
Subject **COVAX: Key Strategic Issues**

Agenda item **09**

Category **For Information**

Section A: Executive Summary

Context

Emerging variants and evolution of the COVID-19 pandemic, new vaccine products, and evolving policy guidance exemplify the continued volatility and uncertainty surrounding the pandemic. In June 2022, the Board agreed that Gavi continue administrating the COVAX Facility in 2023, delegated authority to the CEO to adapt programmes based on updated World Health Organization (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) recommendations and approved limited provision of donated paediatrics doses. In line with these decisions and as participants work toward their own coverage ambitions, COVAX will continue to support AMC participants' vaccine demand with an increased emphasis on higher-risk groups, including as new appropriate and recommended products enter the market, such as variant-containing vaccines.

COVAX's 2023 strategy will bridge to the Gavi 5.1 COVID-19 vaccine investment approach that would begin in 2024 and is focused on ongoing protection of higher priority population groups, pending Board approval in December 2022 (Doc 10) and Board approval of the financial envelope in June 2023. COVAX will also use 2023 to transition its operating model from one of leading an emergency response to a programme utilising existing Alliance processes. Some established elements of the COVAX model will continue in 2023 including retaining the capacity to respond to the WHO worst-case scenario through the Pandemic Vaccine Pool, while some components will evolve, such as COVID-19 vaccine delivery support and the sunseting of the Humanitarian Buffer, with humanitarian access continuing to be provided via other means.

Questions this paper addresses

- What progress has COVAX made in 2022 in supporting AMC participants achieve their COVID-19 vaccination goals?
- What is the state of supply and demand and what are the projections for 2023?
- How does COVAX plan to keep its vaccine portfolio 'fit for purpose' in 2023, especially in light of variant-containing vaccines?
- How will COVAX adjust specific initiatives in preparation for the shift from emergency response to a programme that uses existing Alliance processes?

Section B: Content

Part I: 2022 Progress

1. COVID-19 Vaccine Delivery

- 1.1 AMC countries continue to make good progress with overall population coverage levels increasing, especially amongst lowest coverage countries.** As of November 2022, 59% of people in all AMC countries have received at least one dose of a COVID-19 vaccine and 52% have completed primary series. Recent modelling from Imperial College, London estimates that 75% of deaths averted in countries in the WHO African region and 79% of deaths averted in low-income countries are attributable to COVAX-supported doses (based on data through till end of June 2022). However, inequities persist, and coverage is reaching a plateau partly due to the decreasing risk perception and competing priorities in many countries.
- 1.2 Reaching the highest-risk individuals remains a significant challenge and the main priority for the remainder of 2022 and into 2023.** Across AMC participants, primary series coverage of highest- and high-risk individuals has continued to improve, reaching 66% coverage of older adults and 81% coverage of healthcare workers. However, a significant and concerning disparity remains across countries with a third of reporting AMC participants below 30 percent coverage for older adults and five below 30 percent coverage for healthcare workers. Across AMC participants, at least 115 million highest-risk individuals have yet to complete their primary series vaccinations. There is also a need to establish/improve reporting on coverage with booster doses across these population groups.
- 1.3 Of the 34 countries with less than 10% primary series coverage identified for concerted support in January 2022, 9 countries have in the intervening time surpassed 10% coverage and 17 countries have surpassed 20%.** For the eight remaining countries¹, common challenges include fragility and conflict, bureaucratic and logistical constraints, and/or limited health systems' capacity to sustain concentrated COVID-19 vaccination efforts. Many of these countries face ongoing humanitarian and other crises that severely constrain their ability to prioritise and dedicate resources to COVID-19 vaccination. Addressing these countries through specific programmes targeted at fragility, emergencies, and displaced populations is a critical priority. Targeted support is ongoing.
- 1.4 In July 2022, Gavi launched the third application window for its COVID-19 Vaccine Delivery Support (CDS3) funding with an additional US\$ 600 million. The funding support focuses on 1) reaching high-risk populations, 2) achieving country coverage targets, and 3) integrating COVID-19 with routine immunisation (RI) and Primary Healthcare (PHC).**

