

## **Invitation to comment on CEPI's Policy Regarding Equitable Access**

CEPI was launched at Davos in January 2017 and governed by an interim board until March 2018. During that period, a policy regarding CEPI's approach to equitable access was drafted and approved for a one-year trial period, with the intent to evaluate and if necessary revise it based on lessons learned. Based on stakeholder feedback and experience in contract negotiation to date, CEPI determined that the policy was too proscriptive regarding how it would be implemented, and inhibited CEPI from fully achieving its mission. A process to revise the document was undertaken and has involved consultation with a wide range of CEPI's stakeholders. Since the consultation process could not, as a matter of practicality, involve all stakeholders who wish to contribute, CEPI is now seeking wider consultation and feedback prior to finalizing its equitable access policy.

Comments should be sent by email to [comments@cepi.net](mailto:comments@cepi.net) and should be received by August 3, 2018. To be most useful, please refer to the section of the document you are commenting on, articulate the reasons for highlighting a concern, and be as specific as possible in proposing any amendments or alterations to the text. If there are important issues that you believe are omitted, please highlight them. While CEPI has not made a commitment to publish all comments verbatim, please indicate if you are comfortable with public posting of your comments. CEPI will provide a summary of comments received at the end of the consultation period.

Thank you for your ongoing contributions to CEPI.

### **Background on CEPI**

CEPI's mission is to prevent epidemics by supporting the development of vaccines against diseases with epidemic potential in cases where market incentives fail, and to support the capability to respond to novel pathogens with rapid vaccine development, if needed. CEPI believes that the value of vaccines in preventing epidemics is a direct function of their stage of development and manufacturing, and their equitable and efficient allocation and deployment. Hence, CEPI will take an end-to-end approach to vaccine development, meaning:

- Beginning with the decision to fund the development of a given product, CEPI will consider the actions it can take at each stage of product development and manufacturing in order to get as close as possible to achieving the goal of equitable access.
- During product development CEPI will fund and coordinate development up to and including phase 2b, including costs associated with regulatory requirements;
- CEPI will also take a role alongside other organisations, including other funders, in support of maintaining investigational vaccine stockpiles and subject to necessary approvals, their release when an outbreak occurs;
- CEPI, together with an awardee and relevant stakeholders, will facilitate and coordinate resource mobilization for phase 3 trials; in some instances, CEPI may consider providing funding for phase 3 trials where there is a clearly identified gap and where resources can be mobilized, and
- If and when a vaccine funded by CEPI reaches licensure, CEPI will also take a role alongside other organisations, in supporting registration and procurement.

## **CEPI's Policy Regarding Equitable Access**

CEPI is committed to achieving equitable access to the vaccines it helps to develop. Equitable access to epidemic vaccines in the context of an outbreak means that *the right vaccines are available when and where they are needed to end an outbreak or prevent an epidemic, that they are accessible to all people as necessary to achieve that objective, and that price does not limit necessary access to vaccine or jeopardize the sustainability of vaccine manufacturing and distribution*. To get as close as possible to achieving this ideal, CEPI will work with its partners to (1) accelerate the development, sustainable manufacturing and authorization of quality, usable, safe and effective vaccines (*right vaccine*), (2) establish mechanisms to allocate, purchase, distribute and administer vaccine in a fair and just manner (*right place/population*), and (3) speed the delivery of these vaccines to those who need them (*right time*).

CEPI recognizes that each stage of the vaccine development, deployment, and administration process involves considerations central to the goal of achieving equitable access; it cannot achieve these goals by working in isolation. While CEPI can take certain direct actions throughout the development process, including through its contracts with development partners, it cannot anticipate or address all potential barriers to equitable access on its own. In those areas, the global community, acting in a concerted and coordinated fashion, must share the responsibility for advancing equitable access. CEPI believes that shared ownership in the success of these vaccines will maximize the return on the investment of public funds.

Towards that end, CEPI commits to:

- ***Respecting the interests of all parties***, aiming to balance the short-and long-term goals of CEPI, and those of other stakeholders, and working as a trusted partner
- ***Prioritizing transparency*** by sharing CEPI policies and other information about how we work, as well as encouraging CEPI partners and other stakeholders to commit to similar transparency
- ***Acting as a catalyst***, understanding that the actions it takes during the development process should result in downstream changes to the vaccine ecosystem that will challenge stakeholders to re-evaluate remaining barriers to access for epidemic vaccines. In addition to taking actions to catalyze these system shifts, CEPI will continually innovate, help develop creative solutions to outstanding challenges, and lend its voice as a thought leader to the discourse exploring ways to increase equitable and efficient access for epidemic vaccines.
- ***Anticipating challenges*** to equitable access and taking proactive steps to prevent them from becoming barriers. To the greatest extent possible, CEPI will seek to mitigate these challenges, through each stage of the vaccine development process, contracting processes, and actions that might be needed in the face of an outbreak. To this end, CEPI aims to be an agile and responsive organization that exhibits continuous learning; solicits, collects and synthesizes stakeholder feedback; monitors, assesses and reports progress toward equitable access; and, as warranted, revises actions or policies to integrate learning and improve its processes and performance.

