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ANNEX 1

ANNEX

to the

COMMISSION DECISION

on the adoption of a financing decision for 2015 for the pilot project "The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes

ANNEX

Pilot project "The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes"

1.1. Introduction

On the basis of the objectives given in the budget remarks this work programme contains the actions to be financed and the budget breakdown for year 2015 as follows:

For grants (implemented under direct management (1.2): EUR 1.000.000

1.2. Grants

1.2.1. Pilot Project "The effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on health Expenditure and Patient Outcomes"

LEGAL BASIS

Pilot project within the meaning of Article 54(2) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

BUDGET LINE

17 03 77 16

Priorities, objectives pursued and expected results

This pilot project will compare, from a micro- and macro-economic perspective, the various treatment modalities for Chronic Kidney Diseases (CKD) in EU Member States and associated countries) by investigating the factors that influence the treatment choice (by patient or doctor) and the impact of that choice on healthcare budgets. In addition, the project will examine obstacles to improving kidney donation and transplantation rates. It will answer the question: "Why is there such an enormous variability in practice in the overall management of CKD and access to transplantation in Europe, and how could these practices be aligned in order to ensure equal and better patient access to all treatment modalities and quality of care while reducing costs?" The first overall project goal, to be implemented via one work package, is to provide an overview of the different treatment modalities and the factors that influence the selection of those modalities in Member States and associated countries, with a view to aligning end-stage kidney disease treatments and improving the availability of transplantation across Member States, while at the same time reducing healthcare costs and improving the quality of care, and patient survival and quality of life. To build upon the first overall objective in the field of kidney chronic diseases and more specifically for the transplantation options (deceased donation and living donation being considered), a second overall objective of the project is to support Member States' efforts in

putting in place operational tools (registers) to follow-up living donors and transplanted patients, based on the experience learned and recommendations formulated by previous EU-funded projects. This second overall objective will be implemented via two work packages, one being dedicated to the follow-up of living donors, the other one being focused on the follow-up of transplanted patients. These two work packages will contribute to ensure the quality and safety aspects required by EU legislation in the field, and hence the protection of donors and patients, but they will also be beneficial for the transplant community as a whole, as learnings from such registers will enable to propose better indications for (future) patients on transplant waiting lists.

It is expected that some of the Member States participating in the project will be able to use it as a stepping stone towards successful implementation of EU policies and legislation in the field of chronic diseases and organ transplantation, in particular of the Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (e.g. Articles 15, 16 and 17, Recitals 23 and 24 and of the EU Action Plan on Organ Donation and Transplantation (e.g. Priority Action (PA) 3 on living donation programmes, PA 6 on organisational models of organ donation and transplantation in the EU Member States and PA 9 on evaluation of post-transplant results).

Description of the activities to be funded under the call for proposals

The pilot project will be implemented by a call for proposals.

The project will be articulated in two steps and along three work packages (WP). It is foreseen to implement one work package for the first step and two work packages for the second one.

(1) The first phase will be a study (Work package 1, WP 1) to assess what are the different treatment modalities for chronic kidney diseases (haemodialysis, peritoneal dialysis, transplantation from deceased donors and living donors, conservative management) currently in the different EU Member States and associated countries (a.o. Iceland, Norway, Liechtenstein, Turkey and Switzerland), the frequency of choice of each of the available options, the factors influencing the treatment choice by patients and doctors, the eventual impact in terms of health and their financial impact from an economic perspective (micro-economics to understand per patient how much money is spent or has to be spent and could potentially be saved or spent in a different manner; and macro-economic to compare the cost and savings of the different options). This Work Package should be built in part upon the information already available, for example in the ERA-EDTA Registry and other European and national databases, and should support Member States efforts to systematically organise data collection on this topic, also after the end of the project, in order to be able to continuously monitor over time health results and economic impact of the options chosen and changes implemented.

