



COVID-19 Vaccine Access

Response to Joint Letter from Human Rights Watch, Public Citizen, MSF Access Campaign and Amnesty International – 25 March 2021

To:

Arvind Ganesan, Director, Business and Human Rights, Human Rights Watch
Peter Maybarduk, Access to Medicines Director, Public Citizen
Sidney Wong, Interim Co-Director, MSF Access Campaign
Stephen Cockburn, Head of Economic and Social Justice, Amnesty International

Dear Mr Ganesan, Mr Maybarduk, Dr Wong, Mr Cockburn,

Thank you for your continued engagement with the COVAX Facility and for the various policy recommendations, questions and feedback, shared both in writing and during the conference call with COVAX leadership on 29 January 2021. As promised, below please find responses to the detailed questions and policy recommendations. In the interest of transparency, the same information will be reformatted for publication on the CEPI and Gavi websites, where it will be continually updated as new information is published. We apologise for the delay in responding. A number of your requests and suggestions relate to new processes and sources of information that have been under development and were only recently finalised; new links and information can now be included in this response.

OVERVIEW OF COVAX

[COVAX](#), the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, is convened by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance and the World Health Organization (WHO) – working in partnership with UNICEF as key delivery partner, vaccine manufacturers, the World Bank, civil society, the private sector and others. COVAX is the only global initiative through which donor-funded COVID-19 vaccines are distributed to 92 lower-income countries and economies at the same time as 98 higher-income countries and economies receive self-financed vaccines. As of 24 March 2021, COVAX has [delivered](#) nearly 32 million safe and effective COVID-19 vaccine doses to 57 countries – including nearly 30 million donor-funded vaccine doses to 46 lower-income countries, as funded through the [Gavi COVAX Advance Market Commitment \(AMC\)](#). UNICEF's COVID-19 Vaccine Market Dashboard is available [here](#).

OVERVIEW OF DIALOGUE WITH PUBLIC HEALTH AND HUMAN RIGHTS ORGANISATIONS

Over the past 12 months, COVAX leadership have been in regular dialogue – both in writing and via conference calls – with public health, civil society and human rights organisations regarding the challenges and issues inherent to providing equitable global access to COVID-19 vaccines. Some of these organisations have identified concerns, while others have shared with COVAX leadership concrete recommendations around transparency, availability and affordability, governance, vaccine injury compensation and other areas. A number of organisations that specialise in delivering health services in fragile and conflict settings with high numbers of zero-dose children now have Memoranda of Understanding (MOUs) with Gavi, with the aim of leveraging each other's strengths to work towards equitable access to immunisation.

Given the urgency of the task to end the acute phase of the COVID-19 pandemic, COVAX's priorities remain volume, price and speed of delivery of safe, effective and stringently regulated COVID-19 vaccines in the context of a rapidly evolving pandemic. Access to life-saving immunisation is a fundamental human right, and the Gavi COVAX AMC was set up to provide safe, effective vaccines to high-risk people in lower-income economies who would have been most likely to miss out on COVID-19 vaccines. COVAX anticipates being able to provide participating countries and economies with enough doses by the end of 2021 to protect high-risk individuals, including health care and other frontline workers, and vulnerable groups – approximately 20% of each participating population (unless a participant has requested a lower percentage of doses). COVAX is also exploring means for economies to achieve higher coverage, through additional donor financing and doses if available, as well as through the support of multilateral development banks. In order to enable COVAX to deliver on its equitable access mission, political will of both economies and manufacturers, together with funding, is needed. The support from human rights-focused and other civil society organisations in this ambition is much appreciated.

COVAX leadership are grateful to these public health and human rights organisations, not only for sharing their expertise, feedback, guidance and time, but also for their candor, commitment and collaboration – which have increased COVAX's attention on human rights standards and principles, and helped inform its operations. COVAX agrees with the need for further alignment with the Sustainable Development Goals (SDGs), particularly SDGs 3 and 9. Please see below for COVAX's response to these detailed recommendations.

