Netherlands Enterprise Agency

Questions & Answers

Product Development Partnerships III Fund

Version 3, May 28th 2015

On 22 May 2015 an information meeting took place at the Netherlands Enterprise Agency in the Hague. Around 40 people from different organizations attended. For more information on the programme and the presentation given see downloads on our website. Below you will find the questions and answers from the meeting on Friday May 22nd and the conference call on Tuesday May 26th 2015

Please see Page 6 and further for previous questions

Question 37
Is there a limit for indirect costs or overhead?
Answer
There is no set limit for the overhead. There is a limit for Dutch organisations but this is not the case for international organisations. A proposal with a relatively high overhead would have to include a clear and elaborate explanation of the high overhead.
See also question 17: *There is no set maximum on 'overhead other'. The information entered here is for acquiring clarity on the distribution of PDP funds. Grants shall be awarded solely to cover costs of the planned activities that are necessary in the light of the objectives and results envisaged, provided it cannot reasonably be expected that such costs can be funded from the applicant's own resources or other resources (see article 14 of the Ministry of Foreign affairs Grants Decree), see also par.V scope.*
Question 38
In par XIV. section 5, there is a request for an overview of all partners. Does this include all partners in general or only partners involved in the proposal?

Answer
This involves only those partners relevant to the proposal, partners involved in activities for which you request funding in the proposal.

Question 39
Can you confirm if the project plan is the same as the 15 pages of the proposal?

Answer
The application should contain (a summary of all) relevant information. It should address all the issues and be as complete as possible, including the threshold criteria and other criteria. Additional information can be added in the annexes, but please clearly refer to this information in the 15-pages application document.

Question 40
Is the application form part of the 15 pages?

Answer

See also question 35: *The interactive Application Form includes basic information on the applicant and the application but is NOT part of the proposal. The proposal should be a 15-page document, excluding the annexes.*

Question 41

Is a clinical trial eligible for funding?

Answer

Yes, There are no restrictions on supporting specific phases in the product development cycle. The applicant has to demonstrate why public funding is necessary, (See par V Scope: R&D and innovation: Which phases in the product development cycle)

Question 42

What do you consider a partnership without a legal personality?

Answer

*"Partnerships without legal personality can also apply for grants. In such cases, the PDP is defined as a not-for-profit **contractual** partnership without legal personality, consisting of at least two legal persons, one public and one private. These must, of course, be organisations as specified above, under A. The grant application will be submitted by one of the partners, the lead party. The lead party must be a not-for-profit legal person. If the partnership's application is approved, the lead party will be the grant recipient. (Par IV. Part B on page 7)". This means that the partnership should include at least a public and a private partner that cooperate based on a contract. Other partners can be included and are not necessarily all contractual partners. However, we do ask you to inform us on the type of relationship and functions that the different partners have. These are the partners involved in the work you apply funding for.*

Question 43

Budget sheet, overhead, other

1. The guidelines state that the multiannual budget should exclude the first year – but the template says – include it? Which of the two is it, please clarify.
2. How detailed does the budget need to be? 2/3 activities per program? Just to have a benchmark.

Answer:

Please consider the budget sheet as a tool that can be (slightly) modified to your own use if that makes it easier. The important aspect is you make it as clear as possible how the funds are going to be spent.

Question 44

We are a PDP without a legal personality. How do we demonstrate the 25% of other financial sources as described in section 7 article 8? How does this apply in case of a PDP with no legal entity? Does the rule apply to all the partners?

Answer

This applies for all partners combined. MoFa will exclude organisations/partnerships that rely only on MoFA funding. The 25% rule is to confirm that the partnership for this application has other sources of income. The applicant needs to demonstrate that at least 25% of its annual income derives from sources other than MoFA grants and or contributions. In case the PDP does not have legal personality, this criterion applies to all the partners together. MoFA wants to support sustainable partnerships and is therefore also interested in learning how the PDP is going to fund the activities after MoFa funding, are there other sources of income? . (See also par 7, section 8: "The applicant demonstrates that, as of 1 January 2015, at least 25% of its annual income derives from sources other than Ministry of Foreign Affairs grants and/or contributions. ***If the partnership does not have legal personality, this criterion applies to all the partners together.*** *Funds which are directly or indirectly obtained from the budget of the Ministry of Foreign Affairs (e.g. a grant or contribution from a Dutch embassy) do not count when determining the extent of the applicant's own income")*

