SUBJECT:	**COVAX: KEY STRATEGIC ISSUES**
Agenda item:	05
Category:	For Decision

Section A: Executive Summary

Context

In less than two years since the creation of COVAX and the Access to COVID-19 Tools Accelerator, COVAX has now delivered over 1.5 billion COVID-19 vaccine doses to 145 economies, including over 1.3 billion doses to Advance Market Commitment (AMC) economies, contributing significantly to coverage rates achieved in AMC countries: 54% with at least one dose and 46% fully vaccinated as of 24 May 2022, though overall coverage between, and within, countries remains uneven as does coverage of high risk populations. Despite a challenging supply situation in 2021, successful fundraising to the COVAX AMC, advance purchase agreements (APAs) with multiple manufacturers, and generous dose donations have ensured that COVAX has adequate supply to meet participants' vaccine demand going forward. As we look to the future, Gavi will begin planning for integration of COVAX, both operationally into the Gavi Secretariat and programmatically as part of the Gavi 5.1 strategy (see Doc 03). We will need to ensure adequate capacity as well as talent to ensure we can continue delivery on the new integrated mission of Gavi 5.0 and COVAX as we continue to monitor and adapt to an evolving environment.

This paper comprises three sections: 1) the current status of COVAX Facility operations; 2) COVAX Facility role and ambition in vaccine procurement and delivery in 2023, including integration of COVAX Facility operations and activities into core Gavi Secretariat and programming as part of Gavi 5.1; and 3) COVAX Facility vaccine policies. This paper builds on previous Board and Committee discussions and presents decisions for the Board to approve of Gavi's continued administration of the COVAX Facility, flexibility to develop new or revised Gavi COVAX AMC positions aligned with SAGE (Strategic Advisory Group of Experts on Immunization) guidance, such as on paediatrics and boosters, and support for the continued limited provision of paediatric doses.

Questions this paper addresses

Part I: Current Status of Operations

- What progress has Gavi made supporting AMC participants achieve their COVID-19 vaccination goals?

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

- What is the latest supply update, and what role is the COVAX Facility playing in ensuring appropriate supply is in place to meet the different pandemic scenarios?

Part II: Looking forward to COVAX's role and ambition in vaccine procurement and delivery into 2023

- How might COVID-19 evolution affect potential integration of the COVAX Facility operations and activities into core Gavi Secretariat and programming as part of Gavi 5.1? What overarching assumptions and lenses should Gavi consider in developing Gavi 5.1?

Part III: Gavi COVAX AMC Vaccine Policies

- To what extent should the COVAX Facility have the flexibility to revise or develop new policies as WHO/SAGE recommendations evolve?

- In view of recent SAGE recommendations and updated priority roadmap, should the COVAX Facility pursue a position on paediatric vaccines, and if so, how should it be designed?

Conclusions

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 continue sharpening its focus in 2022 to support AMC participants' vaccine ambitions and accelerate progress in delivery with renewed attention to reaching the highest risk populations, while considering the longer-term implications and structure of an integrated COVID-19 vaccine programme as part of Gavi 5.1. The vaccine portfolio strategy will prioritise a flexible and adaptive approach, supporting countries' evolving vaccine needs through rolling demand planning and flexibility to adapt to changing epidemiology and policy guidance in the coming year, such as new variants, guidance for boosters, and the introduction of paediatric vaccines.

Section B: Content

1. Context

1.1 This paper provides an update on Gavi's role in COVID-19 vaccination, outlines the ambition for vaccine procurement and delivery for the remainder of 2022 and considers options for the evolution of the COVAX Facility and related activities going into 2023 and for the future.

Part I: Current Status of Operations

The Gavi Alliance Board is asked to:

- Provide guidance on the future evolution of the objectives and scope of Gavi's COVID-19 vaccine delivery and funding, building upon Programme and Policy Committee (PPC) alignment and feedback.

1.2 COVID-19 Vaccine Delivery

1.2.1 This section provides an overview of the current context of COVID-19 delivery efforts, the Alliance's delivery support, countries' achievements and challenges thus far, and how it is proposed to evolve to best support countries going forward recognising continued uncertainty in the trajectory of the pandemic. **The Board is asked to provide guidance on the future evolution of the objectives and scope of Gavi's COVID-19 vaccine delivery and funding following PPC guidance.**