COVAX RESPONSE TO DETAILED RECOMMENDATIONS (ANNEX I)

Note: COVAX response appears in green font.

A. Transparency

Recommendation 1: Publish all agreements, advance market commitments, and statements of intent surrounding vaccine research and development, and procurement. This includes a) all underlying agreements CEPI has signed surrounding the nine vaccine candidates that are part of the COVAX Facility; b) vaccine procurement agreements signed with AstraZeneca, Serum Institute, and Novavax; as well as the Sanofi and GSK Statement of Intent.

COVAX response: To maintain the transparency of COVAX plans and operations – as well as to communicate vital and timely information to a spectrum of COVAX stakeholders – documents relating to COVAX's operations and allocation decisions are made available to the public [via the Gavi website](#), except in such cases where the disclosure of such documents would infringe upon confidentiality obligations. For further information, please refer to the response to Annex II below, items A2 and A3, as well as the [summary of equitable access provisions in CEPI's COVID-19 vaccine development agreements](#).

Recommendation 2. Publish in full all industry responses to the UNICEF Supply Division and Pan-American Health Organization Request for Proposal published on November 11, 2020.

COVAX response: This is best directed to UNICEF.

Recommendation 3: Publish an index that specifies which option (Committed Purchase Arrangement or Optional Purchase Arrangement), what percentage (10-50 percent) of their population, and the total number of doses that each of the Self-Financing Participants have elected to receive through the facility.

COVAX response: COVAX is currently developing a vaccine roll-out heat map that will reflect this information. This is expected to be available in the coming weeks.

Recommendation 3 (continued): Additionally, publish the overall volume of doses that the COVAX Facility (for both Self-Financing Participants and AMC countries) is trying to secure for all participants.

COVAX response: For this information, please refer to the [COVAX Global Supply Forecast](#) published on 2 March 2021; and UNICEF's [COVID-19 Vaccine Market Dashboard](#).

Recommendation 4: Publish an index of each Self-Financing Participant's required down payment and the status of its receipt.

COVAX response: COVAX has received down payments from all self-financing participants. A full list of participating economies can be found [here](#).

Recommendation 5: Publish an index of each AMC country's co-financing/cost-sharing commitment and status of its receipt.

COVAX response: There are no firm cost-sharing agreements yet. Currently, COVAX is launching a process to solicit demand for additional doses from Gavi COVAX AMC countries, after which it will confirm supply expectations before entering into binding commitments with Gavi COVAX AMC countries to finance additional doses via cost-sharing. Cost-sharing information could be available once Gavi COVAX AMC countries make these binding commitments.

Recommendation 6: Publish and periodically update information about each vaccine candidate in the COVAX Facility's portfolio. This should, at a minimum, include information about:

a. How each candidate compared on a set of common criteria used to assess them (for example, cold-chain, previous use of technology; efficacy);

COVAX response: The latest information on which vaccine candidates are included in the COVAX Facility portfolio is provided in the [COVAX Global Supply Forecast](#) mentioned above. This takes into consideration assessment of vaccines against preferred and critical characteristics listed in the [WHO Target Product Profiles for COVID-19 Vaccines](#), as well as emerging considerations such as effectiveness against variants of concern. Please refer to the "[Vaccine specific resources](#)" section of WHO's [COVID-19 vaccine introduction toolkit](#). Also, Gavi maintains a [COVID-19 vaccine race](#) page on its website, which is updated on a weekly basis.

b. Due diligence and related results regarding the patent landscape for the vaccine candidate;

c. Due diligence and related results around legal disputes surrounding the vaccine candidate;

COVAX response: The COVAX governance system was built to ensure high-quality due diligence at every step of the process. Please refer to [this explainer](#) and [COVAX: Structure and Principles](#) for more information about the roles of the technical, advisory and governance bodies such as the Independent Product Group (IPG), Market-Sensitive Decisions Committee (MSDC), and Research and Development and Manufacturing Investment Committee (RDMIC).

