



Embedding equitable access in vaccine R&D:

Why CEPI's access policy and governance need an overhaul

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Summary

The Coalition for Epidemic Preparedness Innovations (CEPI) has become a key actor in the research and development (R&D) of vaccines against emerging infectious diseases and has played a significant role in the COVID-19 pandemic. But CEPI's equitable access policy is wholly inadequate and certainly not fit for purpose to overcome the political and market forces responsible for today's extreme and shameful vaccine inequality. As the world enters the third year of this pandemic, and with CEPI poised to replenish its budget, adapt its strategy, and increase its scope, it is vital that CEPI's access policy and governance be urgently overhauled, and that CEPI commits to a more ambitious diversification of both R&D and manufacturing that prioritises low- and middle-income countries. The People's Vaccine Alliance calls on existing and potential supporters of CEPI to ensure their funding is conditional on achieving this step change.

Introduction: The state of play

As the world enters the third year of the COVID-19 pandemic, profound global vaccine inequity continues unabated. High-Income Countries (HICs) have managed to administer vaccine boosters to 40% of their population while low- and lower-middle-income countries have only been able to give doses one and two to just 6% and 46% of their population, respectively. Pharmaceutical monopolies have artificially limited supplies, kept prices of several vaccines out of reach for LMICs, and inequitably distributed vaccines. Hasty donations of doses near-expiry by HICs have led to wasted vaccines and significant absorption issues in low- and middle-income countries (LMICs) ¹. LMICs are increasingly disillusioned by the failure of existing global health institutions, to remedy persistent inequities created by pharma monopolies and HICs hoarding. LMICs have demanded not just access to vaccine doses but also the knowledge and intellectual property necessary to produce their own vaccines.

In the meantime, COVID-19 vaccine manufacturers continue to make record breaking profits. Vaccines, a pharmaceutical intervention previously neglected by the private sector due to perceived limited profit potential, now represent the pharmaceutical products with

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the highest annual sales in history – a dynamic which has fuelled pharmaceutical corporations’ opposition to equitable access, sharing of know-how and waiving intellectual property (IP).

Global health institutions, chief among them COVAX, continue to struggle to assert themselves over narrow political and commercial interests. The Coalition for Epidemic Preparedness Innovations (CEPI) has established itself as a key actor in both the research and development (R&D) of vaccines against emerging infectious diseases and played an outsized role in the COVID-19 pandemic. With CEPI poised to replenish its budget and adapt its strategy to an evolving landscape, now is a good time to evaluate its actions on one of its core goals - equitable access – and to assess whether its governance appropriately reflects its global mission.

High-Income architects shaping CEPI:

Systemic failures to adequately prioritise and finance R&D into emerging infectious diseases – exemplified by a complete lack of tools to combat the 2014-2016 Ebola outbreak in West Africa – spurred the creation of the CEPI. CEPI was launched at the World Economic Forum in Davos, Switzerland, in 2017. In CEPI’s own words, its mission was to “stimulate, finance and co-ordinate vaccine development against diseases with epidemic potential in cases where market incentives fail”².

CEPI’s first board meeting took place in 2016, at the London offices of the Bill and Melinda Gates foundation, and an interim board began to form, just a few months prior to its official launch³. As a result of its sponsorship and early funding of CEPI, the Foundation has played a key role in its orientation towards funding conditions, intellectual property, and other access issues. In addition, a decision was made to offer interim board positions in exchange for early investments from selected high-income countries– the first step on a path which would result in the overrepresentation of high-income country interests still seen today. By comparison, a further commitment in these early meetings to “ensuring a better representation of civil society through forming a constituency group” never materialised⁴. As a result, the interim board in 2017 was mostly composed of individuals and organisations based in high-income countries with no civil society representation (Doctors without Borders sat on the interim board but stated that it could not represent this constituency)⁵. The CEPI Secretariat composition paints a similar picture, with only 22% of its current staff originating from LMICs⁶.

Industry representation in the Board’s governance following the launch was also extensive, with up to five interim board members representing industry giants joining early meetings. In one of these meetings the publication of an analysis of public funding allocated to Ebola vaccine development was successfully suppressed – the issue of extensive public funding behind novel pharmaceuticals being a long-standing thorn in the side of pharmaceutical corporations in pursuit of high prices⁷. While the presence of multinational pharmaceutical corporations on CEPI’s board has reduced significantly after the first year– reflecting a continued neglect of emerging infectious diseases by these large actors – their influence on CEPI’s actions and positioning remains ever-present.