Question 45
How do you define a product? May the (to be developed) product also have an indirect impact on poverty related diseases and SRHR or does it have to aim towards a direct impact?
Questions were asked on this subject specifically on a) e-health and vector control, b) mobile health devices, c) cold chain

Answer:
- *The framework requires that the product development or improvement must relate to products for which there is a demonstrable need for public investment owing to market failure*
- *Grants are awarded with a view to achieving the mentioned results (primary and secondary). The proposal should demonstrate how and to what extent the PDP will be able to contribute to achieving these results and will be assessed accordingly.*
- *The activities should target at least one of the priority themes.*
- *Given the threshold criteria the applicant should be focused on the development and/or delivery of affordable, effective, medicines, vaccines, diagnostics for specific poverty-related diseases and/or products for the purpose of SRHR-related conditions, with a view to combating poverty and inequality.*

It is for the applicant/PDP to decide whether their application is in line with the points mentioned above.

Question 46
In par X (Assessment criteria concerning the quality of the partnership) it is mentioned that the partnership has an adequate risk management policy. In par XI (Assessment criteria concerning the quality of the application) there is again mention that there has to be an adequate risk management policy. Does the risk management policy refer to managing the risks of the partnership or the activity?

Answer
The risk management policy refers to both. There should be a risk management for the partnership as well as for the activity as described in Par X and XI.

Question 47
Can PDPs submit more than one proposal?

Answer
Not if it is the same PDP. Applicants can submit more proposals on behalf of different PDPs.
See also Par IV: (Product Development Partnerships within this policy framework): There can only be one applicant/grant recipient per partnership (in the event of a partnership without legal personality: the lead party). The grant recipient is fully accountable to the Minister for fulfilling all obligations pertaining to the grant, even if it includes funding for implementing the activities of partners other than the applicant.

Question 48
Must research take place in Europe or does it have to be carried out in the developing world.

Answer
See par.VI-XI on assessment criteria: here are no criteria linked to the country or origin of the PDP and therefore no priority will be given to PDPs from the Netherlands. The quality of the applications will prevail. Should the quality relating to one or more themes be assessed as inadequate according to the criteria specified in these administrative rules, the funds will be distributed among satisfactory applications relating to the other themes.
See also Par V(Scope): The products that will be developed must be specifically suitable for use in developing countries8 where mortality and/or morbidity due to diseases and conditions related to poverty and SRHR tend to be increasing or disproportionately high, especially among the poorest groups (the Base of the Pyramid). In the proposal the applicant must provide a clear analysis of the added value to these countries of the products that will be developed.

Question 49
Should activities funded with DGIS money start on October 1st or on the moment of submission (June 12th)? How (by which cycle) will funding be distributed from then onwards? Will the Dutch government make a first disbursement in this calendar year still?

Answer
Yes in case the application is selected for funding under PDP III, the starting date can be October 1st 2015. First disbursement will take place in this calendar year, 2015.

Question 50
How far down the development chain do we fund?

Answer
Please see the Policy Rules, page 8 under R&D and innovation, par. V: Which phases in the product development cycle: 'There are no restrictions on supporting specific phases in the product development cycle. The products that will be developed must have a practical application: the fund is explicitly not meant for fundamental research. In the proposal the applicant must make clear what the added value is of the potential investment in the envisaged phase of the R&D and innovation chain, and the impossibility, despite the potential major impact, of attracting sufficient funding for product development without public investment'.

Question 51
In par I (background) there is mention of commercial channels and incentives in the following sentences: "The target group's lack of purchasing power and the lack of commercial incentives mean there is still insufficient investment in R&D and innovation in the areas of healthcare products and technologies specifically aimed at diseases and conditions related to poverty and sexual and reproductive health and rights (SRHR)" and "They focus on developing products that would probably not be developed via standard commercial channels because of the failure of market forces (e.g. the target group's lack of purchasing power and lack of financial incentives for private sector investment). What does a commercial activity entail?

Answer
Commercial activity: activity undertaken as part of a commercial enterprise, aimed at making profit.