CEPI requests information about patent landscape from potential awardees, as well as information about any legal disputes with a view to ensuring a clear and known path to access. The timing of publication of patent applications and the timing of COVID-19 means that a Freedom to Operate (FTO) search is likely not sufficient to provide accurate information in time before a CEPI commitment is made.

d. Price estimates;

COVAX response: COVAX's goal is to maintain transparency, and the usual practice of UNICEF Supply Division is to publish prices unless a specific confidentiality agreement applies.

e. Due diligence and related results to assess manufacturing capacity for the underlying vaccine platform technology, identifying what manufacturing capacity is booked up, what is available, and what can be repurposed or scaled up.

COVAX response: In 2020, CEPI issued two Calls for Expressions of Interest to assess the available manufacturing capacity globally for drug substance and drug product (report available [here](#)). The information gathered was used to connect developers in need of additional capacity to those with suitable capacity. This is being closely monitored as part of project management.

As outlined in this [equitable access paper](#), CEPI supports the scale-up of manufacture for its portfolio of candidates to maximise capacity and mitigate risks to technology transfer. The current market for manufacturing capacity is highly dynamic, which limits the operational value of reporting.

Recommendation 7: Collate and publish vaccine candidate's clinical trial results in a time-bound manner on an open access basis (free and unrestricted access) in line with the 2015 WHO Statement on Public Disclosure of Clinical Trial Results.

COVAX response: In accordance with regulatory obligations, manufacturers are typically required to publish clinical results if public funding has been received for research and development. Meanwhile, CEPI funding agreements contain requirements for awardees to publish and share data and materials to ensure that all can benefit from the work funded by CEPI. For more information, please reference CEPI's [Clinical Trials Policy and Equitable Access Policy](#).

Recommendation 8: Publish, on a timely basis, meeting minutes from each of the COVAX Pillar's working groups.

COVAX response: Each COVAX working group has its own Terms of Reference and modalities. Given the pace at which topics are moving, resourcing constraints and complex nature of discussions, minutes are not published. Meanwhile, there are [ten CSO representatives appointed to all key COVAX working groups](#).

B. Maximize Availability and Affordability

Recommendation 1: Develop and publish—in consultation with civil society—a human rights and equitable access policy that guides the design and work of the COVAX Facility.

COVAX response: Equitable access is the *core principle* of the COVAX Facility and the Gavi COVAX Advance Market Commitment (AMC); as such, it is embedded in every aspect of COVAX's operations – from upstream research and development (R&D) and manufacturing investments, through [fair allocation](#) and, finally, delivery. COVAX doses are being delivered to all countries on the same time frame, regardless

of economic status (reference UNICEF's [COVID-19 Vaccine Market Dashboard](#)). These principles are articulated in a spectrum of foundational [COVAX documents](#) and [CEPI's equitable access documents](#).

Since the October 2020 [dialogue with civil society](#) and subsequent [appointment of ten civil society representatives](#) to all key COVAX working groups, COVAX has benefited not only from their technical expertise, but also from understanding better the concerns of and challenges faced by the constituencies they represent. The role of civil society in enabling equitable access to safe and effective COVID-19 vaccines through their participation in key COVAX working groups is a testament to the priority that COVAX places on maintaining the transparency of its operations. Since August 2020, public dialogue webinars have taken place every few months to share regular updates on COVAX's progress. Information given during these sessions is extremely detailed; senior staff answer questions, and slide decks containing the information are circulated afterwards.

In support of the principle of life-saving immunisation as a fundamental human right, COVAX guidance is that governments prioritise COVID-19 immunisation for all high-risk individuals and populations, according to the WHO Strategic Advisory Group of Experts (SAGE) on Immunization recommendations, independent of their residency and legal status, including internally displaced populations, refugees, migrants and detainees.

Recommendation 2: Endorse the Covid-19 Technology Access Pool (C-TAP) and align the COVAX Facility's design to operationalize and implement C-TAP.

