

Subject	COVAX Update
Agenda item	12
Category	For Information

Section A: Executive Summary

Context

The COVAX Facility was established in 2020 and set up with an initial duration period of three years. In June 2022, the Gavi Board approved its continued administration by Gavi through the end of 2023. COVAX will cease operating at the end of this year as planned, and work is well underway to integrate key COVAX processes into core Gavi and Alliance processes to enable a smooth transition to the 2024-2025 COVID-19 vaccine programme that was approved by the Board in June 2023.

This paper provides a summary of progress achieved by COVAX in its final year of operations in 2023, an overview of the COVAX close out and integration into Gavi, an update on the status of the Gavi 2024-2025 COVID-19 programme, and reflections on major COVAX achievements after over three and half years of operation along with how key learnings are being taken forward.

Questions this paper addresses

- What progress has COVAX made in 2023 in supporting COVAX Advance Market Commitment (AMC) participants achieve their COVID-19 vaccination goals?
- What are the key aspects to the closure of COVAX in 2023, including tail-end activities to be completed in 2024?
- What is the status of the Gavi 2024-2025 COVID-19 vaccine programme?
- What are the major COVAX achievements and learnings and how are we taking these learnings from COVAX forward for Gavi core and future pandemic prevention preparedness and response (PPPR) work?

Section B: Content

Part I: 2023 Progress under COVAX

- 1. COVID-19 Vaccine Coverage
- 1.1 COVAX AMC participants have continued in their efforts to increase COVID-19 vaccination and extend boosting, particularly across highpriority population groups, albeit at a slower pace compared to 2022. This lower incremental progress in coverage is likely a result of



epidemiological changes in the pandemic, the May 2023 declaration that COVID-19 no longer constitutes a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO), evolving WHO Strategic Advisory Group of Experts on Immunization (SAGE) guidance and waning demand. As of October 2023, 57% of people across all AMC countries have received the complete COVID-19 vaccination primary series. 17% of people have also received a booster dose. Only six countries have yet to reach 10% coverage, down from 34 at the start of 2022. Primary series coverage among high priority populations has reached 72% of older adults and 84% of health care workers across all AMCs. While boosting across health care workers has advanced to 57% coverage, only 24% of older adults are reported to have received a booster – noting that boosting coverage is impacted by evolution of national programme schedules and recommended gap between doses.

2. Update on COVID-19 Vaccine Delivery Support (CDS) investments

- 2.1 CDS funding continues to support the delivery of COVID-19 vaccines in countries. 92% of the total US\$ 1.6 billion funding mobilised for COVID-19 delivery has been approved as of September 2023.
- 2.2 The third funding window (CDS3) spanned from July 2022 until 30 June 2023, enabling countries to submit funding requests to support COVID-19 vaccine delivery to scale up coverage of high-risk populations, increase vaccination coverage for the general population and support integration of COVID-19 vaccination with routine immunisation and primary healthcare. CDS3 funding was awarded to 81 AMC participants. A total of US\$ 603 million CDS3 funding was approved, with US\$ 514 million awarded to Gavi 61 eligible countries and US\$ 59 million to the AMC 30 countries managed by UNICEF.
- 2.3 CDS3 approved funding also includes US\$ 30 million of emergency CDS funding, which was disbursed (in an average lead time of six working days) across 12 countries with an urgent and time-sensitive need for COVID-19 delivery support.
- 2.4 Illustrative examples of cross-cutting CDS investments include:
 - 2.4.1 **Targeted support** to Benin, Sierra Leone, Cameroon, Guinea, Madagascar and Zimbabwe focused on developing decentralised planning mechanisms to break operational silos in health care programming and enhancing coordination and efficiency.
 - 2.4.2 **Targeted cold chain equipment (CCE) investments** have delivered 216 walk-in cold rooms/freezer rooms. Without investments in 633 ultracold freezers, it would have not been feasible to ship the ~650 million Pfizer vaccine doses to 74 AMC countries. In addition, 5,639 refrigerators and freezers were procured under COVAX at lower levels



of the supply chain (district and facility level). Vaccine management specialists continue building capacities of national vaccine logistic managers in over 40 AMC countries.

