

## **Call for submission of pre-proposals**

### **1. More Knowledge with Fewer Animals programme (MKMD) – Life Sciences & Health Module – ‘PPP for 3R Research’ call**

Deadline: **6 February 2013**

Keywords: alternatives to animal testing, public-private partnership, LSH Topsector

Issued on: 15 November 2012

### **2. Goal and background**

#### *Background to MKMD programme*

With its ‘More Knowledge with Fewer Animals’ programme (known by the Dutch acronym MKMD), ZonMw hopes to accelerate developments in the ‘3R Alternatives’: Replacement, Reduction and Refinement of animal testing. The programme has several modules. The Life Sciences & Health module (LSH) focuses on 3R research in public-private partnership. This module will primarily consist of calls for projects related to the LSH Topsector and LSH Plaza. For background information on the MKMD programme and the Life Sciences & Health module, see the programme website, [www.zonmw.nl/mkmd](http://www.zonmw.nl/mkmd).

#### *Goal of the call*

- *Development* of innovative 3R methods
- *Application* of new and existing 3R methods

#### *Research area covered by the call*

The research area concerns the ‘development of medicines for human use’ (Alternatives to Animal Testing Programming Study), since this ties in closely with the LSH Topsector.

#### *Preparations for application*

Given the fact that it can take some time for several public and private partners to form a consortium, this call has a longer deadline than normal for the submission of applications.

NB: In this call, a Dutch or international company, fund or non-profit foundation will be regarded as a private partner.

### 3. Conditions

#### 3.1 Conditions pertaining to projects

Applications must comply with the following conditions:

- The research must tie in with at least one of the ‘roadmaps’ of the Life Sciences & Health Topsector; see [www.top-sectoren.nl/lifesciences](http://www.top-sectoren.nl/lifesciences) (in Dutch only).
- The research must fall within the knowledge domain ‘development of medicines for human use’; see Alternatives to Animal Testing Programming Study.
- The project must be based on national or international public-private partnership, in a broad-based strategic consortium.
- Projects must cover at least two phases of the Research – Development – Pre-validation – Validation chain. Projects in the phases Research and Development should at any rate include clarification of biological mechanisms associated with diseases.
- Regulators must be involved in the project from the outset. The project proposal should set out how this is to be achieved.
- The research should focus on Replacement, Reduction and/or Refinement of animal testing.
- The project proposal should set out work packages with specified deliverables that are delivered at the end of each phase.
- The project proposal should set out arguments for the project’s impact on the 3Rs. It should include an implementation plan for application of the research results after completion of the project.
- If the grant application is successful, a supervisory committee will be established to advise the consortium of public and private partners on the progress of the project, based on progress reports and deliverables defined in the grant application. During the project, the supervisory committee may meet with the project group on several occasions, and at least after each phase of the project is completed.
- Every project will be co-funded: besides the ZonMw grant, matched funding will be provided by the private partner(s) in the consortium. The ZonMw contribution will be no more than 50% and the contribution from the private partner(s) must be at least 50% of the total. At least 10/50 of the funding provided by the private partner(s), in other words 10% of the *total* funding, must be in cash.
  - *Example:* the total funding for a project is € 400,000. In this case, ZonMw will contribute no more than € 200,000 (50% of the total), and the matched funding must be at least € 200,000, of which at least € 40,000 must be in cash (10/50 of the

matched funding). The other € 160,000 (40/50 of the matched funding) may be provided in kind.

- If extra resources become available from the Life Sciences & Health Topsector, any additional TKI funding will be based only on the cash contribution from the companies to the research institution, as described in the Top Knowledge and Innovation Consortia additional funding scheme (*TKI-toeslag regeling, Staatscourant* 4 September 2012).
- Within six months of the grant being awarded, the partners in the consortium must sign a consortium agreement specifying, among other things, how intellectual property based on project results is to be dealt with. The institution that employs the project leader will be responsible for ensuring an intellectual property agreement is put in place. As a rule, the institution's Technology Transfer Office will generally draw up a suitable agreement. ZonMw will order the start of the project as soon as it has received and approved the consortium agreement and intellectual property agreement.
- ZonMw will be unable to provide funding for any public or private partner outside the Netherlands participating in the project.

### **3.2 Criteria for matched funding 'in kind'**

Part of the research may be conducted by third parties. Matched funding in kind will be accepted only on condition that it is an integral part of the work plan and can be identified and monitored as such; guidance and consultancy are expressly excluded. Capitalised in kind contributions specified in the budget must be supported by a letter of intent from the private partner committing the matched funding and specifying the amount to be provided.