Equitable access policy and its implementation:

Alongside the need to prioritise and finance R&D into emerging infectious diseases, CEPI was also founded on the understanding that innovation and equitable access must go hand in hand with R&D investments. Despite equitable access featuring in some formulations of its mission, CEPI's approach to and policy on equitable access has generated long standing debates and criticism even before the COVID-19 pandemic.

Calling equitable access “central to its focus”, CEPI's interim board developed an equitable access policy spanning 13 pages and including commitments on pricing, transparency, and management of intellectual property (IP) in line with its equitable access goals². This original policy was revised down to just two pages a year later and adopted on a board meeting in which none of CEPI's board members representing low- and middle-income countries (LMICs) were present⁸.

The strongest commitments to equitable access were removed in this revised policy, in particular the expectations CEPI had of its grantees' conduct on pricing of vaccines, thus leaving out a critical determinant of vaccine access. Whereas the hope was that CEPI investments would result in guarantees of more affordable “access pricing” and price transparency in terms of costs of goods and permissible mark-ups, dropping price conditionalities significantly weakened CEPI's access policy. When compared to the original policy, the revised policy only contains vague references to affordable access; a limited scope covering only access to stockpiles of investigational vaccines (vaccine doses which have not been approved for sale by a regulatory agency); and places most access obligations on itself rather than its grantees.

CEPI justified limiting the policy's scope only to investigational stockpiles because at that time CEPI only funded vaccine development up to phase 2b clinical trials (mid-sized clinical trials conducted to assess safety and efficacy before large phase 3 clinical trials). That means that any vaccines produced at that stage could only be considered “investigational vaccines” for use in future clinical trials and not for commercial sale. CEPI's scope expanded at the beginning of the COVID-19 pandemic to include not only phase 3 clinical trials but also manufacturing and technology transfer issues. CEPI's policy, however, remains the same.

The issue of affordable pricing is only briefly touched upon by the current policy and dilutes responsibilities by claiming that prices will be set in collaboration with “others in the global health community”⁹. This stands in stark contrast to the original policy which promised that CEPI would “set out the processes by which the boundaries for the price of a licensed vaccine will be determined”¹⁰.

Who was responsible for diluting CEPI's access policy?

The process of negotiating CEPI's revised policy is described in detail in a CEPI publication titled "Finding equipoise: CEPI revises its equitable access policy"². Although comments and feedback the CEPI secretariat received on its equitable access policy are not attributed to specific entities, one stakeholder group is highlighted in opposition to the detailed access policy – pharmaceutical corporations. "Multinational vaccine companies" in particular argued the policy was too prescriptive and would prefer to see it as a guideline rather than a policy so as not to conflict with a "competitive business model" – an ironic argument given that CEPI was founded on the basis of a market failure². It is also important to note that this stakeholder group represents a small minority of CEPI's partners to date, raising the question if concessions to this group were necessary or even effective in attracting pharmaceutical companies as collaborators.

The primary path to implementing CEPI's equitable access policy is through negotiated terms in partnership agreements⁹. Specific contractual provisions are negotiated on a case-by-case basis and are therefore unique to the situation, context, and relative leverage of the negotiating parties. That notwithstanding, it is best practice for funders to set parameters or "red lines" for what is deemed the bare minimum. CEPI has on several occasions published summaries of equitable access provisions that it has been able to negotiate with partners which could provide an indication of the way that CEPI has implemented its policy and whether it has a minimum standard. However, reviewing the documents, one finds no consistent minimum standard beyond obliging partners to commit "to terms that are fully consistent with CEPI's equitable access policy" – a relatively low bar. According to CEPI's 2020 annual progress report, one of CEPI's COVID-19 grantees was not able or willing to meet even this requirement⁶. To make matters worse, CEPI makes no claim on intellectual property generated through their financial support, relinquishing all ownership over data, IP and materials¹¹.

