CEPI Policy Documentation

1. Equitable access policy
2. Shared risks/shared benefits policy
3. Management of intellectual property

Introduction

This document supports awardees and potential awardees of CEPI funding in understanding CEPI's mission and role, as well the expectations on awardees and CEPI in working together to develop new vaccines to prevent future epidemics. This document is to guide potential awardees in responding to Calls for Proposals and the establishment of contracts between CEPI and awardees.

CEPI's role

CEPI's mission is to stimulate, finance and co-ordinate vaccine development against emerging infectious diseases with epidemic potential by partnering with relevant stakeholders from the public and private sectors (academia, governments, philanthropies, NGOs and industry). Developing vaccines before the epidemics arise will allow the global health community to prevent outbreaks from becoming international public health emergencies, contain loss of life, limit social and economic disruption, and protect against future epidemics.

CEPI's contractual agreements with awardees will be guided by our three core operating principles:

- Equitable access
- Cost coverage
- Shared benefits

This document outlines CEPI's three policies of **equitable access policy**, **shared risks/shared benefits policy** and **management of intellectual property (IP)**.

Equitable access is CEPI's most important principle; the policies on shared risks/ shared benefits and management of IP support CEPI's aim of achieving equitable access to CEPI-supported vaccines.

CEPI expects to make awards to non-profit organisations, government research institutions and academic institutions, as well as for-profit organisations including small and medium sized biotechnology companies, developing country vaccine manufacturers and multinational organisations.

This policy should be interpreted in the context of markets for vaccines for diseases with epidemic potential being very unusual in that successful vaccines may never be used; if they are used, the demand for such vaccines may be erratic, unpredictable and unlikely to be at a sufficient level to allow manufacturers to benefit from large economies of scale. CEPI recognizes that awardees willing to develop vaccines for diseases with epidemic potential are doing so in response to global health concerns. Since CEPI expects to partner with many different types of awardees (as outlined above), the Board may on a case-by-case basis allow justified exceptions from this policy to fit specific types of awardees – recognizing that some awardees will need to partner with others to achieve CEPI's aims. In some cases CEPI may invest in organisations running programmes that are dedicated to CEPI's mission (dedicated programmes, as defined below).

To fulfil CEPI's vision, CEPI will take an end-to-end approach to vaccine development,

meaning:

- during product development CEPI will fund and co-ordinate development up to and including phase 2, including any costs associated with regulatory requirements.
- CEPI will also take a role alongside other organisations, including other funders, in support of maintenance of investigational vaccine stockpiles and subject to necessary approvals, their release if and when an outbreak occurs;
- in an outbreak situation, CEPI, together with the awardee and relevant stakeholders, will facilitate and coordinate resource mobilization for phase 3 trials; in some instances CEPI may consider 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 procurement processes.

A diagram illustrating CEPI's approach is available here.

Awardee's role

To ensure public benefit is achieved from CEPI funding, CEPI and the awardee will need to agree up-front obligations on the awardee. These obligations will establish a process whereby (i) investigational stockpiles and vaccines will be available in sufficient quantities in affected countries and (ii) vaccines sales prices will be as low as possible to maximize access taking into account the unusual market for vaccines for diseases with epidemic potential (as described above) and the particular disease in question.

CEPI recognizes that certain types of awardees will not be in a position to create/maintain an investigational stockpile, or deliver or test a vaccine fully. In these cases, CEPI and the awardee will work together to find relevant partners for the CEPI-funded vaccine candidate, and the awardee's obligations will be novated to the partner identified.

CEPI's preferred approach is not to take ownership of IP. As stipulated in the sections on equitable access and management of IP, CEPI needs to be able to access IP, know-how, trade secrets, and other undisclosed knowledge and materials to facilitate technology transfer where contractors are unable or unwilling to further vaccine development and equitable access.

CEPI is committed to public disclosure of results and open access of publications and requires that awardees should share all data and information arising from CEPI funding with the broader scientific community so as to foster follow-on research to increase innovation.