When it comes to staff support from third parties, ZonMw will apply fixed rates for the capitalisation of the number of man hours supplied (up to a maximum of 1250 direct hours/year/FTE) of € 116 per hour for a senior researcher, applicable to all staff with a university degree and € 81 per hour for a junior researcher, applicable to all staff with another higher degree (HBO). This on condition that the expertise supplied in the form of man hours is used specifically for the MKMD project and is not already available at the research institution(s). The hours worked by these staff will also have to be recorded. The input (hours) and output (envisaged results) of the staff support for each task or work package will have to be described in the application.

Cost price will be calculated for the material resources committed to the project; commercial rates will not be accepted. When equipment has been committed to the project, applicants should take account of past depreciation and the intensity of use.

*Inadmissible* as matched funding:

- ZonMw will be guarding against improper mixing with direct and indirect (NWO, KNAW, ZonMw) government funding. In this call, matched funding may not therefore be provided by the research institution that employs the applicant or co-applicants, or from institutions that may themselves independently apply for ZonMw funding.
- Discounts on prices (commercial or otherwise) for material, equipment, services etc.
- Overheads and costs of guidance and/or consultancy.
- Conditional costs of services. No conditions may be set regarding the delivery of matched funding, nor may it be made dependent on reaching a certain stage in the research plan (e.g. go/no-go point).

### **3.3 Policy on intellectual property**

If one of the partners in a project subsidised by ZonMw is a commercial party, agreements must be made concerning ownership of intellectual property such as the knowledge and products developed during the project. ZonMw's grant terms and conditions are applicable to subsidised projects, and in this call ZonMw has based its policy on intellectual property on the principle of 'ownership follows inventorship'. In compliance with the Framework Scheme for Research, Development and Innovation (*O&O&I-kaderregeling*; specifically article 3.3.2) and the Top Knowledge and Innovation Consortia additional funding scheme (*TKI-toeslag regeling*, *Staatscourant* 4 September 2012) intellectual property agreements must guarantee that:

- The results of collaborative projects from which intellectual property rights may be derived may be widely disseminated, and any intellectual property rights ensuing from the activities of the public partner(s) are awarded in full to the public partner(s).
- The public partner(s) receive remuneration from the private partner(s) in accordance with the market price for any intellectual property rights ensuing from the collaborative project that are transferred to the private partner(s). Any contribution by the private partner(s) to the costs incurred by the public partner(s) will be deducted from the compensation.

### **3.4 Who is eligible to apply?**

The call is open to researchers in the public and private sectors. Dutch research institutes include the Netherlands' research universities, universities of applied science (HBO) and University Medical Centres, NWO and Royal Netherlands Academy of Arts and Sciences (KNAW) institutes, the Netherlands Cancer Institute, the National Institute of Public Health and the Environment (RIVM) and TNO. Dutch research institutes must meet the following criteria: the institute must be based in the Netherlands; the institute must have the task of conducting independent research; the institute must be not-for-profit; researchers must be free to publish in the international academic literature.

A public-private partnership may consist of a consortium of several public and private partners. In the public-private partnership a public partner will supply the project leader (also the main applicant), who will liaise with ZonMw throughout the procedure. All the other partners (public and private) are co-applicants. The call is open to co-applicants from institutes and companies both in the Netherlands and in other countries.

In the context of this programme, public-private partnership is defined as: a long-term arrangement whereby one or more research institutions collaborate(s) on a project with one or more private partners, each party retaining its own identity and responsibility, and working on the basis of a clear and appropriate allocation of tasks and risks.

ZonMw requires that grant applications must not give rise to state aid of which the European Commission must be notified. The document 'Background Information on Rules Pertaining to State Aid' (see 5.1 Downloads, only available in Dutch) explains how this condition must be met. NB: it is the responsibility of the applicant to explain in the application how this condition has been met.

The ZonMw Grant Terms and Conditions 2009 and ZonMw Procedures 2002 are applicable (see 5.1 Downloads).

### **3.5 Funding available**

A total of € 1,854,000 is available for the call. ZonMw will contribute a minimum of €200,000 and a maximum of € 500,000 to each project. The resources provided may be used to pay for academic and non-academic staff. Part of the budget may also be used for consumables and small equipment required specifically for the project. Projects may last no longer than four years.

