

December 7, 2023

Dr. Richard Hatchett
Chief Executive Officer
Coalition for Epidemic Preparedness Innovations (CEPI)

Dear Dr. Hatchett,

As civil society organizations and access to medicines advocates, we are writing to encourage CEPI to publish the terms of its partnership agreements to advance public trust and confidence in these partnerships.

During the COVID-19 pandemic, governments awarded companies billions in taxpayer dollars to de-risk research and development and increase manufacturing capacity for COVID-19 vaccines, with too few limitations or conditions to price reasonably, to license intellectual property and transfer technology, to promote transparency or to ensure equitable access in low- and middle-income countries (LMICs). Vaccine nationalism and profiteering contributed to harrowing disparities in access and morbidity. CEPI, the World Health Organization (WHO), and GAVI aspired to create a mechanism for equitable access and delivery of vaccines through COVAX. Though COVAX helped deliver nearly two billion vaccine doses throughout the pandemic,¹ insufficient access conditions with developers receiving CEPI's funding, such as Moderna and AstraZeneca, allowed companies to prioritize high-income country sales.

We share CEPI's belief that the "focus on speed should not distract from the importance of achieving scalability of manufacturing and ensuring equitable access to all in need of being protected during an outbreak, regardless of geographic location or ability to pay."² As CEPI enters into partnerships to advance its 100 Days Mission, we ask that it leverage its position to achieve an inclusive preparedness architecture. CEPI can facilitate inclusion and build public trust by increasing transparency of its partnership agreements. We particularly urge disclosure of terms related to equity, including:

- 1) Terms pertaining to pricing and the extent to which CEPI is ensuring affordability, such as through auditing cost-of-goods (COGs) and limiting mark-ups;
- 2) Terms pertaining to supply and delivery of products to LMICs, including details on stockpiling of investigational doses;
- 3) Terms pertaining to licensing and technology transfer of products that result from CEPI R&D funding. CEPI can ensure compliance with its access policy and contribute to manufacturing scale-up by including provisions requiring IP licensing and technology transfer to developing country manufacturers and WHO partners like the mRNA technology transfer program.

¹ Halabi, S., Gostin, L., Aneja, K., Nardi, F., Gottschalk, K., & Monahan, J. (2023). The Coalition for Epidemic Preparedness Innovations (CEPI) and the Partnerships of Equitable Vaccine Access. *Journal of Law, Medicine & Ethics*, 51(2), 234-246. doi:10.1017/jme.2023.85.

² Delivering Pandemic Vaccines in 100 Days, CEPI (Nov. 29, 2022), https://100days.cepi.net/wp-content/uploads/2022/12/CEPI-100-Days-Report-Digital-Version_29-11-22.pdf

CEPI's Transparency and Confidentiality Policy acknowledges that the effectiveness of its programs is strengthened by public access to information about CEPI's activities.³ CEPI's standard for overriding confidentiality in exceptional circumstances includes the determination that the overall benefits and public interest of such disclosure outweigh the likely harm to protected interests.⁴ CEPI's policies and actions towards increased transparency and equitable access are based on principles that value public interest disclosure and accessibility of products developed with CEPI funding.

We believe that the public interest in equitable access terms outweighs confidentiality interests, and CEPI should broaden its transparency policy to reflect this. Brief summaries and variable indications of access terms included in agreements are insufficient to protect the public interest and limit the public's ability to support CEPI in its mission. With the vast majority of CEPI's funding coming from public investors,⁵ greater disclosure of equity terms is necessary to ensure that the products derived from public resources are accessible.

In its Equitable Access Policy, CEPI defines equitable access during an outbreak as appropriate vaccines being first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay.⁶ CEPI's Equitable Access Framework helpfully details some of its thinking around achieving equity goals, including through "a demonstrable commitment to transparency" as a means to enhance CEPI and its development partners' accountability for enabling equitable access.⁷ Yet the execution of these policies in funding agreements remains opaque.

Recent CEPI partnership announcements include statements on enabling equitable access, though these are varied and, we believe, lack necessary detail. For example, recent funding announcements with Emervax Inc. and the University of Oxford include commitments to transfer technology to ensure affordable access.⁸ Such commitments are absent from its partnership announcements with BioNTech and Moderna.⁹

The strategic partnership recently announced between CEPI and Moderna to accelerate pre-clinical testing of vaccine candidates based on CEPI-owned antigen designs includes only sparing references to

³ Transparency and Confidentiality Policy, CEPI (Nov. 2018), <https://cepi.net/wp-content/uploads/2019/01/Transparency-and-Confidentiality-Policy-2.0.pdf>

⁴ Ibid.

⁵ Investor's overview, CEPI (Dec. 1, 2023), https://cepi.net/wp-content/uploads/2023/12/2023_12_01-CEPI-Investors-Overview.pdf

⁶ Equitable Access Policy, CEPI (Dec. 2018), <https://cepi.net/wp-content/uploads/2019/01/Equitable-Access-Policy.pdf>

⁷ Equitable Access Framework, CEPI (May 2023), https://cepi.net/wp-content/uploads/2023/05/CEPI_Equitable-Access-Framework_May-2023_2.pdf?swcfpc=1

⁸ CEPI and University of Oxford to accelerate vaccine development against Disease X, CEPI (Aug. 29, 2023), https://cepi.net/news_cepi/cepi-and-university-of-oxford-to-accelerate-vaccine-development-against-disease-x/; CEPI to support circular RNA-based platform technology for vaccine development against emerging viral threats, CEPI (Oct. 25, 2023) https://cepi.net/news_cepi/cepi-to-support-circular-rna-based-platform-technology-for-vaccine-development-again

