



Australian Government
Department of Foreign Affairs and Trade

Investment Design Title: Accelerating Vaccine Development for Emerging Infectious Diseases	
Start date: December 2019	End date: December 2022
Total proposed DFAT funding: AUD 4.5 million	Total proposed funding: USD 750 million
Current program fund annual allocation: AUD 4.5 million	AidWorks investment number: INM412
Overall Risk Profile: Low risk	
Concept approved by: Robin Davies	Concept endorsed by AGB: N/A
Quality Assurance completed: Dr Stephanie Williams, Principal Sector Specialist (Health)	
Approval by Delegate in Canberra: Robin Davies	

A. Executive Summary

This investment represents Australia's contribution to the core costs and operations of the Coalition for Epidemic Preparedness Innovations (CEPI), an innovative global partnership between public, private, philanthropic, and civil society organisations. This investment in vaccine development will complement and expand Australia's portfolio of support in Product Development Partnerships.

CEPI aims to stimulate and accelerate the development of vaccines against emerging infectious diseases and enable access to these vaccines for people during outbreaks. CEPI aims – through the Strategic Objectives in its Programme Document – to:

- Advance access to safe and effective vaccines against emerging infectious diseases, and
- Accelerate the research, development and use of vaccines during outbreaks, and
- Create durable and equitable solutions for outbreak response capacity.

This investment builds on a contribution to CEPI of \$2 million made by Australia (from the Medical Research Future Fund) in 2017. This investment extends Australian support for vaccine development and equitable access, an important thematic component for health security in the region and beyond. Vaccines offer one of the most cost-effective approaches to controlling infectious diseases and new vaccines are among the most important tools to prevent deadly infectious diseases from becoming global health emergencies.

DFAT's development policy framework, *Australian aid: promoting prosperity, reducing poverty, enhancing stability*, and the 2017 *Foreign Policy White Paper*, Australia's aid policy recognise that identifying and mitigating health-related risks are central to ensuring regional stability and economic prosperity. In particular, DFAT's *Health for Development Strategy (2015-2020)* identifies strengthening regional preparedness and capacity to respond to emerging health threats as a priority strategic outcome. Combatting health threats with the potential to cross national borders, and the development of new approaches and solutions that strengthen health security in the region, are among key investments required to achieve this outcome.

This investment also aligns with the 2017 Office of Development Effectiveness evaluation of Australia's efforts to combat pandemics and emerging infectious diseases (EIDs) in Asia and the Pacific between 2006 and 2015. The Management Response to this evaluation noted that DFAT will continue to invest in research

and development targeting infectious diseases for the Indo-Pacific region, a confirmed epicentre for EIDs with pandemic potential.

The Health Security Initiative for the Indo-Pacific region made a substantial investment in the development of new drugs and diagnostics through the \$75 million Product Development Partnerships (PDP) Fund in 2017. A multi-year investment in CEPI would complement existing investments in global health product development, increasing the breadth of Australia's health security investments to include vaccines, a very effective preventative safeguard in the control of infectious disease.

CEPI's model for the rapid and efficient development of vaccines against EIDs has garnered strong support. Although CEPI is a relatively young organisation – having formally launched in 2017 at the World Economic Forum – it has completed two grant-making rounds: one for vaccines against Lassa, MERS-CoV, and Nipah virus diseases, and one for platform technologies to enable rapid vaccine development, which could apply against a broad range of diseases. A third call will support vaccine development against Rift Valley fever and chikungunya viruses. Three of the five specific pathogens (MERS-CoV, Nipah virus diseases and chikungunya) identified in these calls are diseases affecting countries of the Indo-Pacific.

In selecting priorities and making funding decisions, CEPI refers to the World Health Organisation (WHO)'s Research and Development Blueprint list for Action to Prevent Epidemics, which assigns priorities based on a set of criteria including the risk of an outbreak occurring, transmissibility of the pathogen, burden of disease, and feasibility of vaccine development. The Blueprint is a global strategy and preparedness plan that allows the rapid activation of research and development activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crisis. WHO as convenes a global coalition of experts to develop the Blueprint. The Blueprint was discussed at the World Health Assembly in May 2016 and remains an important document to guide resourcing.