1 Equitable access policy

Developing new vaccines against emerging infectious diseases with epidemic potential and ensuring equitable access to those vaccines is CEPI's most important objective. Through its role as a funder of product development, CEPI will work with key stakeholders, including the awardee, public sector and procurement agencies, governments, non-governmental organisations and multilateral institutions, to achieve (i) equitable access to investigational vaccine stockpiles during an outbreak necessitating a phase 3 trial and emergency deployment, and (ii) should the vaccine attain licensure, equitable access to the licensed vaccine.

a. Equitable access during an epidemic or a public health emergency of international concern

CEPI is aware that it is critically important that manufacturing capacity is available (i) to maintain sufficient volume of investigational vaccine stockpiles in advance of an epidemic (and to replenish when needed), and (ii) to produce investigational doses of vaccines during an epidemic.

- With this in mind, where awardees have agreed to utilize their manufacturing capabilities and capacities for CEPI purposes, CEPI will negotiate contracts that specify manufacturing commitments and volumes, and will facilitate conversations between the awardee, regulatory authorities, procurement agencies and other relevant stakeholders for long-term maintenance of investigational stockpiles to facilitate a speedy response during an epidemic.
- In cases where the awardee does not have the necessary manufacturing capabilities/capacities already in place or does not wish to do this in a timely manner, the awardee will need to present a feasible plan and agree with CEPI during contracting about the process by which relevant manufacturing partners for the CEPI-funded vaccines will be contracted, and how licensing of background IP, foreground IP, and other necessary rights to partners will be managed.
- CEPI will not have reach through rights to the manufacturing capacity of the awardee (or in the case of the dedicated programs, to the manufacturing capacity of the parent company) other than through a negotiation that may identify such party or an alternative third party as the larger scale supplier.
- In the case of an epidemic or a public health emergency of international concern declared by the WHO that necessitates emergency use, CEPI will:
    - follow the recommendations made by the WHO with respect to access to and release of the investigational vaccine stockpiles for emergency use; and
    - together with the WHO, affected countries and other partners, decide on the use of investigational vaccine stockpiles for conducting and completing phase 3 clinical trials.

b. Equitable access to the final product (post- licensure)

While the main role of CEPI is to finance the R&D and maintenance of an investigational vaccine stockpile in preparedness for phase 3 trials and emergency use during an epidemic, the individual contract between CEPI and the awardee will set out (i) the processes by which the boundaries for the price of a licensed vaccine will be determined, and (ii) the awardee's obligations in terms of registration and launch of the licensed vaccine in countries, manufacturing and availability, volume of doses and regulatory steps to best facilitate timely and sustainable access for populations in need. In the event

that ownership of the foreground IP changes hands, the obligations on the awardee under the individual contract will be novated – such that the obligations shall remain with the technology.

- As a funder of product development, CEPI will seek to support procurement agencies and the public sector in establishing price with the awardee at the appropriate time, independent of the point in time CEPI funded the product development:
    - CEPI will provide direction for equitable access through its request for proposal processes and by using target product profiles under the direction of WHO, to define ideal product characteristics, including an affordable target price range and access terms, as defined for the populations in countries with the greatest likelihood of being affected by an epidemic.
    - CEPI and the awardee will agree up-front a series of engagement and re-engagement points based on agreed milestones during product development to discuss the price range as more information becomes available about the vaccine being developed.
    - CEPI and the awardee will agree that obligations around pricing will be established through a transparent and agreed methodology that will relate to information about public and philanthropic investments/risks in the vaccine (made through CEPI or through other government- or foundation-financed incentives for developing vaccines lacking market potential), cost of goods, expected volume/scale of production, price of existing comparable products, cost of maintaining manufacturing capacity, procurement agreements (entered into by CEPI partners), and other mechanisms for recovering cost of manufacturing the vaccine, and other relevant information.
    - CEPI recognizes the importance of making pricing decisions quickly at the time of an outbreak, with the goal of maximizing access to needed vaccines.
    - CEPI will ensure transparency of pricing levels.
    - In cases where CEPI provides funding to an organisation running programmes dedicated to CEPI, CEPI will use its position to determine price levels, taking into account advice from awardee and other relevant partners.
    - In cases other than for dedicated programs, CEPI will ensure that the awardee will undertake to make the CEPI-supported licensed vaccine available at prices as low as possible and as close to optimal marginal cost of production as possible for any affected populations for procurement through public sector, procurement agencies and relevant NGOs, recognizing there is a proportionately higher ability to pay in upper middle income and high income countries and acknowledging the need to secure equitable access for humanitarian need, vulnerable populations, countries in crises, fragile states and sub-populations not sufficiently cared for. CEPI will work with public sector, procurement agencies and relevant NGOs to define criteria to identify such countries and populations and specify equitable pricing regimes.
- Prices, while set as low as possible and as close to optimal marginal cost as possible, must be sustainable for the awardee to maintain manufacturing, supply, and availability (thereby maximizing equitable access to the vaccines for affected populations or populations at risk of being affected during an ongoing epidemic and

over the longer term as part of epidemic preparedness).

