Product Development Partnerships Fund, 2018-2022

Addenda Two – 13 November 2017

Q1. We are in the process of developing the proposal to apply for funding to the PDP competitive bid. There is some confusion about the number of proposals we need to submit. The announcement says that we need a proposal for each project. We work both on Malaria and TB. In this case would we need to submit two proposals-one for each or do we submit one for both?

A1. A separate application is not required for each project, however, PDPs have the flexibility to submit more than one proposal covering different portfolios of work. It is up to the applicants to determine how they package the proposed portfolio of work to demonstrate how their application meets the selection criteria.

Q2. We would like to clarify (1) to what extent the PDP Fund is specifically targeting established PDPs or whether new public-private partnerships would be eligible, and (2) the role Australian researchers can have as partners on an application.

A2. (1). Any PDP that has a focus on TB, malaria and vector control for malaria and other high burden mosquito bore disease is eligible to apply. Please read the excerpt below from page three of the Competitive Grant Guidelines on eligibility

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.

All applicants are encouraged to read the Competitive Grant Guidelines and review the selection criteria against which applications will be assessed to ensure they are able to submit a competitive bid.

A2. (2) Please read the excerpt below from the selection criteria contained in the Competitive Grant Guidelines on page 5, which outlines the specific requirements for PDP applications with respect to Partnerships

Partnerships (10% weighting)
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.

The actual role of an Australian researcher or any other partner on an application would be determined by the arrangements made with PDP submitting the application. We would encourage

all partners to discuss with relevant PDPs how they can contribute to applications and how the explicit nature of their partnership is described in the application as per selection criteria above.

Q3. Has DFAT already decided which PDPs will be funded?

A3. No.

Q4. In relation to this tender, please provide the following clarifications:

In the Investment Design, vaccines are referred to in the description of the 'new tools' included in the rationale for the PDP Fund, e.g. at pages 1, 2, 5 and 6. DFAT's Health Security Initiative website states that DFAT investments will support development of "new drugs, diagnostics and vaccines". Please clarify whether PDPs with a focus on vaccines are eligible for funding.

If so, please clarify whether PDPs with a focus on any or all of the following are eligible for funding:

- Vaccines for prevention of TB infection.
- Vaccines for prevention of TB disease, i.e. vaccines that prevent progression from latent TB infection to active disease.
- Vaccines that prevent active TB disease recurring in patients who have already completed a treatment program.
- Vaccines designed specifically for therapeutic use to help treat drug-resistant TB.

A4. Proposals with an emphasis on therapeutic vaccines for TB and/or malaria and other high burden mosquito borne diseases would be eligible. Please refer to **Section 3. Eligibility** of the Product Development Partnerships Fund Competitive Grant Guidelines on page 3 which states:
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.

The selection criteria refer to diagnostic and therapeutic products for TB and/or malaria, and/or vector control products for high burden mosquito borne diseases, with the potential for high impact on the target disease. This does not exclude therapeutic vaccines but does exclude preventive vaccines.

Please note the expected outputs from PDPs include:

- 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.

It is up to applicants to demonstrate that can deliver the expected outputs within the time frame and demonstrate how the proposal is competitive against the selection criteria.

It should be noted that the reference to vaccines on the website of the Indo-Pacific Health Security Initiative does not fall under the PDP Fund heading and relates to scenarios in which rapid vaccine development is judged feasible as part of the international response to a disease outbreak.

Q5. Can you comment on how you see the opportunities and timelines for collaborations between PDPs and Therapeutic Goods Administration (TGA) for access to new products through the Regional Health Securities' TGA funding for regulatory strengthening activities? Which countries are priorities? Will a collaboration be desired or required for grantees under the PDP Fund?

A5. Under the government's Health Security Initiative for the Indo-Pacific region, DFAT is designing a regulatory strengthening program to improve the availability of quality new and important therapeutics and diagnostics, including for malaria and tuberculosis, with particular emphasis on drug-resistant forms of those diseases.

Central to this program is a partnership between DFAT and Australia's Therapeutics Goods Administration (TGA) to support National Regulatory Authorities to fast-track product registrations. In line with WHO's guidelines on the promotion of regulatory convergence and harmonization, the partnership aims to enable the TGA to work with the National Regulatory Authorities to develop mechanisms that will allow timely and effective assessments of new product dossiers, in order to help inform their sovereign registration decisions.

It is envisaged the regulatory strengthening program will provide direct support to Myanmar, Laos, Cambodia, Vietnam, Indonesia, and Papua New Guinea, subject in each case to partner government approval. The program will operate from mid-2018 to 2022.

No particular therapeutic or diagnostic products will be specified in the design of the program, however products aimed at malaria and tuberculosis will be used as entry points for regulatory strengthening activities.

As per the PDP Fund's Competitive Grant Guidelines, there is no requirement for PDPs' proposals to demonstrate any prior or prospective collaborative relationship with the TGA. It is for individual PDPs and/or product sponsors to determine which regulatory authorities they approach regarding evaluation of their product dossiers.

Q6. (1).On the http://indopacifichealthsecurity.dfat.gov.au/Pages/Investments/Accelerating-Access-To-New-Products.aspx page it says

"Investments in this area will support research, development, commercialisation and adoption of new drugs, diagnostics and vaccines, as well as measures to improve regulation, procurement, storage and distribution in relation to all relevant products"

This seems to allow us to apply to build an open source software (addressing the last 4 points of the above). However, the Request for Proposals (RFP) documents seem to then focus in on therapeutic product development and/or vector control…..

Just wondering if software development is within scope?

ii. Would a not-for-profit company be acceptable for a PDP ?

I guess there are two aspects-

- **would such a structure be acceptable?**
- **and could such a company implement a project itself, as opposed to getting other entities to do implementation(s)?**

A6. (2) The reference "Investments in this area will support research, development, commercialisation and adoption of new drugs, diagnostics and vaccines, as well as measures to improve regulation, procurement, storage and distribution in relation to all relevant products" relates the broader strategy of '*Accelerating access to new and effective* products'. This strategy covers a range of investments. The PDP Fund is only one of these investments; the other investment underway is the partnership with the Therapeutic Goods Administration. It has not been decided if and what other activities may be funded under this strategy. The RFP documents relates only to the PDP Fund.

For you information, PDPs 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. Unlike large pharmaceutical companies, or academic institutions, PDPs tend not to undertake R&D, manufacturing, nor distribution in-house, but rather allocate resources to the most promising projects, provide technical insight, facilitate partner R&D and access activities and manage project portfolios to fulfil objectives. This "virtual R&D" structure also provides additional flexibility and lowers overhead costs, which frees up capital for other investments.

For this round of funding the 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.

This means that any proposal would need to demonstrate how these outputs will be achieved by 2022.

A6.ii Applications will be assessed using the technical selection criteria, which is included in the Competitive Grant Guidelines. Please note that the ability for PDPs to demonstrate a pipeline of relevant products is weighted at 40% and the ability of PDP to demonstrate contribution to access is weighted at 10%.

It is up to organisations to determine if they are eligible. We encourage any institution or organisation that is interested in the PDP Fund to review the Competitive Grant Guidelines and the Investment Design to determine if they likely to be competitive and where they may only play a part contribution, to discuss their proposed contribution with a relevant PDP. DFAT will not comment on the potential merit of any aspect of any proposal prior to the formal assessment.