

## IV

(Notices)

## NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

## EUROPEAN COMMISSION

## COMMISSION DECISION

of 22 February 2011

**concerning the adoption of a financing decision for 2011 in the framework of the second programme of Community action in the field of health (2008-2013) and on the selection, award and other criteria for financial contributions to the actions to this programme**

(Text with EEA relevance)

(2011/C 69/01)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on European Union and to the Treaty on the Functioning of the European Union,

Having regard to Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) <sup>(1)</sup> (hereinafter referred to as the 'Health Programme'), and in particular Article 8(1) thereof,

Having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities <sup>(2)</sup> (hereinafter referred to as the 'Financial Regulation'), and in particular Article 75 thereof,

Having regard to Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities <sup>(3)</sup> (hereinafter referred to as the 'Implementing Rules'), and in particular Article 90 thereof,

Having regard to Commission Decision 2004/858/EC of 15 December 2004 setting up an executive agency, the 'Executive Agency for the Public Health Programme', for the

management of Community action in the field of public health — pursuant to Council Regulation (EC) No 58/2003 <sup>(4)</sup>, and in particular Article 6 thereof,

Whereas:

- (1) In accordance with Article 75 of the Financial Regulation and Article 90(1) of the Implementing Rules, the commitment of expenditure from the EU budget shall be preceded by a financing decision setting out the essential elements of the action involving expenditure and adopted by the institution or the authorities to which powers have been delegated by the institution.
- (2) In accordance with Article 110 of the Financial Regulation and Article 8(1) of the Health Programme, an annual work plan for the implementation of the Health Programme and selection, award and other criteria for financial contributions to the actions of the Programme have to be adopted.
- (3) According to Articles 4 and 6 of Decision 2004/858/EC, the Executive Agency for Health and Consumers carries out certain activities for the implementation of the Programme on public health and should receive the necessary appropriations for that purpose.

<sup>(1)</sup> OJ L 301, 20.11.2007, p. 3.

<sup>(2)</sup> OJ L 248, 16.9.2002, p. 1.

<sup>(3)</sup> OJ L 357, 31.12.2002, p. 1.

<sup>(4)</sup> OJ L 369, 16.12.2004, p. 73.

- (4) The 2011 work plan being a sufficiently detailed framework in the meaning of Article 90(2) and (3) of the Implementing Rules, the present decision constitutes a financing decision for the expenditure provided in the work plan for grants, procurement and other actions.
- (5) Under Article 168(1) point (c) of the Implementing Rules, grants may be awarded without a call for proposals to bodies with a *de jure* or *de facto* monopoly and under Article 168(1) point (f) for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power.
- (6) This Decision is also a financing decision for the expenditure in the context of indirect centralised or joint management chargeable to the EU budget.
- (7) Evidence of existence and proper operation of the elements listed in Article 56 of the Financial Regulation, within the entity to be entrusted by the Commission with the implementation of EU funds in indirect centralised management, has been obtained.
- (8) The present financing decision may also cover the payment of interest due for late payment on the basis of Articles 83 of the Financial Regulation and 106(5) of the Implementing Rules.
- (9) It is appropriate to define the terms 'substantial change' within the meaning of Article 90(4) of the Implementing Rules for the application of this Decision.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 10 of Decision No 1350/2007/EC,

HAS DECIDED AS FOLLOWS:

#### Article 1

The work plan 2011 for the implementation of the Health Programme, as set out in Annex I and related Annexes II, III, IV, V, VI, and VII on the selection, award and other criteria for financial contributions to the actions of the Health Programme, is hereby adopted. It constitutes a financing decision in the meaning of Article 75 of the Financial Regulation.

#### Article 2

The maximum contribution authorised by this Decision for the implementation of the Programme is set at EUR 49 751 348 to be financed from the following Budgetary Lines of the General Budget of the European Union for 2011:

- Budgetary Line 17 03 06 — EU action in the field of health: EUR 47 060 000,
- Budgetary Line 17 01 04 02 — Expenditure on administrative management: EUR 1 400 000.

and estimated additional contributions from the EFTA/EEA countries and Croatia for their participation in the Health Programme:

- EFTA/EEA countries: EUR 1 153 348,
- Croatia: EUR 138 000.