COVAX response: COVAX's foundational goal is to enable equitable access in an unprecedented time frame. In the current context, this means working with vaccine manufacturers around the world to attain ambitious goals of delivering at least two billion doses of vaccine to COVAX's participating economies in 2021. The scope of the WHO COVID-19 Technology Access Pool (C-TAP) is much broader and involves a number of issues that are outside COVAX's remit. Additionally, the time frames of C-TAP (i.e. medium to longer term) and COVAX (i.e. addressing a current pandemic emergency) are different.

In line with C-TAP proposals, CEPI funding agreements contain requirements for awardees to publish and share data and materials to ensure that all can benefit from the work funded by CEPI, as outlined in this February 2021 [summary of CEPI's COVID-19 vaccine development agreements](#). CEPI does not seek to own the Intellectual Property (IP) developed from its partnerships but, rather, requires its awardees to manage their IP in such a way that equitable access can be realised (i.e. doses are made available to the COVAX Facility for fair allocation and procurement). CEPI believes this is the most effective way of delivering accessible vaccines as quickly as possible, without stifling innovation or delaying the urgent vaccine development process. Furthermore, CEPI collaborates with partners in the selection of additional manufacturers to increase manufacturing capacity and enable equitable access. Developers agree to technology transfer to trusted partners, and/or standing up manufacturing capacity in two or more countries, if applicable.

Recommendation 3: Ensure that contracts with companies developing and manufacturing vaccines:
a. require open and non-exclusive licensing, and wherever needed, technology transfers to share all relevant intellectual property to scale-up manufacturing;

COVAX response: COVAX shares the ambition of building capacity for manufacturing vaccines in lower-income countries, expanding diversity in vaccine manufacturing and ensuring healthy markets for vaccines. COVAX encourages technology transfer to economies that have the capacity to produce vaccines, facilitating introductions and pairing where this is helpful, and where resources permit providing financial support to enable such processes.

Technology transfer works best when it is based on close partnerships in which both parties – the innovator company and the recipient – are committed to overcoming the many challenges involved in replicating the complex manufacturing processes in partnership. COVAX is committed to expanding diversity of manufacturing and has been supportive of two technology transfer deals involving Serum Institute of India (SII), as well as further scale-out agreements between other manufacturers to [increase available volumes](#). Agreements such as these recognise that the role of expertise and capital-intensive start-up costs alongside intellectual property are effective in shaping markets, as demonstrated by the success of the Vaccine Alliance model over the past two decades: through technology transfer, Gavi has been able to dramatically reduce the price of vaccines.

b. price vaccines in a way that maximizes affordability, minimizes debt for low- and middle-income countries, and prioritizes public benefit over private profit;

COVAX response: With 190 participating countries and economies, COVAX has a collective purchasing power to negotiate highly competitive, sustainable prices from manufacturers that are in turn passed on to participating countries and economies, while being sensitive to their income levels. COVAX is also working with manufacturers committed to minimal profit pricing – which form the core of the COVAX vaccine portfolio.

Ninety-two lower-income countries and economies are eligible for free, donor-funded COVID-19 vaccine doses through the Gavi COVAX Advance Market Commitment (AMC) – enabling them to protect high-risk populations without having to spend constrained domestic resources or take on additional financing.

As mentioned above, as of 24 March 2021, COVAX has [delivered](#) nearly 30 million donor-funded vaccine doses to 46 lower-income countries, as funded through the Gavi COVAX AMC. UNICEF’s COVID-19 Vaccine Market Dashboard available is [here](#). COVAX distributes vaccines equitably according to a [Fair Allocation Mechanism](#).

COVAX Allocations are published on a regular basis, starting with the [first round of allocations](#) published on 2 March 2021. COVAX is also developing a mechanism through which Gavi COVAX AMC-eligible countries that choose to complement the essential foundation built by donor-funded doses should be able to access vaccines at COVAX-negotiated prices through a [cost-sharing approach](#).

