

## **Product Development Partnership Fund, 2018-2022**

### **Addenda 4 – 10 December 2017**

**Q1. Can we partner with a US company? Can we make multiple submissions? (for different partnership combinations)**

**A1.** Yes you can partner with a US company. Yes you may make more than one application.

**Q2. As a research institute, to put in a funding submission, do we have to partner with a commercial enterprise (ie a private sector company) or can we partner with another research institute**

**A1.** There is no requirement for applicants to partner with any specific type/s of organisations. It is up to applicants to determine what partnerships are most relevant to deliver the expected outputs.

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.

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%.

**Q3. Part 1. It is understood that applications should include all indicators stated in the DFAT design document if relevant to the projects. We would like clarity on if the indicators must be included as written in the design document or if there can be flexibility in wording of the indicators to reflect the stage of technologies throughout the grant period. Specifically would like clarity on how DFAT envision the following indicators to be structured for technologies which are in late stage development and early piloting during the grant period. Guidance on what DFAT envisions the denominator [i.e. : denominator to be those in demonstration/early pilot catchment area or is this intended to capture national or regional proportions?] of these indicators is appreciated:**

Proportion of eligible patients/at risk population who use the product/tool
Proportion of end-users who find product/tool affordable.

**Q3 Part 2.** For the following sections of Q3 of the application we have some specific questions below:

- *Analysis underpinning the programming choices made and program logic to show how the PDP will achieve its objectives, including the political economy impacting program choices;*

Could you provide more information on what you mean by political economy? We have a few definitions and interpretations but we are not totally sure on what you are looking for in this question.

- *Knowledge gap and barriers to success. Identify and resources for further monitoring/analysis as necessary as part of implementation arrangements.*

In the highlighted portion, some text seems to be missing after “identify”. Could you supply that text as the questions seems a bit incomplete without that information?

**A3. Part 1.** It is not necessary for an application to include all of the indicators in the DFAT design, these are provided as an example. The final results frameworks specific to each grant will be refined and agreed with successful applicants once grants are finalised. Please refer to Section 2 Competitive Grant Guidelines. It is up to applicants to propose what they consider they most appropriately defined *draft* indicators in the M & E frameworks applicable for their projects.

**A3. Part 2**

a) There is no set definition of political economy for the PDP Fund. It is up to applicants to demonstrate how they have analysed political economy factors that impact programming choices.

b) Text should read “Identify any resources for further monitoring/analysis that are required as a necessary part of implementation arrangements.”

**Q4. Part 1.** What are the document requirements for the proposal –

- Font size
- Margins
- Page numbers
- Page shape – Letter or A4

**Q4. Part 2.** On page 2 of the invitation to submit, the document says that section 3 is the template format in which applicants are supposed to submit their proposals.

- When doing this, do we need to include the section explanations/selection criteria? Or can we delete those parts out and just reply to each question?
- In terms of formatting, do we need to keep the document in tables or can we keep the sections but format it without tables?

**A4. Part 1**

- 11 or 12 pt
- Normal or moderate margins
- Include page numbers (these are already included in the template)
- A4 page size, portrait

**A4. Part 2,**

- You may delete the ‘Instructions for Applicants’. Please keep the section and all table headings and text.

- f. You may remove the tables, however we strongly recommend that all of the headings and text relating to that heading is included your application and presented in the same order.

**Q5. Part 1. Can the PDP be a collection of public and private organisations submitting under one lead applicant (e.g. a University). Or does the lead applicant (that submits the proposal) need to be a registered not-for-profit entity with a formal business structure.**

**Q5. Part 2. Does DFAT require a certain ratio of applicant, partner, and third-party contributions, to match the amount provided by DFAT?**

**Q5. Part 3. Do you have an estimate of the number of applications you expect to receive?**

**Q5. Part 4. Is the funding intended to support the PDP to identify and choose the best technology platforms once funding is received, or does the PDP need to choose a specific technology platform upfront - and promote this technology platform as part of the grant application in order to receive DFAT funding earmarked specifically for that technology platform.**