Access provisions going beyond this minimum and indistinct standard seem to vary greatly across CEPI's portfolio of projects, but the lack of transparency around the terms of funding agreements and whether and how they were implemented presents a barrier to assessing CEPI's standard negotiating procedure. This is surprising given CEPI's commitment to "prioritise transparency" featured in its equitable access policy⁹. Not even CEPI's equitable access board sub-committee has access to the text of the contractual clauses on equitable access, instead merely receiving summaries in the form of checklists and headlines. Also surprising is that often companies themselves are more transparent about the text of specific access provisions in their US government SEC filings, as demonstrated in Public Citizen's report "COVAX's choices"¹². The Medicines Patent Pool has been publishing the full text of the licenses it negotiates since its inception, proving that transparency of even commercially sensitive information is possible.

In 2019, CEPI published a template funding agreement for its program for vaccines against Rift Valley Fever and Chikungunya, providing a clue to the standard clauses CEPI would propose in the future. It is unclear, given that the template is not a policy, how frequently the standard clauses are included in CEPI's contracts with developers and producers. This

template funding agreement is discouragingly weak, again containing only a passing reference to affordable pricing. The only way in which affordable pricing is mentioned is by referring to CEPI's equitable access policy, which, as already mentioned, offers no real guidance on affordable pricing. It also does not reflect stronger clauses which CEPI later reported to have included in many of their COVID-19 agreements¹³. What this template agreement – in connection with publicly available contract texts – does shed light on, however, is what CEPI calls “public health license”, which CEPI includes in many of its funding agreements. CEPI's public health license typically includes a worldwide, non-exclusive, royalty free, sublicensable license of the IP needed to manufacture, market, and supply the vaccine candidate in question. The public health license also allows CEPI to require technology transfer to a pre-agreed manufacturer, including a transfer of the necessary know-how, materials, and information to produce the vaccine. While the public health license remedy can represent a strong tool to ensure equitable access, CEPI can only exercise the license under very limited terms. The triggers required to activate the public health license either rely on rare administrative events such as default; situations where a grantee is unwilling to engage in additional work funded by CEPI; or are linked to CEPI's equitable access policy, which lost most of its specificity in the revision. So far, in this pandemic, not a single public health license has been issued.

CEPI's impact on access beyond the policy

CEPI's impact on equitable access to its vaccine portfolio is not limited to the equitable access policy and its implementation. CEPI is one of the few global health actors engaged in pandemic preparedness and administers a vaccine R&D budget second only to the US government¹⁴. This being the case, CEPI wields significant political and economic power as well as playing an important role in setting global health norms around equitable access.

One way in which CEPI attempts to use its political power to improve equitable access is by increasingly centring equitable access as one of the selection criteria in new calls for proposals. These calls for proposals show a laudable trend in the way they set out expectations on equitable access over the course of the COVID-19 pandemic. The first call for proposals for vaccines targeting SARS-CoV-2 in 2020 only included access-related selection criteria pertaining to low-resource appropriate storage and delivery¹⁵. By contrast, later calls for proposals included expectations to participate in COVAX, a commitment to technology transfer to LMICs, and specific mentions of “affordable access” to vulnerable populations^{16–18}. This, in combination with repeated and clear communication about the importance of not only equitable but also affordable access and geographically distributed manufacturing, sends an important message to developers seeking to be supported by CEPI and sets the stage for negotiations on specific terms.

CEPI falls short on its role as a standard setting organisation in its slow release of important information to its governing body and making it available for public scrutiny. Moreover, there is a lack of transparency about key decisions affecting access. Aside from maintaining the text of contractual access provisions a secret, CEPI has been very slow in releasing summaries of its equitable access board committee meetings – publication on their website often lags behind by several months. Also, the summaries of the access provisions which CEPI has successfully negotiated with partners have been publicly shared only many months after the fact – the first summary of equitable access provisions relating to Covid-19

vaccines was only shared in late 2020 (see examples in the table below). This delay made real-time assessment of CEPI's performance on equitable access impossible and hindered inclusion of appropriate provisions in public vaccine procurement contracts.

CEPI is one of the co-creators of the COVAX Facility, the vaccines pillar of the Access to COVID-19 Tools Accelerator (ACT-A), and as such wields significant power within this architecture. In May 2020, the WHO launched the WHO COVID-19 Technology Access Pool (C-TAP), an initiative by 40 countries to facilitate the sharing of COVID-19 technologies and know-how to secure sufficient supply in LMICs. Despite aligned goals, CEPI's response was lukewarm. Richard Wilder, CEPI's chief legal counsel at the time, joined C-TAP's launch but CEPI did not associate with C-TAP in any meaningful way and did not adapt its calls for proposals to make willingness to contribute a technology to C-TAP a selection criteria¹⁹. This non-participation likely undermined C-TAP which has struggled significantly for political and financial support as well as not receiving any expressions of interest from vaccine developers until November of 2021.