A “[humanitarian buffer](#)” could also be made available as a backstop mechanism to serve as a provider of last resort for if/when national, government-led planning and roll-out fail to reach certain high-risk populations in humanitarian settings. For example, populations living outside government-controlled areas could be served through the humanitarian buffer. This would be implemented once all other options have been explored; and applicants would be asked to demonstrate a gap in coverage among relevant populations within the scope of this buffer.

c. require transparent pricing verifiable by third-party audits that are published; and

COVAX response: COVAX’s goal is to maintain transparency, and the usual practice of UNICEF Supply Division is to publish prices unless a specific confidentiality agreement applies.

Recommendation 4: At a minimum, ensure corporate compliance with CEPI equitable access policy, and exercise public health licenses and other safeguards contained in CEPI contracts to scale-up affordable supply.

COVAX response: COVAX is coordinating and collaborating with CEPI to support [CEPI's Equitable Access Policy](#), and to enable participating countries and economies to benefit from the access terms in CEPI's agreements, including public health licenses and other safeguards. This partnership enables COVAX to leverage CEPI's progress in facilitating equitable access to COVID-19 vaccines, and to ensure CEPI's investments in equitable access translate into equitable procurement and, ultimately, delivery of COVID-19 vaccine doses.

C. Strengthen Governance

Recommendation 1: Integrate low- and middle-income governments and civil society representatives, including those with varied expertise on access to medicines, IP barriers, and human rights, into the various bodies that are part of the COVAX Pillar structure, including in decision-making processes concerning the facility's contract negotiations with companies and vaccine allocation decisions.

COVAX response: Lower-income economy government and civil society representatives form an important part of the COVAX Facility's governance and decision-making processes through their participation in the Gavi Board and committees, such as Programme and Policy Committee (PPC), Market-Sensitive Decisions Committee (MSDC) and Audit and Finance Committee (AFC). Civil society organisations (CSOs) are represented in all key COVAX working groups. Further, the Gavi COVAX AMC Engagement Group is a key component of COVAX Facility governance. Co-chaired by ministers from the Governments of Canada, Ethiopia and Indonesia, the Gavi COVAX AMC Engagement Group is composed of participants from the governments of lower-income countries, as well as donors and other stakeholders.

Recommendation 2: Expand on the principles governing conflicts of interests articulated in the COVAX Pillar Structure and Principles, and develop and publish—in consultation with rights groups and experts on access to medicines—a Conflicts of Interest Policy that applies to the senior leadership of CEPI, Gavi, their boards, and the COVAX Pillar structure. The policy should, among other things:

- a. Outline procedures for publicly disclosing conflicts of interest;
- b. Create an independent high-level committee, including civil society representatives, to assess conflicts of interests and oversee the implementation of the conflicts of interest policy; and
- c. Periodically publish reports about how the policy was implemented.

COVAX response: COVAX's bespoke governance system was designed with equity and transparency at its core and leverages the governance of its component organisations. Each of COVAX's three convening organisations already have requirements for senior staff to regularly disclose conflicts of interest through their governance processes. In addition, all staff engaged in COVAX working groups are bound by a Conflict of Interest policy, as indicated in [COVAX: Structure and Principles](#) (available on the Gavi website), along with the names of staff members in the groups.

COVAX is committed to further increasing the transparency of how its Conflict of Interest principles are implemented and managed. This includes expanding the number of staff and partners to which the Conflict of Interest policy applies; following up to ensure declarations are made; and acting on information provided – ranging from recusing individuals from decisions to removing people from roles if their interests present a perceived, potential or actual conflict.

Recommendation 3: Develop and publish—in consultation with rights groups and access-to-medicine experts—a whistleblower policy and constitute a high-level committee comprised of independent experts. Among other things, the external committee should be empowered to receive and investigate complaints about the COVAX Facility’s work and provide reports to the boards of CEPI, Gavi, and those part of the COVAX Coordination Meeting.