**Q5. Part 5. Can the funding be used to develop diagnostics for other high burden mosquito borne diseases (e.g. Dengue).**

**Q5. Part 6. Can funding be used to test/evaluate products that have not yet been calibrated in a field setting, as part of the pilot stage of the study (prior to formal implementation)?**

**5. Part 7. For new products that are in mid or late stage development, and that have not yet (formally) demonstrated ‘compliance with global good clinical practice standards’, can these be included as part of the study design in the pilot phase, conducted according to WHO guidelines for ‘design of epidemiological trails for vector control products’ (see <http://apps.who.int/iris/bitstream/10665/255854/1/WHO-HTM-NTD-VEM-2017.04-eng.pdf?ua=1>)?**

**Q5. Part 8. Is DFAT looking for proposals that address only one of the two topic areas (that is, either Diagnostics and therapeutics for TB and malaria, OR Vector control tools for malaria and other high burden mosquito borne diseases.**

**5. Part 9. Can the application develop products for both of these topics in a single application (i.e., diagnostics and therapeutics for TB and malaria, AND vector control tools for malaria and other high burden mosquito borne diseases).**

**A5. Part 1.** PDPs are non-profit organisations who fund a range of public, academic and private partnerships. The PDP needs to be a registered entity. Please refer to the technical selection criteria in the Competitive Grant Guidelines for the governance and financial management, budget, and partnership requirements for applicants.

**A5. Part 2.** No.

**A5. Part 3.** No.

**A5. Part 4.** As per the Competitive Grant Guidelines, funding provided to PDPs will either be core funding or semi-restricted funding. It is up to applicants to demonstrate in their application how

they will deliver the expected outputs. Please refer to the technical selection criteria in the Competitive Grant Guideline, in particular, the criteria for PDPs to demonstrate a high impact/late stage product pipeline, which is weighted at 40%.

**A5 Part 5.** No. As per the selection criteria PDP applications should focus on 1) Diagnostics and therapeutics for TB and malaria; and/or 2) Vector control for malaria and high burden mosquito borne diseases.

**A5. A6. Part 6.** Yes. However, please refer to the technical selection criteria in the Competitive Grant Guideline, in particular, the criteria for PDPs to demonstrate a product pipeline of high impact/late stage product pipeline, which is weighted at 40%.

**A5. Part 7.** Yes. However, please refer to the technical selection criteria in the Competitive Grant Guideline, in particular, the criteria for PDPs to demonstrate a product pipeline of high impact/late stage product pipeline, which is weighted at 40%.

**A5. Part 8.** No. However would be up to applicants to demonstrate they have competitive pipeline of high impact/late stage diagnostics and therapeutics for TB and for malaria as well as a pipeline of vector control tools.

**A5. Part 9.** Can the application develop products for both of these topics in a single application (i.e., diagnostics and therapeutics for TB and malaria, AND vector control tools for malaria and other high burden mosquito borne diseases).

**A5. Part 9.** Yes.

**Q6. Part 1.** In regards to the intellectual property clause on page 30 of the agreement <http://dfat.gov.au/about-us/business-opportunities/tenders/Documents/product-development-partnerships-dfat-standard-agreement-template.pdf>

“Unless otherwise specified the Recipient grants to, or must obtain for, DFAT, a perpetual, irrevocable, world-wide, royalty free, non-exclusive licence (including the right to sublicense) to use, reproduce, adapt, Modify, distribute and communicate:

(A) the Agreement Material; and

(B) any Third Party Material and Pre-Existing Recipient Material, required to receive the full benefit of the Agreement Material and the Activity, and for any other DFAT or Commonwealth purpose”

**Will DFAT be open to negotiation around the wording of this clause, and what is the best mechanism to “specify” if changes in the clause are needed (for example, if required by third parties, to gain access to their materials for the project).**

**A6.** Yes. The wording on IP is able to be changed. The grant template is our standard template and can be negotiated to suit specific purposes.

I recommend adding an additional document to the application noting any potential issues with the grant template.