APRIL 2022

EQUITABLE ACCESS REVIEW OF CEPI'S COVID-19 VACCINE DEVELOPMENT AGREEMENTS

O'NEILL INSTITUTE
FOR NATIONAL & GLOBAL HEALTH LAW
GEORGETOWN LAW

CENTER FOR TRANSFORMATIONAL HEALTH LAW

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KEY FINDINGS

CEPI'S STRONG COMMITMENT TO EQUITABLE ACCESS

CEPI maintains a nuanced, robust commitment to equitable access, a commitment that manifested over the course of the COVID-19 pandemic, although necessarily adapted to a context in which it worked with, and alongside, international partners and commercial partners of varying size, capital, and governance structure; did so on accelerated schedules; and, faced significant competition from government funders seeking or requiring bilateral arrangements.

THE CRITICAL RELATIONSHIP BETWEEN CEPI'S EQUITABLE ACCESS COMMITTEE AND SECRETARIAT STAFF

This commitment is explained by multiple factors, including a focused and efficient governance relationship between the CEO, the Secretariat Staff, and the CEPI Board's Equitable Access Committee.

CEPI'S LEADERSHIP IN COVAX AND ACCESS TO THE OXFORD/ASTRAZENECA VACCINE

CEPI's most visible and measurable success, other than its leadership in establishing COVAX, is its role in facilitating global access to ChAdOx1 nCoV-19 (the "Oxford/AstraZeneca" vaccine, "Vaxzevria", "Covishield", AZD1222, among other trade and regulatory classifications). That vaccine has reached more people, and saved more lives, than any other.

•CEPI'S MOST SUCCESSFUL AGREEMENTS WERE WITH SMALLER AND NEWER COMPANIES AND UNIVERSITIES

With respect to its COVID-19 vaccine development, scale-up of manufacturing, and vaccine supply agreements, CEPI enjoyed the most favorable equitable access terms with newer and smaller biotechnology companies, including manufacturers, and universities.

COMPETITION FOR DISEASE X PLATFORMS, A FOCUS OF CEPI 2.0, WILL BE FIERCE AND CEPI WILL NEED TO PARTICIPATE IN THE WIDER BIOMEDICAL INNOVATION ECOSYSTEM TO ENABLE EQUITABLE ACCESS TO THOSE PLATFORMS

Disease X platforms that represent a priority for CEPI 2.0 planning, also represent complex and competitive assets where CEPI's appeal as an investor will depend on multiple factors in the biomedical innovation ecosystem

CEPI SHOULD REVIEW COMMERCIAL BENEFITS

Related to competitiveness for Disease X technologies, CEPI's approach to sharing commercial benefits should be comprehensively reviewed.

BASED ON REVIEWS OF 28 AGREEMENTS COVERING 17 PARTNERS AND INTERVIEWS WITH CEPI STAFF AND EQUITABLE ACCESS COMMITTEE MEMBERS, THE FOLLOWING SPECIFIC AGREEMENT PROVISIONS ARE RECOMMENDED:

- more frequent and robust monitoring of equitable access commitments at the JMAG level including a JMAG member specifically charged with addressing equitable access in JMAG meetings;
- consideration of the appointment of a civil society representative and/or another LMIC representative to the Equitable Access Committee;
- the designation of a CEPI "open access officer" or enhanced auditing and monitoring of partners' open access obligations;
- consistent dispute resolution clauses;
- appropriate conditions or rights to information as to partners' dealings with third parties;
- the development and recommended/required use of template third-party or subawardee equitable access clauses;
- adaptation of force majeure clauses; and,
- adaptation of the CEPI Equitable Access Dashboard into a checklist for both the CEPI Equitable Access Committee and CEPI Secretariat staff

CEPI SHOULD REFLECT AND CONSTRUCT ITS ROLE IN THE GLOBAL HEALTH GOVERNANCE COMMUNITY

CEPI's 2.0 role will unfold in the context of multiple private- , public- and international organizational- partners and CEPI should undertake a comprehensive review of how that context will affect its planning.