B. Development Context and Situational Analysis (What problem are we addressing?)

Developing new, safe, and effective vaccines is expensive and time-consuming. The risks and costs associated with developing new vaccines for emerging infectious diseases (EIDs) are high because pathogens tend to be uncommon. While they have high outbreak potential, this is rarely matched by huge demand for vaccines. Most vaccines tend to be developed with the aim of routine immunisation of large cohorts (e.g. regular supply for seasonal flu) or to target the travel market. There are few industry incentives to develop vaccines 'just in case' or for poor population groups. Multilateral cooperation and innovative partnerships – such as CEPI and other product development partnerships have emerged as solutions to this funding gap. The minimum cost to progress a single vaccine against an epidemic infectious disease is estimated at USD 2.8 billion,¹ and takes over 10 years from preclinical trials to registration.²

Access to vaccines remains unequal and suboptimal, particularly in developing countries. Gaps exist in the development of vaccines for which there is no market in high income countries, owing to low economic incentives for the private sector to justify the investments necessary for vaccine development.³ Public sector funding is therefore critical to stimulate development opportunities where there is evidence of market failure. The limits of market-based incentives in vaccine development is something recognised by other donors, and by Gavi.

¹ Gouglas et al (2018), "Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimisation study". *The Lancet Global Health* 6(12): PE1386-E1396.

² Pronker et al (2013), "Risk in vaccine research and development quantified". *PLoS One* 8(3): e57755.

³ Barocchi Michèle Anne and Rappuoli Rino (2005) "Delivering vaccines to the people who need them most" *Philosophical Transactions of the Royal Society B*, p370

There is no shortage of disease targets in need of vaccines. Although development of vaccines against HIV continues to pose serious challenges for both basic and clinical researchers, vaccines against malaria and dengue (both infectious diseases that cause major burdens of morbidity and mortality concentrated in developing countries) are in advanced stages of clinical assessment.⁴ Vaccination campaigns in developing countries have had well-known impacts in reducing mortality among children under five, and there is potential for that success to be matched in the prevention in work to control emerging infectious disease. In selecting priorities and making funding decisions, CEPI refers to the World Health Organisation's Research and Development Blueprint list for Action to Prevent Epidemics, which assigns priorities based on a set of criteria including the risk of an outbreak occurring, transmissibility of the pathogen, burden of disease, and feasibility of vaccine development. The R&D Blueprint is a global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crisis. With WHO as convener, the broad global coalition of experts who have contributed to the Blueprint come from several medical, scientific and regulatory contexts. The development of the Blueprint was discussed at the World Health Assembly in May 2016 and remains an important document to guide resourcing.

C. Strategic Intent and Rationale (Why?)

Strategic Setting and Rationale for Australian/DFAT Engagement

DFAT's development policy framework, *Australian aid: promoting prosperity, reducing poverty, enhancing stability*, and the 2016 *Foreign Policy White Paper*, Australia's aid policy recognise that identifying and mitigating health-related risks are central to ensuring regional stability and economic prosperity. In particular, DFAT's *Health for Development Strategy (2015-2020)* identifies strengthening regional preparedness and capacity to respond to emerging health threats as a priority strategic outcome. Combatting health threats with the potential to cross national borders, and the development of new approaches and solutions that strengthen health security in the region, are among key investments required to achieve this outcome. This investment also aligns with the 2017 Office of Development Effectiveness evaluation of Australia's efforts to combat pandemics and EIDs in Asia and the Pacific between 2006 and 2015. The Management Response to this evaluation noted that DFAT will continue to invest in research and development targeting infectious diseases for the Indo-Pacific region, a confirmed epicentre for EIDs with pandemic potential. Product Development Partnerships – including for vaccine development – represent an important priority reflected in the Health Security Initiative for the Indo-Pacific's Strategic Framework.

Gender, innovation and cross-cutting themes

CEPI is a partnership of public, private, philanthropic, and civil society organisations, and demonstrates innovation through its use of science and technology to enable change, and by bringing together multiple stakeholders.