CEPI will seek to enter into discussions with the awardee, governments, procurement agencies, non-governmental organisations and the WHO on the funding, maintenance and size of a global stockpile, in order to ensure timely access to vaccines during future epidemics. However, CEPI does not have the responsibility to distribute vaccines in the case of emergencies.

c. Data sharing

CEPI commits to data and trial results sharing, and will inform and adhere to emerging global standards in this area. It is CEPI's belief that the transparency and 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. In this way, CEPI will ensure that all data and information from CEPI-funded projects should be rapidly shared with affected countries (researchers, government officials, and the public) in ways they can understand and, as needed, act on the information.

CEPI will require:

- awardees conducting clinical trials to register trials in a publicly accessible database before patient recruitment;
- awardees conducting clinical trials to implement sharing of data and results, including negative results, via an easily discoverable, public route (website or system) that includes a metadata description, where patient privacy is upheld, and the system follows a request-for- information-approach where requests are fulfilled subject to an independent review and approval step;
- awardees to share clinical trial results as close to real-time as possible and within 12 months of study completion in line with the WHO Statement on Public Disclosure of Clinical Trial Results (14 April 2015), and that awardees commit to a specified expedited timeline before trials commence. If a compelling rationale to postpone the release of data and/or trial results exists, exemptions can be made with CEPI's consent; and
- publications produced with CEPI funding to be published by awardees 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).

Both CEPI and awardees must respect all matters of confidentiality and attribution of research efforts to individuals and communities from whom data has been collected.

In support of ongoing global efforts CEPI will revise, adopt and implement data sharing best practices consistent with global norms and with the WHO, and make use of global platforms for sharing clinical trial data and results in order to facilitate collaboration between stakeholders, and expedite regulatory approval and equitable access during a public health emergency.

2 Shared risks/shared benefits policy

The shared risk/ shared benefit policy guides the nature of risk- and benefit-sharing

between CEPI and the awardee as both seek to collaboratively engage in vaccine development for emerging infectious diseases that lack market potential. It provides direction for contracts between CEPI and awardees, with the objective of reaching an optimal balance between the risks and investments undertaken by CEPI and the awardee, and the potential benefits which could accrue to CEPI and the awardee. CEPI acknowledges there may be co-funders of an awardee for a given project whose risks/investments may also need to be taken into account.

a. Funding arrangements

The funding arrangements established between CEPI and awardees will take the form of shared risks/shared benefits agreements, and CEPI's contributions to such agreements may encompass:

i. Core funding
ii. Advance funding
iii. Milestone-based funding
iv. Combinations of the above
v. Other possible future arrangements

Core funding can be provided to dedicated programmes in which case payments would be released in a predictable manner in order to sustain dedicated programme operations.

Milestone payments will be based on project milestones agreed up-front between CEPI and the awardee, and payments will be released where the awardee shows proof of achievement of those milestones to CEPI's reasonable satisfaction.

There will be up to 100% coverage of direct costs. CEPI may choose to fund direct costs in full, or may enter into funding arrangements where it co-funds projects with others (including in some cases awardees who elect to cover some of the direct and indirect costs themselves in-kind). The proportion of total direct and indirect costs covered by these arrangements by CEPI, other co-funders and awardees will be documented and agreed in contracts negotiated with awardees.

b. Tiers of CEPI funding arrangements

(i) Basic package of funding

CEPI will cover up to 100% of direct costs incurred where direct costs relate to research and development projects, and maintenance and operation of manufacturing facilities. Direct costs will include items described in CEPI's cost eligibility policy. Also see CEPI's cost guidance document for details on indirect cost coverage.