BACKGROUND

THIS EQUITABLE ACCESS REVIEW (hereafter the Review) of CEPI's (Coalition for Epidemic Preparedness Innovations) COVID-19 vaccine development agreements was commissioned by the CEPI Secretariat in 2021 as an external review of how equitable access has been achieved through COVID-19 vaccine development agreements. This Review aims to evaluate and generate lessons learned on how CEPI performed against its mission on equitable access, and how these learnings may contribute to further enhance CEPI's agreements within its core portfolio moving forward.

In accordance with the proposal as initially accepted, the primary audience for this retrospective Review is CEPI's Investors, Board and Secretariat. These findings may also be of interest to other stakeholders, namely the CEPI Scientific Advisory Committee and the Joint Coordination Group.

Following a competitive process, the Center for Transformational Health Law, housed at the O'Neill Institute for National and Global Health Law at Georgetown University, was selected to undertake the external review. The work of the Center for Transformational Health Law focuses on examining legal and health policy responses to the COVID-19 pandemic, advancing evidence-based public health law, and supporting more equitable systems for improved health around the world. Its experts are current and former practitioners in the law of biomedical innovation, scholars of public health preparedness law and regulation, and leaders in the law of technology transfer.

The Review began in December 2021, and focused on evaluating the implementation of CEPI's Equitable Access Policy in COVID-19 vaccine agreements, the advances made towards CEPI's commitment to enabling equitable access to vaccines, and prioritizing efforts so that "vaccines are available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay." The Review also included focus on CEPI's commitment to enable open access to data, results and publications arising from its funding and facilitate access to materials to accelerate vaccine development. The Review was conducted using a mixed methodology, and included a review of literature available in the public domain, CEPI reports and publications, documents filed with the U.S. Securities and Exchange Commission (SEC), non-public documents made available by CEPI for the Review, and interviews with key stakeholders.

CEPI'S EQUITABLE ACCESS POLICY

Equitable access to epidemic vaccines in the context of an outbreak has been defined by CEPI as ensuring that appropriate *"vaccines are first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay."* CEPI's Equitable Access Policy seeks to facilitate equitable access to epidemic vaccines in three fundamental ways:

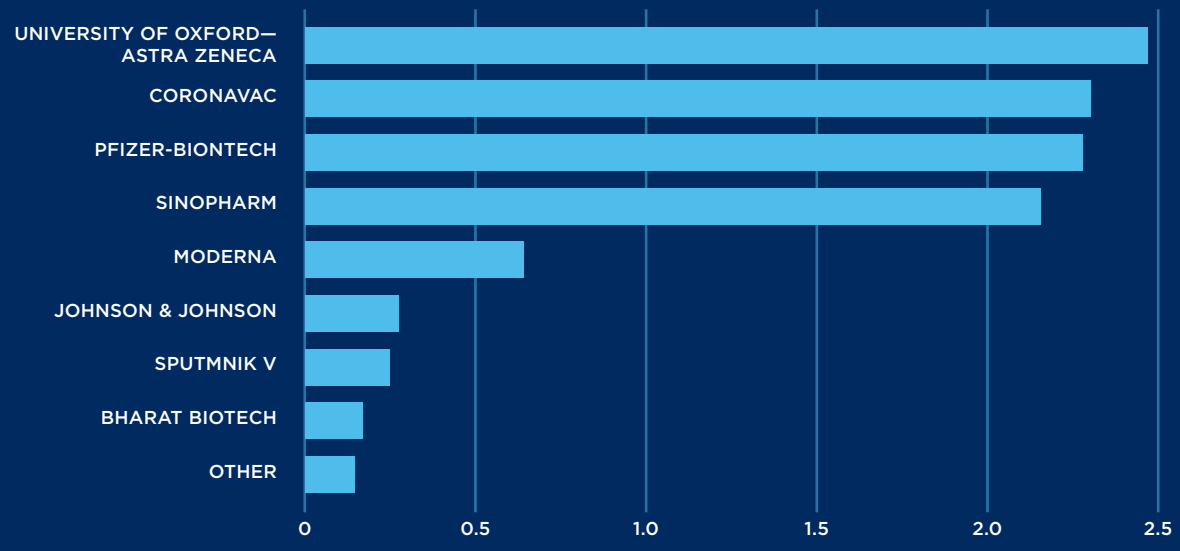
1. Funding the development of vaccines and maintaining investigational stockpiles, to be used free of charge when an outbreak occurs;
2. Coordinating with others in the global health community to enable licensure of vaccines funded by CEPI, including by securing resources for pivotal clinical trials and;
3. Collaborating with others in the global health community to enable the procurement, allocation, deployment and administration of licensed vaccines to protect global health, at a price that does not limit equitable access and is sustainable to the manufacturer.