¹ Burundi, Cameroon, Democratic Republic of Congo (DRC), Haiti, Madagascar, Papua New Guinea, Senegal, Yemen

To date, 46 CDS3 applications have been received. As of 17 November 2022, four CDS3 applications have been approved, totalling US\$ 6.4 million. The final total funding amount availed of will be confirmed once the review and approval process are completed. Based on early analyses of applications received, countries plan on leveraging CDS3 funding mainly for COVID-19 integration into RI, a trend that we expect will continue. This will lay the foundation for the proposed future COVID-19 vaccine programme (Doc 10) and help countries prepare their systems for other future outbreaks.

- 1.5 Within this new CDS window, there are two earmarked pools of funding to support specific delivery priorities. One is US\$ 25 million dedicated to Civil Society Organisations (CSOs). These partners can unblock critical delivery, access, and uptake bottlenecks, specifically to reach underserved and unserved populations, including high-risk groups and humanitarian settings. The second is a US\$ 30 million pool of emergency funding jointly managed with the COVID-19 Vaccine Delivery Partnership (CoVDP) for immediate needs in the 34 countries receiving concerted support (para 1.3). Both pools of funding will directly support in-country delivery efforts.
- 1.6 **Through the CDS3 window, Gavi aims to disburse and support as many high-impact delivery efforts as possible between now and the end of 2022. Although overall demand for CDS and delivery funding remains robust, Gavi is beginning to observe early risks with in-country absorption and utilisation of funding along the ambitious target timelines originally outlined.** CDS Early Access Window funding disbursed in the second half of 2021 remains less than 80% utilised at the country level, with some countries remaining below 50% utilisation. Low absorption is mainly due to competing health and other priorities during the pandemic, overburdened planning and financial management capacities, health workforce constraints, and other external factors such as additional funding being made available bilaterally and through multilateral development banks.

2. Other Programmatic Policy Updates

- 2.1 In line with Decision 11 approved at the June 2022 Board meeting, **COVAX continues to adapt its programmes in line with updated SAGE recommendations for COVID-19 vaccination.** COVAX has updated its policies regarding initial and additional boosters and has continued to provide access to paediatric doses in alignment with WHO recommendations that consider sustainability, avoid disrupting efforts to reach the highest priority populations and mitigate the impact on routine immunisation programmes. As of 16 November 2022, 85 million paediatric doses have been allocated to participant countries all sourced from donations. In order to meet country demand for any doses – primary series, booster, or paediatric – as efficiently as possible, a “Rolling Allocations Process” has been developed and implemented, which allows COVAX to quickly make allocations in response to verified, incoming requests.

