Gavi – The Vaccine Alliance

EVALUATION MANAGEMENT RESPONSE

COVAX Facility and COVAX Advance Market Commitment (AMC) Formative Review and Baseline Study

Business Owner: Office of the COVAX Facility
Evaluation Title: COVAX Facility and COVAX AMC Formative Review and Baseline Study
Evaluation Year: 2022 – March 2023

Evaluation Purpose: The purpose of the Formative Review and Baseline Study is to ensure the successes, challenges, and lessons learned from the COVAX Facility and COVAX AMC are independently documented – both from a learning and an accountability perspective.

Evaluation Key Objectives:

- Inform potential course correction through early assessment of core design elements, considering both accountability for immediate results and learning for potential course correction.
- Enable appropriate measurement over time of the effectiveness and performance of the COVAX Facility and COVAX AMC.

Gavi
The Vaccine Alliance

| Gavi Secretariat Overall Response to the Evaluation: | We welcome this report of the first phase of the multi-stage independent evaluation of the COVAX Facility and COVAX AMC, which covers the period from March 2020 through December 2021. We, the Gavi Secretariat, take our responsibility to contribute high quality, credible, and insightful evidence on the response to the COVID-19 pandemic seriously, and are pleased that such a robust independent report will be added to the public record, representing a significant contribution to preparing for future pandemics. We are committed to continue contributing to this space through further evaluation and learning work in the coming months, including the next phase of the evaluation covering the period 2022-2023.

The report, delivered by Itad (www.itad.com), offers an important and generally balanced critique of the COVAX Facility and COVAX AMC. We welcome many of the findings and recommendations and in many cases, recommendations put forward by the evaluators have already been acted upon. We are gratified that many of these recommendations are aligned with the strategy and operational model that COVAX adopted while also offering useful guidance on how to further build on COVAX's approach.

There are a few insights that we feel are especially important and worth underlining. In particular, we fully agree with one of the core lessons of the evaluation that while COVAX was unprecedented in speed and scale, a future mechanism will need to deliver faster and at a larger scale to fully overcome the forces of vaccine inequity. The evaluation highlights where COVAX approaches were effective while providing specific advice on what we collectively must do better next time, including the need to:
• Increase access to at-risk funding at the start of future outbreaks to enable earlier engagement and contracting with vaccine suppliers as a critical complement to a strong resource mobilisation function and approach, which during COVAX leveraged Gavi's pre-existing capabilities and donor relationships and was "highly successful" according to evaluators;
• Leverage established organizations with strong stakeholder engagement and governance mechanisms to anchor pandemic response, with evaluators commenting that "Gavi, as a public-private partnership (PPP)… was a legitimate body to lead an international, multi-stakeholder effort to rapidly scale up vaccination programming";
• Design a future mechanism well before the next pandemic, including specific solutions to promote a more equitable flow of supply, a recommendation that Gavi has fully embraced and is committed to advancing through its broadened pandemic preparedness work; Make significant investments in the expansion of vaccine production capacity, which Gavi is responding to through its African Vaccine Manufacturing initiative.

Such an evaluation is a complex endeavor. We recognize it was not able to cover some aspects that we deem important. We also challenge some of its findings. As a point of principle across all evaluation and learning work linked to the COVID-19 pandemic, we believe that appropriate contextualisation is essential. Consider what was accomplished in under two years given the starting place: a new disease lacking data on fundamental questions like how it spreads, its severity, and who was |

The Vaccine Alliance

	most at risk; no available pharmacological tools; vaccine R&D timelines typically on the order of a decade with success rates under 20%; health systems not set up to rapidly vaccinate entire populations; no available funding; a near total lack of mechanisms, processes, policies, and infrastructure suitable for the crisis response. While the evaluation does make some references to this context, we feel it does not consistently reflect on the bigger picture and broader context COVAX was operating in, particularly that the starting place of the COVAX response was one of inequity; the international order was inequitable going into the pandemic, and these underlying, structural inequities shaped every aspect of the pandemic response. Unpacking this broader context is something we note that Itad did address during a dissemination event for Gavi partners, board members, and donors earlier in April – for example, recognising that supply shocks and particularly export bans fell largely outside of the COVAX Facility's ability to control. Similarly, while certain trade-offs were explored and highlighted in the report, we would have appreciated further analysis of COVAX's decisions/actions from the perspective of what was known and what it was trying to optimise for at the time. The evaluation offers many sensible recommendations with the benefit of hindsight, but pandemics are inherently unpredictable and necessitate urgent action with only limited information at hand. What alternative actions could COVAX have pursued? Which hard trade-offs did we get wrong? Making these decisions is challenging, and during the dissemination event, the evaluators recognised the complexity of trade-offs required to optimise for speed and agility. A more comprehensive interrogation of decisional counterfactuals based on what was known or possible when the decisions were being made would have been valuable. Furthermore, we believe the report could have more explicitly considered COVAX's response compared to other historical or contemporaneous initiatives and how it performed against broader "what if" scenarios (e.g., no COVAX at all). Finally, one area not comprehensively covered in the evaluation, but which was at the heart of COVAX's strategy, is resilience. Given the levels of uncertainty, COVAX was designed to be viable under a wide range of scenarios and expressly put in place measures to prevent risks from materializing that otherwise would have been highly disruptive. A more thoughtful assessment of the extent to which COVAX prevented, withstood, and adapted in the face of shocks would have been beneficial. Stepping back and mindful of the areas that could be strengthened, what is most important is that the report offers us and the broader health community rich insights and learning to shape future outbreak and pandemic responses. We reiterate our commitment to acting on these learnings and have already taken on board many of them in our current COVID-19 operations. As approved by the Gavi Board, we are engaged in implementing a broader pandemic preparedness and response strategy which is embedding learnings from COVAX as a core element alongside other ambitious initiatives in the innovative financing, regional manufacturing, and digital health spaces.