Funding Vaccine Development

The CEPI Equitable Access Policy recognizes that equitable access principles must be implemented throughout all stages of vaccine development, manufacture, and deployment. CEPI funding agreements reflect this need both through the flexibility built into elements of the funding agreements, and the diversity of funding agreements.

THE RACE TO VACCINATE

Nearly 10 billion doses of COVID-10 vaccine have been delivered around the world since mid-2020, 8.5 billion of which has been administered by late 2021. Eight different vaccines make up the vast majority of doses.*



*Data as of 14 December 2021

An essential mark of CEPI's role in vaccine development is the achievement of the ChAdOx1 nCov-19 vaccine, marketed as Vaxzevria and Covishield, among other names. According to recent analyses in *Nature* and the *Economist*, the vaccine, which enjoyed early and substantial support from CEPI, is not only the most widely available and administered, it has also saved more lives than any other. As of November 16, 2021, two billion doses of the vaccine have been supplied to countries across the world in less than 12 months after first approval. Approximately two-thirds of these have gone to lower-and lower-middle income countries, including more than 175 million doses delivered to 130 countries through COVAX.

Global Coordination for Equitable Access

An essential component of CEPI's equitable access commitment is its role in coordinating with others in the global health community to enable licensure of vaccines supported by CEPI. Together with Gavi and WHO, CEPI led the global health community in the establishment, strategy, and sustainability of COVAX, the Vaccine Pillar of the ACT Accelerator. Framework partnering agreements, Step 1 and Step 2 vaccine development agreements, manufacturing supply and reserve agreements, and clinical trial readiness agreements integrate the role and responsibility of affiliated partners.

Accessible and Sustainable Pricing

Over the course of the COVID-19 pandemic, CEPI adapted policies deployed for its pre-pandemic portfolio – including tiered pricing, cost-of-goods plus pricing, claims on real-time production and commercial benefits, and the public health license – to its COVAX-directed relationships with international public- and private-sector partners.

OPEN ACCESS, DATA, RESULTS AND PUBLICATIONS

CEPI's Equitable Access Policy includes that it will "ensure open access to data, results and publications arising from its funding and facilitate access to materials to accelerate vaccine development." In its agreements, this has tended to be interpreted as publication strategies that follow (i) WHO's 2016 Guidance for Managing Ethical Issues in Infectious Disease Outbreaks; (ii) WHO's 2016 Guidance on Good Participatory Practices in Trials of Interventions Against Emerging Pathogens; (iii) and Wellcome Trust's Statement on Sharing Research Data and Findings Relevant to the Coronavirus (COVID-19) Outbreak.

LOOKING AHEAD TO CEPI 2.0 AND THE 100 DAYS VISION

CEPI HAS PRESENTED AMBITIOUS EQUITABLE ACCESS COMMITMENTS IN THEIR CEPI 2.0 STRATEGY, weaving equitable access commitments through all three pillars of their strategic vision. Lessons from the negotiations of these vaccine contracts, and the role of equitable access in CEPI 1.0's work will be critical in effectively designing and executing a number of the stated goals in the three-pronged CEPI 2.0 strategy.

In their strategy for "prepare", CEPI seeks to "[e]nsure all manufacturing output corresponding to the CEPI-funded part of COVID-19 vaccine development are to be offered first to the COVAX Facility; and accelerate the availability and affordability of COVID-19 vaccine doses for COVAX through grants and loans to help developers scale up and scale out production and secure raw materials."* A thorough evaluation of the lessons learned from the negotiation and execution of the contracts included in this Review will be critical for the successful implementation of this goal through future agreements. Likewise, CEPI's successful implementation of open access commitments in their funding contracts can serve as a lesson in good practice for its goal to "[c]ontinue its commitment to open access publication of results so that everybody can benefit from the work that CEPI funds."**

The documents reviewed and interviews conducted provided important insight into the complexity of the negotiation process. One challenge that was identified was the short period of time in which to negotiate and finalize complex contracts and the situational limitation of working with partners who also sought both commercial and public procurement opportunities elsewhere. This condensed time frame and competitive environment presented challenges for the implementation of equitable access provisions.

