dual purpose** to ensure **rapid roll-out and scale up of COVAX-funded doses over the next two years, hence contributing to mitigation of risks to Gavi 5.0 and RI** where possible, and **to help countries take these opportunities to use COVID-19 vaccine delivery to strengthen their RI programmes** in the medium term. Joined-up Alliance support to countries for both delivery of COVID-19 vaccines and the Gavi 5.0 mission will be an opportunity to ensure that such opportunities are identified and leveraged on the ground, and risks to delivering on Gavi 5.0 and RI are mitigated where possible. Moreover, the COVID-19 pandemic has also highlighted the importance of equitable access to vaccines and provides an opportunity to galvanise longer term financial support to Gavi's equity agenda and coalesce efforts to counter vaccine hesitancy.

- **COVID-19 vaccine planning and delivery would also provide an opportunity to strengthen access to primary health care (PHC)** for missed populations and communities in the medium-longer term, including through COVID-19 vaccine outreach and campaigns co-delivering other PHC interventions. The PPC underlined the **collective responsibility of Alliance Partners to integrate with other vaccines and PHC interventions and avoid the creation of another vertical disease programme.**
 - Furthermore, it was noted that new opportunities to **expand on the development and use of new models for market shaping, global procurement and vaccine product innovations** should be explored. These would complement the Gavi 5.0 Market Shaping goal and could also benefit former and never Gavi-eligible countries with the aim of expanding access to vaccines as a global public good in line with Gavi's MIC strategy.
- 3.3 During the design phase of Gavi 5.0, the Board discussed **Gavi's role in Global Health security (GHS) going forward**, and advised that Gavi focus on ensuring access to vaccines for the prevention and control of vaccine-preventable (VPD) diseases (incl. those with epidemic potential), and consider limited support for specific areas within VPD surveillance. The COVID-19 pandemic has refocused attention on pandemic preparedness and response. As the global agenda for Global Health Security is reviewed and redefined, the PPC noted the importance of further defining Gavi's comparative advantage and role in pandemic preparedness, including reflections on its engagement in ACT-A and the COVAX Facility and Pillar.
- 3.4 **The delivery of COVID-19 vaccines also poses significant risks to Gavi's 5.0 mission, such as maintaining, restoring and strengthening immunisation services and reaching zero-dose children and missed communities**, particularly through the diversion of resources away from RI towards COVID-19 vaccine delivery at country level and the potential increase in vaccine hesitancy. This diversion is most acute at country level but also affects partners and Secretariat. Higher coverage ambitions for COVID-19 vaccines may amplify these risks. The PPC noted that if deployed carefully and deliberately the timely provision of dedicated delivery support (through CDSS for example) can help in mitigating these risks by providing resources needed for COVID-19 vaccine delivery, while also providing the opportunity to reinforce Gavi 5.0 goals and objectives in the medium term where possible.
- 4. Strategic, programmatic and policy considerations: Gavi's role in COVID-19 vaccine delivery**
- 4.1 **Gavi's support to COVID-19 vaccine delivery has so far been focused on providing a US\$ 150 million envelope for Technical Assistance (TA) and Cold Chain Equipment (CCE) support to countries³.** In recognition of the significant resources available from World Bank and other multilateral

³ Approved by Board in September 2020 (redirection of Gavi core funds to COVAX)

development banks and donors for vaccine delivery, Gavi/COVAX had previously planned to provide additional support for delivery only in exceptional circumstances. However, since then, there has been growing concern from countries, donors, and partners on the lack of delivery support in the near and medium term. As of 4 June 2021, only 25 countries had approved World Bank projects for COVID-19 vaccines and only 20% of the World Bank funding for these countries was allocated to delivery. To help mitigate the risk of inadequate delivery resources, Gavi has **mobilised US\$ 775 million for this purpose**. The total funding needs remain unclear due both to many countries having weak budgets for the National Development and Vaccination Plans and the complex donor landscape and the Alliance will continue to monitor the financing situation and may seek to mobilise additional resources if these are required.