Question 52
Can you elaborate on the role of industry? What is your view on their involvement in the PDP framework?

Answer
We would like to encourage private sector partners to engage in PDPs. This also includes industry. It is of course essential to have clear agreements with all partners about sharing of costs, risks, results, IP, et cetera.

Question 53
Can you elaborate on the level of detail you expect for the organizational description in the proposal?

Answer
It should be made clear which parties are involved in the activities mentioned in the application, what their role and contribution is.

Questions 54
Is the project plan the proposal and not a separate addition?

Answer
Please see answers to questions 35 and 40.

Question 55
Is the order of the sections listed in the table of contents mandatory, or can organizations shuffle these around*?*

Answer
No this is not possible, you should follow the table of content, this is mandatory.

Question 56
Should the required liquidity planning refer only to lead partners or to the whole consortium?

Answer
The liquidity forecast mentioned in par XIV (Checklist of documents to be included with the application) is for the activity to be undertaken. The planning refers to all parties involved in the funding of the activities in the application.

Question 57
What type of agreements do you require as 'proof' of solidity of the partnership? An MoU or contract? How do I prove I have a partnership?

Answer
There is no specific format but you have to provide a detailed description of the partnership, who the partners are, how long you have been working together on which activities etc. The partnership should however consist of at least one public and one private partner who cooperate on the basis of a contract. See Par IV (Product Development Partnerships within this policy framework)

Question 58
DGIS funding may not be used to fund past activities – does it need to be a complete new activity or can it build on prior product development work?

Answer
It cannot be the exact same activity that has been funded by DGIS in the past, but can build on previous work.

Question 59
Can PDPs hire subcontractors?

Answer
The PDP can enter in different relationships with its partners. The type of relationship should be clearly demonstrated in the proposal.

Questions & Answers

Product Development Partnerships III Fund

Version 2, May 19th 2015

Please see Page 13 and further for questions 1-6

Question 7
Is priority given to PDPs within Netherlands, meaning as the competition will be high, do you advise not applying when from Sweden?

Answer
There are no criteria linked to the country or origin of the PDP and therefore no priority will be given to PDPs from the Netherlands. The quality of the applications will prevail. Should the quality relating to one or more themes be assessed as inadequate according to the criteria specified in these administrative rules, the funds will be distributed among satisfactory applications relating to the other themes. (See par.VI-XI on assessment criteria)

Question 8
[…….] is non-for-profit and I am not sure we have all of the annexes mentioned, for example:

Checklist of annexes
- Liquidity forecast for each year of the entire activity period and a summary of other donors' financial contributions.
- Multiannual plan (summarising activities, objectives, results and expected effects) for the period to which the application refers, excluding the period already covered by the activity plan.
- Financial multiannual budget for the period to which the application refers, excluding the period already covered by the activity plan budget. The financial estimate must be itemised by type of expenditure.

Answer
All applicants, including not-for-profit, must include the documents mentioned in the checklist. The financial prognosis of the coming years is not linked to the fact if an organisation is a profit or not-for-profit. See also par XI: "The proposal demonstrates clear internal logic and consistency in terms of objectives, results, activities and resources and represents value for money (in terms of the relationship between costs (including procurement), activities and additional proceed". The documents mentioned above are necessary to assess this.

Question 9
SCOPE OF PROPOSAL: Please can you **clarify further what is meant by 'fundamental research'** (as mentioned in paragraph 3/page 8 of the translated Staatscourant 2015-198527-PDPIII 2015)?

Answer
The OECD defines basic research (or fundamental research) as experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view. (See definition here). The PDP III fund is explicitly not meant for fundamental research. The products that will be developed must have a practical application. (See par V. Scope)

Question 10
Linked to our question on 'fundamental research', we have a further request for clarification. In the Staatscourant (Section 1. Background/pages 3-4), it is mentioned that "*Activities can focus on individual stages of the product development process, or on closing gaps in the innovation cycle. With their portfolio approach to R&D and innovation...*". If the Ministry recognises this as being the role of PDPs and it is core to the call (as mentioned at different stages of the document), what do they include within the definition of 'innovation' as the cycle could also potentially cover fundamental research?