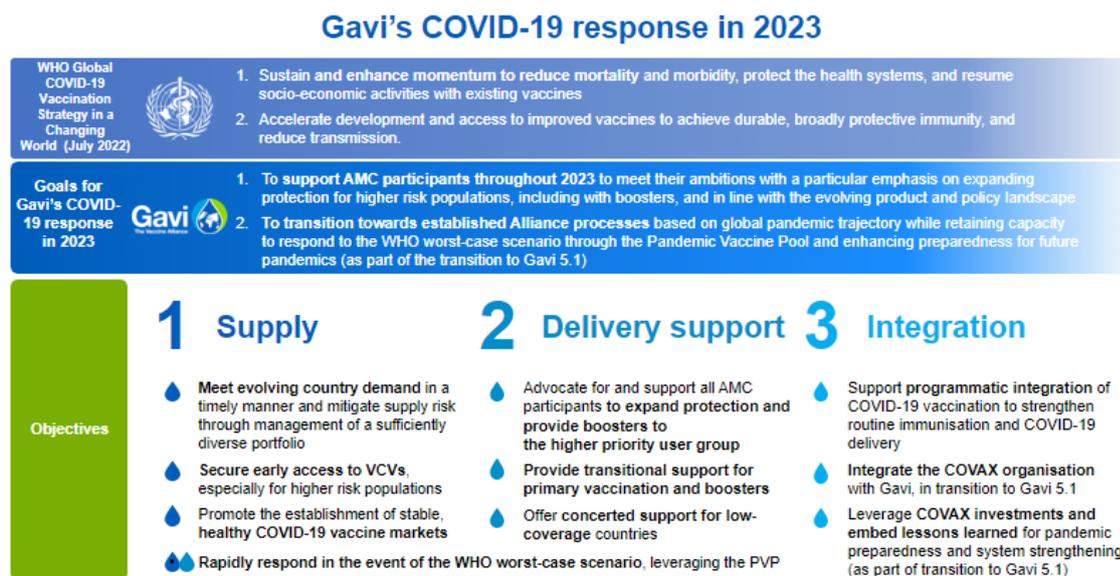
Part II: Looking Ahead to 2023

3. Gavi's COVID-19 Response in 2023

3.1 **Gavi's and COVAX's efforts build upon strategies developed by and with partners**, including the WHO's July 2022 update to the Strategy to Achieve Global COVID-19 Vaccination², and the COVAX Pillar 2023 Plan, which outlines how COVAX partners coordinate work to offer a comprehensive response to the pandemic.

3.2 **In that context, and despite ongoing high levels of uncertainty across multiple dimensions including disease trajectory, optimal vaccination strategies, vaccine effectiveness, and demand, COVAX is preparing for a 2023 strategy based on WHO's base case scenario.** COVAX aims to continue supporting AMC participants to meet their ambitions with a particular emphasis on expanding protection for higher-risk populations and in line with the evolving product and policy landscape. In preparation for 2024 and a future COVID-19 programme (Doc 10), pending Board approval, COVAX will continue to transition towards established Alliance end-to-end processes while retaining capacity within COVAX to respond to the WHO worst-case scenario through the Pandemic Vaccine Pool and enhancing preparedness for future pandemics (as part of Gavi 5.1). The following figure details Gavi's COVID-19 response goals and objectives for 2023. **The Board is requested to provide guidance on Gavi's planned response to COVID-19 in 2023.**

Figure 1: Gavi's COVID-19 Response in 2023



² <https://www.who.int/publications/m/item/global-covid-19-vaccination-strategy-in-a-changing-world--july-2022-update>

4. **Supply and Demand Projections for 2023**
 - 4.1 **Demand forecasting remains an important part of the COVAX planning process to understand future trends and to offer continuous support to countries.** A cross-partner Demand Working Group co-led by Gavi and UNICEF has been set up to develop and lead the 2023 demand planning process.
 - 4.2 **A first high-level vaccine forecast for 2023 and beyond has been developed based on demand modelling and scenario planning** and looks at three segments: 1) expansion of primary and first booster coverage in line with national targets; 2) introduction of additional booster campaigns for higher priority use groups; and 3) limited continued provision of paediatric doses for high-risk children aged 6-11 years. There is still a high level of uncertainty, but the preliminary top-down estimates of demand for 2023 from COVAX range between 190-460 million doses with the variance driven by the degree to which countries continue to pursue national coverage targets and vaccination with additional boosters. Based on the current state of the pandemic, the lower end of the demand range is more likely, as countries might slow or stop primary vaccination and/or stop boosting the full adult population and shift focus to only the high-risk population in 2023.
 - 4.3 **In line with established Alliance demand planning processes, and in preparation for 2023, COVAX is conducting two demand exercises with countries before the end of 2022.** In August, UNICEF incorporated questions about countries' COVID-19 2023 plans into its existing annual vaccine forecasting process. Eighty-three countries responded to the exercise, out of which the majority of respondents are planning COVID-19 vaccination in 2023, targeting 18+ population. Ninety-four percent of countries conducting COVID-19 vaccination in 2023 indicated to continue primary vaccination; 88 percent plan to boost in 2023. In late October 2022 COVAX conducted a more detailed bottom-up demand exercise by volume and product with the countries. The outcomes of this exercise will be available in early December 2022 and will be used to further refine supply portfolio planning to ensure a stable vaccine supply and access to devices and cold chain equipment, and to build strong country support plans. The country bottom-up forecast will be updated on a quarterly basis to capture changes linked to high levels of uncertainty and volatility in the demand.
 - 4.4 **COVAX continues to work with manufacturers and donors to better align the volume and timing of supply to the evolving country demand, including for 2023, while reducing the risk of vaccine expiries.** COVAX's successful portfolio risk management to date is due in part to its strong due diligence process which screened a pipeline of new manufacturers and vaccines entering the market. As a result, COVAX did not contract with numerous manufacturers for candidate vaccines which did not pass due diligence; subsequently, many of these same manufacturers failed to gain regulatory approval or had significantly delayed vaccine development. For the