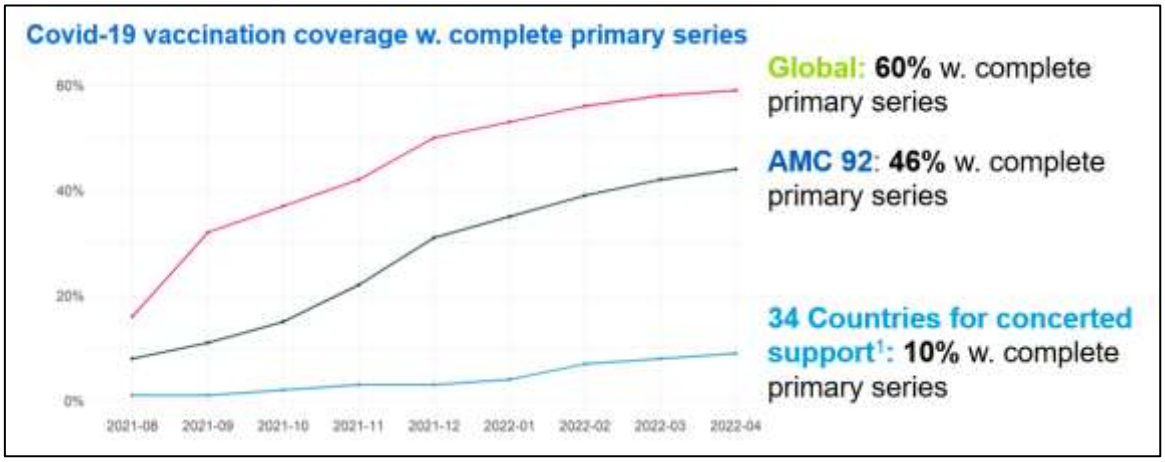
1.2.2 **AMC participants have made significant progress in vaccine delivery efforts, enabled by increasingly consistent and predictable vaccine supply provided through COVAX and other sources, and intensified support to countries for uptake activities.** As of May 2022, AMC participants have reached 54% coverage with a first dose and 46% fully vaccinated (with two doses if a two-dose vaccine)[1]. Despite the significant challenges that COVAX and countries have faced, the size and speed of the scale-up has been unprecedented. AMC participants have administered 4.0 billion doses of COVID-19 vaccines and reached over 2.1 billion individuals[2]. To put this into historical perspective, Gavi routine programmes reached 888 million total unique children from 2000-2020[3] and delivered more than 1.19 billion vaccinations through campaigns, although it should be noted that COVID-19 support is extended to a larger number of countries, the context is very different from Gavi's routine immunisation (RI) programmes, targets different groups, and has different needs and modes of delivery.

1.2.3 **However, the increase in coverage and absorption has been uneven between AMC participants.** Despite global advances, progress has lagged in low-income [4] countries - currently only at 14% fully vaccinated. Geographically, the African[5] region also continues to fall behind with just 14% fully vaccinated compared to 58% for AMC participants in the rest of world. The Alliance together with other partners have coalesced around 34

[1] Full vaccination equates to complete primary series. AMC coverage with complete primary series, excluding India is 37%
[2] On average from 2017-2019, AMC 92 countries administered around 1.3 billion doses of vaccines per year across RI and campaigns.
[3] Analysis of Gavi routine programmes in 2021 (excluding campaigns such as polio, yellow fever, measles, etc)
[4] All of whom are AMC participants
[5] WHO AFRO Region, which includes most but not all African continent countries. Not all AFRO countries are AMC. Including non-AMC countries, African Region at 15% primary series coverage. https://www.afro.who.int/countries

countries[6] with the biggest needs for concerted support coordinated by the recently formed COVID-19 Vaccine Delivery Partnership (CoVDP; see Section 1.2.8).

Figure 1: COVID-19 Coverage: Global vs. AMC92 vs 34 Participants for Concerted Support



1.2.4 In February 2022, 28 AMC participants reported 2022 national coverage targets below the global 70% target. Many have further highlighted growing risk of shortfall or delay in reaching even national targets including many countries expecting delivery efforts to continue into 2023. From an overall peak in December 2021, absorption is trending downward in a majority of AMC participants with 49 countries reporting decreasing absorption rates in May 2022. While it is normal to see varying levels of absorption rates as countries roll out campaigns at different times, and this is expected in many countries reaching higher coverage levels, it also reflects other constraints. These include:

- Declining risk perception for COVID-19
- Continued limitations on funding and human resources amidst economic challenges such as increased debt, inflation, and rising food costs[7] - further exacerbated by the crisis in Ukraine
- Countries' needs to catch up on essential health services underserved over the past two years

1.2.5 These drivers are combining to create a challenging environment for COVID-19 vaccination in many AMC participants. **Coordinated support and funding from Gavi, the CoVDP, other development partners continues to be critical in the second half of 2022 and into 2023 as requested by countries.**

1.2.6 **Prioritised vaccination of highest-risk populations (older adults, health care workers, and immuno-compromised) requires renewed**

[6] These 34 countries each had <10% fully vaccinated coverage as of Jan 2022

[7] For example: World Food Programme (WFP) food procurement costs up 30% since 2019, shipping costs also up amidst global inflation, food shortages, and supply chain issues. https://www.wfp.org/stories/wfp-glance

and sustained focus, and COVAX is emphasising this focus as it supports countries in achieving national coverage targets. WHO's Strategic Advisory Group of Experts on Immunization (SAGE) has called for prioritisation of high coverage for highest- and high-risk [8] populations to achieve the greatest effect on prevention of morbidity and mortality. This prioritisation was also reinforced by the Gavi Board at its April 2022 retreat. The COVAX Reporting Framework included in Annex C reflects our aspirational target of 100% coverage across both health care workers and older age population in AMC participants by end 2022. Immunosuppressed populations are also high risk but currently there are no estimates of coverage in these groups, something which we are trying to rectify.

1.2.7 Most high-income countries have already protected at least 90% of their older adults[9]. Yet, based on limited indicator data, primary series coverage across reporting AMC participants[10] remains just 57% for older adults and 75% for healthcare workers. These numbers further drop to 16% and 45% respectively in the African region [11] . **While coverage for high-risk populations has recently shown encouraging upward trends in AMC participants, it is imperative that countries prioritise reaching high-risk populations first and foremost when they make critical trade-off decisions on where to dedicate resources in this increasingly challenging environment.** Furthermore, countries will need to consider implementation of booster doses for high-risk populations concurrent with or even before primary series rollouts for younger adults and adolescents to follow the SAGE roadmap for population prioritisation[12].