This brings up the total for budgetary line 17 03 06 to EUR 48 313 028 and the total for budgetary line 17 01 04 02 to EUR 1 438 320.

These appropriations may also cover interest due for late payment in accordance with Article 83 of the Financial Regulation.

The implementation of this Decision is subject to the availability of the appropriations foreseen in the draft budget for 2011 after the adoption of the budget for 2011 by the Budgetary Authority.

#### Article 3

The management system set up by the Executive Agency for Health and Consumers to be entrusted with the implementation of EU funds complies with the conditions for the delegation of tasks under indirect centralised management. The budget implementation of tasks related to project grants, operating grants, grants for joint actions, conference grants and direct grant agreements with international organisations and part of procurement can thus be entrusted to this entity.

The budget allocations necessary for the management of the Health Programme shall be delegated to the Executive Agency for Health and Consumers under the conditions and within the limits of the amounts laid down in the work plan in Annex I.

The operating subsidy entered in budget line 17 01 04 30 shall be paid to the Executive Agency for Health and Consumers.

*Article 4*

The budget implementation of tasks related to direct grants with international organisations can be entrusted to the following international organisations: Council of Europe (CoE), International Agency for Research on Cancer (IARC), Organisation for Economic Cooperation and Development (OECD) and World Health Organisation (WHO).

*Article 5*

Cumulated changes of the allocations to the specific actions not exceeding 20 % of the maximum contribution authorised by this Decision are not considered to be substantial provided that they do not significantly affect the nature and objective of the work plan. This may include the increase of the maximum contribution authorised by this Decision up to 20 %.

The authorising officer, in accordance with Article 59 of the Financial Regulation, may adopt such changes in accordance with the principles of sound financial management and of proportionality.

The Director-General for Health and Consumers shall ensure the overall implementation of this financing decision.

*Article 6*

Grants may be awarded without a call for proposals to bodies with *de jure* or *de facto* monopoly under Article 168(1) point (c) of the Implementing Rules and for actions with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative power under Article 168(1) point (f), in accordance with the conditions detailed in the annexed work plan.

Done at Brussels, 22 February 2011.

*For the Commission*

John DALLI

*Member of the Commission*

## ANNEX I

**Work Plan 2011 for the second programme of Community action in the field of health (2008-13)**

## 1. GENERAL CONTEXT

## 1.1. Policy and legal context

Article 168 of the Treaty on the Functioning of the European Union requires the EU to ensure that a high level of human health protection is part of all its policies. The European Union is to work with the Member States to improve public health, prevent human illness and eliminate sources of danger to physical and mental health.

To this end the European Commission put forward a new approach for EU health policy for the period 2008-13 in its White Paper Together for Health: A Strategic Approach for the EU 2008-13 (COM(2007) 630 final). This strategy provides an overarching framework which covers not only core European health issues but also broader aspects such as health in all policies and global health.

The second programme of Community action in the field of health (2008-13) (hereinafter referred to as the 'Health Programme' or 'Programme') supports the implementation of this strategy. It is based on Decision No 1350/2007/EC (hereinafter referred to as the 'Programme Decision').

The mission of the Health Programme is to complement, support and add value to the policies of the Member States. It also seeks to contribute to increased solidarity and prosperity in the European Union by protecting and promoting human health and safety and by improving public health. The Programme pursues the following objectives, as set in article 2.2 of the Programme Decision:

- (1) improving citizens' health security;
- (2) promoting health, including the reduction of health inequalities;
- (3) generating and disseminating health information and knowledge.