- 2.4.3 US\$ 25 million has been dedicated to strengthening civil society organisations' (CSOs) and local partners' contributions to COVID- 19 vaccine delivery and cementing these local partnerships with a view to longer-term collaboration with Gavi. CSOs in Sudan, the Democratic Republic of Congo, Côte d'Ivoire, the Central African Republic and Niger, among others, support achieving CDS objectives while also identifying zero-dose and under-immunised children.
- 2.5 Latest programmatic reporting on CDS across AMC recipients has been analysed and key benefits from CDS from countries' perspectives are summarised in Figure 1 below. Notably, there has been an observed increase in utilisation of CDS support towards innovative demand creation and engagement over the course of 2023.



Figure 1: Positive impact of CDS on health systems strengthening

2.6 Remaining unallocated COVID-19 Delivery funding has been reallocated towards a set of targeted projects including a Health Facility Solar Electrification (HFSE) pilot for catalytic funding for four countries (Ethiopia, Malawi, Pakistan and Uganda) to enable reliable electricity to power cold chain, medical equipment and health care facilities and projects focusing on targeted capacity building.



3. Supply against demand in 2023

- 3.1 The deadline for final dose requests from countries for allocation under COVAX for the remainder of 2023 was 15 September 2023. For 2023, a total of 120 million doses have been requested by AMC participants. This is below the originally indicated 2023 demand of nearly 550 million doses. COVAX has routinely engaged countries over the course of 2023 to understand the changing demand landscape caused by: i) the lifting of the PHEIC in May; ii) the regularly updated SAGE guidance on priority groups for vaccinations, which deprioritised healthy adolescent and paediatric groups over the year; and iii) the move towards routinisation of COVID-19 vaccination programmes in countries leading to a slowing of absorption and uptake. Of these 120 million doses requested from COVAX, 90 million have been allocated and 68 million delivered to date. All pending COVAX deliveries are expected to take place by the end of 2023, and all future demand for vaccines beginning in 2024 will be administered by UNICEF and the Pan American Health Organization (PAHO) under the new 2024-2025 COVID-19 vaccine programme.
- 3.2 During 2023, COVAX was able to meet most country requests, although it continued to face a few external supply challenges due to: 1) donated messenger RNA (mRNA) vaccines not materialising as expected with lower volumes, shorter shelf lives and in formulations that were not yet approved by WHO; and 2) lack of access to mRNA vaccines for primary series due to manufacturers discontinuing production of original strain mRNA vaccines in early 2023 and due to delays in the WHO approval of the primary series indication for new variant-containing vaccines (VCVs) (ultimately approved in October 2023).
- 3.3 In response to these supply challenges, the Secretariat continued to actively manage its dual-sourced portfolio. The Gavi Market-Sensitive Decisions Committee (MSDC) approved two new Advance Purchase Agreements (APA) to serve contingency needs in 2023. From these APA agreements, 8 million doses have been ordered so far to fulfil unmet country needs.

Part II: COVAX Close-Out and Integration

4. COVAX close-out

- 4.1 **COVAX and its country-facing operations will end on 31 December 2023.** A COVAX close-out working group, including both internal and cross-partner teams, has established milestones for closure and regularly reports progress to COVAX partner leadership. This work encompasses over 25 different COVAX- related areas with an aim to systematically conclude activities.
- 4.2 **Cost-sharing close-out:** Since 2021, 16 countries have requested doses through the COVAX cost-sharing mechanism, at a total value of almost US\$ 800 million. Delivery of these doses is complete across 13 countries, with



the aim to close out the remaining three countries by December 2023, with one of these via a financial settlement between the country and manufacturer as the financial liabilities are no longer with Gavi. The two remaining countries will have their purchase agreements terminated should they continue to decline efforts to deliver their remaining doses. Once closed, approximately 97.5% of contracts in the programme by value will have been successfully collected, with the remaining 2.5% – just under US\$ 20 million – to potentially be written off. The amounts are already included in the approved COVAX forecasts meaning that this will be done without additional financial liability to Gavi.