4.2 **The Alliance, in collaboration with other key funders, has designed an approach to supporting COVID-19 vaccine delivery with two key components (see Figure 1 below):**

- a) **An integrated COVID-19 Delivery & System Strengthening (CDSS) funding envelope (~US\$ 650 million).**
- b) **An envelope for cross-cutting delivery elements (~US\$ 125 million).**

Figure 1

PRELIMINARY		
New COVAX delivery funding will be divided across: A) CDSS funding envelope B) cross-country delivery elements		
Delivery funding	Indicative funding amount	Notes
A. COVID-19 Delivery & System strengthening (CDSS) funding envelope	~\$650M	Includes bridge funding of \$20-30M to support near term needs until full envelope launch in June Upon Board approval, will focus on addressing countries' TA and CCE needs and provide support broader delivery and systems strengthening with a recommended minimum amount for scaling innovations . US \$50m reserves retained to cater for unforeseen delivery needs arising at later stages. If Board approves PPC recommendation, countries could receive up to 30% of their ceilings already from July
B. Envelope for cross-country delivery elements	~\$125M	Includes USD \$125M funding for global investments including: support for delivery of humanitarian buffer doses (US\$ 7.5m for 2021), risk mitigation for both COVAX doses and delivery support, regional/ global TA and global innovation investments.
Total	~\$775M	1

4.3 **COVID-19 Delivery & System strengthening (CDSS) funding envelope:**
The primary and immediate objective would be to ensure successful rapid roll-out and scale up of COVAX-funded doses over the next two years by making funding rapidly available to countries for delivery. A secondary and more medium-term objective will be to strengthen health systems and immunisation programmes for both longer term delivery of COVID-19 vaccines and routine immunisation, contributing to Gavi 5.0 goals and objectives (see section 3). Based on the December 2020 Board decision to provide exceptional delivery support to countries with no other immediate source of funding, the Alliance has already started to make exceptional

'bridge' funding available for near term delivery funding gaps for COVAX doses already delivered in countries⁴. To date, bridge funding has been provided to 10 countries with another 13 applications in the pipeline. The bridge funding will be deducted from the CDSS allocation of each country once the CDSS is approved by the Board. Eligible countries will have until the end of 2021 to apply for CDSS funding and will be able to programme funds through to 2023 (though most will be expected to frontload funding).

- 4.4 **Several key principles guide the CDSS** including equality in access across AMC economies, a needs-based approach and focus on rapidly mitigating delivery risks and idle doses; CDSS funding should be complementary to other donor support and contribute to Gavi 5.0 goals in the medium term; it should incentivise innovative strategies and expanded partnerships where possible; and it should be aligned to other Gavi support processes to minimise transaction costs for countries.
- 4.5 **All AMC92 economies would be eligible for CDSS.** To balance the principles of a needs-based approach and equality in access, country ceilings would be determined based on an adapted Gavi HSS allocation formula⁵ and be validated and adjusted through an assessment of country needs and gaps with Alliance partners. The Secretariat recommends introducing an indicative cap of US\$ 50 million per country, including for India, to avoid disproportionate allocations to the largest countries and building in indicative funding "floors" of US\$ 2 million and US\$ 0.5 million for Gavi-57 and AMC35 respectively (the significantly lower floor for AMC35 countries recognises that several have very small populations), to factor in higher fixed and delivery costs in smaller nations. **Gavi will ensure close alignment and complementarity of CDSS support with other donors, multilateral development banks and agencies.** For example, at global level Gavi is part of the Global Fund to Fight AIDS, Tuberculosis and Malaria's CTAG advisory group⁶ that provides input into funding requests for their COVID-19 response mechanism. At country level, Gavi Senior Country Managers closely coordinate with the World Bank, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and others to ensure alignment.
- 4.6 The Secretariat will introduce **a short, single, and integrated application across all types of CDSS support** and regularly convene the Independent

⁴ Based on the Board Decision from December 2020 on exceptional support; An additional US\$ 150 million 'exceptional funding' envelope was also approved by the Board in December 2020 (subject to fundraising) to cover critical funding gaps that cannot be funded from other sources.