vaccines within the portfolio, the current strategy to align supply with demand while continuing to mitigate portfolio risk aims to reduce the risk of vaccine expiries while maintaining a margin of supply to react to any pandemic upswings. These actions are being taken against a backdrop of broader market shifts (e.g. the transition of the main mRNA manufacturers towards production of variant containing vaccines (VCVs)) and an increasingly complex demand picture (e.g. primary vs. booster, paediatric vs. adult doses, original prototype vs. VCVs). COVAX will continue to manage portfolio risk with an eye toward the future and amidst these broader market shifts.

- 4.5 **COVAX has made substantial progress in its negotiations with manufacturers and donors to rephase and reduce incoming supply and has now achieved reductions to its Advance Purchase Agreement (APA) supply within the target range of 400-600 million doses.** Additionally, a restructuring of the contract between Pfizer and the U.S. Government has reduced potential donations by 400 million doses, with these volumes being converted into options that could be exercised by the U.S. depending upon demand and new funding. These actions mean that, to date, above-country expiries have been limited to 3% of the total available portfolio volumes.
- 4.6 **COVAX expects to have sufficient volumes to meet anticipated demand under WHO's base- and best-case scenarios. In WHO's worst-case scenario, COVAX would take steps to secure additional supply via additional donations and/or procurement using the Pandemic Vaccine Pool.** Several uncertainties nonetheless remain about the size and composition of COVAX's 2023 portfolio, including but not limited to: outcomes of remaining APA renegotiations, and the longer-term availability of, and access to, VCVs through APAs and donations.
- 4.7 **COVAX's 2023 portfolio aims to include original prototype vaccines and VCVs. COVAX is working with manufacturers and donors on access to VCVs if there is demand from countries.** At its October 2022 meeting, WHO SAGE made a non-preferential recommendation for the use of VCVs as booster doses for individuals aged 12 and older. Importantly, SAGE did not recommend VCVs for use as primary series or paediatric use; for which COVAX has other suitable vaccines available. As a result, COVAX is not currently encouraging countries to switch to VCVs but is responding to any explicit country demand; several country allocations of VCVs have now been made. As more data emerges about VCVs, COVAX will continue to assess these vaccines' role in COVAX's portfolio and in supporting countries to achieve their targets. While mRNA VCVs from Moderna and Pfizer/BioNTech have been first-to-market, COVAX has potential access from other manufacturers working on VCVs, should they be successful and if demand for them exists.
- 4.8 **COVAX continues to monitor the development of other prophylactic vaccines for COVID-19.** As new data and products emerge, demonstrate advantages, and receive WHO approval, the Facility will consider policy

positions to include new products as appropriate, in line with SAGE recommendations and country-led requirements.