(ii) Funding under emergency situation

If CEPI is operating in an emergency situation, direct contracting will be undertaken and funding provided up-front based on rapid assessment of the developer or manufacturer's capabilities in order to facilitate a rapid response and meet the equitable access goals.

c. Commercial benefits

While equitable access is CEPI's most important principle, there may be circumstances where commercial benefits may accrue to the awardee as a result of CEPI funding, including both from licensed vaccines or from any other foreground IP generated from a CEPI funded project, CEPI will recoup a share of such commercial benefits or elect an alternate benefit sharing arrangement of equivalence commensurate with CEPI's investment. These are the principles by which specific arrangements will be entered into with awardees on a case-by-case basis during contracting. Any commercial benefits recouped by CEPI will immediately be returned to the funding pool for re-investment in other projects since CEPI is a non-profit organisation.

If commercial benefits arise, the awardee will be allowed to recoup the agreed value that it has contributed to the development of the vaccine (taking into account quantifiable awardee contributions in-kind to the project). Once the awardee has recouped its agreed contribution, CEPI shall be entitled to the second portion of these commercial benefits up to the agreed value contributed to by CEPI (usually the award amount). If there are sums left over after this recoupment, the remaining portion will be shared between parties based on a proportional split of total investments made during vaccine development from an agreed start and end-point established in contracts. These conditions will apply beyond the contract period between CEPI and the awardee. These arrangements will be documented as part of the shared risks/shared benefits agreements established between CEPI and awardee.

In cases where CEPI provides funding of a dedicated programme, the potential commercial benefits from licensed vaccines or from any other foreground IP generated will be re-directed to the sustainment of the dedicated programme.

d. Termination of the contract

CEPI may terminate the contract if the awardee is found to be in breach of terms of the agreement, including those stipulated in relation to equitable access. Such a termination will not remove the awardee from fulfilling equitable access obligations.

e. Transparency of agreements

A summary of the provisions in agreements which CEPI enters into with awardees will be made publicly available unless there is an exceptional reason not to, which would require Board approval. 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.

3 Management of intellectual property (IP)

While the specific terms of IP management will be negotiated on a case-by-case basis with each awardee, the default position of CEPI is not to seek ownership of background or foreground IP. It is noted that in some cases the awardee funded by CEPI may not be the entity taking the foreground IP forward, e.g. because this is not within the remit/scope of the awardee (by its nature) or as a result of a change of control of the awardee. In these cases, the specific obligations in relation to IP management agreed between CEPI and the awardee will be novated to any new entity that comes to control the foreground IP.

In cases where CEPI provides funding of a dedicated programme, as described under the shared benefits/shared risks policy, CEPI will seek a non-exclusive, sub-licensable, worldwide license on necessary background IP and foreground IP related to priority pathogens. While CEPI would normally only anticipate using the IP to address issues in affected countries, it is necessary for CEPI to have a worldwide license to allow CEPI flexibility in identifying appropriate manufacturing partners. CEPI will notify awardees which have sub-licensed IP to CEPI of any subsequent sub-sub-licenses established.

To manage IP in a manner that facilitates equitable access to vaccines, while incentivising innovation, CEPI will:

- Require awardees to articulate during contracting how their particular IP management and protection strategies will best facilitate achievement of the equitable access obligations and progress vaccine development to the creation of investigational stockpiles and a future licensed vaccine;
- 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
- Through use of an information management system, actively monitor foreground IP of funded awardees, and require awardees to disclose foreground IP as part of milestone reports.

To contribute to CEPI's overall mission, foster broader research efforts and innovation of vaccines for emerging infectious diseases that lack market potential, CEPI may accept offers of arrangements from awardees whereby necessary background IP and foreground IP related to priority pathogens, for which the awardee is receiving funding from CEPI to develop a vaccine candidate, is made accessible to third parties through a non-exclusive, royalty- free, sub-licensable, worldwide license.

a. Follow through and step-in rights

In some cases CEPI may have invested in a promising vaccine candidate where the awardee is unable or unwilling to further vaccine development and equitable access (as more particularly defined between the parties in the contract) - for example because the awardee discontinues development of a promising vaccine candidate for reasons other than scientific failure, does not launch a vaccine within a specified timeframe, or does not meet commitments to manufacturing, affordability and availability (a trigger). CEPI and the awardee will agree a process at the time of contracting to discuss potential triggers.