1.2.8 **The COVID-19 Vaccine Delivery Partnership (CoVDP) was formed in January 2022 as a temporary inter-agency coordination mechanism to further consolidate and concentrate efforts to support countries to accelerate vaccine delivery following discussions with the Gavi Board and Alliance partners (UNICEF, WHO).** Since then, the CoVDP has focused on 34 countries with full population coverage rates below 10% as of January 2022 [13] . These countries represent nearly half of the unvaccinated population remaining in AMC participants. The CoVDP approach builds upon prior COVAX partner Country Readiness and

[8] High-risk further includes persons with co-morbidities, pregnant women, essential workers, and disadvantaged sub-populations as defined in the SAGE guidelines

[9] Refinement of methodology to calculate older adult coverage now defines older adult population as age 65+, age 60+ or age 50+ depending on country-specific definition. US at 95%+ At Least 1 dose, 90% Full coverage (https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total); EU at 92% / 92% (https://vaccinetracker.ecdc.europa.eu/public/extensions/covid-19/vaccinetracker.html#target-group-tab)

[10] 63 countries representing 88% of AMC population reporting on older adult population; 68 countries representing 88% of AMC population reporting on HCW population

[11] Defined by WHO region

[12] See Annex, or https://www.who.int/publications/i/item/who-sage-roadmap-for-prioritizing-usesof-covid-19-vaccines

[13] 34 CoVDP focus countries include: Afghanistan, Burkina Faso, Burundi, Cameroon, CAR (Central African Republic), Chad, Cote d'Ivoire, Djibouti, DRC (Democratic Republic of the Congo), Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Haiti, Kenya, Madagascar, Malawi, Mali, Niger, Nigeria, Papa New Guinea, Senegal, Sierra Leone, Solomon Islands, Somalia, South Sudan, Sudan, Syria, Tanzania, Uganda, Yemen, Zambia

Delivery (CRD) work with a country-centric lens, aiming to combine the efforts of all country-level partners to support streamlined vaccine delivery scale-up. At the global and regional level, the CoVDP has sought to further coordinate across partners to bring countries the support they need. The Delivery Partnership itself is focused on offering countries support through four primary levers: political engagement, delivery funding, demand planning, and technical assistance.

1.2.9 **The 34 low-coverage countries have overall made gradual but positive progress since November 2021 as supply has become consistently available.** They have increased their aggregate full vaccination coverage to 10% of the population in May 2022 from 3% in January 2022, and 16 of the 34 have reached full coverage levels above 10%. While difficult to untangle the specific contribution of the CoVDP amongst established in-country efforts, some countries have benefited from direct intervention such as Nigeria, DRC (Democratic Republic of the Congo), and Ethiopia (e.g. political advocacy missions, co-development of new operational rollout strategies, provision of urgent funding). Others such as Uganda, Kenya, and Ghana have independently made significant progress backed by engaged governments, and early, sustained support through in-country partners as well as Gavi's COVID-19 Delivery Support (CDS) funding since earlier in 2021. However, overall vaccination pace in the 34 countries remains limited, currently collectively fully vaccinating less than 1% of their population each month and on pace to reach less than 20% full coverage by the end of 2022.

1.2.10 Going forward, the **CoVDP's support for countries will need to adapt to meet evolving country priorities and needs. This includes adopting an increased focus on reaching country-defined national targets and prioritisation of high-risk populations in an equitable manner at sub-national level, as well as increasing focus on integrated planning and delivery approaches together with routine immunisation and other health services to avoid cannibalisation, leverage synergies and open up opportunities to reach harder to reach populations.** Beyond concerted support for the 34 countries, the CoVDP will also broaden its set of Delivery "common goods" it offers for all AMC participants over time. This includes supporting all AMC participants with increasingly complex demand planning to enable supply/demand matching, tracking information and taking action on expiry and wastage of COVID-19 vaccines, data and analytics to track progress and derive insights from country progress, and improve communication with countries on changing technical and policy guidance over time.

1.2.11 The Gavi Secretariat has supported the CoVDP's efforts by enabling direct dialogue with country governments to understand country needs through Gavi country teams and Senior Country Managers (SCMs), leveraging its routine immunisation (RI) experience to both advocate for sustainment of RI and identify opportunities for integration, and providing the 34 focus countries over US$ 200 million of direct delivery funding through CDS so far. Gavi has also provided the CoVDP central team space in its offices, further supporting the close collaboration.

1.2.12 **Gavi COVID-19 delivery vaccine funding has been instrumental to readiness and scale-up of country absorption and will continue to be critical to supporting country needs. Through Gavi, nearly US$ 1 billion in delivery funding has been made available to countries.** Over US$ 500 million of this funding was committed earlier in 2021 to support countries with over 400 TA positions for planning and readiness through WHO and UNICEF, targeted expansion of cold-chain infrastructure and vaccine management capabilities through UNICEF, and "Early Access" COVID-19 vaccine Delivery Support (CDS) funding direct to countries to launch service delivery scale-up efforts. The impact of this catalytic early funding has borne fruit over the past six months, with many countries citing funding and support as critical factors enabling absorption scale-up in late 2021 and early 2022. In late 2021, Gavi made another US$ 350 million available directly to countries through its "Needs Based" CDS. This delivery funding has been in high demand from countries and significantly oversubscribed, with over US$ 450 million received in requests from 36 countries (including 25 of the 34 concerted support countries, where majority of funding needs are from) received so far. US$ 260 million in funding requests had to be deprioritised mainly given the oversubscription. CDS has been a primary source of funding for countries that are increasingly hesitant to tap into multilateral banks financing in light of increased debt burdens and fiscal constraints. Allocations have been made for all but US$ 25 million of the "Needs Based CDS". At the April 2022 COVAX AMC Summit, Gavi raised an additional US$ 600 million in delivery funding which will be made available as quickly as possible to relieve bottlenecks. In the meantime, Gavi has been working closely with the CoVDP to connect other major delivery funders (WHO, UNICEF, Africa CDC, World Bank, and bilateral donors) to funding gaps that CDS cannot fulfil.