5. COVID-19 Vaccine Delivery Support and CoVDP

5.1 **In 2023, preparation for a gradual pivot of COVID-19 vaccination towards delivery through Primary Health Care (PHC) services will be critical to enable the near- and long-term success of COVID-19 vaccine delivery programmes.** This will enable countries to capture synergies between investments in infant, adolescent and adult immunisation to enhance service delivery, community engagement, demand generation, and data systems. This is critical to optimise and sustain the delivery of COVID-19 vaccines without long-standing parallel (and expensive) delivery approaches. Through CDS3, the Alliance's support is already moving in this direction, putting increased focus on strengthening the immunisation system capacities that would benefit sustainable delivery of COVID-19 vaccination.

5.2 **While continuing to accelerate its delivery support through to the end of 2022, CoVDP is preparing a transition plan** in which CoVDP will completely phase out by the end of Q2 2023. This will feed into the ongoing work to fully integrate COVID-19 into immunisation programmes and primary healthcare for countries that choose to pursue continued COVID-19 vaccination. Following the acceleration and scale-up phase that started in June 2022 and will continue until December 2022, the partnership will enter an integration and knowledge management phase. It will transition out completely in June 2023 while ensuring a handover of functions, knowledge management products, and assets to agencies and/or phasing out some activities.

6. Humanitarian Buffer

6.1 COVAX has been a major source of vaccines in humanitarian settings, delivering 48 percent of doses.³ Continuing to deliver in these contexts is a COVAX priority, even as there is agreement across COVAX partners that operational obstacles and fit-for-purpose issues render the Humanitarian Buffer of low utility. Thus, **COVAX partners have agreed that the Humanitarian Buffer mechanism will not accept new applications after 31 December 2022. Thereafter, COVAX will rely on the on-going CDS-funding opportunities** available to deliver doses that are already in country to populations in humanitarian settings via governments and CSOs. Articulating recommendations, including lessons learned, and supporting efforts to convene discussions on how to design and operationalise a future pandemic humanitarian response and humanitarian mainstreaming will continue.

6.2 **The robust Humanitarian Buffer learning agenda offers the Gavi Alliance and the broader global health community a wealth of learnings on strengthening efforts to reach populations in humanitarian settings.** It also

³ In the 28 countries and contexts with dedicated Humanitarian Response Plans.

seeks to address bottlenecks and establish mechanisms such that humanitarian populations can be better served in future pandemics. Successfully reaching humanitarian settings means understanding and overcoming the limitations to working outside state-based architecture. Some of these limitations are not unique to public health emergencies or disaster response but can be exacerbated during a pandemic or global crisis; thus recommendations must focus on the chronic issues as well as those specific to pandemic circumstances. In June 2022, Gavi published the ‘Taking Stock of Humanitarian Access to Pandemic Vaccines’⁴ discussion paper which examines some pandemic specific challenges and Gavi plans to engage Alliance and CSO partners to understand, document and problem-solve critical issues that humanitarian actors and Gavi Alliance partners need to address; these efforts are in support of the Global Summit “COVID-19 Vaccinations in Humanitarian settings and the contribution to broader pandemic preparedness” planned for Q1 of 2023 co-convened between the CoVDP, Gavi, and Alliance partners. At its meeting on 1 November 2022, the PPC noted the importance of implementing these learnings to continue reaching these populations.

Section C: Actions requested of the Board

The Gavi Alliance Board is requested to **provide guidance** Gavi’s planned response to the COVID-19 pandemic in 2023, including the goals:

- a) To support AMC participants throughout 2023 to meet their ambitions with a particular emphasis on expanding protection for higher risk populations, including with boosters, and in line with the evolving product and policy landscape;
- b) To transition toward established Alliance processes based on the global pandemic trajectory while retaining the capacity to respond to the WHO worst-case scenario through the Pandemic Vaccine Pool and enhancing preparedness for the next pandemic (as part of the transition to Gavi 5.1).

Annexes

Annex A: COVAX Reporting Framework

⁴ <https://www.gavi.org/sites/default/files/covid/covax/taking-stock-of-humanitarian-access-to-pandemic-vaccines-dp.pdf>