	We want to conclude by thanking the evaluators, Itad and 3ie, who conducted this evaluation, and the many contributors to this work including Gavi's Evaluation Advisory Committee and the Evaluation Steering Committee who have collectively made a major contribution towards achieving a more equitable response to the next pandemic. While the following formal responses to specific findings and recommendations have largely been compiled by the Gavi Secretariat, we appreciate the review and inputs received from our COVAX Pillar partners - CEPI, WHO and UNICEF.

Design - High-level design principles and features	
Finding 1	COVAX, and specifically the COVAX Facility and AMC, was a bold and ambitious proposal to avoid the problem of unequitable allocation of vaccines experienced during previous pandemics.
Finding 2	The COVAX Facility and AMC design was clearly articulated across a range of documents, with a ToC and indicator framework developed during implementation.
Finding 3	Significant design components were new, innovative and untested, and as such it was unclear at the outset whether the COVAX Facility and AMC would work as intended. While most stakeholders considered it a risk worth taking, some aspects of the design were heavily contested.
Finding 4	COVAX aims to achieve fair access within the global vaccine ecosystem rather than seeking to fundamentally reshape this system.
Finding 5	Assumptions underlying the vision of the COVAX Facility and AMC as a channel for global joint procurement were revealed to be too optimistic.
Finding 6	While equity is a guiding principle of COVAX, the COVAX Facility and AMC design focuses on cross-country distribution of vaccines. Its role in ensuring within-country distribution and in relation to human rights and gender equality is not clearly articulated or understood.
Alliance Management Response to Findings 1-6	We are in general agreement with these findings. We believe it was right to be ambitious and would contend that an aspiration of global solidarity was important. The ability or not to realize global joint procurement was not exclusively a function of an overly optimistic vision, but also choices that partners and other global actors made that were outside of COVAX's control despite offering the opportunity for all to procure via COVAX. The solidarity that came from 193 countries working together also helped to create visibility for needs of developing countries and arguably helped in resourcing and dose mobilization which was ultimately necessary. It is accurate that COVAX made a decision to work within the global vaccine ecosystem in order to prioritize speed and access, leveraging existing relationships, capacities, etc. – it was determined that COVAX's objectives were already highly ambitious in a highly complex context, without also taking on the responsibility of designing and implementing a new and parallel vaccine ecosystem in the midst of a rapidly expanding global pandemic. At the same time, COVAX was supportive of those who advocated for broader

	systemic changes towards a more equitable ecosystem. Equity was the core guiding principle for COVAX. Finally, the COVAX theory of change was clear that our primary role in early response was in ensuring cross-country equity (e.g., via the fair and equitable allocation mechanism), with in-country equity as a secondary objective particularly as we increased our role in delivery.
Recommendation area 1: Design - High-level design principles and features **Recommendation 1a**	**The overall design approach to ensuring equitable access to health technologies in a health emergency should be based on the understanding that stakeholder behaviors will echo those seen in the early stages of the COVID-19 pandemic. In particular, HICs will serve their own national interests first in seeking to secure scarce commodities, and manufacturers will in most cases give priority to markets in HICs. While the international community works towards agreements based on global solidarity and effective regulations for knowledge sharing, pandemic preparedness and response mechanisms should plan for and proactively mitigate the negative effects of vaccine nationalism and commercial interests.**
Alliance Management Response *(Agree, Partially Agree, Reject)*	Agree
If recommendation is rejected/ partially accepted, indicate reasons:	We are broadly supportive of the recommendation. We note that COVAX was aware of the risk of vaccine nationalism from the outset and worked to mitigate it (e.g., by building a geographically diversified portfolio) yet believed in the importance of setting an ambitious goal of global solidarity to try to hold the world to a higher standard despite possessing limited levers to prevent vaccine nationalism from arising. At the same time, we recognize the challenge and are committed to exploring improved ways of responding to a future pandemic.
Actions planned	• Apply learning from COVAX on dose sharing to a future pandemic dose-sharing strategy and arrangements • Supporting international agreements on real time access to supply, including through dose sharing, for example leveraging the Berlin Declaration and Pandemic Accord • Ensure adequate funding is available via the Pandemic Vaccine Pool (PVP) and front loading instruments for effective and rapid pandemic response