- 4.3 **Self-financing Participants (SFP) close-out:** Gavi took on significant legal and financial risk at the outset of the pandemic, building a portfolio of vaccines prior to regulatory approval to guarantee equitable access to lower income countries and SFPs. The Gavi Board allowed upper-middle income and high-income economies to join the COVAX Facility with the requirement that they self-financed vaccine procurement and the associated Facility expenses. By joining the Facility, SFPs gained access to an additional route to market to procure additional COVID-19 vaccines (once available) outside of bilateral agreements. SFPs made financial commitments to Gavi based on these terms and the prevailing environment at the time.
- 4.4 The SFP programme formally closed on 18 September 2023 (as per original operational SFP timeline of three years) ending the participation of all 101 countries that joined the COVAX Facility as SFPs. 91 countries exited the Facility by mutual agreement via Termination Agreements. Several of these SFPs donated their COVAX surplus funds back to the AMC. 10 countries exited the Facility via Termination Notices issued by Gavi upon the closure of the Facility. The close-out terms for all 101 SFPs are consistent, and there is no liability to Gavi following the programme close-out. A comprehensive approach has been taken to understand, assess, and mitigate the risks associated with a handful of SFPs that are dissatisfied with the close-out terms. The details on these risks and risk management were reported to the Audit and Finance Committee (AFC) at their October 2023 meeting. With the partnership of SFPs and 92 participants in the AMC, we have together worked to control the COVID-19 pandemic, protecting billions of people around the world, and mitigating the enormous strain it has put on health systems.
- 4.5 A cross-partner COVAX Repository is being developed to capture key operational documents for reference and access in future pandemics. The COVID-19 Vaccine Delivery Partnership (CoVDP) has completed its work to capture key documents, which will be linked to this COVAX Repository.
- 4.6 The final phase of the independent **multi-stage COVAX Evaluation**, is also underway, with the request for proposal launched in September 2023. **This phase of the evaluation will focus on two components:** i) implementation and results of the COVAX Facility and COVAX AMC covering the period 2022-2023, and; ii) a joint evaluation of COVAX Pillar delivery efforts and results across UNICEF, WHO, Gavi and the Coalition for Epidemic



Preparedness Innovations (CEPI) over the period 2020-2023. Key stakeholders will be engaged throughout this evaluation process, and a final COVAX evaluation report will likely be available at the end of Q4 2024.

5. COVAX integration into Gavi

- 5.1 **The Office of the COVAX Facility will maintain its operational transition through December 2023**, integrating relevant COVAX functions into Gavi Secretariat and Alliance partner core processes to enable a smooth transition to the 2024-2025 COVID-19 vaccine programme.
- 5.2 **COVAX** integration, as one of the widest-ranging Gavi operational excellence (OE) programmes, has several focused workstreams, including the transition of human resources (both offboarding/downsizing and modest talent retention); maintenance of institutional knowledge; process design of the 2024-2025 COVID-19 vaccine programme; diligent risk management and mitigation related to integration efforts and incorporating process innovations from COVAX, including leveraging the tools and interfaces developed for the COVID-19 response to further automate and accelerate Gavi-internal and cross-partner processes. The few remaining COVAX "tail end" activities that stretch into 2024 have been mapped and are ready for implementation.

Part III: Update on the 2024-2025 COVID-19 vaccine programme

6. Design of the 2024-2025 COVID-19 vaccine programme

- 6.1 The Gavi Board approved a Gavi COVID-19 vaccine programme for 2024-2025 in June 2023 to launch on 1 January 2024. The two core objectives of the programme are:
 - 6.1.1 To maximise health impact by continuing to support COVID-19 vaccine delivery for high priority user groups per the SAGE Roadmap; and
 - 6.1.2 To continue to support health system strengthening and integration of COVID-19 vaccination into routine immunisation (RI), primary health care (PHC), and other health care services.
- 6.2 The Secretariat, along with partners, has advanced several key milestones since the Gavi Board approval. These include the **implementation of a country dose application and High-Level Review Panel (HLRP) for 2024-2025 as part of COVID-19 Integration into Gavi routine processes:** Countries have the possibility to submit their dose requests in two waves, each of which is followed by an HLRP review and approval process. Applications for the first wave opened in July 2023 and were approved in early September 2023. The second wave of applications will open in October 2023, with the wave II HLRP scheduled for December 2023.