⁹ BioNTech and CEPI Announce Partnership to Advance mRNA Mpox Vaccine Development and Support CEPI's 100 Days Mission, CEPI (Sept. 18, 2023), https://cepi.net/news_cepi/biontech-and-cepi-announce-partnership-to-advance-mrna-mpox-vaccine-development-and-support-100-days-mission/; CEPI and Moderna harness mRNA technology to advance 100 Days Mission, CEPI (Oct. 30, 2023), https://cepi.net/news_cepi/cepi-and-moderna-harness-mrna-technology-to-advance-100-days-mission/

equity. We are concerned that the announcement does not adequately address ownership of eventual candidates, though CEPI does state that it retains the rights to the antigen designs. As the announcement states that this is only the first of multiple vaccine development projects under this partnership, greater transparency would be helpful to understand the balance of these agreements.

In its 2020 funding agreement with CEPI to accelerate manufacturing of its COVID-19 vaccine candidate, Moderna agreed to abide by CEPI's equitable access policy and agreed in good faith to develop an equitable access plan with CEPI in the event of a more complete funding agreement.¹⁰ Although no further agreement was signed, had CEPI exercised greater leverage in its initial agreement providing critical early funding to Moderna, we might have seen greater access to Moderna's mRNA COVID-19 vaccine in LMICs. Instead, Moderna was able to dictate pricing and prioritize supply agreements with high-income countries.¹¹

We appreciate the responsibility of other funders, including the U.S. government, to ensure equitable access conditions and acknowledge that this 2020 agreement was notably rushed due to the urgent need to address the COVID-19 pandemic. However, lack of adequate transparency in CEPI's more recent funding agreements leaves continuing uncertainties regarding equitable access and the extent to which CEPI-funded vaccines will be available to populations with the most pressing need. Without adequate disclosure of R&D partnership terms, it is impossible to assess whether the funding CEPI is injecting into global pandemic preparedness adequately takes on equitable access lessons from the COVID-19 pandemic response.

We appreciate CEPI's support for Global South manufacturers, including in the recently announced partnership with Bio Farma and other manufacturers participating in the WHO-backed mRNA technology transfer program.¹² However, we ask CEPI to consider how its other agreements advance the development of independent local manufacturing capacity in LMICs.

CEPI's recent partnership announcement with BioNTech to advance its mpox vaccine candidate includes a reference to BioNTech's efforts to establish "a decentralized and robust end-to-end manufacturing network in Africa aiming to enable scalable production of mRNA-based medicines."¹³ But BioNTech's efforts to move 'BioNTainer' facilities under its control to a few African countries are far from the innovation and manufacturing ecosystem needed to ensure accountable, locally-led development of sustainable and equitable supply of existing and novel mRNA vaccines throughout Africa. Similarly,

¹⁰ CEPI Equitable Access Committee (EAC) Meeting Minutes, CEPI (Feb. 13, 2020),

<https://cepi.net/wp-content/uploads/2020/04/Minutes-13-02-2020-EAC-Meeting.pdf>

¹¹ Moderna, Racing for Profits, Keeps Covid Vaccine Out of Reach of Poor, The New York Times (Oct. 9, 2021),

<https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html>

¹² CEPI and Bio Farma partnership boosts rapid response vaccine manufacturing for the Global South, CEPI (Sept. 19, 2023),

https://cepi.net/news_cepi/cepi-and-bio-farma-partnership-boosts-rapid-response-vaccine-manufacturing-for-the-global-south/

¹³ Update on First BioNTainer for African-based mRNA Manufacturing Facility, BioNTech (Dec. 21, 2022),

<https://investors.biontech.de/news-releases/news-release-details/update-first-biontainer-african-based-mrna-manufacturing>

BioNTech's plans for manufacturing in Africa are not guaranteed¹⁴ and provide no assurance of technology transfer to facilitate access. In our view, this is not a meaningful effort toward achieving equity.

The agreement additionally includes a statement on making licensed vaccines available to LMICs at affordable prices. However, the statement does not indicate how this price will be arrived at or monitored, nor how delivery to LMICs will be executed. CEPI's Equitable Access Framework states that "increasingly, CEPI seeks to cap the price at COGs + X% for allocation to LMICs and requires that purchases by CEPI or GAVI, or their respective designees, cannot be higher than the lowest price at which an Awardee sells a project vaccine to any third party in any LMIC," and that, where possible, CEPI seeks to obtain the right to verify COGs. We would welcome clarification on whether CEPI's Access Framework pricing provisions have been fully incorporated in the BioNTech agreement, as well as other agreements with pharmaceutical industry partners.

We agree that CEPI has a key role to play in "promoting leverage of R&D and procurement agreements by public funders, countries, and regions to enable [equitable access] by contractual obligations," including through "conditions for rapid data/sample sharing, tech transfers, volume allocations, [and] pricing." We urge CEPI to use its leverage toward increasing inclusion of adequate equity provisions in partnership agreements and ask that CEPI broaden its transparency policy regarding such provisions. The opacity around equity terms in recent funding announcements signals to us a real risk of repeating COVID failures by leaving supply and pricing too much in the hands of pharmaceutical industry partners, despite critical de-risking investments by CEPI.

Sincerely,

Public Citizen
Health GAP
Médecins Sans Frontières Access Campaign
People's Vaccine Alliance

¹⁴ BioNTech Is Revising Plans for African Vaccine Factory Network, Bloomberg (Sept. 23, 2023), <https://www.bloomberg.com/news/articles/2023-09-23/biontech-is-revising-plans-for-african-vaccine-factory-network>