Recommendation area 1: Design - High-level design principles and features Recommendation 1b	**A future international vaccine procurement and allocation mechanism should be clear that its primary focus is to support those countries with the least ability to procure independently and most likely to be dependent on such a mechanism. If countries with the ability to self-finance are allowed to opt into the mechanism, care must be taken that this does not jeopardize access for the lowest-income countries.**
Alliance Management Response *(Agree, Partially Agree, Reject)*	Agree
If recommendation is rejected/partially accepted, indicate reasons:	We agree with the underlying notion that countries with the greatest barriers to access should be the primary focus. However, additional analysis of key assumptions made, trade-offs debated, flexibilities extended through the SFP model, or cost-benefit analysis would be valuable to support the recommendation. The ethos of global solidarity was core to the COVAX Facility design, and we believe that assembling nearly all governments in the world to be part of a shared response carried tremendous benefits, even if not always direct or quantifiable. For example, for some HICs, involvement in the Self-Financing Participant arrangement paved the way for their active engagement as dose donors. Furthermore, we would caution against being overly prescriptive as each pandemic is unique and any consideration of future participation would need to be responsive to the trajectory of that particular pandemic. CEPI further contributed that procurement and allocation mechanism design evolutions will by themselves not "fix" these issues. CEPI, for example, is also advocating for more geo-distributed manufacturing and regional procurement mechanisms as important elements towards a better-designed holistic system.
Actions planned	• Develop high-level guidance on country scope considerations reflecting lessons from COVAX in preparation for a potential future crisis as part of a "Pandemic Playbook"

Recommendation area 1: Design - High-level design principles and features **Recommendation 1c**	**Before the next pandemic, WHO, WTO, or other agencies with a normative mandate, should assess the best way to address the liability risk to manufacturers and enable them to provide new health products in emergencies, without shifting liability to recipient LICs, LMICs or humanitarian agencies.**
Alliance Management Response *(Agree, Partially Agree, Reject)*	Partially agree
If recommendation is rejected/partially accepted, indicate reasons:	We agree with the spirit of the recommendation but believe the contract holder, which was Gavi during COVAX, should also be consulted. Additionally, we believe managing manufacturers' liability risk should only be considered in exceptional circumstances during a PHEIC wherein a significantly large scale up of a novel vaccine is necessary to be achieved in a shorter period of time and during that time the focus should be on preventing liability from limiting access, as opposed to protecting manufacturers from the liability risk of any new health product used in emergencies. We also note the conclusion in the text of the report that the requirement for the NFC hampered access to vaccines. Our view is that the implementation of the NFC was in fact an enabler of access and ensured that deliveries could be made to the AMC92 countries and did not hamper access. We also note the conclusion that the NFC was costly to administer, and although we accept that providing capital for compensation was costly, the administration of the NFC itself is not a costly exercise. Furthermore, the relatively low number of claims in part reflects the relatively favorable safety profile of COVID-19 vaccines that were approved for use and should not be directly construed as proof that the scheme was overcapitalized. Note that this response also integrates feedback from WHO.

Actions planned	• Based on lessons from COVAX, further elaborate the approach to indemnity and liability (I&L) in advance of the next pandemic – this should be consultative in nature across key stakeholders including industry associations (e.g.: IFPMA, DCVMN) • Identify requirements for I&L provisions and NFC program design and implementation in the context of delivery in humanitarian settings • Actively engage with the International Negotiating Body process to support the formulation of clauses on I&L and NFC
Design – Design Process	
Finding 7	The COVAX Facility and AMC were designed by a relatively small group of people with a shared vision, principles and sense of urgency.
Finding 8	COVAX Facility and AMC design decisions reflected the disproportionate influence of donor countries.
Finding 9	The pharmaceutical industry was represented in the COVAX design process and governance, influenced design decisions, and did not always work to further the COVAX Facility's ultimate objective: equitable access to COVID-19 vaccines
Finding 10	COVAX leadership was slow to engage low and middle-income countries, resulting in public criticism of COVAX.
Finding 11	There was hesitation to engage civil society in the early design discussions on the COVAX Facility as it was thought that this would delay decision making.
Alliance Management Response to Findings 7-11	While the design process could have been more inclusive, there were meaningful attempts to engage all of these groups (over 300 stakeholders consulted in the early design phase). Moreover, in critical governance contexts, for example at meetings of the Gavi Alliance Board, key stakeholder groups were represented. Finally, management was acutely aware of the need to be inclusive, but also the need to move quickly, and strived to take a balanced approach between the two. Interactions could therefore be targeted. Industry was engaged as critical partners to accessing supply. Countries were also engaged in the context of developing country agreements and mechanism design.

Recommendation area 1: Design process **Recommendation 1d**	**The process of designing an international vaccine procurement and allocation mechanism for the next pandemic should be more inclusive, transparent and accountable than was the case for the COVAX Facility and AMC. Global south countries, regional bodies, civil society and humanitarian agencies must have a meaningful role from the earliest design stages.**
Alliance Management Response *(Agree, Partially Agree, Reject)*	Agree
If recommendation is rejected/partially accepted, indicate reasons:	We agree with the aspiration of inclusivity and transparency – we recognised all these stakeholders need to be at the table and COVAX did have meaningful outreach to hundreds. In preparation for the next pandemic, we are already proactively engaging with broader stakeholders in important design components that are linked to key COVAX learnings (one key example being our close engagement with the African Union towards building out our Regional Manufacturing Strategy).
Actions planned	• Active participation in the on-going WHO/G7/G20 led initiatives regarding the design of future response platforms advocating for early engagement and inclusivity including specifically the roles of regions • Co-lead work on operational plans for future pandemic response with Alliance and other partners, in consultation with broader stakeholders including countries and regions • Leverage and implement actions arising from the Joint Convening on COVID-19 vaccinations in humanitarian settings and the contribution to broader pandemic preparedness
Recommendation area 1: Design process **Recommendation 1.e**	**The design of a future mechanism should begin well before the next pandemic, thereby allowing the time for broader engagement of global south countries, regional bodies, civil society and humanitarian agencies.**
Alliance Management Response *(Agree, Partially Agree, Reject)*	Agree