Formats for budget breakdowns are available on the ZonMw website (see 5.1 Downloads).

In the event that the application is successful, the grant will be paid to the institute for which the main applicant works; the main applicant will also be responsible for any allocation of financial resources to the partners.

#### **4. Assessment procedure**

Grants will be awarded on the basis of pre-selection of preliminary applications, followed by a final assessment of full applications.

##### **4.1 Scientific criteria**

Applications will be assessed for their relevance and quality, in accordance with the standard ZonMw procedure (see 5.1 Downloads).

##### *Relevance*

The proposed project:

- should be consistent with the objectives of the Life Sciences & Health module
- should comply with the conditions set out at 3.1
- should have added value thanks to collaboration on a national or international basis in a consortium of public and private partners

##### *Quality*

Project proposals will be assessed on the basis of:

- innovative nature, clarity and scientific quality:
  - originality and innovative nature of the proposed research
  - clarity of the research question and the proposed research
  - scientific quality of the proposed research
- suitability of the action plan:
  - feasibility of the project and completion of the proposed research within the planned duration
  - concrete step-by-step plan, including allocation of tasks, milestones and deliverables
  - effectiveness of the approach chosen
  - soundness of the budget
- academic standard and expertise of the project group:

- academic excellence, demonstrated by academic publications, grants and prizes awarded, training, mobility and supervision of staff
- plan for implementation of research results:
  - step-by-step plan for communication on and implementation of the results, both during and after the project
  - experience of implementation and involvement of professional support for implementation

### Concise background information on the assessment of relevance and quality

In the pre-proposal phase, the emphasis is on the assessment of relevance, while quality will be less rigorously assessed. The committee will also consider the potential for disseminating and implementing project results in its assessment of the pre-proposal. To be invited to submit a full application, a pre-proposal should at least be judged as Relevant; ZonMw aims to achieve a three to one ratio of full applications to grants awarded.

At the full application stage the emphasis is again on assessing relevance, but quality is assessed in more detail than in the pre-proposal. The committee will rank the applications on the basis of their assessment of relevance and quality using the matrix below. Applications must achieve at least 'relevant' and 'very good' to be eligible for a grant. The committee will make recommendations to ZonMw based on the full application, the reviewers' reports and the applicant's rebuttal. ZonMw will take the final decision on the grant applications.

		RELEVANCE		
		Highly relevant	Relevant	Not relevant
<b>QUALITY</b>	Excellent	<b>1</b>	<b>3</b>	-
	Very good	<b>2</b>	<b>4</b>	-
	Good	-	-	-
	Satisfactory	-	-	-
	Unsatisfactory	-	-	-

### **4.2 Procedural criteria**

- All applications must be written in English.
- 5% of the project budget must be reserved for communication and implementation. Include this in your breakdown.
- Pre-proposals/grant applications must comply with the ZonMw Grant Terms and Conditions. Information on grant terms and conditions, METC/DEC ethics committee certificates, Population Screening Act (*Wet op het bevolkingsonderzoek*) licences, the Animal

Experiments Disclosure Code (*code Openbaarheid Dierproeven*) and the Biosecurity Code of Conduct (*gedragscode Biosecurity*) is available under 5.1 Downloads.

### **Preliminary-proposal**

- Except for the preliminary application form, biosketches and letters of intent from private partners, no extra attachments will be accepted.
  - The biosketch is to allow better assessment of the expertise of the project leader and research group. No more than 2 x A4 (single-sided) per person. A document format is available on the MKMD website.
  - A letter of intent from a private partner or partners to participate in the project (at the applicant's discretion).

### **Full grant application**

- The project leader must submit the following attachments with the full application:
  - An itemised budget, in which the ZonMw contribution may not exceed € 500,000.
  - A letter of support committing matched funding and specifying the amount to be contributed by the private partner(s).
  - Biosketch, to allow better assessment of the expertise of the project leader and research group. No more than 2 x A4 (single-sided) per person. A document format is available on the MKMD website.
  - An implementation plan: a step-by-step plan and standard format are available via the ZonMw website (see 5.1 Downloads).

Applicants may also include an optional attachment of no more than 2 x A4 containing figures and tables. No other attachments will be considered in the assessment of the application.

### **In the event that a grant is awarded**

In the event that a grant is awarded, ZonMw expects project leaders to:

- submit a progress report (mid-term) and a final report on the project.
- prior to the start of the project (and within six months of the grant being awarded), sign a consortium agreement with all partners, setting out both arrangements concerning work and intellectual property rights. The institution's Technology Transfer Office (TTO) should be able to provide expert help on this.