This dynamic was repeated when, in June of 2021, the WHO announced an mRNA vaccine technology transfer hub. The global WHO mRNA Hub was established to enable LMIC's in building manufacturing capacity to produce vaccines based on the novel mRNA platform²⁰. Soon after its launch, the WHO issued a call for expressions of interest from all mRNA vaccine developers who would be willing to share their vaccine technology with the hub²¹. One of the most advanced developers with extensive experience in the mRNA platform is CureVac, a German company which has received over \$49 million in funding from CEPI for both its platform technology and its COVID-19 vaccine candidate²². CEPI has rights to both the platform technology as well as the COVID-19 vaccine candidate, including the ability to add a "trusted manufacturer" to further develop the technology and produce it for "affected territories"¹². Despite the COVAX facility being official supporters of the mRNA Hub and the fact that CEPI's stated equitable access objectives are aligned with the Hub, CEPI did not use its leverage to make CureVac share its technology.

In fact, CEPI's efforts did not support manufacture of vaccines in developing countries outside specific producers in Asia until the announcement that CEPI would support the Institute Pasteur Dakar in building a regional manufacturing hub in January of 2022, two full years after its first investments into COVID19 vaccine candidates²³.

CEPI's impact on equitable access to COVID19 vaccines

CEPI has undoubtedly played an important role in advancing the development of vaccine candidates across a broad range of platform technologies. CEPI was one of the first institutions to provide meaningful funds to develop COVID-19 vaccines even before the WHO had declared SARS-CoV-2 a Public Health Emergency of International Concern (PHEIC) and has invested in 18 COVID-19 vaccine candidates to date (see Appendix 1). Overall, CEPI's portfolio of COVID-19 vaccines reveal a significant skew towards HICs, with just a third of candidates being from companies based in LMICs (all in Asia).

To assess CEPI's performance in enabling equitable access to COVID-19 vaccines, one must understand the way its investments have been made. CEPI's investments typically follow a two-step process. In the first step, an initial preliminary contract is signed that outlines the

scope of the collaboration and comes with a small amount of funding. This first step includes a commitment to the principles in CEPI’s equitable access policy but normally does not go into any detail on specific provisions. The second step involves more detailed contracts which address the “scale up and scale out” (expanding the volume and geographic scope) of manufacturing as well as provisions on supply of licensed vaccine doses and technology transfer to “trusted manufacturers”, in exchange for more substantial funding.

Although early Covid-19 investments were signed under time pressure, several step-one agreements could build on previous agreements CEPI had signed to support the development of vaccine platform technologies and their application to other emerging infectious diseases (eg. Middle East Respiratory Syndrome (MERS) related coronaviruses). This made it possible for CEPI to carry over some equitable access provisions into the new Covid-19 step one agreements.

For new partners with no previous history of CEPI investments, meaningful access provisions were sacrificed for speed. For example, CEPI’s early and small investment into Moderna and Inovio were accompanied by an obligation to abide by CEPI’s equitable access policy, but contained no licensing or step-in rights, effectively making their commitments toothless²⁴. While the Inovio vaccine candidate has not made it to licensure, the highly monopolized, unaffordable, and inequitable supply of the Moderna vaccine revealed the risks associated with signing funding agreements prior to obtaining robust contractual access provisions. As of Feb 2022, just 1% of the Moderna vaccine had been delivered to low-income countries.