## **Implementation of CEPI's Equitable Access Policy**

CEPI is committed to working with the global community to develop appropriate target product profiles, and innovating in the development, manufacture, stockpiling, deployment and

administration of vaccines in a manner that ensures sustainability of the epidemic vaccine enterprise. CEPI partnership agreements with vaccine developers are a critical mechanism through which vaccines will be developed and become available. While there is not a one size fits all approach to partnership agreements, these agreements do provide the opportunity and context to ensure alignment with and commitment to CEPI's equitable access goals. CEPI understands that the use of public funds to achieve its goals carries with it responsibilities for delivering vaccines for public health needs at a cost that ensures that CEPI-developed vaccines can be used as necessary to prevent or end an epidemic, and for supporting sustainable systems for manufacture and distribution. Achieving this goal will require foresight and flexibility, given the unique market realities for CEPI-supported vaccines and legitimate business constraints of private sector partners.

Recognizing that each organizational awardee brings different business needs, priorities and capabilities, CEPI will evaluate each potential partnership on a case-by-case basis and use tailored approaches to ensure that all awardees are aligned at the outset on a plan to achieve equitable access and through each stage of development. As such, the structure of a given agreement may vary between awardees, but will always remain consistent with CEPI's goals and commitments to equitable access.

As vaccine development can be unpredictable, CEPI recognizes the need for flexibility in dealing with its various partners while simultaneously ensuring that it achieves its goals. To do this, CEPI has developed multiple different approaches that it might take to address important contracting issues bearing on equitable access, such as (1) ensuring follow through on agreed terms of award, so that CEPI's investments in product development ultimately produce viable and sustainable vaccines, (2) sharing risks and benefits, (3) management of intellectual property, and (4) data sharing. It is important to underscore that these issues and approaches do not comprise a comprehensive list. They do not foreclose CEPI's use of alternative approaches that achieve CEPI's access goals nor imply that any of the examples provided are the exclusive or even CEPI's preferred approach. Several specific examples of issues and responses are:

### **Ensuring follow-through of vaccine development**

CEPI and its awardees are committed to completing the work packages agreed to in funding agreements. However, there may be circumstances under which an awardee cannot or will not complete work that has been agreed to (including meeting scientific milestones and other commitments), or will not be in a position to create/maintain an investigational stockpile, deliver or test a vaccine fully, or make vaccines as needed to end an outbreak or prevent an epidemic. Anticipating the possibility of such contingencies, funding agreements will outline ways to ensure that work agreed to with an awardee can continue in the event such barriers to producing a usable product that can be made available during an outbreak emerge. Such contingency plans should include agreed-upon ways to ensure the product is developed, milestones are met, and that a sustainable manufacturing plan is in place. In the case where funds are used to create or improve platforms for vaccine development or manufacture, CEPI will need to agree with its awardees as to how such platforms may be used now and in future – even against pathogens that have yet to be identified. For all supported projects, partnership agreements will spell out how intellectual property (IP), including know-how, will be used to ensure product development continues.

The range of approaches to ensuring awardee follow-through to enable CEPI to fulfill its mission are broad and may include but are by no means limited to one or more of the following:

- Including step-in rights for CEPI to intervene under defined circumstances, including placing all relevant IP, materials, and other undisclosed knowledge and know-how in escrow for the event CEPI exercises these rights. CEPI will work with potential awardees during the contracting process to identify triggers for action commensurate with the stage of development, and create process steps to ensure such step-in rights are exercised only when needed.
- Requiring the awardee and CEPI to agree upon a plan by which relevant manufacturing partners for CEPI-funded vaccines will be contracted, and how licensing of IP, transfer of biological materials, and necessary technology sharing will be managed.
- Providing contractually that CEPI and the awardee may choose another mutually agreed upon development or manufacturing partner (as a trusted partner) to take over development commitments as needed, by agreeing to license/transfer all required IP to the chosen company to the extent it is needed to further develop the vaccine candidate or achieve equitable access obligations. In some cases, the awardee and CEPI may consider involving a trusted, mutually agreed upon, low-cost manufacturing partner during the development process so that it can take over if and when the manufacturing need arises.