In Article 8(1) of the Programme Decision it is stated that the Commission shall adopt:

- (a) the annual Work Plan for the implementation of the Programme, setting out:
  - (i) priorities and actions to be undertaken, including the allocation of financial resources;
  - (ii) criteria for the percentage of Community financial contribution, including criteria for assessing whether or not exceptional utility applies;
  - (iii) the arrangements for implementing the joint strategies and actions referred to in Article 9;
- (b) selection, award and other criteria for financial contributions to the actions of the Programme in accordance with Article 4.

According to Article 75 of the Financial Regulation (FR) applicable to the general budget of the European Communities, the commitment of the expenditure should be preceded by a financing decision adopted by the institution or the authorities to which powers have been delegated by the institution. According to Article 90 of the detailed rules for the implementation of the Financial Regulation (IR), the decision adopting the annual work programme referred to in Article 110 of the FR, may be considered to be the financing decision provided that this constitutes a sufficiently detailed framework. This document aims to fulfil those obligations and present the different activities scheduled for 2011 which is the fourth year of the implementation of the Health Programme.

In addition to the Member States of the European Union, the Health Programme is open for the participation of third countries. EFTA/EEA countries Iceland, Liechtenstein and Norway participate in the Programme in accordance with the conditions established in the EEA agreement. Other third countries, in particular European neighbourhood policy countries, countries that are applying for, are candidates for, or are acceding to membership of the EU as well as the western Balkan countries included in the stabilisation and association process may participate in the Programme provided that the necessary agreements are in place. Out of these third countries Croatia has concluded these arrangements and participates in the Programme.

## 1.2. Resources

The Programme Decision sets a total budget of EUR 321 500 000 for the period 1 January 2008-31 December 2013. The budgetary authority has approved a total budget of EUR 48 460 000 [indicative amount, subject to the final adoption of the budget by the Budgetary Authorities] for 2011 for budget lines 17 03 06 and 17 01 04 02:

- EUR 47 060 000 for 17 03 06 — EU action in the field of health (operating budget),
- EUR 1 400 000 for 17 01 04 02 — Expenditure on administrative management (administrative budget).

Additional contributions from the EFTA/EEA countries and Croatia are estimated at EUR 1 153 348 from EFTA/EEA and EUR 138 000 from Croatia.

This brings up the total for budget line 17 03 06 to EUR 48 313 028 and the total for budget line 17 01 04 02 to EUR 1 438 320.

The amounts given in the following chapters are indicative. In accordance with Article 90(4) of IR, non-substantial variations in the order of +/- 20 % of each item are possible under each financing mechanism.

The budget line 17 01 04 02 — Expenditure on administrative management will be used to finance activities such as organisation of conferences, expert meetings and workshops, including seminars organised at national level among groups of experts to exchange best practices in the areas covered by this work plan. This budget line will also be used to cover publications and communication initiatives.

The Executive Agency for Health and Consumers (EAHC) assists the Commission in the implementation of this work plan according to Commission Decision C(2008) 4943 of 9 September 2008. The budget line for administrative appropriations related to EAHC is 17 01 04 30.

## 2. FINANCING MECHANISMS

The available appropriations under budget line 17 03 06 — EU action in the field of health will be used to award project grants, operating grants, grants for joint actions, conference grants and direct grants to international organisations as well as to cover procurement and other actions. All grants are covered by written agreement.

In accordance with recital 33 of the Programme Decision, collaboration with third countries not participating in the programme should be facilitated. However, these countries cannot receive any financial contributions under the Health Programme. Nevertheless, travel and subsistence expenses for experts invited from or travelling to such countries can be considered eligible costs in duly justified, exceptional cases, where this directly contributes to the objectives of the Programme.

### 2.1. Project grants

The total indicative amount for project grants is estimated at EUR 4 650 000. They are calculated on the basis of eligible costs incurred. The maximum rate for EU co-financing is 60 %. However, this may go up to 80 % in case a proposal meets the criteria for exceptional utility. Annex II contains the exclusion, eligibility, selection and award criteria for project grants. Annex VII contains the criteria for exceptional utility.