1.2.13 At its retreat in April 2022 the Board discussed that **Gavi's COVID-19 vaccine delivery support should evolve to prioritise comprehensive coverage of high-risk populations, help countries achieve national targets, and start to focus on integration with routine immunisation and other essential health services.** These three objectives represent a shift from the previous "emergency" posture that sought to prioritise rapid scale-up in a more vertical, campaign-based manner. Integration approaches leveraging routine delivery structures (fixed and outreach) and targeted communication approaches are increasingly needed to reach populations that are less accessible through mass vaccination approaches and less likely to urgently and actively seek out COVID-19 vaccination. They also offer opportunities to reach back with boosters and additional doses as needed, and to make COVID-19 delivery innovations accessible to routine programmes. Moreover, integrated planning, delivery and communication would increase the efficiency of the immunisation programme overall. It is imperative for the Alliance to responsively adjust its goals and approach to meet these shifting country needs, including adapting the objectives and scope of CDS funding accordingly. **The PPC was supportive of this evolution of the objectives and scope of Gavi's COVID-19 vaccine**

delivery support and funding, and emphasised the need to balance speed and simplicity for countries while achieving these goals.

1.3 Supply and Demand

1.3.1 **COVAX now has higher-than-expected realised supply from its APAs and dose donations.** Based on the historical precedent that fewer than 20% of vaccine candidates successfully achieve regulatory approval, COVAX, like many others, set out to construct a diversified portfolio. Thanks to the high success rates of COVID-19 vaccines, the portfolio now contains nine products with WHO EUL (Emergency Use Listing)[14]. In addition, COVAX established a successful dose sharing programme that has facilitated vaccine donations to COVAX. As many high-income countries secured access to more doses than were required to fully vaccinate their populations, they are therefore now faced with a surplus of doses, a large portion of which are now being converted into donations channelled through COVAX.

1.3.2 Across APA and dose-shared supply, COVAX has secured 3.3 billion doses in total for AMC92 participants. Of this, **COVAX has so far delivered 1.3 billion doses, and remaining supply includes a total of 1.1 billion APA doses for AMC countries and 400 million donated doses which have already been accepted or allocated, and an additional 500 million donated doses which are potentially available.**

1.3.3 **COVAX has confirmed approximately 2.0 billion doses in AMC 92 demand.** Of this, COVAX has already fulfilled 1.3 billion doses of demand through shipment, another 335 million have been accepted by countries but not yet been shipped, and COVAX has received country requests for an additional 320 million doses in 2022, including 100 million doses in remaining committed supply for India. Current forecasts show that we will have sufficient supply to continue providing vaccines into 2023 for countries that may absorb more slowly or have additional needs.

1.4 Looking Ahead

1.4.1 **Given remaining uncertainties in this pandemic, it is important that COVAX maintains some level of excess supply beyond currently-stated country demand to be able to respond to future demand and supply shocks.** WHO initially delineated four broad scenarios for the evolution of the pandemic, which were discussed at the April 2022 Board retreat. WHO has since evolved its thinking to reflect three scenarios: base, best, and worst cases[15]. Implications for the original fourth "reset" scenario is reflected in Doc 06 on Pandemic Preparedness and Response. COVAX is exploring how to best prepare for each scenario in terms of ability to manage supply and demand during 2022, associated vaccination strategies in the longer term, and implications for potential future Gavi programmes (see Section 2). Under the "base case" working scenario, the burden of

[14] WHO Emergency Use Listing for Clover's SCB-2019 vaccine candidate is pending.
[15] https://www.who.int/publications/i/item/WHO-WHE-SPP-2022.1

COVID-19 becomes manageable with routine boosting for high-risk populations, resulting in an ongoing need for vaccines although most likely on a smaller scale than in the first two years of the pandemic. The "best-case" scenario assumes significantly less severe future variants, resulting in a minimal need for vaccines in the future. Under a "worst-case" scenario, COVID-19 becomes more virulent and highly transmissible variants require boosters for the general population to maintain protection against severe disease. These scenarios are not wholly mutually exclusive, and for base and worst-case scenarios, additional supply would be needed either from existing or new vaccines (depending on the extent of viral evolution) and be sourced through a combination of donated or APA supply, recognising timing risks regardless of the source as actors urgently compete for limited supply. We are working to mitigate that risk, including by drawing on innovative financing mechanisms such as the Pandemic Vaccine Pool (PVP). These ongoing uncertainties regarding the global progression of the pandemic (new waves of transmission, new variants) as well as the pace at which countries can reach coverage targets, and the global policies needed to continue to protect people (booster doses, paediatric doses, additional boosters for high-risk populations, variant-adapted vaccines), could lead to further demand fluctuations in later 2022 and into 2023. As COVAX manages its portfolio against this shifting landscape, it will exercise supply and demand levers with the objective of maintaining some margin of excess doses, sufficient to offer boosters to high-risk populations in case of urgent, unexpected need, taking into consideration shelf life, country product preference, and a balance between APA and donated supply. It is important however to acknowledge that as time goes by this margin would be at risk of expiry.