Gavi The Vaccine Alliance

If recommendation is rejected/partially accepted, indicate reasons:	
Actions planned	• Participate in the external WHO, G7 and G20 led design initiatives • Leverage and implement actions arising from the Joint Convening on COVID-19 vaccinations in humanitarian settings and the contribution to broader pandemic preparedness • Co-lead work on operational plans for future pandemic response with Alliance and other partners, in consultation with broader stakeholders including countries and regions
Recommendation area 1: Design process **Recommendation 1.f**	**Decision making after a pandemic has begun, when speed is critical, should be overseen by a robust and participatory governance function.**
Alliance Management Response *(Agree, Partially Agree, Reject)*	Agree
If recommendation is rejected/partially accepted, indicate reasons:	COVAX strived for a robust, participatory governance function and are working towards incorporating learnings (e.g., clearer decision-making pathways, less fragmentation) into designs for a future response.
Actions planned	• Build on VIS epidemics framework for process on decision-making for emerging infectious diseases which lack current Gavi programs including expedited track for outbreaks with pandemic potential as part of the work underway on implementation of Gavi's expanded role in Pandemic Prevention, Preparedness and Response that will be further considered by the Gavi Board in June 2023 • Co-lead work with Alliance partners and others on a cross-Alliance pandemic response plan detailing operational plans for future response including clear hand offs as well as agency specific governance decision making, delegation of authority, funding arrangements, etc.

Recommendation area 1: Design process Recommendation 1g	**The assumptions underlying the design of a future mechanism should be made explicit so the corresponding risks can be assessed and mitigation measures be in place where possible.**
Alliance Management Response *(Agree, Partially Agree, Reject)*	Agree
If recommendation is rejected/partially accepted, indicate reasons:	We agree and are planning to prepare as much as possible for a future pandemic before it happens to promote sufficient risk mapping. However, we also believe that pandemics are highly differentiated (e.g., COVID-19 vs. Mpox), so it will be critical to revisit these assumptions, risks, and mitigations once new emergencies arise.
Actions planned	• Identify and document key assumptions underlying a future mechanism and associated mitigation strategies as part of the "Pandemic Playbook" that is under development and cross-Alliance pandemic response plan

Implementation: Governance and management	
Finding 12	Over the course of 2020 and 2021, despite a very difficult operating environment, Gavi and partners successfully launched and implemented the COVAX Facility and AMC.
Finding 13	Gavi, as a public–private partnership (PPP) with broad-based stakeholder governance and engagement, was a legitimate body to lead an international, multi-stakeholder effort to rapidly scale up vaccination programming.

Finding 14	Gavi was created, in part, to be able to take action quickly and at scale. Its structure and governance model are perceived by stakeholders to offer a number of comparative advantages for responding to the COVID-19 pandemic.
Finding 15	The scope and scale of the COVAX Facility and AMC posed a challenge to Gavi's existing governance arrangements.
Finding 16	A range of governance structures were established for the COVAX Facility and AMC to meet different purposes, broadly focused on stakeholder engagement, soliciting external expertise and guidance, and accountability to donors.
Finding 17	COVAX Facility governance arrangements have been overly complex, with a lack of clarity over roles and with overlapping responsibilities between bodies. These arrangements have created a huge administrative burden and have not provided an effective forum for genuine stakeholder engagement in decision making.
Finding 18	Partner working relationships for the COVAX Facility have at times been challenging and blurred the usual lines of accountability for Gavi business.
Finding 19	Stakeholder engagement and external communications posed significant challenges for the COVAX Facility and AMC.
Finding 20	While a strong management team was created, it was under-resourced for the scope and scale of its responsibilities.
Finding 21	A very strong mission-driven culture within the Office of the COVAX Facility has enabled it to rapidly implement a hugely ambitious agenda, though the extent to which inclusivity in decision making has influenced the speed of implementation is unclear.
Finding 22	The initial COVAX Facility design was agreed in mid-2020 without a full understanding of the associated risks. Strong risk management systems and processes have been established over time.
Finding 23	A strong resource mobilization function was established around the COVAX AMC.
Finding 24	The COVAX AMC was not able to access sufficient financial resources immediately in 2020.
Finding 25	COVAX AMC resource mobilization in 2021 was highly successful.
Finding 26	Dose donations were handled primarily by the Resource Mobilization Team and became an important source of supply, but this created some tensions internally and with receiving countries.

