Product Development Partnerships Fund Competitive Grant Guidelines Request for Proposals

Product Development Partnerships Competitive Grants Fund

1. Background

The Product Development Partnerships (PDP) Competitive Grants Fund (the Fund) has been established by the Australian Department of Foreign Affairs & Trade (DFAT) under the Health Security Initiative for the Indo-Pacific to assist to reduce the burden of high prevalence diseases (TB, malaria) in the Indo-Pacific, and to halt the spread of drug-resistant strains of TB and malaria in the region. DFAT invites proposals from eligible PDPs to submit applications for funding that focus on the development of diagnostics and therapeutics for TB and malaria and/or vector control tools for malaria and other high burden mosquito borne diseases.

The total investment will be up to AUD75 million over five years. This will comprise of up to AUD50 million for an initial three year period, with up to AUD25 million in the subsequent two years, subject to an external evaluation. DFAT expects to fund up to four PDPs for AUD 10 - 15 million per proposal over three years. However funding of up to AUD 20 million may be considered for outstanding proposals.

Product Development Partnerships are non-profit organizations that use public and philanthropic funds to engage the pharmaceutical industry and academic research institutions to undertake research and development (R & D) for diseases of the developing world that they would normally be unable or unwilling to pursue independently without additional incentive. The Fund aims to capitalise on the strengths of the PDP model to incentivise medical product development solutions for the Indo-Pacific.

The Fund contributes to the strategic objectives of the DFAT Health for Development Strategy, 2015-2020 by developing new approaches and solutions to cross-border health threats.

Proposals will be reviewed and assessed according to the:

- Merit of the technical proposal
- Assessment of the capacity of the proposing organisation to deliver the desired results
- Expected value for money from the proposed activities
- Alignment of the proposal to goal of the PDP design

2. Objectives

The objective of the Fund is to accelerate access to new and effective tools and approaches to emerging and acute public health threats, including drug resistance in the Indo-Pacific.

The Fund will help to address the need for cost-effective, new and adapted products for TB, malaria, and vector control for mosquito borne diseases more broadly, and to make them safely and effectively available to target populations.

Grant proposals are expected to deliver results which contribute to the outcome of:

 Improved availability of new PDP technologies with the potential to reduce burden in the Indo-Pacific.

Expected outputs from PDPs are:

- Registration of a minimum number of new or modified products/regimes for patient use in the Indo-Pacific by 2022. (Actual number of products to be determined depending on specific PDP pipeline.)
- Availability dimensions of access (affordability, market analysis, geographic availability, stock, partnerships for procurement and distribution) for products that are ready for market in the Indo-Pacific are addressed where relevant.

Performance of PDPs will be measured by a results framework specific to each grant and which will be refined and agreed with successful applicants finalised. Please refer to the draft framework attached in the PDP Design document for an example of the types of indicators which DFAT will require reporting against.

3. Eligibility

Product Development Partnerships with a focus on diagnostics and therapeutics for TB and malaria and/or vector control tools for malaria and other high burden mosquito borne disease will be considered eligible for funding.

3.1 Minimum Capabilities

Organisations that apply for funding must be able to demonstrate the following capabilities at a minimum:

- A Public-Private-Partnership model that develop and deliver affordable, quality medicines, diagnostic tools and innovating products for specific neglected disease to combat poverty and disadvantage
- Track record of timely implementation and successful delivery of results
- Sound financial and administrative processes for managing donor funds
- Robust procurement processes that comply with acceptable probity standards and protect against corruption and misappropriation and
- Acceptable risk management, child protection policies and mitigation strategies.

3.2 Type of Funding

Funding will be provided for:

- Core funding where the PDP has a single disease focus on TB and/or malaria
- Core funding for PDPs with a focus on vector control
- Semi-restricted to TB and/or malaria where the PDP has a broader mandate

3.3 Ineligible costs

Funds will not be available for:

- Seed capital and/or other start-up costs
- Infrastructure activities
- Assets not for the direct use of outputs specified in the proposal and subsequent grant agreement

The selected organisation/s will be considered grant recipients and agree to a grant agreement, which will require the organisation to meet DFAT policies and principles governing its aid program.

The specific DFAT policies and guidelines will be outlined in the grant agreement. Organisations must note any issues about compliance with DFAT policies and guidelines on their proposal.