Answer
The PDP III fund is explicitly not meant for fundamental research. Products that are to be developed must have a practical application.

Question 11
SCOPE OF PROPOSAL regarding Intellectual Property. The Staatscourant states the following: "Clear agreements have also been made regarding the intellectual property of the products that will result from the partnership, aimed at making treatment and diagnostics affordable for the poorest population groups in developing countries". There was a similar clause in the previous grant agreement. Please can you provide any further clarification on the IP terms and conditions for potential PDP III grantees?

Answer
The PDP must determine which IP terms and conditions are important in their own field of work in order to ensure that the products eventually will be accessible and affordable for the target group. There are no restrictions from DGIS/RVO concerning the contents of those terms. Potential PDP grantees must demonstrate that IP terms and conditions guarantee accessibility and affordability of the to be developed products for the target group.

Question 12
SCOPE OF PROPOSAL: The application requires an 'Activity Plan detailing [the PDP's] objectives and intended results, how these are to be achieved, and the activities to be implemented in the first 12 months'. Is there a preferred format for the Activity Plan? And, would this also require the inclusion of relevant indicators and milestones for the full 5 year award period, not just the detail for the first 12 months?

Answer
There is no preferred format for the Activity plan. Preferably there is a clear link between the information in the activity plan and the information on the PDP Budget sheet.

Question 13
BUDGET/BUDGET TEMPLATE: Are there any additional guidance notes available for completing the budget?

Answer
No, there are no additional guidance notices available for the budget. Available notices can be found in the PDP Budget sheet, in par XIV (checklist of documents to be included with the application)

Question 14
The overall format suggests a requirement for the budget to be **highly activity-focused.** This is not consistent with our understanding from earlier BuZa feedback about delivering against strategic (end of 5 year) outputs i.e. focus on what we expect to accomplish by the end of the granting period).

Answer
The budget is not highly activity-focused. However, DGIS/RVO would need to understand what the PDP is planning to do with the funding in terms of objectives linked to different types of activities for at least the coming first year. For DGIS/RVO it is important to get an insight in the activities of the programme that will take place and for which funding is being sought from DGIS/RVO.

Question 15
Linked to this [budget] (and the Activity Plan/M&E question above), it would be helpful to understand the hierarchy from *Goal* down to *Activities* to ensure that we are correctly aligning the Year 1 Activity Plan to the budget. From the tender documents, we understand that at the highest level is the project **Goal**, which is achieved by delivering (a number of) **Results** areas (or, Strategic/end Outputs) which reflect the impact of the project. However, there is 'Results' level in the budget template but rather there are ***Objectives,*** *under which there are a number of* ***Activities***. Please can you provide an explanation of how we link Results to Objectives?

Answer
Please be informed that the budget sheet is not based on an M&E/logical framework. Consider it as a tool for acquiring insight in the activities of the programme that will take place and for which funding is being sought from DGIS/RVO.

Question 16
Can you provide **definitions** for each column in the Year 1 tab (i.e. starting with 'R&D preclinical', followed by clinical development phase I-IV etc.)?

Answer
Please see FDA's website for definitions:
www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm. If an activity does not fit within one of the definitions, use the column 'other'. If no clinical trials are involved it is possible to replace/add terms with ones that are more suitable, for example 'other 1', 'other 2' etc. accompanied with, for example, 1.feasibility, 2. optimisation 3. scaling up 4. validation for production 5. production

Question 17
Please can you confirm if there is a **% cap on 'overhead other'?** If there is, what is the maximum % allowed?

Answer
There is no set maximum on 'overhead other'. The information entered here is for acquiring clarity on the distribution of PDP funds. Grants shall be awarded solely to cover costs of the planned activities that are necessary in the light of the objectives and results envisaged, provided it cannot reasonably be expected

that such costs can be funded from the applicant's own resources or other resources (see article 14 of the Ministry of Foreign affairs Grants Decree), see also par.V scope.

Question 18

For defining ***'other funding'*:** if there is more than one i.e. multiple sources of funding against the same activity/theme, how detailed do we need to be i.e. break this down by every donor or can we categorise into total 'public' or 'private' sources?

Answer

There is no need to break this down by every donor. The funding can be categorised into a 'total'. Please include the names of the funding sources and preferably the type of funder as well: public/private, profit/ non-profit, academic etc.