1.4.2 **The demand environment continues to be highly volatile.** There could be some moderate demand increase of ~200 million doses due to e.g. increases in absorption rates, adoption of higher coverage targets, expansion of target populations, more widespread boosting, and needs for supply in 2023, but currently expressed demand is taken to be a more realistic planning assumption. Overall, if the current state of the pandemic persists, recent signals from countries indicate demand may further soften and/or shift into 2023. However, if WHO's worst-case pandemic scenario materialises, demand is likely to spike again.

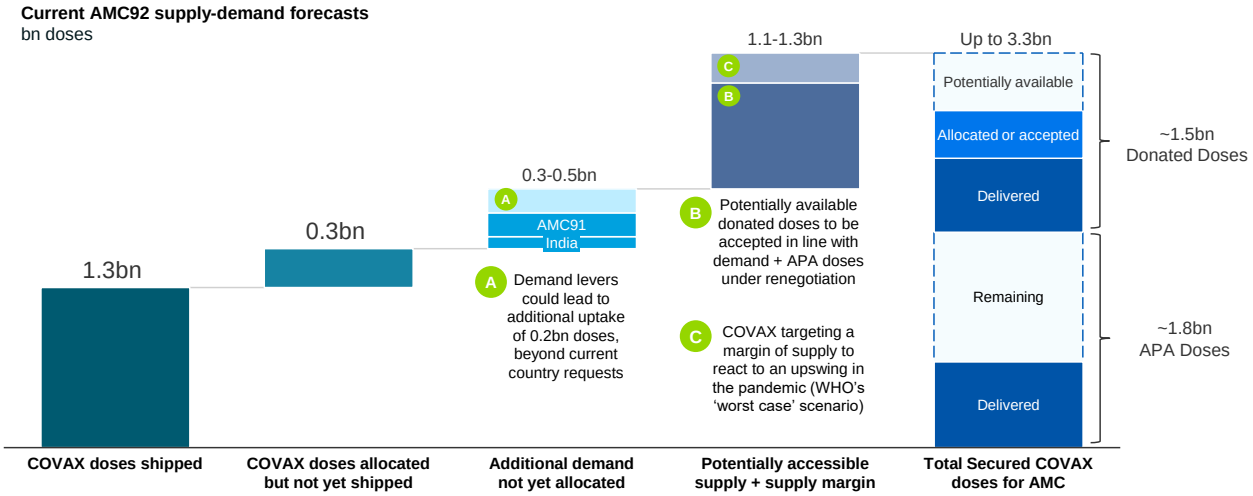
1.4.3 **COVAX is supporting countries to continue the scale-up of the vaccination rollouts and plan their demand for doses, in line with their own targets.** Gavi and the Alliance partners continue exploring how to best provide countries with resources and support to accelerate scale up of COVID-19 vaccination through increased responsiveness and accuracy of demand planning, provision of additional delivery funding, specialised technical guidance, and political advocacy to support demand generation. Such support aims to help countries reach their national coverage targets. As of 1 June 2022, COVAX has not received any substantial demand from

self-financing participants (SFPs) that would materially impact our advance purchase agreements and require substantially more doses[16].

1.4.4 **In response to epidemiological and market dynamics, COVAX is continuing to manage its portfolio and is actively engaging in opportunities to rephase and/or reduce APA supply and donation supply.** COVAX is currently aiming to reduce APA supply by 400- 600 million doses (subject to successful negotiations and as reviewed with the Market-Sensitive Decisions Committee (MSDC)) and will regularly reassess as demand forecasts evolve.

1.4.5 If COVAX can successfully negotiate APA supply reductions of 400- 600 million, COVAX's unshipped portfolio for AMC92 would consist of approximately 500-700 million APA doses, approximately 400 million donated doses which have already been accepted or allocated, and up to 500 million additional donated doses which are potentially available. Therefore, the unshipped AMC92 portfolio could consist of approximately 900 million doses on the lower end and up to 1.6 billion doses on the upper end. These volumes would be available to service unmet expressed demand of approximately 600-800 million doses and any additional demand that may materialise, for example under the various WHO pandemic scenarios (see Figure 2).

Figure 2: Balancing supply and demand to minimise expiry



1.4.6 **With scale-up of vaccine supply and waning demand, risk of in-country wastage due to expiry continues to increase.** While limited reporting from a sub-set of COVAX participants suggest that expiration of COVAX doses remains low compared to overall volumes delivered (~2%), over 600 million doses of in- country stock[17] are estimated to be in AMC91 participants today (excl. India)[18]. Most of these doses have less than nine months total shelf life and will present increased risk for major in-country

[16] Only one SFP is procuring doses under 2.0; demand from SFPs for donated doses for 2022 is limited and targeted to specific products (e.g. paediatric doses).
[17] From all sources, COVAX and non-COVAX
[18] Enough doses for 4-6 months of absorption at current rates

expiry events later in 2022. This risk will be mitigated more systematically by the COVID-19 Vaccine Delivery Partnership (CoVDP) through rigorous monitoring of expiry and wastage data signals, timely intervention to support countries to utilise doses at risk of expiry, and proactive optimisation of supply and demand matching to ensure countries do not take on excess in-country supply. COVAX will continue to operate a dynamic portfolio management strategy to respond to supply and demand shifts as they occur.