4. Technical selection criteria

The following selection criteria will be used to assess the proposal:

Selection Criteria	Description	Approximate Weighting (%)
 PDP focus on: Diagnostics and therapeutics for TB and malaria Vector control tools for malaria and high burden mosquito borne diseases 		Yes', (if 'Yes', Continue)
Product pipeline (high-impact/late stage)	 Demonstrate overview of pipeline diagnostic and therapeutic products for TB and/or malaria, and/or vector control products for high burden mosquito borne diseases, with potential for high impact on target disease, provide detailed information on pipeline products in terms of development stage, clinical / diagnostic indications, risks, benefits and probability of impact on health (modelled DALYs, lives saved, etc.), poverty, and security, as well as projected timelines for each product. Describe pipeline product/s that will be ready for registration in the next 3-5 years, including relevant milestones or requirements for development. Describe pipeline products with particular <u>relevance to targeted diseases in the Indo- Pacific region.</u> Demonstrate compliance with global good clinical practice standards where relevant to particular products. 	40%
Contribution to access	Demonstrate contribution to access – where access is defined as availability and affordability of products – including extent of access-enabling initiatives and	10%

	 partnerships, where appropriate to the partnership model and/or product. These could include, but are not limited to, registering products for compassionate access schemes, understanding appropriate regulatory pathways, reducing time to registration of products, ensuring affordability to target markets, market analysis, and appropriate partnerships for regulation, procurement and distribution (where relevant) 	
Achievements	Track record of registration of new TB, malaria and vector control products (medicines, diagnostics, vector control tools) to market in the previous 5-10 years.	10%
Governance & Financial Management	Demonstrate organisational capacity to deliver against PDP strategy and objectives. Provide evidence of leadership, governance and management procedures of the PDP, including gender and disability breakdown of employees. PDPs should demonstrate appropriate risk management, and consideration of ethical issues, PDPs should demonstrate they have adequate financial management systems in place, including independent audits;	10%
Gender and disability- sensitive research and capacity building focused activities in Indo Pacific	Demonstrate operational research and capacity building activities relevant to particular products, such as product trials or field studies which contribute to capacity building in research in countries in the Indo Pacific region. Able to provide evidence of contribution to gender-sensitive and social inclusive capacity building activities.	10%
Budget	Demonstrate available funds, existing funding gaps, diversity of funding sources, provide breakdown of current funders. And proposed/projected allocation of core spending,	10%
Partnerships	Demonstrate ongoing and appropriate engagement with key global health partners including multilateral institutes, academia, country governments, industry (e.g. manufacturing, distribution, implementation partners), Include detailed information on partnerships: - In the Indo Pacific region including specific mention of research institution partnerships in Australia - Private sector partnerships - Explicit nature of partnerships to be described.	10%

5. Safeguards and cross-cutting issues

Proposals must include the applicants approach to:

- do no harm
- gender and social inclusion of people with disabilities
- child protection
- Minimising risk

All organisations must comply with DFAT's Child Protection Policy

6. Application process

6.1 The indicative timeline for this competitive grant process is:

Date	Event
9 October 2017	Request for proposals opens
24 November 2017	Deadline for applicant questions
1 December 2017	Deadline for DFAT responses to applicant questions
15 December 2018	Closing date for submission of proposals
16 February 2018	Notification of selection to PDPs
30 March 2018	Grant agreements with successful PDPs signed
30 April 2018	First tranche payment to PDPs (amount to be determined by proposal
	and pipeline

6.2 Applications

Stage 1: Applications

PDPs are invited to submit a proposal on the Invitation to Submit an Activity Proposal template provided along with other supporting documents as outlined below. Proposals should include draft log frame with performance indicators, pipeline of products and budget, and where applicable an activity schedule.

All enquiries about this competitive grant process must be submitted via email to <u>opportunities@chs.dfat.gov.au</u> as soon as possible and not later than 1 December 2017. The subject line of the email must clearly indicate that this is an enquiry regarding the PDP grant process.

DFAT will publish answers to enquiries on the DFAT Business Opportunities website (without identifying the organisation that submitted the enquiry).

Stage 2: Assessment

Proposals will be assessed on their technical merits and compliance with the conditions of this Request for Proposal (RFP).