Question 19

The budget template requires a detailed first 12 month budget and only a topline multi-annual budget for subsequent years. Will there be the same requirement as the previous award for PDPs to **submit annual Activity Plans plus detailed 12 month budgets** which are reviewed, discussed and subsequently approved by the Ministry on a per year basis?

Answer

Yes.

Question 20

Reporting cycles: Oct 1 2015 is published as the anticipated start date for the award(s). Will this mean that annual reporting cycles will follow this timeline – or will be re-aligned at some later date (e.g. Year 1) to follow calendar year cycles as with BuZa financial cycles?

Answer

To limit the burden of reporting, reporting cycles, templates etc. of other donors will be taken into account. This information will be included in the Administrative Decision.

Question 21

The Application Form contains a checklist of annexes and the first item listed is a **'Project Plan'.** However, this is not included in the list of annexes in the corresponding list in Staatscourant (section XIV). Is the Project Plan the same as the overall (15 page max.) application with the contents as listed on 'Instructions for Application'? If this is a separate requirement, what should the Project Plan cover vs. the Activity Plan vs. the proposal?

Answer

Please see the application form with the corresponding list of annexes: http://english.rvo.nl/sites/default/files/2015/04/Application%20Form%20Product%20Development%20Partnerships%20Fonds%20III.pdf. The Project Plan is the same as the application.

Question 22

If an application is deemed to be incomplete and where a supplement may be requested (ref. Staatscourant, section XII.), it states that the requested supplement must be submitted before the deadline. However, given the timing of the call this will not be a feasible turnaround. We are presuming that in this instance 'incomplete' means *missing* documentation, so if we comply with the requirements in the call, this should not be an issue. We also assume that it is at the discretion of MoFA to decide whether they still may request documentation, as they have done in the past. Please can you confirm if this interpretation is correct.

Answer

An application is incomplete if does not comply with the formal requirements mentioned in par XII. (Application procedure. DGIS/RVO can always request for clarification of the information provided but not for new/missing documents after the official deadline.)

Question 23
We understand from the call that the submission should be completed by email no larger than 10MB. However, this is likely to present challenges, given the number of annexes requested which include substantial supporting documents such as audit and annual reports. Therefore, please can you clarify how we should deal with annexes within this space limitation?

Answer
In case of documentation of more than 10 MB, please do send the documents in separate batches, mentioning clearly part 1, 2 etc.

Question 24
Could the MoFA please provide a more specific definition of 'public partner'? For example, could this include national ministries of health as implementing partners, parastatal organizations, government agency donors?

Answer
Public partner: these may be government or semi-government organisations (including research organisations). (see par IV). This includes national ministries of health, parastatal organizations and government agency donors. It is important to demonstrate that the mentioned partnerships are indeed true partnerships.

Question 25
Could the MoFA please provide examples of a 'semi-government organization'?

Answer
This could be a government or state agency, or state owned enterprises.

Question 26
How must the 'adequate risk management policy' be presented in the proposal? For example, should we include a formal risk matrix?

Answer
Yes, including formal risk matrix is a good option, as well as other means that identify, mitigate and present the risks.

Question 27
For PDPs without a legal personality, is there a set format for the partnership agreement required as Appendix 6?

Answer
No, there is no format for the partnership agreement.

Question 28
Should the liquidity forecast (Appendix 9) cover all of the anticipated contributions to the applicant organization during the 2015-2020 project period, or should it focus on the anticipated contributions for the scope of work presented in the proposal?

Answer
The applicant must demonstrate that, as of 1 January 2015, at least 25% of its annual income will derive from sources other than Ministry of Foreign Affairs contributions. (See par XIV). This applies to the total income of the applicant and not only on the scope of work presented in the proposal

Question 29
What are the specifications for the proposal regarding: page size (8"X 11" or A4), font type and size, margins, spacing?

Answer
There are no specifications for the proposal regarding page size, font type and size, margin or spacing. The specifications are as follows: applications for PDP III Fund grants should preferably not exceed 15 pages (excluding annexes). The application must be written in English and submitted using the table of contents provided for this purpose. It must include the documents listed in section XIV. (See par XII)

Question 30
The official notice for this grant opportunity makes several references to other Ministry of Foreign Affairs documents. Can you please provide links to these documents?