- 6.3 The 2024-2025 COVID-19 vaccine programme is fully aligned to the September 2023 updated WHO SAGE prioritisation roadmap and standing recommendations for COVID-19 issued by WHO in accordance with the International Health Regulations (IHR) in August 2023.
- 7. Updated COVID-19 demand forecast for 2024-2025 and status of COVID- 19 supply portfolio
- 7.1 A total of 17 countries submitted requests for vaccines to the 2024-2025 COVID-19 vaccine programme, from which the HLRP approved 16 applications, for a total of 20 million doses in full (one application has been deferred to later approval in wave II).
- 7.2 The HLRP has approved a conservative global envelope of 60 million COVID-19 doses for AMC91 countries in 2024, with the option of increasing the global envelope later in the December 2023 HLRP, based on incoming COVID-19 dose applications from countries in wave II.
- 7.3 The UNICEF tender process launched in May 2023 is in its final stages as of end of October 2023. Given the evolving demand landscape, a staged award is being considered, with the stage 1 award expected to be announced in November 2023. Together with doses procured via tender, remaining doses from Gavi's APA and donated doses comprise the COVID-19 supply portfolio.
- 8. Continued CDS in 2024-2025
- 8.1 In 2024-2025, Gavi will support countries in reallocating their approved CDS funding when needed, to continue supporting COVID-19 vaccination for high priority use groups and integrating COVID-19 into RI and PHC. RI Catch-up activities will also be supported.
- 8.2 A contingency fund of US\$ 20 million will be available to support eligible countries that may require additional CDS funding support for 2024-2025, should gaps / needs emerge.

9. Integration of COVID-19 programmes at country-level

9.1 As part of the CoVDP sunsetting activities, a stock-taking event was organised in May 2023. Countries reflected on their COVID-19 vaccine delivery efforts and defined steps for integrating COVID-19 vaccination into RI and PHC platforms. Examples of Alliance and expanded partners efforts towards integration include increased engagement with communities reluctant to vaccinate in Togo and integrated social and behavioural change communications in Syria.

10. Potential risks to the 2024-2025 COVID-19 vaccine programme

10.1 The potential risks associated with COVAX close out and transition/preparation for the 2024-2025 COVID-19 programme are being regularly monitored. Some key risks have been successfully mitigated (such as concerns about potential delays in UNICEF tendered doses in early 2024,



successfully mitigated through compressed disbursement timelines and intensive planning across UNICEF and Gavi). Key residual risks include:

- 10.2 **Continuing evolution:** COVID-19 continues to be coupled with uncertainty. There is ongoing uncertainty in demand. While countries are expressing demand for 2024, with more requests anticipated, COVAX dose requests have certainly decreased over the course of 2023. SARS-Cov-2 itself also continues to evolve, with shifts in variants and waves of infection continuing to emerge (with tracking of these proving increasingly challenging with reduced sequencing and reporting to WHO). Should there be a resurgence of COVID-19, the COVID-19 programme is developing mitigation mechanisms whereby countries can request adjustments to their demand in 2024, and the volume of doses in the UNICEF tender can be increased.
- 10.3 **Potential mismatch in country product preferences and available supply:** Future allocations conducted by UNICEF/PAHO are subject to supply availability. **If countries do not receive their preferred product and do not accept an alternate, there could be unallocated doses leading to wastage.** Countries have been informed that while UNICEF/PAHO will endeavour to meet product preferences, they are not guaranteed.