A Scientific Advisory Committee (SAC) will review the proposals against the Invitation to Submit an Activity Proposal (the Invitation) technical selection criteria. The SAC will rank proposals based on their technical merit and make recommendations to DFAT.

Concurrently DFAT will conduct capacity and due diligence assessments to confirm the prospective Partner is compliant with the conditions of the RFP and has the capacity to undertake the suggested program. Applications that do not comply with DFAT's Child Protection Policy and that they have not appropriately addressed safeguards and crosscutting issues identified above will be considered non-compliant.

The final decision on successful PDPs and funding amounts will be made by DFAT.

The assessment will be confidential and applicants must not seek contact with any members of the SAC or DFAT staff to discuss the assessment. Contact between applicants and SAC members and/or DFAT staff will be considered a breach of confidentiality and may result in DFAT rejecting the proposal of the applicant.

Unsuccessful applicants will be notified and offered an opportunity for feedback on their application.

Stage 3 - Implementation

Following acceptance by DFAT of the proposal, partners will implement the grant in accordance with the agreement and budget. All grants will have specific reporting and results frameworks that the partner must adhere to. These will be negotiated with successful organisations prior to finalising grant agreements. DFAT and the partners will agree a process whereby DFAT may withhold or cancel funding if performance is considered unacceptable.

Stage 4 – Review

DFAT will undertake an external review of all PDPs in 2020 (year three) of the agreement to determine performance, results achieved and make recommendations on whether funding for years four and five shall be allocated and disbursed.

7. Level of funding

The total funding envelope available for the PDP Fund is up to AUD75 million over five years. Grants funded by DFAT are expected to be in the range AUD10 - 15 million, for an initial period of up to three years.

The figure provided above is an indicative range to enable the applicant organisations to craft and pitch their proposals appropriately. However funding of up to AUD 20 million may be considered for outstanding proposals. The decision to provide extra funding will be based on an exceptional pipeline of late stage products, as per the selection criteria. DFAT will reserve the right to negotiate final funding amounts, which may be lower than the range indicated above.

PDPs may be eligible for further funding of up to AUD 10 million for an additional two year period, subject to performance and budget availability.

Funds will be paid in annual tranche payments and according to agreed budget schedule.

8. Documents required from lead organisation for submission to the RFP

- a) Completed Application Form on DFAT template
- b) Completed Organisations Declaration
- c) Copy of legal registration'
- d) Copy of tax registration
- e) Governance structure details, including names, board of directors, CEO and senior executives (i.e. Head of Finance, Head of Operations, Head of Human Resources)
- f) Financial management and accounting policies and processes
- g) Procurement policies and processes

- h) Child protection policy and procedures
- i) Anti-terrorism, fraud and corruption
- j) Monitoring and evaluation framework, with proposed indicators, data collection and analyses strategies
- k) Risk management framework and strategy
- I) Sub-grant management if it is proposed to use sub-grantees in the proposed project.

9. Non- compliant applications

Applicants are responsible for ensuring that they comply with all the requirements of the RFP and submit necessary documents. DFAT does not accept responsibility for notifying all applicants with regard to issues of non-compliance. However, where applications are submitted prior to the deadline and/or a minor issue of non-compliance is identified, DFAT will endeavour to alert the applicant to this shortcoming so that it can be rectified.

10. Due Date

The deadline for responding to the RFP is the 15 December 2017. Submissions must be emailed to <u>opportunities@chs.dfat.gov.au</u> by 17:00 Australian Eastern Daylight Time. Responses must be in English and must use the Application Form provided. The subject line of the email must clearly identify that it is an application in the PDP competitive round.

11. Grant Agreement

Interested organisations must review the standard Grant Agreement prior to submission, specifically the contractual terms and conditions that will be used for agreements to release funds from DFAT. Submission of applications for grants under this Fund will be taken as agreement to the general terms and conditions of the standard grant agreement. However, DFAT reserves the right to negotiate the grant agreements with specific organisations.

12. Reporting

The organisations will be expected to successfully deliver agreed outputs and provide the following types of reports (format to be negotiated) during the life of the Grant

- Regular (up to monthly) telephone calls with DFAT
- 6 monthly progress reports
- 12 month annual progress report including financial acquittals.