- Minister for Foreign Trade and Development Cooperation's current policy agendas, including on SRHR and 'from aid to trade', and to the neglected diseases roadmap of the 'life sciences and health top sector'. (Referenced on page 5)
- General Administrative Law Act (Referenced on page 7)
- Ministry of Foreign Affairs Grants Decree (Referenced on page 7)
- Ministry of Foreign Affairs Grant Regulations 2006 (Referenced on page 7)

Answer
Please find the links to the documents below:

- Minister for Foreign Trade and Development Cooperation's current policy agenda's: http://www.government.nl/issues/development-cooperation/documents-and-publications/reports/2013/04/30/a-world-to-gain.html
- the neglected diseases roadmap of the 'life sciences and health top sector': www.zonmw.nl/nl/themas/thema-detail/topsector-life-sciences-health/neglected-diseases/
- General Administrative Law Act: www.rijksoverheid.nl/documenten-en-publicaties/besluiten/2009/10/01/general-administrative-law-act-text-per-1-october-2009-wordversie.html
- Ministry of Foreign Affairs Grants Decree: the Dutch version can be obtained, please send a request to PDP@rvo.nl
- Ministry of Foreign Affairs Grant Regulations 2006: the Dutch version can be obtained, please send a request to PDP@rvo.nl

Question 31
Can you please set and state a percent limit on overhead? Is equipment considered a direct cost on which applicants can take overhead?

Answer
There is no set percent limit for the overhead. Equipment is considered as a direct cost.

Question 32

For applicants who are successful and receive funding, will there be a specified reporting template? If a recipient has received previous PDP funding from the Ministry of Foreign Affairs, may the recipient plan to continue using their same reporting template?

Answer
To limit the burden of reporting, reporting cycles, templates etc. of other donors will be taken into account. This information will be included in the Administrative Decision.

Question 33
Is having a partner in a developing country considered as a threshold criterion?

Answer
No.

Question 34
Is it an asset if we involve partners of more than 1 developing country?

Answer
Yes. One of the objectives of the funds is "Increased involvement and active participation of developing countries in product development partnerships." (See par III, page 6 and IX 3). However, it is not a recipe for success.

Question 34
Would it be an asset if we provide evidence of collaborative projects with EDCTP and/or Topsector Life Sciences and Health?

Answer
Please feel free to provide evidence of collaborative projects with EDCTP and/or Topsector Life Sciences and Health. It is an asset if the proposal is (more) relevant to the objectives of the fund (see IX 2). However, it is not a guarantee for success.

Question 35
The RFP mentions a specific description of the format of the application (15-page document). At the same time on the RVO international website, a specific application form (interactive pdf) is mentioned. How are the two documents related?

Answer
The two documents are both to be included in the application package. The interactive Application Form includes basic information on the applicant and the application but is NOT part of the proposal. The proposal should be a 15-page document, excluding the annexes.

Question 36
Are in kind donations of private partners/donors considered as eligible or are only cash contributions by private partners/donors considered eligible?

Answer
In kind contributions are eligible, however, see VII. 7 : the PDP should be financed by more than one donor (can be different types) and VII. 5 the PDP cooperates with at least one public and one private donor.

Questions & Answers

Product Development Partnerships III Fund

Version 1, May 12th 2015

Question 1a
In the (attached) document "Translation Staatscourant …" under "VIII. Threshold criteria for applications" it is written:
6. Under article 9 of the Ministry of Foreign Affairs Grants Decree, a grant will be refused if the application is submitted after the activities have started. For the record, it should be noted that a grant will not be refused if preparatory project activities are carried out before submission of the application, but the costs of such activities will not be covered by the grant.
7. If a grant is sought for an existing product development line, or for (part of) a product development line for which a grant was previously awarded, the activities for which a PDP III grant is sought must concern a clearly defined part of the product development line that is clearly distinguishable (in terms of type or phase) from the previously launched and/or funded part of the product development line.