Gavi The Vaccine Alliance

Alliance Management Response to Findings 12-26	We agree with many of these findings and note again the context that the team was operating in, particularly in relation to findings 18, 21, 22. It was a highly uncertain environment, and management had to navigate many trade-offs and competing priorities. It is also not clear the extent to which many of the challenges that the evaluators catalogue could have been avoided. What is clear it that further preparation before the next pandemic including through taking on board the lessons of COVAX is essential for any future response. We also would emphasise that while some of these findings may have had some relevance in the early stages of COVAX, approaches changed over time to adapt to changing context and early learnings. For example, regarding finding 17, we did evolve our governance arrangements, and roles and responsibilities were clarified. We look forward to the next phase of the evaluation shedding light on how COVAX evolved over time.
Recommendation area 2: Governance and management **Recommendation 2a**	**Establish a governance mechanism that:** **1) oversees the entire initiative, including the actions of all participating agencies; and** **2) balances participation with transparency and accountability. Governance should be as inclusive as the need for rapid decision-making permits. Where broad engagement is not possible, full transparency and public accountability on processes and outcomes become even more important.** *(Ref 2.1 and 2.2)*
Alliance Management Response *(Agree, Partially Agree, Reject)*	Agree
If recommendation is rejected/partially accepted, indicate reasons:	We agree with the principles described in the recommendation - end-to-end oversight, transparency, accountability, inclusivity, agility - and propose working to improve how to operationalize these principles for a future response, noting that these principles were also at the core of COVAX's governance structures. We would propose that using existing governance structures where possible is an additional principle to consider given the potential for efficiency gains and the benefits of relying on existing, trust-based relationships. We also believe that the need for rapid and flexible decision

	making in a pandemic response is paramount, and governance mechanisms must be designed accordingly. CEPI further complemented by noting the importance of both collective mechanisms and recognizing accountability of agencies to their existing governance.
Actions planned	• Develop designs for potential future governance structures as part of pandemic preparedness planning and taking into account the Gavi Board's guidance on Pandemic Prevention Preparedness and Response (PPPR) and findings from this evaluation
Recommendation area 2: Governance and management **Recommendation 2b**	**Build management structures that draw on the established systems, processes, staff and culture of one or more existing organizations without allowing these structures and processes to impede unnecessarily the speed and flexibility required in emergencies.** *(Ref 2.3)*
Alliance Management Response *(Agree, Partially Agree, Reject)*	Agree
If recommendation is rejected/partially accepted, indicate reasons:	We agree and also note the lesson from this pandemic that care must be taken that a future response does not significantly detract from an agency's core work, and measures to maintain the ability to deliver on core work are considered in addition to responding to the emergency. However, we believe that COVAX offers a positive example of the model proposed in the recommendation as it was built off of existing organizations, systems, processes, and staff, and we intend to take this model forward in planning for future pandemic responses
Actions planned	• Development of HR surge strategy for Alliance to augment functions (e.g., market shaping, legal contract negotiation, country comms) needed in earliest and subsequent phases of the pandemic response and to foster structures that minimize distraction from core work (e.g., dedicated resources and teams)

Implementation : Market shaping and supply	
Finding 27	The shifting supply–demand context in late 2021 may have limited the potential of the cost-sharing arrangement introduced in mid-2021, which allowed AMC countries to purchase doses beyond the fully donor-subsidized doses they were already due to receive from COVAX.
Finding 28	In the initial design, it was anticipated that COVAX would play a significant role in market shaping, increasing total supply through a combination of direct funding to product developers and manufacturers ('push') and the incentive effects of purchase commitments ('pull').
Finding 29	Within the broader market shaping effort, the division of labor between Gavi's role in administering the COVAX Facility and AMC (focused on 'pull mechanisms') and CEPI's (focused on 'push mechanisms') played to respective organizational strengths. However, the distinction between push and pull was not always completely clear.
Finding 30	Ultimately a market-wide guarantee, backed by secure funding and formal legal and operational machinery, was not put in place.
Finding 31	The COVAX Facility did not engage in or seek to incentivize tech transfer, with the exception of an early deal with SII
Finding 32	The COVAX Facility's market-shaping efforts relied on bilateral APAs with manufacturers, along with pooling of resources and procurement.
Finding 33	The COVAX Facility and AMC ultimately lacked the market power to meet its market-shaping objectives in the early phase of the COVID-19 pandemic.
Finding 34	With the exception of the deals with SII, the influence of the COVAX Facility and AMC's APAs on manufacturing capacity was probably modest in the early stages of the pandemic.
Finding 35	The COVAX Facility and AMC was successful in achieving reasonable pricing for LICs and LMICs.
Finding 36	The COVAX Facility and AMC design relied primarily on negotiation of APAs with manufacturers to secure supply.

Gavi The Vaccine Alliance

Finding 37	The approach to securing supply produced some early successes, but deliveries from the COVAX Facility and AMC quickly and increasingly lagged behind targets and expectations.
Finding 38	The COVAX Facility and AMC's supply shortfall in 2021 has been attributed to several causes, including India's decision to halt exports, regulatory and manufacturing delays, limited cash in hand in 2020, lower priority accorded to the COVAX Facility and AMC by some manufacturers, and lack of pre-established arrangements for handling dose donations.
Finding 39	Although in the first months the COVAX Facility and AMC had limited cash in hand to commit to deals with manufacturers, it is not clear that this constraint substantially delayed the signing of APAs or affected supply.
Finding 40	The halt to vaccine exports imposed by India in April 2021 was a major blow to COVAX's supply during a critical period.
Finding 41	Some manufacturers may have accorded a lower priority to the COVAX Facility and AMC than to other customers, particularly HICs.
Finding 42	Most of the COVAX Facility and AMC APAs did not include enforceable clauses on delivery timing.
Finding 43	The COVAX Facility and AMC ultimately lacked the market power to meet its supply objectives in the face of aggressive competition from HICs.
Finding 44	In response to the supply crisis stemming from the decision in India to halt exports, the COVAX Facility and AMC gave greater priority to donations, which became a critical source of supply for much of 2021.
Finding 45	Lack of pre-established arrangements for donations slowed supply from this source.
Finding 46	By the end of 2021, the COVAX Facility had built a broad portfolio of vaccines and could project abundant supply for 2022.
Finding 47	Going into 2022, the COVAX Facility faced significant oversupply.
Alliance Management Response to Findings 27-47	While we agree with many of these findings, we would challenge three points in particular: 1. We believe lack of funding that could be used "at risk" materially affected our negotiating ability with manufacturers. 2. We do not think that a lack of pre-established arrangements for handling dose donations meaningfully slowed supply availability as this was largely dictated in the early days by