Part IV: Key COVAX reflections

- 11. Key COVAX achievements
- 11.1 As COVAX closes out, there is an opportunity to reflect on key milestones and achievements. COVAX achievements are testament to the work conducted across COVAX partners, COVAX Facility and Gavi Secretariat colleagues and particularly the tremendous efforts by colleagues at country-level.
- 11.2 COVAX has shipped 1.97 billion vaccine doses to 146 countries. These COVAX-supported vaccines make up 74% of all doses delivered to low- income countries (LICs), 68% of all doses to AMC-supported African countries and 39% of all doses to 20 lower- income AMC countries that have never been previously supported by Gavi. And whilst inequities persist in population coverage, for some high priority population groups, this gap is less stark (primary coverage of healthcare workers in lower income countries is at 84% compared to 89% in HICs; primary coverage of older adults in lower- income countries is at 72% compared to 95% in HICs).
- 11.3 In addition to COVID-19 vaccines delivered, **COVAX has also committed and disbursed US\$ 1.188 billion in COVID-19 vaccine delivery support funding across 88 AMC participants.** These investments have improved cold chain infrastructure, rapidly catalysed efforts to digitise health data, expanded critical capacities, and helped integrate COVID-19 into routine programmes.
- 11.4 Estimates show that COVAX helped avert more than 2.7 million deaths by the end of 2022. COVAX doses averted 75% of vaccine-preventable deaths in



low-income countries and 73% of vaccine-preventable deaths in AMC- supported African countries by the end of 2022.

11.5 Beyond these milestones, **COVAX also provided a wealth of diverse learnings across the vaccine value chain** – from deal-making, regulatory approvals, indemnification and liability, funding modalities, delivery in country, shared risk management and mitigation – as well as learnings on the "how" – across core Alliance and expanded partners.

12. How Gavi is taking key COVAX learnings forward

- 12.1 COVAX has generated learnings for both Gavi's core work, as well as its future engagement in PPPR. Annex A provides links to published learnings as well as reports from the independent COVAX evaluation commissioned by Gavi.
- 12.2 Select examples of learnings for Gavi's core work include:
 - Learnings linked to improving access to vaccines in complex humanitarian settings and the necessity to strengthen partnerships with humanitarian agencies which are equally applicable to Gavi's core work as for PPPR.
 - Process adaptations, particularly CDS experience in expediting disbursements to countries, have been explored as part of Gavi's Operational Excellence agenda and the 2024-2025 COVID-19 programme.
 - Aspects of COVAX's "ways of working" have also already been replicated for Gavi's core work such as the adoption of "must-wins" to unite leadership on top priorities.
- 12.3 Beyond core, Gavi and partners are bringing together lessons from the COVID- 19 response and COVAX experience with other learnings from outbreaks to strengthen PPPR. Select key learnings emphasise the need to:
 - Start planning and preparations for future pandemics now which should include a strong network of partners able to take on risk and coordinate broader stakeholder engagement across the entire vaccine value chain.
 - Ensure regional, country, CSO and local perspectives are part of future design for PPPR.
 - Secure earlier and greater access to at-risk / contingency financing for both procurement and vaccine delivery.
 - Diversify vaccine manufacturing.
 - Further enhance efforts towards building resilient health systems.
- 12.4 Doc 10a and Doc 10b include further information about how Gavi proposes to strengthen country, vaccine and partner readiness for future public health events based on some of these critical learnings.



13. Closing reflections

13.1 The Secretariat and the Office of the COVAX Facility would like to close with a sincere note of appreciation for the dedication, passion, collaboration, innovation and strong partnerships that were the cornerstone of COVAX and its work. We recognise and value the contributions and collaborative efforts from those we engaged directly with and beyond, particularly our COVAX Pillar partners, Alliance partners and constituencies, regional colleagues as well as the steadfast guidance and support from COVAX and Gavi governance bodies and the Board. Our greatest gratitude is reserved for our country colleagues who made miracles happen on the ground and worked tirelessly to introduce, ramp up and deliver the largest and quickest vaccination effort in history. We look forward to taking learnings forward and continuing to work together to ensure a healthier future.

Section C: Actions requested of the Board

This paper is for information only.

<u>Annexes</u>

Annex A: COVAX Reporting Framework