1.4.7 As presented to the Audit and Finance Committee (AFC) in May 2022 (Doc 03 Annex B *Risk Management Update*), **the level of supply and subsequent risk of expiry is in line with the level of risk the Board has accepted as necessary to take in order to fight the pandemic** (which required upfront procurement at risk while vaccine candidate success and country demand was still unknown, and with demand continuing to evolve with the pandemic). Gavi's risk awareness and robust risk management continues to put it in a good position to take, anticipate and mitigate these evolving risks and achieve balanced outcomes in this uncertain context (e.g. minimising waste while allowing a margin for unexpected supply and demand shocks). The PPC was also presented with the supply and demand outlook at its meeting in May 2022. Perfect supply-demand matching in a pandemic is extremely difficult, and there is merit to maintaining some supply excess to mitigate risks, meaning there will be wastage. This is not only true for COVAX but across many procurers, including among high-income countries (HICs).

Part II: Looking Forward to Gavi's Role and Ambition in Vaccine Procurement and Delivery into 2023

The Gavi Alliance Board is asked to:

- Approve the continued administration of the COVAX Facility by Gavi for 2023.
- Note the potential disease scenarios outlined in Section 1.4, provide guidance on the proposed framing to develop a longer-term approach to supporting COVID-19 vaccination, including learning from other Gavi work and to note the interim steps taken to ensure Gavi continues to deliver on its joint 5.0 and COVAX objectives, and provide guidance on the high-level planning assumptions guiding operational decision-making toward Gavi 5.1.

2. Planning for Gavi's role and ambition in COVID-19 vaccine procurement and delivery into 2023

2.1 As outlined in Doc 03 on Strategy, Programmes, and Partnerships, **the Secretariat has started exploring how COVID-19 vaccination and COVID-19 learnings will come together with Gavi's 5.0 strategy through 'Gavi 5.1'.** A key aspect of Gavi 5.1 is the alignment of COVID-19 vaccine support with core Gavi programmes, recognising also the unique requirements of COVID-19 vaccination, namely the targeting of older age

groups and other high risk populations. The Board is presently asked to provide guidance on a set of high-level planning assumptions outlining the likely evolution of the COVID-19 response and a framing for a longer-term approach to supporting COVID-19 vaccination objectives. These considerations are offered with the goal of bringing a proposal to the next PPC and Board meetings.

2.2 Areas that COVAX had previously managed with a large degree of independence or had significantly built out will need to be brought into closer alignment with Gavi 5.0. These are broadly covered in Doc 03. More specifically, **leading up to the December 2022 Board meeting Gavi will explore the following topics related to a future COVID-19 vaccine programme and its alignment with core Gavi programmes**[19]:

- Vaccine programme design: Based on the three WHO pandemic scenarios outlined in Section 1.4 and in consultation with partners, Gavi will develop several illustrative vaccine use cases and analyse any implications for the design of a future Gavi-supported COVID-19 vaccination programme, taking into consideration countries' need for ongoing COVID-19 vaccination including any need for variant-adapted vaccines. As an indication, for the base-case scenario, these use cases might include a routine immunisation strategy (potentially focused on preventive vaccination of high-risk populations akin to a seasonal influenza vaccination programme), delivery through vaccination campaigns (potentially including reactive vaccination targeting broad age groups), and support to a global stockpile or stockpile-like mechanism. A worst-case scenario may require new vaccines and/or broader boosting, while a best-case scenario may determine that Gavi's support for COVID-19 vaccination programmes would cease. Subsequent assessment of these use cases would draw from the Vaccine Investment Strategy methodology [20]. There are financial implications, risks, and trade-offs associated with different vaccination strategies that will need to be considered. This work would also take into account how some of the innovative and exceptional processes developed in the COVID-19 context would either need to be retained and brought into alignment with core processes, ramped down over time, or kept ready to deploy if needed for COVID-19 or in the context of the next pandemic.

- Alignment with Gavi's programmatic policies: Gavi will explore implications such as for the Eligibility, Co-Financing and Transition policies. COVAX currently offers support pathways to any participant

[19] Acknowledging that large parts of the world are still taking an emergency response approach to controlling COVID-19 and depending on normative guidance and policy developments, the Secretariat may propose an interim position on a COVID-19 vaccine programme in advance of a more detailed discussion in 2023

[20] As examples, these could include following aspects: disease scenarios (target populations, need for periodic boosters); product landscape and pipeline (duration of protection; antigen); demand scenarios for COVID-19 vaccines (including the availability of alternative interventions); and financial implications

that expresses need, including Gavi-eligible countries, LMICs that are not Gavi-eligible, and separately offers procurement services without financing support to SFPs. The Secretariat intends to bring the revised Eligibility, Co-Financing and Transition policies for decision to the Board in December 2022. The cost-sharing mechanism will remain open for AMC countries to use, subject to their demand. Regarding the remaining AMC participants that are not Gavi eligible, the Secretariat will review any potential modalities for Gavi to provide support for these countries with COVID-19 vaccines and revert to the PPC and Board with a proposal on eligibility.