D. Proposed Outcomes and Investment Options (What?)

CEPI has prepared a comprehensive Programme Document, which sets out intended objectives and outcomes for future work and grants to be funded. The Programme Document includes a Theory of Change, which includes eight outcomes:

1. Investigational stockpiles established
2. Plans for trials and manufacture in place
3. Expedited development and manufacture of vaccines for known and unknown pathogens
4. Facilitated field use and rapid response
5. Plans in place for testing and deployment during outbreaks
6. End-to-end market failures addressed

⁴ "Vaccine development and developing countries" (2014) *The Lancet* Volume 383, Issue 9935, P2099, June 21

7. Costs reduced across the end to end spectrum of vaccine development
8. Successful products available to support outbreak response.

The Programme Document also includes indicators and a Results Framework, which will be used to monitor CEPI's progress. The Results Framework was developed in October 2018 and presented to the Investors Council, and notes that as CEPI continues to evolve, additional indicators may be added and existing reviewed, following consultation with our Investors. As this is a new Framework, it has yet to generate outcomes and results. Results related to outcomes and impact are purposefully ambitious within the 5-year time period.

CEPI is not the only actor working in the field of vaccine research and development and part of a complex ecosystem. Recognising challenges with attribution, the Results Framework notes that CEPI aims to contribute to achievement of outputs and outcomes, and that often success or failure cannot be attributed solely to one donor.

Delivery Approach

As outlined above, CEPI is a significant funder of vaccine development, focused on developing countries with capability to work at this global scale. DFAT and CEPI will partner through a Complex Grant Agreement. CEPI has been closely consulted on the detail and requirements of the Agreement.

E. Implementation Arrangements (How will DFAT engage?)

DFAT plans to enter into a complex grant agreement with CEPI for three years. Funding will be provided in three tranches with reporting milestones. Through the Investors Council, and through liaison with CEPI's Australian-based representative, DFAT has several opportunities to engage in CEPI's work and monitor progress.

Governance Arrangements and Structure

CEPI has established arrangements for governance, which includes a Board, Investors Council, Partners Group, a Scientific Advisory Committee and Joint Coordination Group.

With this investment, Australia will be represented on the Investor's Council. The Board is currently chaired by an Australian, formerly a senior public servant who headed Australia's departments of finance and health. To engage stakeholders and solicit advice on direction, CEPI convenes a Scientific Advisory Committee (of university and industry-based researchers) and a Joint Coordination Group of independent institutions with an interest in seeing CEPI's vaccines successfully developed and deployed in an outbreak. The current members of the Joint Coordination Group include multilateral, regulatory and non-government such as the World Health Organization, UNICEF, Gavi, the Red Cross, EMA and US FDA. These arrangements are outlined in a transparent way on CEPI's website and in official documents, such as its annual report.

Early Activities, Profile and Public Diplomacy

DFAT representatives have taken part in CEPI meetings and events previously and there is a positive working relationship, and opportunities for Australia to engage with other donors through existing mechanisms, such as the Investors Council. Australia has supported CEPI through a grant provided by the Department of Health. CEPI and DFAT collaborated on a joint media opportunity with the announcement of a grant to the University of Queensland in early 2019.

Sustainability

CEPI is focussed on maintaining and increasing contributions from a variety of donors. Other major donors include Norway, Germany, Japan, Canada, the Bill & Melinda Gates Foundation, and with other support from Belgium, the UK and European Commission under consideration. CEPI has already secured USD 750 million in contributions from other donors, and in this context, Australia's contribution is relatively small. In-kind and institutional support, from the Norwegian Institute of Public Health which houses CEPI, also demonstrates sustainability. Through its various governance and advisory committees, CEPI also has access to a long list of global health leaders that would be able to champion ongoing support.

F. Monitoring and Evaluation (How will DFAT measure performance?)

CEPI has developed a comprehensive Results Framework, which is contained in CEPI's Programme Document as Annex B. This framework was developed in October 2018 and presented to the Investors Council. The Framework is flexible and as CEPI evolves, additional indicators may be added and reviewed through consultation with members of the Investors Council. This will help to ensure the Framework is aligned and meets the reporting needs of donors, including Australia. To reduce reporting burdens and duplicative efforts by CEPI or its grantees, the Framework and measurement of output aims were designed to link with existing grantee reporting arrangements.