In previous meetings, the evaluation of the PDPs and other exchanges the Ministry of Foreign Affairs expressed that it intended to provide flexible funding for the overall discovery and research portfolio of a PDP that was selected for a grant. With the long program horizons and attrition risk associated with R&D in new drugs, vaccines and diagnostics the above criteria, that is in our opinion the best approach.
Could you clarify that ongoing research efforts, whether in discovery, early or late stage clinical research (phases 1-4) can be presented in an overall organization development plan and that, obviously without any retro-active funding being allowed, DGIS/RVO is ok to start co-investing grant funds with other donors in ongoing activities after a contract would be awarded and signed. More concretely, would we for instance be able to propose in our application to DGIS/RVO co-funding to promising late stage (for instance phase IIb or phase III) research, even if the trial has started already, but will continue adding sites and recruiting patients for a number of years to come?

Answer
Ongoing research efforts, whether in discovery, early or late stage clinical research (phases 1-4) can indeed be presented in an overall organization development plan for at least the coming first year. For DGIS/RVO it is important to get an insight in the activities of the programme that will take place and for which funding is being sought from DGIS/RVO. When the contract is being awarded by DGIS/RVO it will be possible to adjust the activities but only in consultation with DGIS/RVO and after approval has been given by DGIS/RVO for the changes.
In regard to the last sentence of the question this is related to co-financing of the late stage research, even if the trial has started already. Please be informed that the co-funding from the Dutch government needs to deliver added value in the relevant phase of the R&D and innovation chain. The proposal must demonstrate that there is a funding need.(see also article 6 under par. IX).
DGIS/RVO accepts co-funding for existing activities but cannot and will not accept retrospective funding nor funding for activities that have been previously financed with MoFA funds. This is a strictly legal condition and the applicant has to make sufficiently clear that this is not the case in relation to their application.

Question 1b
If DGIS/RVO is looking for flexible overall support as I believe is the intent, could you confirm you would like the attached format to be used for the overall organizational budget, clearly marking the contribution of DGIS/RVO as a percentage of the total. If the intent is to provide flexible funding on an organizational level it would be more logical to only show the total contribution of DGIS/RVO as part of the overall organizational budget and not for each activity. Could you clarify the specific requirements.

Answer
DGIS/RVO indeed would like to support the selected PDP's in the most flexible way possible. However, DGIS/RVO is not able to provide ' institutional ' support (core funding). We would therefore like to

understand what the PDP is planning to do with the funding in terms of objectives linked to different types of activities (but not necessarily on the project level). For some PDP's this may concern their whole portfolio, for others just a part of it. There will be flexibility in the sense that changes may be made along the way, but in consultation with DGIS/RVO and only after approval. The application should provide sufficient information to understand what the PDP intends to do with the DGIS/RVO funding in relation to its total portfolio and what other funders are contribution to this (part of the) portfolio.

Question 1c
If the budget is represented on organizational level, the participation of DGIS/RVO in the overhead is equal to everyone else's and DGIS/RVO will be able to see our efficiency ratio as an organization. However, if DGIS/RVO wants to see specific programs and activities funded by DGIS/RVO as seems to be indicated in the paragraph and article numbers referred to above, it would be important to hear how much indirect cost DGIS/RVO will allow on top of direct program activities. As mentioned we would recommend an overall portfolio approach and for DGIS/RVO to request an overall organizational budget (the attached budget sheet could accommodate this) but if the choice is for a more classical program/activity based funding the additional requirements for the budget need to be more specific. This would also include the question of whether each activity needs to be co-funded for at least 75% by other funders than DGIS/RVO or whether DGIS/RVO would fund 100% of an activity as long as the overall organizational budget would remain less than 25% funded by DGIS/RVO.

Answer
See also above. DGIS/RVO prefers an overall portfolio approach with an overall organizational budget. There is no need to indicate the co-funding per activity level. The budget sheet facilitates room for clarification if available.

Question 1d
Under section XIV, I notice that RVO requests "2. Annual reports and financial statements of the applicant organisation for 2012 to 2014 inclusive.". In many countries, including the Netherlands, the legal deadline for preparing an annual audit has not passed and for a relatively small non-profit it is not practically feasible to have an audit fully completed by May. Therefore, and because a separate request is made for "3. Most recent auditor's report and management letter relating to the applicant." I assume it is acceptable for this latter one to be for the calendar year 2013 and the 2014 annual report to be the PDP funders report (as shared with DFID, DFAT etc) and the financial report for 2014 to be (as yet) unaudited. By the time of contracting we can have the 2014 annual audit completed.