Transplantation, in particular from living donors, is often considered to be the best therapy available for kidney failure. The second phase of this project will concern the implementation of concrete tools to improve both the protection of living donors and the results of transplantation, in line with the Directive 2010/53/EU and the EU Action Plan on Organ Donation & Transplantation. This second phase will be implemented within two work packages:

(2) Work package 2 (WP 2) will support the establishment by EU Member States of registries to follow-up kidney and liver* living donors, in line with Article 15 of

Directive 2010/53/EU. This WP will support MS in building up their national systems to follow-up living donors, and for Member States interested, in the development and implementation of a common, supranational tool to share their data. This WP should build upon results of previous and on-going EU-funded projects (EULID, ELIPSY, WP4 within the Joint Action ACCORD, POSAT, COPE, DIREKT, Kidney Injury, Technology, OLDIAS and SCOPE) and also take into account professional associations (e.g. ESOT, kidney-oriented associations) and tools and networks already available such as in the ERA-EDTA registries. Sustainability of this WP after the end of the project should be taken into account from the beginning of the project and ensured after the end of the project even without further EU funding.

[* the project is originally focused on kidney diseases. Organ living donation is available at large scales both for kidney and liver transplant procedures. The largest numbers of living donors are kidney donors, however it is asked to take into account in this project also liver donors, as their follow-up is important and as methodologies and data set were already produced and made available for liver donors.]

(3) Work package 3 (WP3) will support the establishment of follow-up registers for transplant recipients: a minima at national levels (supporting national efforts) and possibly at European level if Member States confirm the need of having a common tool (e.g. in a European meeting of National Competent Authorities in 2015). This WP should be based on methodologies already developed and recommendations already formulated, for example in the EU-funded EFRETOS project, and should take into account experiences with already existing registries such as the ERA-EDTA and ELTR. Here also sustainability of this WP after the end of the project should be taken into account from the beginning of the project and ensured after the end of the project even without further EU funding.

In each of the three work packages it must be ensured, for a high added value and wide implementation at EU level and beyond, that not only healthcare professionals and the scientific community implement the actions, but that national competent authorities and delegated bodies (established in a European network via Article 19 of Directive 2010/53/EU) are involved in the participating countries, in order to ensure that results of the project are relevant and implemented at national level in each country.

Results of the three work packages must include involvement of and promotion activities addressed to healthcare professionals in order to make them use/fill out the registries (user-friendliness and user-feedback/learnings will be key success factors) as well as concrete plans on how to implement and maintain the registers in the long term, after the end the project. These results shall include proposals for governance and concrete options to be decided upon and implemented at the end of the project.

Essential eligibility, selection and award criteria

ADMISSIBILITY, EXCLUSION AND ELIGIBILITY CRITERIA

Admissibility criteria:

Proposals received after the deadline for submission laid down in the call for proposals will not be considered for funding. Other formal requirements regarding the grant application will be specified in the call for proposals.

Eligibility criteria:

Proposals must be submitted by consortia of legal entities (with or without legal personality) established in at least five different EU Member States. Actions that have already commenced by the date on which the grant application is registered will be excluded from participation.

SELECTION CRITERIA

Only proposals which meet the admissibility, exclusion and eligibility criteria will be admitted to evaluation and therefore further evaluated. The following selection criteria have to be met.

1. Financial capacity:

   Applicants must have stable and sufficient sources of funding to maintain their activity throughout the period during which the activity is being carried out and to participate in its co-financing.

   The verification of financial capacity will not apply to public bodies and international public organisations.

2. Operational capacity

   Applicants must have the professional resources, competences and qualifications required to complete the proposed action.