The following sections set forth the methodology applied by the O'Neill Institute (or O'Neill Team) in identifying lessons learned, elaborating the broader context in which CEPI negotiated equitable access over the course of the COVID-19 pandemic, and elaborates recommendations that are relevant to its future outlook, including CEPI 2.0 and the 100 Days vision.

* https://cepi.net/wp-content/uploads/2021/12/20211202-CEPI-2_0-Programme-Document-v1_wl.pdf

** https://cepi.net/wp-content/uploads/2021/12/20211202-CEPI-2_0-Programme-Document-v1_wl.pdf

METHODOLOGY

LITERATURE REVIEW

Secondary Literature

Methodologically, this Review is based upon a structured literature search using Bloomberg Law, Westlaw, PubMed, Excerpta Medica dataBASE (EMBASE), Cumulative index to Nursing and Allied Health Literature (CINAHL) and Global Online Access to Legal Information (GOALI) using the following predefined keywords: CEPI AND equitable access; COVAX AND CEPI; vaccine AND CEPI AND [name of partner]. Annexed to the Review is a bibliography that may be used as a resource for the CEPI Secretariat, Board, Equitable Access Committee, and partners. From that review, the research team developed a stakeholder map for the CEPI agreements provided for review. This map built on our existing contacts, the literature review and the use of the 'snowball' technique to identify additional literature relevant to the Review analysis.

As part of its literature review, the O'Neill Institute analyzed the public positions of civil society organizations, academic institutions with affiliated researchers who've analyzed CEPI's Equitable Access Policy specifically, as well as international organizational and governmental statements relevant to the Equitable Access Policy. These positions are reflected in O'Neill analysis and recommendations.

Securities Filings

The O'Neill Team also reviewed securities reports, updates, and notifications filed by partners for which such filings were required by the U.S. Securities and Exchange Commission (SEC).

DOCUMENT REVIEW

Governance Documents

In addition to agreements and interviews facilitated by the CEPI Secretariat, the O'Neill Team undertook an extensive review of CEPI's publicly available governance and strategy documents, including the CEPI 2.0 Program Document and its annexed Results Framework and CEPI's periodic updates to its own equitable access summary document. The O'Neill Team reviewed Board meeting summaries for the period August 2016 to September 2021, the minutes from the Board's Equitable Access Committee from November, 2019 to October, 2021, the Board's Audit and Risk Committee minutes from November 2019 to March 2021, and the Board's Executive and Investment Committee minutes from November 2019 to July 2020.

The O'Neill Team reviewed the current Equitable Access Policy, the original Equitable Access Policy approved by the Board on 20 February 2017, and the analysis of relevant changes

surveyed by CEPI leadership in *Vaccine*.*** The most recent version (V7.0) of the Enabling *Equitable Access to COVID-19 Vaccines: Summary of equitable access provisions in CEPI's COVID-19 vaccine development agreements* was also reviewed. The [*Draft*] *Proposal to establish a globally fair allocation system for COVID-19 vaccines, March 25, 2020* was reviewed along with pre-COVID-19 EA related documents, namely, the Overview of CEPI's "CfP3i" Call for RVF and CHIK Vaccine Proposals and the summary document dated March 20, 2019 - the Advancing Equitable Access to Epidemic Vaccines through CEPI's Vaccine and Platform Development Agreements.

Other governance documents reviewed include:

- Business Plan 2019-2022 and preliminary business plan of 2017-2021.
- Joint Coordination Group (JCG) Meeting Summaries from 2018 to 2021.
- Summary of CEPI Scientific Advisory Committee (SAC) meetings held from June 2018 to August 2020.
- Board of Directors Report, Annual Accounts and Auditors' Reports from 2017 to 2020.

Vaccine Development, Manufacturing, Supply, and Clinical Trial Readiness Agreements

The O'Neill Institute was provided access to 28 agreements covering seventeen (17) CEPI partners. These agreements include the Outbreak Response Funding Agreements, both Step 1 and Step 2; Wave 2 Award Agreements; Trusted Manufacturer Agreement, and various subsequent amendments to the agreements. Two sets of pre-COVID-19 agreements were also reviewed, namely the Framework Partnering Agreements ("FPA") entered between CEPI and the University of Queensland, and between CEPI and CureVac AG. The classifications used by O'Neill may differ than those used internally by CEPI.