- where the research involves animal testing, to conduct a ‘synthesis of evidence’ based on the literature available at the start of the project, with the aim of justifying the design of the research (e.g. the choice of model and implementation of 3Rs). The synthesis of evidence is similar to a systematic review, applied to research based on animal testing. The synthesis of evidence is described in further detail in the MKMD Amendment 21 module.
- publish all project results, even ‘negative results’ (no effect found). Funding options for publication are described in the Amendment 21 module (see 5.1 Downloads).
- comply with ZonMw’s and NWO’s Open Access policy in the event of publication:
  - *Golden Road*: publish in Open Access peer-reviewed scientific journals. If a peer-reviewed scientific journal is not Open Access, or not entirely Open Access, Open Access publication can be redeemed. MKMD project leaders will be encouraged to use NWO’s incentive fund for Open Access publications.
  - *Green Road* (in disciplines and sub-disciplines where Golden Road is not yet possible): publications/pre-publications must be deposited in a public database, such as a repository for the researcher’s own discipline or university.
- ensure that the hours worked by staff supplied by third parties are registered.

### 4.3 Procedure and timetable

For details of the procedures for assessing applications, the reader is referred to the ‘ZonMw Procedures’ booklet (see 5.1 Downloads).

#### Intended timetable<sup>1</sup>

Deadline for submission of pre-proposal	6 February 2013
Committee recommendations received	late April/early May 2013
Deadline for submission of grant application	26 June 2013
Reviewers’ comments received	late July/early August 2013
Deadline for submission of rebuttal	20 August 2012
Decision	late October 2013
Projects must start by	1 May 2014

<sup>1</sup>Please note: this timetable is subject to change.

## 5. Further information

### 5.1 Downloads

- [General programme document for More Knowledge with Fewer Animals programme](#) (only available in Dutch)
- Life Sciences & Health Module programme document (available shortly in English)
- [Background Information on Rules Pertaining to State Aid](#) (only available in Dutch)
- [ZonMw Grant Terms and Condition 2009](#)
- [ZonMw Procedures 2002](#) (only available in Dutch)
- [Animal Experiments Disclosure Code](#) (*code Openbaarheid Dierproeven*, only available in Dutch)
- [Biosecurity Code of Conduct](#) (*gedragscode Biosecurity*, only available in Dutch)
- [Link to information on METC/DEC ethics committee certificates, Population Screening Act \(Wet op het bevolkingsonderzoek\) licences](#) (only available in Dutch)
- [Programmeringsstudie Alternatieven voor Dierproeven-deel 1](#) (only available in Dutch)
- [Programmeringsstudie Alternatieven voor Dierproeven-deel 2](#) (only available in Dutch)
- [Biosketch](#)
- [Implementation plan tips](#) (only available in Dutch)

### 5.2 Questions

For questions on procedure, please contact the programme office: Corina van Duin, secretary, tel. +31 (0)70 349 5209, email: [duin@zonmw.nl](mailto:duin@zonmw.nl)

For questions on content, please contact:

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### 5.3 Technical questions

If you experience any problems with ProjectNet you may telephone the helpdesk from Monday to Friday, 08.00-17.00, on +31 (0)70 349 5178 or mail them at [projectnet@zonmw.nl](mailto:projectnet@zonmw.nl). Please include your telephone number so that our support staff can call you if necessary.

## **6. Submission (via ProjectNet)**

All applications must be submitted online, and in accordance with the guidelines, via ZonMw's ProjectNet system. The **deadline for the submission of pre-proposals is 6 February 2013, at 15.00.**

Immediately after submitting your application online, you should print out a final PDF which should then be signed by the person with administrative responsibility and the project leader and secretary, and sent to ZonMw, attn. Corina van Duin, Postbus 93245, 2509 AE Den Haag, the Netherlands. Please ensure ZonMw receives the print-out within one week of online submission.

### **ProjectNet tips**

- If you have never worked with ProjectNet before, you will first need to register as a new user. Click on the guide to make an account.
- You are advised, before submitting your application online, to print out a PDF of your application and check it for any irregularities. If you have first produced your application as a Word document and then copied it to ProjectNet, you may find that some symbols (such as quotation marks) have not been converted properly. This cannot be corrected in ProjectNet.