	availability of surplus doses, donor willingness to share them, and the time it took donors and manufacturers to agree contracts, which they did not engage with until a decision to donate had been made. That said there are certainly learnings from our experience with dose sharing, including around ways that doses could have been allocated and shipped faster, that we would take forward in planning for potential use of dose sharing in a future pandemic. 3. Through the use of APAs, we were able to assemble the largest portfolio of COVID-19 vaccines globally. Although market wide guarantees had been considered early in the design, APAs can be a more forceful, targeted instrument by committing specific manufacturers to supply COVAX while providing sufficient assurance to them to bring capacity online to produce the large quantities of doses (sometimes 100s of millions) that were needed. This was not a negligible market shaping impact. The evaluators also note the tech transfer to SII whose market-shaping importance should not be understated given SII's capabilities and production capacity; however, CEPI carried primary responsibility within the COVAX pillar for tech transfer investment and activities, which was then backed by APAs from Gavi, e.g., in the case of AZ, Novavax and Clover. More broadly, we believe our ability and actions successfully taken to manage supply uncertainties and risks could have been documented and highlighted more clearly in the report, such as the extensive use of options in contracting to manage demand uncertainties and a robust candidate screening process to maximise chances of achieving portfolio outcomes.
Recommendation area 3: Market shaping and supply **Recommendation 3a**	**Play a stronger role in expanding global supply, including through investment to expand vaccine production capacity in preparation for future outbreaks and greater support for technology transfer during an outbreak. Other agencies should have primary responsibility for tech transfer and building supplier capacity, but Gavi should align its actions as a buyer with these investments by others.**
Alliance Management Response *(Agree, Partially Agree, Reject)*	Agree

If recommendation is rejected/partially accepted, indicate reasons:	Gavi is already increasing its support for the expansion of global supply. In December 2022, the Gavi Board approved a new regional manufacturing strategy with a particular focus on Africa. This strategy is based around four key pillars focused on using Gavi's market shaping power to help build more sustainable and regionally distributed vaccine markets. Gavi is also already aligning with investments of others from a technology transfer perspective. For example, future iterations of the COVID-19 Market Shaping Roadmap and tender strategy will take into account full awareness of upstream technology transfer movements by other agencies and manufacturers. *CEPI also embraced this recommendation, further noting that it is critical that appropriate international pandemic financing mechanisms have the ability and willingness to take risks*.
Actions planned	• Further elaborate Regional Manufacturing Strategy framework and detailed design
Recommendation area 3: Market shaping and supply **Recommendation 3b**	**Refine the approach to APAs through: greater access to at-risk funding at the start of future outbreaks in order to allow purchase agreements with product developers to be struck earlier and at greater scale; making transparency on delivery queues a condition of APAs; and considering the role of price in affecting access to supply in the context of competition with HICs.** *(Ref. 3.2. through 3.4)*
Alliance Management Response *(Agree, Partially Agree, Reject)*	Partially agree
If recommendation is rejected/partially accepted, indicate reasons:	We partially agree with this recommendation. We welcome the recommendation on greater access to at-risk funding, and this is something we have been strongly advocating for as essential for rapid response to future pandemics. While we agree with pushing for greater transparency where feasible, we do think trade-offs need to be considered in a desperate struggle for limited supply. While COVAX did have multiple positions in our negotiations with manufacturers that were

	non-negotiable, insisting on any absolute conditions during a negotiation carries the risk of jeopardizing the goal of achieving prioritized and rapid access to vaccines and would need to be weighed responsibly to ensure reasonable trade-offs are applied. We also are unconvinced that modest price increases would be sufficient to affect access to supply given the many factors that play into determining a manufacturer's shipment queue. Likewise, insisting on enforceable delivery schedules would also have required trade-offs, particularly as an objective was to lock in access early, generally before manufacturers had sufficient clarity to forecast delivery schedules.
Actions planned	• Ensure adequate funding is available via the Pandemic Vaccine Pool for effective rapid pandemic response • Publish a white paper detailing the role of Gavi APAs for COVAX in the COVID-19 pandemic, and lessons learned for future pandemics
Recommendation area 3: Market shaping and supply **Recommendation 3c**	**Ahead of the next pandemic, put arrangements into place for facilitating and efficiently managing other sources of vaccine supply, including dose-sharing commitments (e.g. Berlin Declaration), donations of excess vaccine procured by HICs and others, and facilitated purchases on the model of the arrangement with the US and Pfizer.** *(Ref 3.5 through 3.6)*
Alliance Management Response *(Agree, Partially Agree, Reject)*	Partially Agree
If recommendation is rejected/partially accepted, indicate reasons:	We believe this recommendation could be worded more clearly, but in general, we agree with the idea of pre-arranging equitable supply access in advance of a pandemic to the degree possible. We do not agree that facilitated purchases are necessarily the go-to solution; they offer some benefits, but also carry notable drawbacks and think this aspect of the recommendation needs to be unpacked further. Gavi will publish a review of dose donations to COVAX to support learning from the experience. Gavi notes that the Berlin Declaration is not a dose-sharing commitment, but a preliminary concept proposed by industry with many pre-conditions and few operational details.