After grouping the agreements, the O'Neill Team analyzed pairs of agreements for material differences between agreements in each classification. These differences are identified within each agreement grouping below and the relevance of those differences highlighted for purposes of lessons learned.

Each of the COVID-19 agreements entered into by CEPI to-date seeks to accomplish one or more of the following major objectives: (1) preclinical and clinical development and testing of candidate vaccines; (2) development and validation of a manufacturing process capable of producing large quantities of vaccines; (3) the supply of vaccines by that manufacturing process; and (4) supporting these aspects of development both through specific supply chain elements, like adjuvants. Subsequent agreements entered into by CEPI involve development or advance development of vaccine candidates against variants of concern. This approach is specific to CEPI's vaccine development agreements and CEPI internal governance.

TABLE OF REVIEWED AGREEMENTS

O'NEILL CLASSIFICATION		DATE SIGNED	BRIEF DESCRIPTION
AGREEMENTS PURSUANT TO FRAMEWORK PARTNERING AGREEMENT			
CureVac AG	Framework Partnering Agreement	15 February 2019	Vaccine development •Scale-up of manufacturing • Supply of vaccine
	COVID-19 Amendment Agreement	29 January 2020	mRNA COVID-19 vaccine development
University of Queensland and CSL	Trusted Manufacturer Agreement	5 June 2020	Vaccine development • Scale-up of manufacturing • Supply of vaccine
STEP 1 AGREEMENTS			
Inovio Pharmaceuticals, Inc	Rapid Response	19 March 2020	Vaccine development
ModernaTX, Inc.	Rapid Response	23 January 2020	Vaccine development
University of Hong Kong	Rapid Response	18 March 2020	Vaccine development
The Institut Pasteur	Rapid Response	19 March 2020	Vaccine development
Clover BioPharma	Rapid Response	09 April 2020	Vaccine development
Novavax, Inc.	Rapid Response	20 March 2020	Vaccine development • Scale-up of manufacturing • Supply of vaccine
Bio E	Rapid Response	21 December 2020	Scale-up of manufacturing

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TABLE OF REVIEWED AGREEMENTS (CONTINUED)

O'NEILL CLASSIFICATION		DATE SIGNED	BRIEF DESCRIPTION
STEP 2 AGREEMENTS			
Novavax		11 May 2020	Outbreak Response Funding Agreement (Step 2)
Clover BioPharma		8 July 2020	Outbreak Response Funding Agreement (Step 2) – Vaccine Development Agreement
University of Hong Kong		4 March 2021	Outbreak Response Funding Agreement (Step 2)
NEXT GENERATION COVID-19 VACCINE DEVELOPMENT AND MANUFACTURING			
SKBio		8 December 2020	Wave 2 Award Agreement
VBI VACCINES INC / VARIATION BIOTECHNOLOGIES INC.			
		10 March 2021	COVID-19 Outbreak Response Agreement
SHANGHAI ZERUN BIOTECH [GUARANTOR – WALVAX BIOTECHNOLOGY CO., LTD.]			
		21 July 2021	Covid-19 Outbreak Response Agreement
GRITSTONE BIO, INC.			
		17 August 2021	COVID-19 Outbreak Response Agreement

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TABLE OF REVIEWED AGREEMENTS (CONTINUED)

O'NEILL CLASSIFICATION		DATE SIGNED	BRIEF DESCRIPTION
ADJUVANT SUPPLY			
Dynavax		1 February 2021	CEPI and Dynavax Technologies Corp. entered into a partnership on 29 January 2021 to supply its proprietary CpG 1018 adjuvant to CEPI Partners.
		07 May 2021	Agreement Amendment to reserve specified additional quantities of the CpG 1018 adjuvant for purchase by CEPI Partners.
MANUFACTURING SUPPLY			
Oxford/ AstraZeneca		4 June 2020	Rapid Response