To ensure further vaccine development/equitable access, CEPI will:

- agree with the awardee at the time of contracting, a non-exclusive sub—licensable, worldwide license of foreground IP, as well as relevant background IP to the extent it is needed to further develop the vaccine candidate, to enable third-parties to advance development of the vaccine candidate or achieve equitable access obligations; while the license will be signed up-front, it will only become active in the event of a defined trigger to ensure such access in appropriate contracts.
- CEPI will negotiate sub-licensing agreements to ensure that the scope of the license on background IP is limited to advancing development or equitable access to the vaccine candidate funded by CEPI, and the right holder will be compensated for use of background IP (unless the step-in occurs as a result of a serious breach as defined in the specific terms of individual contracts); and
- Be entitled to activate arrangements agreed up-front in the contract, for accessing the awardee's know-how, trade secrets, and other undisclosed knowledge and materials related to the vaccine candidate in cases where facilitating technology transfer to one or multiple third-parties is deemed necessary to advance development of the vaccine candidate or achieve equitable access obligations.

CEPI recognizes that transfer of IP and technology may impact on the business interests of the awardee and will consider with due regard to awardee's concerns and input in relation to whom IP and/or technology should be transferred.

Definitions

Affected country/population: countries with populations or populations identified by the WHO and national governments to be affected by an epidemic, or at risk of being affected.
Availability: manufacturing, stockpiling, and supply of the vaccine in levels sufficient to meet public health needs during an emergency and ongoing epidemic, and over the longer term as part of epidemic preparedness.
Awardees: recipients of CEPI funding/investments.
Background IP: IP declared and previously developed by an awardee prior to entering into funding agreement with CEPI.
Commercial benefits: profits generated from or arising as a result of foreground IP that CEPI's investments have contributed to developing, including profits from higher pricing in upper middle income and high income countries where there is a proportionately higher ability to pay. This will not include profits made on sales to affected countries which have a lower ability to pay in accordance with the agreed equitable access obligations.
Dedicated programmes: Programmes can be fully or partially dedicated to CEPI, and CEPI's cost coverage of these programmes will vary according to the share of capacity dedicated to CEPI, with cost coverage available up to 100% dependent upon joint funding arrangements. CEPI reserves the right to negotiate joint management and shared ownership options of dedicated programmes. Dedicated programmes can include research, development and manufacturing capacities and capabilities committed to CEPI, in the form of facilities / infrastructure or technology platforms / know-how, whereby any revenues generated directly due to CEPI investments will be re-invested into the sustainment of the dedicated programmes.
Equitable access: populations will have timely and facilitated access to vaccines developed through CEPI funding where need will be the primary determinant.
Equitable access obligations: a suite of commitments made by the awardee to meet the objective of a vaccine with a sales price as low as possible and as close to the optimal marginal cost of production as possible and an available vaccine (or investigational vaccine stockpile) consistent with the principle of equitable access that extends beyond the direct period of funding from CEPI.
Foreground IP: any IP generated during the CEPI-funded research and development of the vaccine candidate.
In-kind contributions – Definition in the CEPI policy on cost eligibility.
Investigational vaccine stockpile: An investigational stockpile of a vaccine product which is manufactured and stockpiled according to good manufacturing practices, where the vaccine has been approved for use in clinical trials on humans, but are still in the testing and evaluation phase and are not yet licensed for use in the general public.
Intellectual Property/IP: Intangibles associated with the vaccine candidate that are protected by patents, copyrights, trademark, trade secrets, data exclusivity and other rights.
Populations in need/or at risk: covers any country that has its population or some of its population affected by or at risk of being affected by an ongoing epidemic.
Public health emergencies of international concern (PHEIC): as defined under the International Health Regulations, a PHEIC is an extraordinary event declared by WHO to constitute a public health risk to other countries through the international spread of disease, and which potentially require a coordinated international response.

Public sector or procurement agency: government agencies/institutions or specific agencies such as Gavi, UNICEF, PAHO.
Trigger: a trigger is a situation where the awardee is not willing or able to take a project forward in accordance with agreed development and exploitation plans – such that foreground IP will not be developed, or exploited in a timely manner in accordance with equitable access obligations and the terms of the funding agreement.

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2.0	Prepared by: Board Working Group and Secretariat	Jan-Feb 2017
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Policy Review	Review after one year for initial assessment of alignment between policy and its implementation and interpretation.	