	Gavi strongly believes that there should be commitments made to equitable access in advance of the next pandemic.
Actions planned	• Engage IFPMA/DCVM, and other stakeholders to clarify commitments and effectively operationalize the Berlin Declaration and draft Pandemic Accord to deliver equitable access through pre-arranged supply obligations across all supply sources including dose donations and procured supply • Apply learnings from COVAX on dose sharing to a future pandemic dose-sharing strategy and arrangements
Recommendation area 3: Market shaping and supply **Recommendation 3d**	**Make greater use of soft power to seek to influence the behavior of vaccine manufacturers and HICs. This influence, which should be exercised in cooperation with LMICs and civil society, could involve public communication, transparency indices and other tools.** *(Ref 3.7)*
Alliance Management Response *(Agree, Partially Agree, Reject)*	Partially agree
If recommendation is rejected/partially accepted, indicate reasons:	Throughout its formation and execution, COVAX was prolific in leveraging soft power to achieve its objectives. This approach was successful in some areas, for example in influencing HICs to support and participate in COVAX or in accelerating dose sharing. However, its utility was more limited in the context of constrained supply when national interest dictated that countries would seek to protect their own population first. Soft power, in this area, was no match versus the hard needs of nations. Having said the above, Gavi will of course build from our communications and broader soft-power experiences in future responses, and remains very committed to exploring additional ways to work even more effectively with LMICs and CSOs in this area and beyond.
Actions planned	• Greater collaboration with regional and national actors, including through MOUs

Implementation: Allocation	
Finding 48	Relying on WHO and SAGE for a normative allocation framework was appropriate, given COVAX partners' mandates and the sensitivity around global allocation decisions.
Finding 49	Dose allocation in 2021 and for Phase 1 was not conducted as anticipated, with no two rounds conducted in the same way and with several different processes being involved. The approach evolved as a pragmatic response to a challenging operating environment.
Finding 50	Most stakeholders outside of the JAT consider the allocation mechanism, and the algorithm in particular, to have been overly complex and difficult to understand.
Finding 51	Until Round 7, conducted in September 2021, the allocation mechanism was operationalized broadly in line with the WHO Allocation Framework and the principle of proportional allocation. This did not factor in other, non-COVAX, sources of vaccine supply, and as a result did not optimize global equality (equal access to vaccines) or equity (prioritization of those most in need) as much as it could have.
Finding 52	The allocation of doses from September to December 2021 did factor in other sources of vaccine supply, which gave the COVAX Facility and AMC more flexibility to prioritize countries with low vaccine coverage and led to a more equitable allocation.
Alliance Management Response to Findings 48-52	We agree with these findings. We acknowledge that communicating such an inherently complex and multilayered allocation mechanism proved challenging and contributed to the perception of excessive complexity. As per these findings, we did evolve the allocation mechanism over time while retaining equity as a core principle. We also stress the important learning that allocation alone cannot ensure equity, as this requires a more holistic approach to supporting country uptake, for example COVAX's delivery efforts undertaken in concert with our partners.
Recommendation area 4: Allocation **Recommendation 4**	**Design a framework for global allocation of scarce commodities based on a set of guiding principles. As with the COVID-19 WHO Fair Allocation Framework, this should set out principles for equitable allocation across countries and population groups. Principles should not be interpreted as rules and trade-offs between principles should be considered at the outset. The framework should be flexible enough to apply in an uncertain context while maintaining focus on global objectives.**

Alliance Management Response ***(Agree, Partially Agree, Reject)***	Agree
If recommendation is rejected/partially accepted, indicate reasons:	We agree with the recommendation and note that this approach was generally followed by the COVAX Facility. We would emphasize the point around the need for flexibility to respond to evolving needs.
Actions planned	• Document and interrogate learnings from allocation during the COVID-19 pandemic to ensure these learnings underpin future design

Implementation: Vaccine roll-out and delivery support	
Finding 53	Throughout 2020 and into mid-2021, there was an expectation that other partners would be responsible for funding and implementing vaccine delivery support. During this time, Gavi did not envisage taking a substantial role in this area.
Finding 54	Despite initial delays in implementation, which meant that very little support was received before the first vaccines were delivered, Gavi's CCE support was used to procure over 5,900 cold chain units for more than 40 countries in 2021.
Finding 55	Gavi funds, alongside WHO and UNICEF resources, were used to deploy more than 400 TA providers at the country level for the development of NDVPs and to support planning for the delivery of COVID-19 vaccines in eligible AMC92 economies.
Finding 56	Amid substantial concern in early to mid-2021 from countries, donors and partners on the lack of vaccine delivery support in the near and medium term, Gavi mobilized and approved $775 million to support vaccine delivery in June 2021.
Finding 57	By the end of 2021, only a small amount of Gavi funding had been made available to countries, with many stakeholders noting that country needs were not met in a timely way.