CEPI signed its first second step agreement in May 2020 with Novavax, followed by Oxford/AstraZeneca in June 2020. In total, CEPI has signed 4 agreements of a more substantial size to date with the reported equitable access elements of each summarised below:

Table 1: CEPI’s step 2 agreements and their respective equitable access provisions

Developer	CEPI’s investment (USD Millions)	Equitable access provisions and actions attributable to CEPI
Novavax	399	<p>CEPI reports including provisions which ensure that all the antigen and adjuvant² funded by CEPI will result in doses going to COVAX, and includes CEPI’s standard step-in rights²⁵. Additionally, Novavax US SEC filings reveal that CEPI has the right to audit Novavax’s cost of goods and secured a commitment to reasonable pricing¹².</p> <p>The vaccine is also produced by the Serum Institute of India but the</p>

² A substance that enhances the immune system’s response to a viral antigen.

		technology transfer deal is likely attributable the Bill and Melinda Gates Foundation rather than CEPI ²⁶ .
Oxford/AstraZeneca	383	CEPI reports to have a provision allowing it to audit AstraZeneca's cost of goods to ensure its commitment to non-profit pricing (see below) ²⁵ .
Clover Biopharmaceuticals	397.4	CEPI's multiple contracts with Clover Biopharmaceuticals include provisions which require all of CEPI's funded supply expansion to go to COVAX during the pandemic period, 50% of post-pandemic supply capacity to be supplied to LMICs and allows for an additional agreement for manufacturing outside of China. However, there are no commitments to affordable pricing ²⁵ .
SK Biosciences	210.1	The contracts reportedly include a cost of goods + % margin pricing requirement and an obligation to supply COVAX. However, there are no commitments to affordable pricing ²⁵ .

Together, these investments represent more than two-thirds of CEPI's overall investment into COVID-19 vaccines. Out of all CEPI's funded vaccine candidates, only Novavax and Oxford/AstraZeneca have reached WHO Emergency Use Listing status and only the Oxford/AstraZeneca vaccine has been distributed globally in significant volumes. This makes an assessment of CEPI's impact on real world availability and accessibility of COVID-19 vaccines difficult.

The Oxford/AstraZeneca vaccine is arguably the most accessible, affordable, and equitably distributed COVID-19 vaccine, but it would be incorrect to attribute this success entirely to CEPI. CEPI ensured that vaccine doses would be supplied to COVAX through alternate manufacturing sites such as SK Biosciences, but by its own account the majority of the technology transfers they facilitated were to European manufacturers rather than to those in LMICs²⁷. It secured a right to audit the not-for-profit cost of the vaccine but was not responsible for including the provision in the license between Oxford University and AstraZeneca. By all accounts of the vaccine's development history, multiple actors played important roles which affected the vaccine's eventual accessibility and availability. The university agreement with AZ included the company's commitment to prioritize LMICs and to charge non-profit price during the pandemic²⁸.

Beyond vaccine platforms and vaccine candidates, CEPI has engaged in other activities, contracts, and initiatives throughout the pandemic with impact on equitable access. These can be broadly classified as either investments into enabling science initiatives or reserving manufacturing capacity dedicated to vaccines in CEPI's COVID-19 portfolio.

CEPI's most notable enabling science initiative is the centralized laboratory network (CNL). Established in October of 2020, the CNL tackles the major challenge of providing a standardized process by which vaccine candidates' efficacy can be compared on a level playing field. This initiative could be critical in helping resource constrained countries in prioritizing specific vaccines for procurement and support evidence-based R&D investments. Early experiences from public funders of COVID-19 vaccine research showed that companies are reluctant to contribute to cross comparisons of their products voluntarily and therefore, in order to achieve maximum impact, CEPI should have required its grantees to utilize the network and force publication of results in open access journals²⁹. It did not do this.

Reserving manufacturing capacity has mostly taken the form of deals signed with contract manufacturers (e.g., Biofabri and GCPharma) and manufacturers of products that are essential for vaccine production like glass for vials and adjuvants. Although little information on these deals is publicly available, the majority seem to have been signed with HIC-based manufacturers. This once again raises the concern of CEPI's myopic focus on HICs at the expense of many competent manufacturers in LMICs. CEPI has taken little to no steps across its funding agreements to tackle the consolidation of vaccine manufacturing capacity in HICs, instead opting to support the status quo and the inequities this implies.

CEPI's evolution, CEPI 2.0 and its replenishment

As CEPI ends its latest strategic cycle and begins a new one, lessons from the COVID-19 pandemic, shifting priorities and scope are in the spotlight. Three new strategic documents published over the course of the last year set the stage: the 2022-2026 strategy, the \$3.5 billion investment case, and the CEPI 2.0 Program document.

