
THE WRONG PRESCRIPTION FOR VACCINE ACCESS

Affordable access to lifesaving vaccines not guaranteed as CEPI continues to avoid concrete commitments

BACKGROUND

The Coalition for Epidemic Preparedness Innovations (CEPI) was launched at Davos in 2017 in the wake of the devastating 2014-2016 Ebola outbreak in West Africa. The mandate of the publicly funded initiative is to finance and coordinate the development of new vaccines to prevent and contain infectious disease epidemics. As a medical humanitarian organisation and first responder in emergencies and outbreaks, including the 2014-2016 Ebola epidemic, Médecins Sans Frontières (MSF) agreed to join CEPI's interim Board of Directors to help shape this important new public interest research and development (R&D) initiative.

In this capacity, MSF engaged extensively with CEPI as it developed its original Equitable Access Policy¹, which contained clear commitments to ensure affordable prices, transparency and pro-access management of intellectual property (IP) generated with CEPI funding – all a reflection of CEPI's promise of public interest R&D. However, in December 2018 the permanent CEPI Board – which no longer included MSF – adopted a revised policy² that undermines these earlier commitments for CEPI-funded vaccines. MSF responded to this revised policy in a March 2019 open letter³ to CEPI Board members, asking members to reconsider their revisions to the policy and reintroduce an unapologetic and enforceable commitment to affordable access and transparency.

Following MSF's open letter, CEPI published the following documents on its website:

- A summary of development agreements⁴
- A template funding agreement, used as a basis for negotiations⁵

These documents further reflect CEPI's withdrawal from earlier concrete commitments and contain only vague references to ensuring affordable access to CEPI-funded vaccines. CEPI's original Equitable Access Policy specified detailed requirements for the management of IP during epidemic outbreaks and requirements to ensure transparent and affordable pricing. In its revised policy, these have been reduced to just five 'principles' of collaboration – and promises that CEPI would, separately to funding the development of vaccines, fund the maintenance of investigational vaccine stockpiles in cases of outbreaks.

UNPRECEDENTED PUBLIC FUNDING SHOULD MEAN GREATER CONTROL OVER RESEARCH RESULTS

CEPI has raised more than US\$740 million in public and philanthropic contributions and offers grantees non-dilutive funding (even covering a proportion of indirect costs) for clinical development, manufacturing and stockpiling. However, despite this unprecedented level of public funding and financial support for grantees, CEPI relinquishes all control over results generated. In its most recent "CfP3i" call for Rift Valley fever and chikungunya vaccine proposals, CEPI even advertises that grantees will have the "opportunity to own and use all resulting IP, data and materials"⁶.

It is well documented that the commercial R&D model has led to unaffordable medicines and vaccines, which contributes to the need for organisations like CEPI in the first place. Regrettably, by putting its commercial partners so firmly in the driver's seat, CEPI is emulating the business-as-usual model for conducting biomedical R&D – which runs counter to its public interest mandate and responsibility for ensuring CEPI's public and philanthropic funding is used responsibly.

Instead of continuing on this path, CEPI should proactively pioneer new models of research governance that put people's health first, ensure affordable access to research results, and reflect the public and philanthropic contributions that underlie CEPI-funded R&D.

TREATMENT OF IP: PUBLIC HEALTH LICENSE, STEP-IN RIGHTS AND TRIGGERS

Presumably to compensate for relinquishing all ownership of IP, CEPI's template funding agreement includes step-in rights* in the form of a "public health license", but the triggers to evoke these rights are limited and therefore the rights cannot be considered robust safeguards for affordability and access. In its summary of development agreements, CEPI asserts that it has reserved the right to step in when a grantee breaches its access policy; however, it fails to stipulate any clear access and affordability triggers for

* Rights which allow CEPI to take control over all IP, materials and data, and continue the development of the vaccines with another partner if contractual agreements have not been met.

these step-in rights. An example contract text provided by CEPI refers only to vaccines being made available at “reasonable costs”⁴, which are not further defined. This mimics language contained in the march-in rights of the 1980 United States Bayh-Dole Act, which the US government has repeatedly rejected as means to remedy unaffordable prices⁷.

Although step-in rights cannot be considered an effective remedy for handing over all IP, in order for CEPI’s step-in rights to safeguard access, they must have clearly defined triggers including pricing, availability and affordability of CEPI-funded vaccines.

DETERMINING AN EQUITABLE PRICE FOR CEPI-FUNDED VACCINES

Although CEPI’s summary of development agreements states that access conditions include agreed methodologies for determining prices, no example contract text has been made publicly available to support this. This is a worrying departure from the original Equitable Access Policy’s much clearer commitment, which stated that CEPI would “set out the processes by which the boundaries for the price of a licensed vaccine will be determined”¹ with grantees.

Vaccines funded by CEPI should be priced according to a reasonable, pre-agreed margin based on auditable costs of goods with a clear commitment to independently audit these figures regularly. Currently, there is no indication that CEPI plans even to conduct independent assessments of costs of goods, which strongly suggests these assessments will be left to grantees to conduct without independent oversight.

IMPORTANCE OF TRANSPARENCY AND ACCOUNTABILITY

In its revised access policy, CEPI repeatedly refers to “coordinating” and “collaborating with others in the global health community” to achieve access. These non-specific references are weak substitutes for the clear commitments required of CEPI and its grantees in CEPI’s original access policy, and they represent an inappropriate diffusion of CEPI’s fundamental responsibilities as a steward of public and philanthropic resources. The summary of development agreements and template funding agreement that CEPI has made publicly available provide no additional meaningful clarity on how CEPI ensures transparency and accountability.

Importantly, CEPI has also failed to live up to its stated commitment to “prioritising transparency” by delegating the development of detailed access provisions to its secretariat and providing almost no detail whatsoever on the terms of existing agreements in its public summary of development agreements. The appendix to the summary of development agreements⁴, which lists all of CEPI’s partnerships, merely lists the titles of clauses in each funding agreement. By disclosing so little information on its concrete access provisions, CEPI makes public accountability of all stakeholders impossible and risks patients being denied access to lifesaving vaccines.

EXTENDING CEPI’S MANDATE IS A NEW OPPORTUNITY TO ENSURE STRONG AND ENFORCEABLE ACCESS COMMITMENTS

While CEPI was originally established with a five-year mandate to bring vaccine candidates to phase II clinical development, including stockpiling, it is expected that the Board will be asked to consider extending this mandate beyond its initial term and to include supporting the further development of vaccine candidates through marketing approval and availability to at-risk populations. If approved, this change in mandate will have to be reflected in CEPI’s approach to affordable access. Future funding agreements must take this mandate expansion into consideration and include provisions on affordable access that go beyond stockpiling and use in outbreaks. New access strategies must safeguard affordability, establish ‘in-country’ stockpiles and ensure sustainable manufacturing practices. CEPI should make these provisions and strategies publicly available more transparently than it has to date, and these provisions should be evaluated by an independent expert advisory committee on affordable access.

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