- Implications for programmatic approaches: Gavi has started to explore opportunities to pivot the focus of CDS towards leveraging opportunities for integrated planning, delivery and communication of COVID-19 vaccination with routine immunisation programmes to increase the efficiency and effectiveness of the immunisation programme overall (see Section 1.2.13). It will also explore broader implications for programmatic approaches such as for cold chain, demand generation/social mobilisation, and adult immunisation platforms.

2.3 **To lay the foundation for Gavi 5.1 and taking into consideration the current COVID-19 vaccination outlook, COVAX has begun planning for 2023 based on several assumptions**, which will be further informed by the learning from evaluations and other evidence generation activities that are ongoing this year. First, COVAX expects to continue to support participants into 2023, with many AMC countries signaling that they will not reach current coverage targets until H1 2023 at the earliest. A consequence of the volatile demand situation is the increased likelihood vaccination efforts may last longer than originally expected. Second, COVAX is equipped with a portfolio of supply that can address these protracted needs, and therefore should continue to meet demand and ship doses well into 2023. In the absence of a compelling need to secure variant-adapted vaccines, COVAX would not pursue new APAs for example and instead would transition over time to standard UNICEF-led procurement. If variant-adapted vaccines are recommended, COVAX is prepared to launch new APA processes leveraging the PVP and with appropriate MSDC oversight. Donations will continue to play an important role to maintain a diverse portfolio, provide supply security, and provide variant adapted vaccines if necessary. Third, in line with the demand dynamics and the two previous considerations, delivery coordination and support structures would continue to have an important role to play into 2023. Fourth, as the emergency response phase of the pandemic recedes, Gavi would continue to develop and maintain the innovative financing instruments supporting the COVID-19 response (Doc 06), which provide flexibility to respond in the case of future variants and future pandemic preparedness. These assumptions and principles provide an important foundation for decision-making and planning. The Board is requested to provide guidance on these high-level principles and assumptions to inform operational decision-making.

2.4 As outlined in Section 1, the COVAX Facility has access to sufficient supply to serve currently expressed demand into 2023, under most WHO scenarios. This portfolio of supply offers the COVAX Facility the ability and flexibility to continue supporting countries' needs and ambitions while developing and then implementing a longer-term model of support for COVID-19 immunisation. It will be critical for the COVAX Facility to maintain capacity while coordinating planning for integration. In this context, **the Board is asked to approve that Gavi continues to administer the COVAX Facility for 2023, noting that the Secretariat will return to the relevant Committees and Board before the end of 2022 for a decision on future COVID-19 vaccination support modalities.**

Part III: COVAX Vaccine Policies

The Gavi Alliance Board is asked to:

- Delegate to the CEO, with reporting to the Board, the authority to approve flexibility to adapt programmes based upon updated SAGE recommendations for COVID-19 (such as on vaccine use, additional boosters, need for variant-adapted vaccines), contingent on available supply and funding.

- Informed by the interim approach outlined in Annex A to Doc 05, approve future paediatric support (July 2022 onwards) that supports continued limited provision of paediatric doses, with guardrails related to participant's coverage of COVID-19 vaccines in higher priority use groups, maintaining routine immunisation and monitoring any adverse impact on immunisation programmes.

3. COVAX Vaccine Policies

3.1 Update to COVID-19 vaccine policies and recommendations and implications for COVAX policy positions

3.1.1 WHO/SAGE COVID-19 technical guidance and recommendations have evolved since the last Board meeting, with updates to product-specific recommendations and to cross-cutting policy-making guidance[21]. **We expect WHO/SAGE COVID-19 vaccination policies and vaccine recommendations will continue to be updated throughout and beyond 2022, and COVAX policy positions will shift accordingly to support countries' targets and goals most effectively.** One of the policy areas undergoing rapid evolution and where a Board decision is required is that of paediatric vaccines for children aged 11 and under (hereby referred to as "paediatric"), as outlined in Section 3.2 below.

[21] Product specific-recommendations: new recommendation for Novavax CoV-2373 and revised recommendations for all products to include boosters, with the exception of Janssen Ad26.COV2.S, which was also updated to indicate benefits of a 2-dose schedule; Cross-cutting policy-making guidance: additional doses for moderate to severely immunocompromised persons (ICPs), heterologous schedules, review of higher priority-use groups, and boosters.

3.1.2 **There will potentially be other areas where the COVAX Facility will need to respond to emerging policy positions pending WHO/SAGE recommendations and will therefore require an operationally flexible programme design to avoid a long delay between WHO/SAGE recommendation and COVAX Facility operationalisation.** The COVAX Facility may also need to respond if the Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC [22]) recommends any updates to current vaccines in response to the emergence of any new antigenically distinct variants as well as a related SAGE recommendation. The COVAX Facility will continue to report policy and programmatic updates to the PPC as part of its regular reporting process.

3.1.3 At its meeting in May 2022, the PPC acknowledged the rapidly changing policy environment and the importance of a timely response to SAGE recommendations in order to facilitate countries' vaccination needs. The PPC agreed that current governance processes are insufficiently agile to quickly respond to updated guidance and therefore recommends that the Board approve the decision, highlighting the need for consultations with partners as part of the process and reporting programmatically relevant updates to the PPC.