Answer
For DGIS/RVO it is acceptable, when annual reports and financial statements for 2014 are not yet available to submit the PDP funders report and the unaudited financial report for 2014. The audited annual report for 2014 will then need to be submitted by the time of contracting.

Question 1e
Finally, the restriction on number of pages (15) is we assume for the main application text and does not include the annexes like the annual reports.

Answer
This is correct. The 15 pages relate to the main application and should touch upon all listed topics in the table of contents. The applicant may wish to add annexes to explain (parts of) the proposal in more detail. Please make sure clear references are made in the main text and the annexes to the different parts of the table of contents and related assessment criteria. We do not welcome general descriptions, publications or documentation.

Question 2

Does it make sense to submit an application that is focused on the market introduction of a product that has been developed yet? With other words, de application only related to the last phase of the product development cycle, or is this too narrow?

Answer

We do acknowledge that it is not made explicit that market introduction of a product is perceived here as part of the product development process. Please note however that commercial activities will not be funded. Whether the market introduction will be funded depends on how well the proposal fits the criteria, amongst which the criteria on the added value of the potential government investment and demonstration of a funding need/gap (i.e. insufficient interest and investment from the private sector despite a significant disease burden and applicability of this specific product)

Please see the Policy Rules, page 8 under *R&D and innovation, par. V: Which phases in the product development cycle: 'There are no restrictions on supporting specific phases in the product development cycle. The products that will be developed must have a practical application: the fund is explicitly not meant for fundamental research. In the proposal the applicant must make clear what the added value is of the potential investment in the envisaged phase of the R&D and innovation chain, and the impossibility, despite the potential major impact, of attracting sufficient funding for product development without public investment'.*

See also article 6 of par. XI assessment criteria concerning the quality of the application:

Public investment by the Dutch government (i.e the grant requested from the Minister) delivers added value in the relevant phases of the R&D and innovation chain. The proposal adequately demonstrates that there is a funding need and/or a funding gap. This means that the proposed products are intended for people in countries where there is a significant disease burden and an acute need for R&D and innovation and for public funding.

Question 3

Is it permissible for our organization to submit more than one proposal to the PDP III Fund from different "PDP" teams we manage to implement separate and independent PDPs?

Would the PDP III consider funding both applications if they are compliant and successful?

Answer

This is possible. However, there can only be one applicant/grant recipient per partnership, see also par. IV, C.

Question 4

Could you let us know what is the overhead applied in this call for proposal?

Answer

Grants shall be awarded solely to cover costs of the planned activities that are necessary in the light of the objectives and results envisaged, provided it cannot reasonably be expected that such costs can be funded from the applicant's own resources or other resources (see article 14 of the Ministry of Foreign affairs Grants Decree), see also par.V scope.

Question 5

Is it necessary to have the manufacturing partner based in the Netherlands?

Answer

No it is not necessary to have the manufacturing partner to be based in the Netherlands

Question 6

What exactly is meant with the following sentences under par. XII:

"With regard to the application procedure, particular attention is drawn to article 7, paragraph 3 of the Ministry of Foreign Affairs Grants Decree. If an incomplete application is submitted, the Minister may request a supplement. In this case, the date of receipt of the application will be the date on which the application was supplemented. If the application is submitted less than two weeks before the deadline, the lead party runs the risk that, if it is incomplete, the Minister will not use her discretionary powers to request a supplement because it cannot be submitted before the deadline. In that case, the application would have to be assessed as it stands''.

Answer
Please be informed that the above is applicable for incomplete applications. If an application is incomplete and submitted two weeks before the official deadline DGIS/RVO can request for a supplement. This is not related to content information but only related to the formal requirements, see also par XII. Application procedure.

Information session
Please be informed that the information session will be held on Friday 22nd May at RVO, Prinses Beatrixlaan 2, The Hague, registration 14:30, start 15:00 till 17:00. Please use PDP@rvo.nl for registration.

For more information on the PDP III, please look at the Policy rules published on the website: http://english.rvo.nl/subsidies-programmes/how-apply-pdp-iii