⁵ Adjusted HSS allocation formula provides equal weightage to four criteria: COVAX target population, GNI per capita, DTP3 and DTP1 coverage. Additionally, Gavi-57 countries received higher proportion of funds, due to a 50% "weightage" factor as compared to AMC-35. To ensure countries receive a minimally viable envelope for programming, the formula also includes funding floors, set at US\$ 2 million for Gavi-57 and US\$ 500,000 for AMC-35. AMC-35 floors were set lower given many of these countries are small island populations, and a US\$ 2 million floor would result in significantly higher per capita support versus more populous countries.

⁶ Technical advisory group composed of relevant ACT-Accelerator (Act-A) partners with technical COVID-19 expertise

Review Committee (IRC) review⁷ to allow rapid review of proposals. **The PPC recommended that the Board approve the proposed design of the CDSS funding and that the Secretariat prioritise meeting urgent country needs** over longer term investments. Given the urgency of country needs, it also **recommended that the Board delegate to the Secretariat the authority to allot and disburse up to 30% of CDSS funds** rapidly to scale-up delivery of COVID-19 vaccines without requiring independent review for rapid disbursement. The PPC acknowledged the higher risk of this approach yet considered it was required given the emergency context and urgent country needs. **If approved by the Board and agreed with the relevant donors, countries will be able to access up to 30% of their ceilings already from July while they prepare their application for remaining CDSS support.**

5. Gavi COVAX AMC Resource Mobilisation update

- 5.1 The Gavi COVAX Advance Market Commitment (AMC) has one central goal: to get effective, safe COVID-19 vaccines to lower income countries regardless of wealth on the same urgent timeline. It was established as an innovative finance mechanism to frontload financing of procurement of vaccines, investing early in a broad portfolio of vaccine candidates, mitigating the risk of vaccine failure, and creating extra manufacturing capacity for the benefit of lower income countries.
- 5.2 The AMC's first phase began at the 4 June 2020 Summit, where US\$ 500 million in funding was pledged towards the (then) goal of securing at least one billion doses of vaccines by the end of 2021. By the end of 2020, US\$ 2.4 billion had been pledged towards the AMC against a target of US\$ 2 billion. At its December 2020 meeting, the Board reviewed three scenarios for the AMC, with a range of prices and doses. In the light of Board and donor feedback, in the AMC's second phase a new target was set for at least US\$ 7 billion in pledges to secure 1.3 billion doses by the end of 2021.
- 5.3 By the G7 Summit in February 2021, US\$ 6.7 billion had been pledged to the AMC. At its March 2021 meeting the Board was updated on funding for the AMC, and a revised target of US\$ 8.3 billion in donor funds, with an additional US\$ 1 billion in cost sharing supported by multilateral development banks (MDBs) was presented to the Board. The AMC's third phase started on 15 April 2021, when the US Secretary of State and Gavi hosted the launch of an Investment Opportunity for an additional US\$ 2 billion funds to reach the target of US\$ 8.3 billion, to lock in 1.8 billion doses.
- 5.4 The third phase concluded on 2 June 2021 when the Prime Minister of Japan and Gavi hosted the COVAX AMC One World Protected Summit, bringing together world leaders to rally support and commit funding to secure vaccines for AMC countries. The Summit concluded successfully with US\$ 2.4 billion pledged against the target of US\$ 2 billion, bringing the

⁷ Process will look like that employed for COVAX-CCE reviews with reviews happening every ~3 weeks.

total pledges for the AMC to date of US\$ 9.6 billion of donor and private sector funds. These pledges allow Gavi to lock in 1.8 billion doses for delivery in 2021 and early 2022. In addition, US\$ 775 million has been pledged for delivery funding.