The Results Framework includes 19 indicators (with definitions) and outlines the rationale, measurement type, baselines, targets, data sources and limitations for each. Indicators at an impact level are developed around the Sustainable Development Goals (in particular goals 3, 18 and 17).

CEPI will be responsible for the reporting under the Results Framework, collecting data from grantee. Most reports will be shared with others on the Investors Council and through annual reporting, highlights and other outputs (such as social media and websites) from CEPI.

The CHS will work with CEPI to identify opportunities to jointly release data and highlights from time to time.

G. Gender, Disability and Other Cross Cutting Issues

Cross cutting themes

CEPI has an Equitable Access Policy, which seeks to ensure 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. Through the policy, CEPI undertakes to facilitate equitable access to epidemic vaccines by:

- › Funding the development of vaccines and maintaining investigational stockpiles, to be used free of charge when an outbreak occurs
- › Coordinating with others in the global health community to enable licensure of vaccines funded by CEPI, including by securing resources for pivotal clinical trials
- › Collaborating with others in the global health community to ensure 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.

CEPI does not have an explicit strategy, policy or program area that focuses on gender equality and disability. Given the pro-poor focus of CEPI's work in vaccine development, these benefits will flow to women and people with disabilities, and that assessments of gender and disability barriers will be critical in the distribution and financing of vaccines. Australia will continue to advocate for this through the Investors Council and to opportunistically seek equity opportunities and to identify structural barriers for women in leadership and science.

Private Sector and Innovation

CEPI is a partnership of public, private, philanthropic, and civil society organisations. The resources of private sector drug and vaccine development organisations are harnessed through grants. Given the high costs and low returns, there are few incentives for private sector organisations to support drug and vaccine development that has an equitable focus. CEPI addresses this challenge through its design and grant-making.

H. Budget and Resources (What will it cost?)

Budget

DFAT has agreed to provide AUD 4,500,000 to CEPI, over three years commencing in Dec 2019. This will contribute to CEPI's organisational budget, contained in the Programme Document (Annex A).

Resources

This agreement will be managed alongside DFAT's PDP investment by a Senior Project Officer based at the Indo-Pacific Centre for Health Security in Canberra.

I. Procurement and Partnering

DFAT and CEPI will partner through a Complex Grant Agreement. CEPI has been closely consulted on the detail and requirements of the Agreement.

J. Risk Management and Safeguards (What might go wrong?)

Risk Management Plan

- › The [Risk and Safeguards Tool](#) is included.
- › Risks will be reviewed and managed by the Program Manager.

Environmental and Social Safeguards

Given the nature of CEPI's work in providing funds for the development of vaccines, risks to the environment, vulnerable and disadvantaged groups, displacement and resettlement, indigenous peoples and health and safety risks are assessed as very low.

CEPI has an Equitable Access Policy, which seeks to ensure 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 is developing policies and processes for child protection, in line with expectations of DFAT.

Due Diligence

CEPI has demonstrated a willingness to commit to organisational development in line with the expectation of donors. CEPI has shared with DFAT the findings of an internal audit completed for one of its major donors, the Wellcome and a Due Diligence assessment completed for the UK Department of Health and Social Care. These two documents did not highlight any critical control weaknesses or did not find that an investment in CEPI would pose unacceptable negative fiduciary and/or reputational risk. However, the Wellcome audit noted that CEPI was in an early phase of implementation, following creation in January 2017 and that key processes were new or continuing to be developed, refined and embedded. It identified that financial oversight and reporting at the Board-level required improved controls and would benefit from further improvement. The UK Assessment made similar recommendations. Since 2017, CEPI has developed several documents and policies to strengthen internal governance and operations, and in a commitment to transparency, provides these documents when approved on the CEPI website.

K. Annexes

- A) CEPI's Programme Document.
- B) [Risk and Safeguards Tool](#).