Alliance Management Response to Findings 53-57	We agree with these findings and underscore our expectation that early in the pandemic the World Bank and other multilateral development banks would provide the majority of delivery funding required. The Alliance did move quickly to provide $150M in rapid funding (from core resources) for technical assistance and cold chain in September 2020 given these investments needed to be made early. However, given the need to prioritise fundraising for vaccine procurement, further investments in delivery through COVAX were not confirmed until funding was secured in mid-2021. CCE deliveries faced constraints including delays in country applications, supply constraints, shipment disruptions and internal process bottlenecks. However, due to historic Alliance investments in cold chain and vaccine management, this was not a barrier in most countries to scale-up of COVID-19 vaccine delivery. The bigger challenge was availability of ultra cold chain –not previously available in most AMC countries prior to the pandemic – for which the Alliance, led by UNICEF, mobilised an emergency response that enabled deployment in most AMC countries within months. Disbursement of delivery support did take longer than hoped. However, it is important to note that Gavi only received most of the $775M from donors in mid 2021 and made a deliberate decision to rapidly disburse a first wave of funding –$250M as 'CDS Early Access' – on a "no regrets" basis while taking the time with countries to better programme and target the remaining funding – so the intent was not to fully disburse the available funds in 2021. It is important to note that although the CDS Early Access window opened in early July 2021 (a few days following the Board approval), applications only came through in August and September as needs clarified upon arrival of vaccines in later 2021.
Recommendation area 5: Vaccine roll-out and delivery support **Recommendation 5a**	**Strengthen coordination among global partners to ensure the timely availability of financial and technical support for vaccine roll-out. Responsibility for coordination should sit with one agency, with others taking responsibility for different aspects of the work, such as financing, procurement and delivery of TA. As well as at the global level, roles and responsibilities at the regional and national level should be set out and defined in advance of the next pandemic.**

Alliance Management Response *(Agree, Partially Agree, Reject)*	Partially agree
If recommendation is rejected/partially accepted, indicate reasons:	While in agreement that effective coordination and clear roles and responsibilities are critical for a timely delivery response, upon further consultation with our key partners, including WHO and UNICEF, we feel this recommendation overall may be too premature and are not clear on the robustness of the evidence underpinning the recommendation around coordination sitting with one agency and then separation of duties across others. This current evaluation phase only covered through till end of 2021 and therefore does not touch upon any of the concerted delivery support provided over the course of 2022 into 2023 and the combined efforts of agencies under CoVDP. We believe more time to reflect and distill the learnings from the last three years is warranted. These efforts are already underway, and discussions on delivery for future pandemics, including roles and responsibilities, are ongoing. The future pandemic response should also build on the Alliance ways of working proven over the last 20 years.
Actions planned	• Develop a pandemic delivery blueprint, which incorporates proposals on financing, learnings from COVID-19 delivery, including CoVDP, and key steps to be taken towards supporting delivery in future pandemics.
Recommendation area 5: Vaccine roll-out and delivery support **Recommendation 5b**	**Pandemic preparedness should be strengthened before the next pandemic, but if this does not take place to the extent required, substantial funding for delivery should be available early and on a no regrets basis, the terms of which should be defined up front. This will be especially important if greater vaccine supplies reach LMICs and LICs more quickly than was the case for COVID-19 vaccines. This support should be used to promote equitable distribution of vaccines within countries.**
Alliance Management Response *(Agree, Partially Agree, Reject)*	Agree

If recommendation is rejected/partially accepted, indicate reasons:	
Actions planned	• Develop a pandemic delivery blueprint, which incorporates proposals on financing, learnings from COVID-19 delivery, including CoVDP, and key steps to be taken towards supporting delivery in future pandemics.

Results	
Finding 58	The COVAX Facility and AMC has made a substantial contribution to the supply of vaccines to and vaccine coverage in LICs. Its contribution has been moderate in LMICs and marginal in UMICs and HICs.
Finding 59	Limited vaccine supplies in LICs relative to HICs constrained vaccine coverage rates, but contextual factors were also important constraints.
Finding 60	Despite the fact that the COVAX Facility and AMC's support was strongly targeted to LICs and LMICs, global vaccine coverage was highly inequitable across countries.
Finding 61	Within-country equity is harder to define and measure, but available data suggests that high-risk groups were prioritized and that women and men had equal access to vaccines in most countries.
Finding 62	Implementation of the COVAX Facility and AMC through the course of 2020 and 2021 resulted in a few unintended consequences.
Alliance Management Response to Findings 58-62	We generally agree with these findings and are proud of the contributions of COVAX, particularly in extending coverage and impact given challenging contexts and needs. As the most significant supplier to LICs, the vaccines we deployed were used efficiently to advance equity and redress imbalances vis-a-vis HICs. We would also note that it is important to consider the COVAX Facility's impact in specific countries/contexts and not just at an aggregate or portfolio level. For example, COVAX contributed significantly to supply and coverage in a number of SFPs even if in aggregate our contributions were more modest.

The full detailed version can be accessed by request to Gavi Secretariat.