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INTERVIEWS

CEPI SECRETARIAT STAFF ARRANGED 10 INTERVIEWS WITH 9 KEY CEPI PERSONNEL. After reviewing key personnel included in the agreements made available for review, the O'Neill Team developed semi-structured interview scripts specific to the role of each CEPI Secretariat or CEPI Equitable Access Committee member. The interview times ranged from 30 to 90 minutes in duration. Consent was sought from the interviewees and their responses and quotes are kept anonymous in this report. In some instances, the observations of interviewees have been augmented with reports from the news media and scientific literature. The interviews consisted of questions regarding CEPI's Equitable Access Policy, the COVID-19 agreements entered with partners, and the negotiations surrounding these agreements. Perceived barriers and facilitators to implementation of the Policy were explored, as were interviewees' views on how CEPI performed against its mission on equitable access. Study participants described a number of challenges and successes in implementing CEPI's Equitable Access Policy while negotiating the COVID-19 agreements that form the subject matter of this Review.

INTERVIEWEE	MEETING TITLE
Richard Wilder	General Counsel and Director, Business Development
Melanie Saville	Director of Vaccine Research & Development
Kwasi Amfo	Business Development Lead
David Reddy	Equitable Access Committee
Tom Johnston	Senior Consultant, Business Development
Richard Hatchett	CEO
Richard Hatchett	CEO
Charlotte Watts	Equitable Access Committee
Emma Wheatley	Deputy General Counsel and Head of Business Development
Cherry Kang	Equitable Access Committee

LESSONS LEARNED

NEGOTIATION CONTEXTS

Rapid Response Agreements Pursuant to Framework Partnering Agreements

Lessons learned

1. Relational versus Discrete Contracts

CEPI's broad "relational" approach to its agreements may require review and adaptation. "Relational" agreements are characterized by relatively high levels of trust between parties and terms such as "reasonable", "best efforts", "best endeavours", "parties' expectations" and similarly broad language and implementation mechanisms guiding cooperation. More specific and discrete commercial benefits terms in framework agreements in particular may better offer CEPI leverage in later pandemic and 2.0 planning.

2. Disease X Platforms, Supply Chains, and Clinical Trial Readiness

CEPI 2.0 and the 100 Days vision emphasize adaptable platform technologies that will likely have (as did preceding platform agreements) multiple and lucrative alternative applications. Steeper investments in platforms therefore carry significant risk of governmental and commercial competition and interference. CEPI's planning for Disease X Platform support will need to weigh the competitive environment.

Step 1 Agreements

CEPI divided its initial approach to COVID-19 vaccine development agreements into two parts: Step 1 and Step 2. Step 1 agreements focused on providing "time of the essence" support to promising vaccine candidates, including scale-up of supply, with broad expectations of equitable access provisions to be included should the vaccine candidate issue proceed to Step 2. Step 2 agreements typically involved more extensive equitable access provisions analyzed in more detail below.

Lessons learned

1. Diverse Commitment Assurance Mechanisms Even at the Step 1 Stage

Even under emergency circumstances, CEPI deployed a diverse set of mechanisms to address equitable access. These included the JMAG, repayment requirements under specified circumstances, and robust, real-time information sharing commitments.

2. Change of Control

Change-of-control possibilities should be addressed in Step 1 agreements, should that structure reemerge in a future public health emergency.

Step 2 Agreements

Step 2 agreements involved significantly larger investments by CEPI and correspondingly more robust commitment assurance mechanisms including JMAGs, Public Health Licenses (PHLs), Stage Gate monitoring of project progress, and robust dispute resolution mechanisms.

Lessons Learned

1. Rights with respect to Third Parties

The Step 2 agreements contained strong equitable access commitment enabling mechanisms, although only one of the candidates covered by the agreements has reached emergency use listing (EUL) by WHO and therefore eligibility for distribution by COVAX. Specificity with respect to rights to information from third-party dealings are necessary to ensure these mechanisms function effectively.

2. Robust and Favorable Dispute Resolution Provisions

CEPI's interests in both routine and emergency contexts will require favorable dispute resolution provisions, including arbitration, choice of forum, choice of law, and availability of interim, equitable, emergency and/or injunctive relief.

NextGen Agreements

The O'Neill Team has characterized agreements with Shanghai Zerun Biotech (Zerun), VBI, SKBio, and Gritstone as "NextGen" both because they support new or variant-specific technologies and because they represent more complex integration of CEPI support across the vaccine development process including, for example, adjuvant supply, vaccine development, and scale-up of manufacturing for Clover's COVID-19 vaccine candidate.