100 days mission

The idea to compress vaccine development into 100 days was first floated by CEPI in April 2021, in its investment case. This ambition was then taken up in a report presented at the G7 summit in 2021, “the 100 days mission”, written by the pandemic preparedness partnership, a group including UK based academics and civil servants, leaders of global health organisations (primarily organisations funded or created by the BMGF), and the pharmaceutical industry.

It is important to note that the only vaccine platform technology currently capable of delivering on this timeline is the mRNA vaccine platform, a vaccine technology monopolised by High Income country based institutions. Without significant and rapid investment into funding mRNA R&D and manufacturing efforts in LMICs, this goal and all the funding and support to help achieve it will overwhelmingly benefit HICs, further widening the inequities in pandemic preparedness and response.

One of the major changes across these documents is a further expansion of CEPI’s scope. Having already moved beyond phase 2b clinical trials to fund end-to-end development and manufacturing of licensed vaccines in the COVID-19 pandemic, CEPI will now also support the development of therapeutics and diagnostics against “epidemic and pandemic threats”.

This expansion is accompanied by an adapted mission and strategic objectives. The new mission statement introduces new language on access for “all people in need” (replacing the previous “affected populations”). This change in language suggests a bigger focus on equity but is missing further elaboration throughout the strategic documents.

Worrisome is a departure from a full acknowledgement of “market failure” as the premise for CEPI’s existence and related terminology that was previously fully embedded in CEPI’s strategic documents. This has been replaced by references to “leveraging market forces” and making “catalytic investments where they are insufficient”. Ignoring market failure as the core of CEPI’s raison d’être is perilous precisely because it leads to solutions which attempt to utilize the very mechanisms which created the necessity for its existence.

Beyond these concerning elements, core themes of increased investment into manufacturing and R&D capacity in LMICs, as well as greater engagement with LMIC governments are welcome and long overdue. But more substantial changes than concepts, language or strategic objectives are required to turn the tide on existing inequities in pandemic preparedness.

The People’s Vaccine Alliance calls for:

CEPI to curb the undue influence of Pharmaceutical Corporations

To maintain its independence and legitimacy as a global health institution, CEPI should end the practice of having representatives from the pharmaceutical industry on its board immediately.

Beyond this CEPI should demonstrate the highest standards of transparency and accountability and act robustly to end any undue influence from industry on CEPI decisions and policies.

CEPI to overhaul its equitable access policy

The current CEPI equitable access policy is wholly inadequate to challenge market and political forces responsible for extreme vaccine inequality and must also be revised to fit CEPI's expanded scope. Importantly, the policy should build on lessons learnt during the COVID-19 pandemic, including to:

- Define, require, and enforce affordable pricing;
- Require partners/grantees to prioritise supply to global or regional procurement entities;
- Mandate technology transfer to geographically diverse manufacturers in LMICs;
- Introduce a standard practice of non-exclusive licensing to enable diversification of manufacturing and production of adequate doses.

Further, when revising the equitable access policy, CEPI must explicitly exclude pharmaceutical companies playing any formal role in defining and agreeing the policy and must end industry undue influence on CEPI decision making.

CEPI to be bolder in enforcing existing and future commitments on access

At a meeting in 2020, CEPI board members stated that issues of “affordability and transparency are critically important” and requested that CEPI implement its policy “in a way that has teeth”²⁴. So far, CEPI is yet to make use of its existing rights, even when doing so could support more equitable access to vaccines. CEPI should:

- Enforce mechanisms which achieve CEPI's goal to make vaccines “first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay”⁹;
- Stipulate clear criteria that will clearly trigger CEPI to use its public health license in the event of industry failure to support equitable access. This will ensure it acts as a genuine threat to incentivise industry and ensure rapid access of products in LMICs.

Create a new template agreement reflecting the gold standard access provisions CEPI strives to include in partnership agreements

CEPI should publish an up-to-date template agreement which reflects the clauses and provisions related to access to products that CEPI will take into each new call for proposals and funding negotiations. These should include prioritising LMICs; affordable prices; and sharing knowledge and technology.