AWARD CRITERIA

Only projects which meet the admissibility, exclusion and eligibility criteria as well as the selection criteria will be further evaluated on the basis of the following award criteria:

1. Policy and contextual relevance (40 points, threshold: 20 points):

(a) Project's contribution to meeting the objectives and priorities defined in the financing decision (8 points);

(b) Strategic relevance with regard to the EU activities in the field of chronic kidney diseases and organ transplantation such as Directive 2010/53/EU and to the EU Action Plan on Organ Donation & Transplantation, also with regards to expected contribution to existing knowledge and implications for health (8 points);

(c) Added value at EU level in the field of public health (8 points):

- impact on target groups (health authorities, healthcare professionals and patients), long-term effect and potential multiplier effect, such as replicable, transferable and sustainable activities,
- contribution to complementarity, synergy and compatibility with relevant EU policies, programmes and specific EU-funded projects;

(d) Pertinence of geographical coverage (8 points):

Applicants must ensure that the geographical coverage of the project is commensurate with its objectives, explain the role of eligible countries as partners, the location of different activities, and the relevance of project resources or the target populations they represent. A sufficient variety of Member States must be covered reflecting different situations in EU Member

States;

(e) Social, cultural and political context (8 points):

Applicants must explain how the project relates to the situation of the countries or specific areas involved, ensuring the compatibility of envisaged actions with the culture and views of the target groups.

2. Technical quality (30 points, threshold: 15 points):

(a) Evidence base (5 points):

Applicants must include a problem analysis and clearly describe the factors, impact, effectiveness and applicability of the proposed measures;

(b) Content specification (5 points):

Applicants must clearly describe aims and objectives, target groups, including relevant geographical factors, methods, anticipated effects and outcomes;

(c) Innovative nature, technical complementarity and avoidance of duplication of other existing actions at EU level (5 points):

Applicants must clearly identify the progress that is expected to result from the project within a given field in relation to the state of the art and ensure that there will be neither inappropriate duplication nor overlap, whether partial or total, between projects and activities already carried out at EU, national and international level;

(d) Evaluation strategy (5 points):

Applicants must clearly explain the methods proposed and indicators chosen and their adequacy;

(e) Dissemination, implementation and sustainability strategy (10 points, threshold: 5 points):

Applicants must clearly illustrate the adequacy of the envisaged strategy and methodology to ensure not only a large dissemination of the projects' results, but also their transferability and self-sustainability into the different healthcare systems of European countries. These aspects are particularly important for the IT components of the project and critical for its success. They should be taken into account in all work packages and over the whole timeline of the project.

3. Management quality and budget (30 points, threshold: 15 points):

(a) Planning, organisation and implementation (5 points):

Applicants must clearly describe the activities to be undertaken, timetable and milestones, deliverables, nature and distribution of tasks to be implemented by all partners to achieve results self-sustainable within national healthcare systems even after the end of the project, and provide a risk analysis;

(b) Organisational capacity (5 points):

Applicants must clearly demonstrate the quality level of the structure of the project by describing its management structure, competence of staff, responsibilities, internal communication, decision-making, monitoring and supervision;

(c) Quality of partnership (5 points):

Applicants must clearly describe the partnerships envisaged in terms of extensiveness, roles and responsibilities, relationships between the partners, and the synergy and complementarity of partners and network structure; The quality of partnerships is critical also in terms of implementation within national healthcare systems;

(d) Communication strategy (5 points):

Applicants must clearly describe the communication strategy in terms of planning, target groups, adequacy of channels used, and visibility of EU co-financing; Communication is understood here both as internal communication (amongst partners involved in the project and related stakeholders to be involved for a successful implementation of the project) as well as external communication (to disseminate project's results);

(e) Overall and detailed budget, including financial management (10 points, threshold: 5 points):

Applicants must ensure that the budget is relevant, appropriate, balanced and consistent in itself, between partners and in relation to the specific objectives of the project. The budget should be distributed between partners at a minimum reasonable level, avoiding excessive fragmentation. Applicants must clearly describe financial circuits, responsibilities, reporting procedures and controls. Any proposal which does not reach all the thresholds will be rejected.

Following the evaluation, a list is drawn up containing proposals reaching all the thresholds and ranked according to the total number of points awarded. Only the highest ranked proposal will be awarded co-financing.

Implementation

Through a call for proposals managed by DG SANTE.

It is foreseen to award only one grant.

Indicative timetable and indicative amount of the call for proposals

Reference	Date	Amount
	Second semester 2015	EUR 1 000 000

Maximum possible rate of co-financing of the eligible total costs

The maximum rate for EU co-financing is 80 %.