### **Management of Intellectual Property**

The specific terms of IP management will be negotiated on a case-by-case basis with each awardee; normally, the default position of CEPI is not to seek ownership of background or foreground IP. To manage IP in a manner that facilitates equitable access to vaccines, while incentivising innovation, CEPI will:

- Require clear agreement with awardees regarding how relevant IP (both background and foreground IP) will be managed to fulfil the equitable access obligations, including when one company is bought by another;
- Require awardees to identify relevant background IP (whether these are owned by the awardee or third-parties), that may be used, incorporated or further developed as part of a CEPI-funded project, and to clarify how such background IP will be managed by the awardee to exploit any foreground IP resulting from a CEPI-funded project; and
- Actively monitor foreground IP of funded awardees, and require awardees to disclose foreground IP as part of milestone reports.

### **Shared Risk/Benefit**

CEPI anticipates that its awardees will derive benefits in working with CEPI to develop vaccines or platforms, including the opportunity to co-invent with CEPI and reputational benefits that go along with developing products for critical unmet global health needs. However, CEPI also recognizes the risks undertaken by its awardees in developing a CEPI-supported vaccine or platform, including the uncertainty of timing and level of product demand, the reputational risk of failure/discontinuing the development program, and the opportunity costs inherent in choosing to partner with CEPI. CEPI realizes that its development awardees in the private sector need to derive an acceptable return on investment and that academic partners often seek to find commercial partners for IP they develop. CEPI will therefore seek agreements that balance

risks and benefits for both CEPI, the populations CEPI serves, and its awardees. Benefits to CEPI may include a share of any profits deriving from emerging IP. CEPI's share of any such profits will be reinvested in the epidemic vaccine enterprise in ways that produce additional global public goods. Approaches to dealing with commercial benefits can include:

- Allowing the commercial benefits to reimburse the awardee its cost of capital + additional funds to account for fully loaded costs;
- Requiring the awardee to take action to ensure that commercial benefits are used to enhance public health; and/or
- Setting out that CEPI will recoup a share of the commercial benefits or elect an alternative benefit sharing arrangement of equivalence commensurate with CEPI's return on investment.

### **Data sharing and transparency**

CEPI is committed to prioritizing transparency in its own actions as well as encouraging other stakeholders, including CEPI partners, to share information and materials in a wide-spread and timely manner while respecting and protecting patient privacy and safety and partner IP. It is CEPI's conviction that a policy of transparency that provides for the availability of data relating to the testing of CEPI-funded vaccines while respecting and protecting patient privacy and safety is of importance to stimulate wider innovation.

CEPI funding agreements will include plans for the dissemination of the data and results from the development of CEPI-sponsored vaccines and platforms. Approaches to outlining data access and transparency can range from, for example:

- Allowing awardees to develop a publication plan agreed upon by CEPI.
- Requiring awardees to publish results on an open access basis (defined as immediate and unrestricted access free of charge, with maximum opportunities for re-use, and including the underlying data) in a timely manner, in line with the WHO Statement on Public Disclosure of Clinical Trial Results (14 April 2015), and make materials widely available in order to receive final disbursements of CEPI monies. If a compelling rationale to postpone the release of data and/or trial results exists, exemptions could be made with CEPI's consent.
- Requiring awardees to post research findings on underlying vaccine science or line-level data on clinical trial outcomes on an appropriate website (e.g. global platforms for sharing clinical trial data and results) in as close to real-time as possible, and within a specified time frame.
- Requiring awardees conducting clinical trials to register trials in a publicly accessible database before patient recruitment, and provide access to anonymized data sets for further research.
- Requiring awardees involved in the development or improvement of vaccine platform technologies to work collaboratively with CEPI and regulatory authorities to define data needs and map out pathways to accelerate the licensure of vaccines made on such platforms.
- Requiring both CEPI and awardees to respect all matters of confidentiality and attribution of research efforts to individuals and communities from whom data has been collected.

A summary of the key provisions in agreements which CEPI enters into with awardees will be made publicly available unless there is an exceptional and compelling reason not to do so. It is anticipated that the summary will focus on equitable access obligations, shared risks/shared benefits arrangements and management of IP. (See also CEPI's Transparency and Confidentiality Policy.)

In conclusion, CEPI seeks to foster a collaborative environment to achieve equitable and sustainable access to the vaccines it helps to develop, enable the efficient use of public funds to secure quality, safe, effective and sustainable vaccines, and deliver the greatest public health benefit while ensuring the sustainability of CEPI's mission.

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