- 5.5 These collective efforts have achieved an unprecedented level of funding for global immunisation, allowing commitments to be made for doses for lower income countries. At the same time, lessons have been drawn as to how the AMC can be more effective. First, as the AMC has developed, the rate of conversion of pledges to signed agreements to funds received has limited Gavi's capacity to progress agreements in principle with manufacturers to legally binding agreements. Secondly, in early phases of the AMC, there was a strong focus on negotiating low prices and minimising upfront payments to manufacturers to reduce risk, alongside early access, while other purchasers did not have this multiplicity of objectives. Gavi's vaccine portfolio strategy has been adapted in recognition of these points.
- 5.6 Gavi's financing strategy has benefitted from the International Finance Facility for Immunisation (IFFIm), which has allowed the frontloading of investment to secure doses, as well as a European Investment Bank (EIB) guarantee which allows frontloading of €440 million. Gavi has also started a cost sharing process which allows lower income countries to procure safe and effective vaccines through COVAX. 56 AMC countries have so far indicated that they would like to participate. In parallel, Gavi has engaged in discussions with the Multilateral Development Banks (MDBs) regarding the commitment of financing to COVAX for cost sharing by countries. The EIB announced a new €300 million facility on 2 June 2021 which would provide support to countries participating in cost sharing, and discussions continue at the highest levels with the World Bank, Asian Development Bank, Inter-American Development Bank and others. Innovative finance has been vital for the AMC and needs to go further and faster to manage risk and lock in doses in the next phase.
- 5.7 The Global COVID-19 Vaccination Strategy set out in paragraph 1.4 provides the context for the AMC's next phase. It is clear that all Gavi's stakeholders expect the pace of delivery of doses to countries to step up, at the same time as the existing funds are deployed to the full to lock in doses for the rest of 2021 and early 2022. Based upon the emerging Vaccination Strategy up to Q3 2021, Gavi will explore and consult on scenarios around the various potential sources of funds: donor funds, domestic resource mobilisation, private capital, and new financing structures. New agreements with MDBs will be central to these scenarios.
- 5.8 As a supplement to doses secured through agreements with manufacturers, Gavi has established a mechanism for countries with surplus doses to donate them, with a focus on AMC countries. By this point, commitments have been made to donate almost 200 million doses primarily through COVAX. Countries with surplus doses are encouraged to donate doses as soon as possible, for delivery as soon as possible, to help address COVAX's short term supply challenges due to the surge in India and the retention of

doses for domestic use and in particular in the short term to complete full courses in countries where first doses have been administered and where there is insufficient visibility on timing of supply to administer second doses.

Section C: Actions requested of the Board

The Gavi Alliance Board is **requested** to:

Approve the continued administration of the COVAX Facility by Gavi in 2022.

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

- a) That it **consider** Option 2 for the future participation model for Self-Financing Participants (SFPs) and the proposal to unify terms and conditions as set out in Annex E to Doc 06 subject to additional information including risk considerations requested by the Programme and Policy Committee being made available to the Board and subject to the analysis of the three models as recommended by the Audit and Finance Committee;
- b) That it **approve** the design of the COVID-19 Delivery and System Strengthening (CDSS) envelope and cross-cutting delivery elements as set out in Annex F to Doc 06 and associated funding of US\$ 775 million pending confirmation of availability of funding by the Gavi Alliance Audit and Finance Committee (AFC); and
- c) Recognising the emergency context, that it **delegate** to the Secretariat, with support from partners WHO and UNICEF, the authority to allot and disburse up to 30% of COVID-19 Delivery and System Strengthening (CDSS) funds to scale-up delivery of COVID-19 vaccines without requiring independent review for rapid disbursement and utilising existing programmatic and fiduciary risk mitigation mechanisms such as those used in emergency and humanitarian contexts on a no regrets basis.

The Gavi Alliance Board is requested to **provide guidance** on:

- a) Gavi's engagement in COVID-19 vaccines and its role in reducing risks and contributing to Gavi 5.0 goals and objectives where possible; and
- b) Gavi's future engagement in COVID-19 vaccines.

Annexes

Annex A: WHO Global Vaccination Strategy work on goals and scenarios

Annex B: COVAX reporting framework

Annex C: COVAX risk report

Annex D: COVAX Country Participation Model: Risk Considerations

Annex E: Participation model options

Annex F: Design of the CDSS envelope and cross-cutting delivery elements

Additional information available on BoardEffect

Appendix 1: COVAX Country Participation Model: Analysis on the various demand scenarios

Appendix 2: COVAX Reporting Framework indicator definition sheets