These agreements are also characterized by CEPI's proximity to governmental parties.

Lessons Learned

1. Complex Negotiations Involving Development, Supply Chain, and Governmental Parties

The NextGen agreements involve terms affected by contemporaneous or pre-existing government agreements and negotiation with provincial level officials. To some extent, CEPI's ability to leverage these moving pieces is limited, but it represents an important lesson in how CEPI's planning will proceed.

2. Competition for Disease X Platform Technologies

CEPI's NextGen agreements introduced complex factors that will accompany platform technology assets: special treatment, if possible, to development and application of the platform for WHO Blueprint diseases; possibilities for change-of-control transactions affecting CEPI's interests; and, monitoring the boundary between CEPI's support for one or more specific Disease X applications and alternative uses of Disease X platform technology.

Adjuvant Supply (Dynavax)

Lessons Learned

The agreement with Dynavax represents the likelihood that CEPI will need to enter into agreements with various partners in the vaccine supply chain. The forgivable loan structure and time horizon for use of CpG1018 appeared appropriate safeguards for CEPI's interest in equitable access to support CEPI's other supported vaccine candidates.

RECOMMENDATIONS

The above Review has analyzed CEPI's equitable access policy in light of its main purpose. The equitable access policy is aimed at offering guidance and on equitable access principles without being a strict box to be applied when creating an agreement. Nevertheless, within and across agreement categories, both by developer and by product or service, the development of a heuristic aid or checklist may assist CEPI Secretariat staff and the CEPI Equitable Access Committee as CEPI 2.0 unfolds. The following recommendations include proposed provisions for each agreement individually, clustered per type of developer and the objective CEPI aimed to accomplish. The recommendations are conscientious of the changing landscape at the time CEPI signed the above-analyzed agreements.

GOVERNANCE RECOMMENDATIONS

CEPI maintains a nuanced, robust commitment to equitable access, a commitment that manifested over the course of the COVID-19 pandemic, although necessarily adapted to a context in which it worked with, and alongside, international partners and commercial partners of varying size, capital, and governance structure; did so on accelerated schedules; and, faced significant competition from government funders seeking or requiring bilateral arrangements.

This commitment is explained by multiple factors, including a focused and efficient governance relationship between the CEO, the Secretariat Staff, and the CEPI Board's Equitable Access Committee.

Consider Adding a Representativve from a Civil Society Organization and/or another Representative from an LMIC to the Equitable Access Committee

CEPI Equitable Access Committee (EAC) and Secretariat staff interviews suggested that despite CEPI's commitment to, and mechanisms adopted for, equitable access, the EAC would benefit from considering the addition of a civil society representative and/or another representative from an LMIC to the Equitable Access Committee. This recommendation is also implied in CEPI's 2.0 planning documents.

Designation of an "Open Access Officer"

While the O'Neill Institute team identified dozens of publications – many in high impact journals - attributing published findings to CEPI funding, it was not clear whether CEPI had designated a responsible official for monitoring this aspect of agreement compliance.

The O'Neill Team recommends that CEPI designate or specifically recruit an "open access officer" who will not only assemble and curate a library of CEPI-funded work, but will also monitor the open access, publication, and dissemination commitments made by partners. This recommendation may also be achieved through enhancement of CEPI's audit and monitoring processes for its current and future agreements.

Clarifications as to the Scope of the Equitable Access Policy

Over the agreements reviewed and interviews conducted, the language capturing the Equitable Access Policy ranged from the CEPI-facing obligations – vaccine access "regardless of ability to pay" or "affordable prices" – to commitments like "sustainable", "commercially sustainable", or that the partner will "suffer no financial loss" in any given market. Each of these articulations of the Equitable Access Policy are consistent with CEPI's general mission, but the codification of each may translate into different outcomes with respect to access and CEPI may consider revisiting the Policy's language and its implementation by the EAC and the Secretariat staff.

AGREEMENT RECOMMENDATIONS

More frequent discussion of equitable access at the JMAG and a specified individual to do so.