CEPI to support public and non-profit initiatives for sharing technology and know-how and diversifying manufacturing

Public and non-profit initiatives are essential in an R&D ecosystem where traditional market dynamics are dysfunctional and counterproductive. CEPI should support initiatives which align with its vision and objectives on equitable access. CEPI should:

- Actively support WHO-led initiatives such as C-TAP and the WHO mRNA vaccine technology transfer hub as well as other future technology transfer hubs including by making participation in these initiatives a selection criterion for receiving funding from CEPI;
- Leverage its rights to CureVac's mRNA platform to share the technology with the WHO and developers in low- and middle-income countries;
- Include provisions in partnerships resulting from its RNA vaccine platform call for proposals which allow CEPI to mandate technology transfer to the WHO or similar public and non-profit initiatives.

Transparency and timely publication of documents related to governance, contracts, and policies

CEPI's inconsistent and late publication of important governance documents and summaries of progress on equitable access not only limit its accountability to the global health community, but also CEPI's potential to set standards and exchange lessons with other emerging infectious disease funders. Similarly, non-transparency of funding agreements contributes to an ongoing culture of secrecy and unaccountability. Therefore, CEPI should:

- Publish contract agreements as soon as they are signed;
- Publish equitable access committee meeting documents in a timely fashion, within a month of the meeting;
- Publish regular progress updates on equitable access objectives, on a quarterly basis.

Meaningful engagement of low- and middle-income countries in CEPI's governance

CEPI's raison d'être is to enhance innovation and access, in particular for LMICs. But few individuals representing these countries have a meaningful influence on CEPI's strategy or decision-making processes. CEPI should:

- Diversify its secretariat by including more staff from LMICs across management levels;
- Ensure equal representation of members from LMICs and HICS on the board and alternate with other members for chair.

Invest in low- and middle-income country innovations and technologies

CEPI's investments continue to be overwhelmingly focussed on developers in high-income countries. Although the new strategic plan sets out to increase its engagement with low- and middle-income countries, all assume a north-south directionality in the transfer of innovation. Resilience and pandemic preparedness should not be based solely on high-income country innovation and CEPI must commit to prioritise investments into LMIC-

owned technologies and developers going forward and should set itself a clear target to increase the proportion of these investments as soon as possible.

Establish a diverse civil society constituency

Civil society has been essential in advocating for equitable access and holding global health actors accountable during and well before the COVID-19 pandemic. Global civil society has a wealth of expertise and experience to offer CEPI on barriers to diversified innovation and equitable access. As such, CEPI should:

- Civil Society should be represented as a core constituency on the CEPI Board. Include civil society as a core constituency, including in CEPI's Joint Coordination Committee (JCG);
- Hold regular meetings with the civil society constituency;
- Include legal experts representing civil society in defining, implementing, and monitoring the equitable access policy.

Mandatory participation of CEPI's grantees in the centralised laboratory network

Taking this step, would facilitate evidenced based decisions by public procurement entities and regulatory agencies as well as foster trust in the comparative advantages and disadvantages of vaccines in the CEPI portfolio.

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ANNEX 1: CEPI's investments during the COVID-19 pandemic

Throughout the COVID-19 pandemic CEPI has made significant investments into its platform and vaccine portfolios. However, CEPI's investments go beyond vaccine platforms and candidates and can be classified into 4 categories:

1. Vaccine candidate development
 - Funding of specific vaccine candidates
 - Funding of clinical trials
2. Vaccine platform development
 - Investments into vaccine development platforms
 - Investments into and advanced purchase of adjuvants
 - Exploring and sterility testing of multidose product bags
3. Manufacturing capacity reservations and advanced purchase agreements
 - Reservation of manufacturing capacity
 - Purchase of glass vials
 - Advanced purchase agreements
4. Enabling environment initiatives
 - Funding studies into correlates of protection
 - Creation and funding of the centralised laboratory network
 - Mapping of vaccine manufacturing capacity
 - Funding research into improving thermostability of vaccines

ANNEX 2: Timeline of first announcements of CEPI investments into COVID-19 vaccine candidates and vaccine platforms

January 2020

- Inovio
- University of Queensland
- Moderna
- CureVac

March 2020

- Novavax
- University of Oxford (prior to AZ deal)
- Uni of Hong Kong
- Institute Pasteur/Themis (later acquired by Merck)

April 2020

- Clover pharmaceuticals' Australian subsidiary

December 2020

- SK biosciences
- Biological E

March 2021

- VBI vaccines

July 2021

- Zerun Biotech

August 2021

- Gritstone bio

November 2021

- MigTax ltd
- uSask

December 2021

- Affinivax

January 2022

- Bionet Asia