COVAX response: Each of COVAX’s three convening organisations have established whistleblower policies and procedures in place (and these are published on their websites), with oversight from their relevant governing bodies as appropriate. Recognising the importance of accountable governance systems, COVAX will ensure transparency on how the existing whistleblower policies and reporting facilities of the COVAX convening organisations, with newly agreed lines of communication among them, will enable appropriate accountability and integrity. Relevant matters will be reported to the COVAX Coordination Meeting (CCM) as appropriate.

D. Vaccine Injury Compensation Programme

Recommendation 1: Develop and publish—in consultation with low-and-middle income governments, civil society, patient rights advocates, and those participating in clinical trials—a vaccine injury compensation policy, program, and related procedures to evaluate claims and compensate individuals meeting defined criteria of injury related to the receipt of a vaccine.

COVAX response: On 22 February 2021, COVAX [launched](#) the COVAX No-Fault Compensation Programme for AMC-Eligible Economies, which is the first and only vaccine injury compensation programme operating on an international scale. The programme will offer eligible individuals in the Gavi COVAX Advance Market Commitment (AMC)-eligible economies a fast, fair, robust and transparent process to receive compensation for certain rare but serious adverse events associated with a COVID-19 vaccine, or the administration of a COVID-19 vaccine, procured or distributed through COVAX until 30 June 2022. The programme will become fully operational through its web portal (www.covaxclaims.com) by 31 March 2021.

COVAX RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION (ANNEX II)

Note: COVAX response appears in green font.

A. Contracts with developers and manufacturers

Question 1: How do contracts procuring vaccine for the COVAX Facility align with CEPI's 2019 [Equitable Access Policy](#)?

COVAX response: The CEPI policy is primarily for CEPI activities. CEPI contracts enable end-to-end access and for COVID-19 vaccines include first right of refusal to supply volumes for COVAX, as well as enabling scale-out to increase available volume. COVAX contracts complement the investments made by CEPI by establishing advance purchase agreements (APAs) of the vaccines to enable this equitable access for COVAX participants.

Request 2: Please provide copies of all underlying contracts signed by CEPI in relation to vaccine candidates that are part of the COVAX Facility.

COVAX response: CEPI is fully committed to transparency and has [published a summary](#) of the equitable access provisions for CEPI partnership agreements in the COVID-19 portfolio. CEPI's Board and Investors receive summaries of the access provisions of these agreements, and they can access the full agreements on request. Contracts with developers and manufacturers contain commercially sensitive and proprietary information protected under confidentiality obligations. Consequently, Gavi and CEPI are not in a position to disclose these contracts without infringing confidential obligations.

Request 3: Please provide copies of all contracts procuring vaccine doses for the COVAX Facility. This includes agreements with AstraZeneca, Serum Institute of India, and Novavax; as well as the Sanofi and GSK Statement of Intent.

COVAX response: COVAX cannot provide full copies of contracts, as these contain commercially sensitive information; however, Gavi is planning to publish publicly a summary of deals in accordance with the usual practice of Gavi purchases. Please note the Gavi Market-Sensitive Decisions Committee (MSDC), which has a CSO representative, approves the key terms of the advance purchase agreements (APAs) that the COVAX Facility enters into with manufacturers.

B. Human Rights Due Diligence

Request 1: Please outline the processes CEPI, Gavi, and COVAX are using to conduct effective human rights due diligence to evaluate the risks that exacerbate vaccine scarcity, including limited vaccine manufacturing capacity by technology, and underlying intellectual property rights.

COVAX response: The foundational principles of corporate responsibility to respect human rights are reflected in CEPI's [Third Party Code](#), as the Ten Principles of the UN Global Compact are built into the Code. This applies for all partners of CEPI and is in scope for audit of partners. For each individual project, due diligence is undertaken to evaluate the risks related to access including the ability to develop a successful vaccine, including manufacturing and supply capacity (e.g. the need for additional capacity and technology transfer to meet volume commitments), vaccine nationalism and intellectual property risks. Steps are agreed to eliminate or mitigate the risk to meet the requirements of CEPI and COVAX as a whole as part of formation of the agreements and monitored throughout implementation.