While the agreements that included JMAGs emphasized their role in ensuring equitable access, the structure of the JMAG itself was sometimes a meeting of an individual from CEPI and another individual from the partner. To date, JMAG meetings have been largely "operational". It is recommended that each JMAG appoint a separate individual from CEPI charged with addressing equitable access terms and implementation and that the issue of equitable access be raised at least quarterly.

Hold a Specific Meeting with Secretariat staff, the EAC, and the CEO to Assess the Step 1 – Step 2 Structure

The Step 1 – Step 2 structure of some vaccine development agreements similarly posed a leverage challenge for CEPI. On the one hand, interviewees defending the structure argued that its equitable access mandate justified risk-adjusted support for any promising candidate in the interest of the world securing a safe and effective vaccine under any circumstances. Other interviewees argued that even with uncertainties surrounding pricing and volume, CEPI could have demanded modest concessions. CEPI should convene a meeting between the Secretariat staff, the CEO, and the EAC to weigh perspectives on the Step 1 – Step 2 structure, and to establish protocols for assessing the leverage CEPI may enjoy at the Step 1 stage.

Preserve CEPI as a Price-Negotiating Party

CEPI's ability to negotiate price represents an important aspect of enabling equitable access. The O'Neill Team suggests that CEPI continue to serve as a price-negotiating party, even when doing so in cooperation with other international governmental partners.

Review Dispute Resolution Provisions for Adherence to CEPI Interests

The dispute resolution clauses varied across the agreements in which they appeared. Given the importance of dispute resolution in vaccine development, manufacturing supply, and future vaccine agreements, CEPI should ensure that dispute resolution clauses default to a position that favors CEPI's preferred forum, applicable law, and access to courts of competent jurisdiction when necessary.

Comprehensively Assess CEPI's Role vis-à-vis International Partners and within the Biomedical Innovation System

CEPI is now embedded in a global framework of vaccine and, to some extent, therapeutic, development, clinical trial readiness, manufacture, and distribution. In that new context, CEPI's equitable access policy will be affected by governments entering into agreements or asserting other legal claims affecting CEPI-covered agreements; the activities and interests of international organizational partners; and, the activities of other major charitable organizations.

CEPI's role as it proceeds with its 2.0 plan will necessarily require analysis of the gaps in the biomedical innovation cycle where it can play a significant role in vaccine development, clinical trial readiness, and manufacturing.

Plan for the Competitiveness of Disease X Platform Technologies

The Disease X mission and the mission toward vaccines where commercial markets are unlikely may come into tension. "Disease X" investments are likely to be toward platforms where applications may be numerous and not necessarily limited to WHO Blueprint diseases. CEPI's value will therefore be in the ecosystem surrounding such technologies including adjuvants, supply chains, manufacturing facilities, and the regulatory interface.

Adapt the CEPI Equitable Access Dashboard into a Checklist for Use by the EAC and the CEPI Secretariat Staff and Pair it with a Matrix Showing Value Added Across CEPI's Portfolio

While each agreement and each partner must be evaluated in its own context, there is substantial evidence supporting the use of uniform checklists as a low-cost mechanism that facilitates goal achievement in numerous contexts. The current draft Equitable Access Dashboard may be adapted to serve as a checklist for both CEPI Secretariat staff and the CEPI Equitable Access Committee. This dashboard could be further enhanced to show nexuses of leverage and synergy across CEPI's portfolio.

Review Representation of LMIC Scientists and Representatives in CEPI Decision-Making Processes

Interviewees generally indicated that CEPI could do a better job of incorporating LMIC perspectives into decision-making processes. This position is also stated in CEPI 2.0 planning documents.

CONCLUSION

This Review summarized our evaluation of the progress made by CEPI on implementation of the equitable access provisions focusing on funding the development of vaccines and maintaining investigational stockpiles that would be used free of charge when an outbreak occurs. It evaluated the success of CEPI's role in coordinating with others in the global health community to enable licensure and distribution of vaccines funded by CEPI. It also evaluated CEPI's work with the global health community to enable the procurement, allocation, deployment and administration of licensed vaccines at accessible and sustainable prices. It lastly evaluated the implementation of CEPI's commitment to enabling open access and to data, results and publications arising from the vaccines and candidates it funds, and its commitment to facilitating access to materials to accelerate vaccine development.

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