3.1.4 **The Secretariat therefore requests, based on the recommendation from the PPC, that the Board delegate to the CEO, with reporting to the Board, the flexibility to adapt programmes based upon updated SAGE recommendations for COVID-19 (such as on vaccine use, additional boosters, and the need for variant-adapted vaccines), contingent on available supply and funding.**

3.2 **Future COVAX support for paediatric vaccination (11-year-olds and under)**

3.2.1 Beyond the interim, time-bound, approach that is in place until June 2022, as outlined in Annex A, **COVAX is considering a future policy position to support COVID-19 vaccination of children aged 11 and under.** At this time, no vaccines for under 5-year-olds have received WHO EUL, so any support for this younger age group would be conditional on products in the COVAX Facility portfolio receiving EUL and SAGE recommendation.

3.2.2 **To develop a future policy position on paediatric support, the COVAX Facility assessed three options against key criteria** (public health impact, supply, demand and equity, implementation feasibility and impact on Gavi's core mission, COVAX comparative advantage, and financial implications) for the PPC's recommendation:

- Option 1: Expand eligibility for paediatric doses to all AMC participants, regardless of priority population groups' coverage levels;

[22] https://www.who.int/groups/technical-advisory-group-on-covid-19-vaccine-composition-(tag-covac)

- Option 2: Continue limited provision of paediatric doses with guardrails associated with the participant's coverage of higher priority use groups with COVID-19 vaccines and their maintenance and extension of routine immunisation; and

- Option 3: No further support of paediatric doses provided beyond the interim, time-bound approach. These options were then reviewed for potential opportunities, risks and mitigation measures and considerations, as summarised in Annex B.

3.2.3 The PPC considered the three options, including the merits of supporting countries to reach their own vaccination targets while recognising the need to continue to focus on higher priority groups. The PPC also discussed the potential for non-health impacts on the introduction of a paediatrics programme such as a country introducing a vaccine requirement for children to go to school. They highlighted the need to monitor impact on other higher priority COVID-19 and routine immunisation programmes. While **consensus was reached for Option 2,** one constituency initially supported Option 1 to allow wider eligibility.

3.2.4 **Option 2 would continue limited provision of paediatric doses with guardrails associated with the participants' coverage of higher priority use groups with COVID-19 vaccines and their maintenance and extension of routine immunisation.** Supply would be sourced from donated doses. Pending a SAGE recommendation, under 5-year-olds could also be supported under the same conditions. Given the funding constraints, it is proposed that CDS support not be provided for paediatric vaccination programmes to avoid diverting COVAX delivery funding from higher priority populations, thereby limiting access to countries that can cover their programme costs.

3.2.5 In addition, it was noted that **any decision taken by the COVAX Facility to support a COVID-19 paediatric vaccination programme would not pre-empt a broader discussion regarding Gavi's role in supporting routine COVID-19 vaccination, including in children, over the longer term** which will be brought to the Board as part of a VIS-type approach as described in Section 2.

3.2.6 **Gavi and COVAX will continue its efforts with Alliance partners to monitor any adverse impacts of the paediatric COVID-19 vaccination programs on routine immunisation. Beyond the IRC (Independent Review Committee) review of the participants' proposed paediatric programme before the doses are delivered, Gavi and COVAX will triangulate across monthly reporting from several Gavi eligible countries, WHO pulse surveys and other country intelligence, noting limitations in the timeliness and sensitivity of some of these data.** In the event that signals suggest a country may be experiencing disruption, Gavi would immediately seek to conduct more intensive review to better understand key drivers and explore support to mitigate and avoid negative unintended consequences.

3.2.7 **After reviewing the assessment of risks and trade-offs outlined in Annex B and acknowledging that countries are likely to seek alternative routes if COVAX does not offer paediatric supply, the PPC recommends Option 2 to capitalise on existing supply whilst maintaining the focus on higher priority populations.** Implementation of Option 2 would be contingent upon supply availability; in a supply-constrained situation, supply of paediatric doses would be deprioritised against programmes serving higher priority populations.

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 continued administration of the COVAX Facility by Gavi in 2023;

b) **Delegate** to the CEO, with reporting to the Board, the authority to approve flexibility to adapt programmes based upon updated SAGE recommendations for COVID-19 (such as on vaccine use, additional boosters, the need for variant-adapted vaccines), contingent on available supply and funding;

c) Informed by the interim approach outlined in Annex A to Doc 05, **approve** future paediatric support (July 2022 onwards) that supports continued limited provision of paediatric doses, with guardrails related to participant's coverage of COVID-19 vaccines in higher priority use groups, maintaining routine immunisation and monitoring any adverse impact on immunisation programmes.

The Gavi Alliance Board is further requested to:

a) **Provide guidance** on the future evolution of the objectives and scope of Gavi's COVID-19 vaccine delivery and funding, building upon PPC alignment and feedback.

b) **Note** the potential disease scenarios outlined in Section 1.4 to Doc 05, **provide guidance** on the proposed framing to develop a longer-term approach to supporting COVID-19 vaccination, including learning from other Gavi work and to note the interim steps taken to ensure Gavi continues to deliver on its joint Gavi 5.0 and COVAX objectives, and **provide guidance** on the high-level planning assumptions guiding operational decision-making toward Gavi 5.1, as outlined in Section 2.

Annexes

Annex A: Interim Approach to Paediatric Support

Annex B: Supporting Considerations for a Future COVAX-Supported Paediatrics Programme and Risks and Trade-offs

Annex C: COVAX Reporting Framework