However, there are many [uncertainties](#) affecting the supply of COVID-19 vaccines, not least around manufacturing capacity, regulation, funding availability, final contract terms and the readiness of countries themselves to begin their national COVID-19 vaccination programmes. Similarly, [allocation timelines](#) are dependent on a variety of factors, including: national regulatory requirements; availability of supply; and fulfilment of other criteria, such as validated national deployment and vaccination plans (NDVPs) from Gavi COVAX AMC participants, indemnification and liability agreements, and export and import authorisations.

COVAX cannot overcome these challenges alone; rather, all stakeholders must work together to build on the efforts of the market shaping work that has been at the core of the Vaccine Alliance operating model for the past two decades, and to ensure that vaccine manufacturers honour their commitments to keep COVID-19 vaccines affordable.

Despite the breadth of expertise and extent of resources invested in COVAX to date, there will always be room for improvement and areas in which additional expertise and resources are required. To this end, COVAX leadership welcome specific guidance on best practices in conducting effective human rights due diligence, in order to study this specific area further and also to assess how best to incorporate relevant considerations in the work of each convening organisation going forward.

Request 2: Please outline the steps CEPI or Gavi have taken to consult diverse intellectual property rights experts to evaluate intellectual property risks and their actual and potential impacts on Covid-19 vaccine supply and pricing, and develop prevention and mitigation measures. Please provide reports of these consultations.

COVAX response: In this compressed timespan, COVAX is working with manufacturers to reach ambitious goals. Negotiations between governments and manufacturers around intellectual property (IP) may take more time, and are not in the purview of the work of COVAX. When it comes to patents, it is essential to note that IP, in the case of vaccine manufacturing, represents only a part of the relevant expertise required to establish new capacity. The more challenging aspect involves know-how and high start-up costs, as vaccine production requires thousands of manufacturing steps. The key constraint in 2021 will not be IP but rather supply constraints, especially in the still evolving context of new variants. Addressing these issues will require utilising all available expertise and resources – including that of industry. Efforts are already under way in this regard, with [recent discussions](#) with global pharmaceutical and public health sector organisations to address COVID-19 vaccine supply chain and manufacturing bottlenecks (upstream, downstream, fill-and-finish) to enable large vaccine manufacturing scale-up to meet the cumulative supply target of up to 14 billion doses by the end of 2021. For more information, please refer to the discussion document [“Towards Vaccinating The World”](#), whose co-authors include CEPI personnel.

Question 3: Have any studies been commissioned modelling vaccine access, controlling for intellectual property rights (for example, if COVAX Facility were designed in a way that was aligned with C-TAP vs. not aligned with C-TAP)? If yes, please provide copies of these studies.

COVAX response: COVAX has not performed such studies in this manner.

Question 4: Have any studies been commissioned modelling vaccine access, controlling for tiered and flat pricing, to demonstrate how many people can get free vaccines under different pricing strategies, or how the debt-burden on low-and-middle income countries are impacted by these pricing strategies? If yes, please provide copies of these studies.

COVAX response: Under the guidance of the Strategic Advisory Group of Experts (SAGE) on Immunization Working Group on COVID-19 Vaccines' COVID-19 Vaccine Impact Modelling Subgroup, which provides high-quality modelling guidance to inform policy recommendations related to COVID-19 vaccine prioritisation, WHO has commissioned modeling vaccine access studies mainly around five main topics that are of critical interest to SAGE:

1. vaccination strategies to maximise in-person schooling;
2. vaccination strategies to keep health system use below maximum capacity;
3. importation into settings with no cases and outbreak response vaccination;
4. extent to which vaccination can allow non-pharmaceutical interventions to be lifted; and
5. strategies to maximise impact of available supply of vaccines.

Results from eight selected modeling groups from both high-income countries (HICs) and low- and middle-income countries (LMICs) are expected by mid-2021.

At this moment, low- and lower middle-income economies, as well as upper middle-income economies that are World Bank International Development Association (IDA)-eligible, are receiving COVID-19 vaccine doses that are fully subsidised by the Gavi COVAX AMC. Therefore, the current pricing structures will not affect them. At present, COVAX is not requiring mandatory co-financing from these Gavi COVAX AMC-eligible economies.

Questions concerning impact on debt-burden on economies are best directed to the World Bank.

C. Global Cooperation

Question 1: What steps are CEPI and Gavi taking to align COVAX Facility's design and work with the WHO's Covid-19 Technology Access Pool?

COVAX response: As mentioned above, the [WHO COVID-19 Technology Access Pool \(C-TAP\)](#) is an innovative and vital initiative, and there is potential for COVAX to align and cooperate with C-TAP in the medium to longer term; however, this is not an immediate priority, given international pressure upon COVAX to deliver at least two billion COVID-19 vaccine doses to 190 countries and economies by the end of 2021.

D. Information about Self-Financing and AMC Countries and Economies

Request 1: Please provide a full list of participating self-financing governments/economies, providing the following details for each of them: whether they have opted for Committed or Optional Purchase Arrangement; what percentage (10-50 percent) of their population they are seeking to have vaccinated; the total number of vaccine doses the participant has elected to receive.

COVAX response: COVAX is currently developing a vaccine roll-out heat map that will reflect this information. This is expected to be available in the coming weeks.

Request 2: For the 92 AMC-eligible countries and economies, please provide information about each AMC country's co-financing/cost-sharing commitment and status of its receipt.

COVAX response: COVAX is currently developing and operationalising the cost-sharing mechanism, so this information is not yet available.

MOVING FORWARD TOGETHER

The COVID-19 pandemic is the biggest economic and social crisis of a lifetime. Human rights are key in shaping our collective pandemic response, both for the public health emergency and the broader impact on people's lives and livelihoods. COVAX was established to support the Access to COVID-19 Tools (ACT) Accelerator goal of accelerating equitable access to COVID-19 tests, treatments and vaccines. COVAX leadership believe that initiatives that are shaped by and respect human rights will result in better outcomes for all, protecting the right to life and health for everyone, and preserving human dignity everywhere. A crucial goal of COVAX is to draw attention to those who are left furthest behind and, most importantly, effect a strategy to include them. In reaching the most vulnerable, whether through furthering the scope of our global coverage or through partnering with civil society and humanitarian actors to reach high-risk individuals in humanitarian settings, COVAX is laying the foundation now to emerge from this crisis with more equitable and sustainable health systems. The gains made through COVAX, for example, in reaching conflict-affected populations in humanitarian settings, will be leveraged to also strengthen routine immunisation in marginalised communities.

To successfully deliver safe and effective COVID-19 vaccines to billions of people across the globe – for which both scale and speed are needed – COVAX must find the right balance between innovation and the reality of the current inter-governmental, legal and trade frameworks. That does not mean “business as usual” – but it does mean upholding human rights standards and principles. Both through the formal channels of the COVAX Facility governance structure and through the personal commitment of the global health professionals who comprise COVAX leadership and staff, there is an unflagging commitment to improving COVAX's adherence to human rights principles and standards. COVAX's dialogue with public health and human rights organisations will continue, as will our work to address the concerns and gaps identified.

Please feel free to contact us if you have any questions. Your advocacy and support for equitable access is critical to ending this pandemic, and we thank you for your ongoing engagement.

Sincerely,

Seth Berkley
CEO, Gavi, the Vaccine Alliance

Soumya Swaminathan
Chief Scientist, World Health Organization

Richard Hatchett
CEO, Coalition for Epidemic Preparedness
Innovations (CEPI)