Only proposals which directly correspond to the topic and description as set out in this work plan and where 'project grant' is indicated as the financing mechanism will be considered for funding. Proposals which only address the wider subject area without matching the specific description of a given action will not be considered for funding. For each of the actions, only one proposal will be funded, except where it is mentioned otherwise.

The indicative timetable for publishing the call for proposals for project grants in the Official Journal is the first quarter of 2011.

### 2.2. Operating grants

The total indicative amount for operating grants is estimated at EUR 4 000 000. They are calculated on the basis of eligible costs incurred. The maximum rate for EU co-financing is 60 %. However, this may go up to 80 % in case a proposal meets the criteria for exceptional utility.

Operating grants may be awarded to the renewal of operating grants awarded to non-governmental bodies and specialised networks under the work plan for 2010. New operating grants may be awarded to non-governmental bodies and specialised networks active in areas corresponding to the priorities of the Health Programme and to the priorities of this work plan as set out below in point 3 Priorities for 2011.

As laid down in Article 4(2) of the Programme Decision, the renewal of financial contributions set out in paragraph 1(b) to non-governmental bodies and specialised networks may be exempted from the principle of gradual decrease. As a general rule, this exemption will apply to applicant organisations not receiving any of their funding from the private sector<sup>(1)</sup> or other conflicting interest for their functioning (core funding). For all other renewed operating grants, a decrease of 5 percentage points as compared to the Community co-financing percentage agreed in the grant agreement following the call for proposals 2010 will be applied. In any case, the amount of EU co-funding cannot be higher than the amount granted in 2010. Annex III contains the exclusion, eligibility, selection and award criteria for operating grants. Annex VII contains the criteria for exceptional utility.

<sup>(1)</sup> The term 'private sector' covers 'for-profit' companies/enterprises/corporations, business organisations or other entities irrespective of their legal nature (registered/not registered), ownership (wholly or partially privately owned/state owned) or size (large/small), if they are not controlled by the public.

The indicative timetable for publishing the call for proposals for operating grants in the Official Journal is the first quarter of 2011.

### 2.3. Grants for joint actions

The total indicative amount for joint actions is estimated at EUR 17 040 000. Joint actions enable the competent authorities of the Member States/other countries participating in the Health Programme and the European Commission to take forward work on jointly identified issues. Public bodies or non-governmental bodies based in a Member State or in other participating country which participates in a given joint action may participate in the joint action. However, they have to be expressly mandated to do so by the authorities of the Member State/other participating country concerned.

Grants for joint actions are calculated on the basis of eligible costs incurred. The maximum rate of EU co-financing is 50 %. However, this may go up to 70 % in cases of exceptional utility. The five joint actions proposed in this work plan significantly contribute to the objectives of the Europe 2020 Strategy set out in Commission Communication COM(2010) 2020 of 3 March 2010 on Europe 2020 — A strategy for smart, sustainable and inclusive growth. Therefore they are considered of exceptional utility. Four of these will be awarded co-funding of 60 % and one of 70 %. These joint actions are:

- support to the implementation of national plans/strategies on rare diseases and related measures to implement Council Recommendation and Commission Communication on rare diseases; maximum EU co-funding EUR 3 000 000, co-funding percentage 60 %,
- cross-border eHealth instruments as supporting tools for medical information and research; maximum EU co-funding EUR 2 400 000, co-funding percentage 60 %,
- complementary joint action on pilot HTA's on targeted health technologies; maximum EU co-funding EUR 6 600 000, co-funding percentage 70 %,
- patient safety and quality of healthcare; maximum EU co-funding EUR 3 600 000, co-funding percentage 60 %,
- assisting Member States in reaching the full potential of deceased and living donation; maximum EU co-funding EUR 1 440 000, co-funding percentage 60 %.

Annex IV contains the exclusion, eligibility, selection, and award criteria for joint actions.

Member States/other countries participating in the Health Programme which wish to participate in joint actions must declare this intention to the Commission. With the exception of NGOs operating at EU level, only organisations established in Member States/other countries participating in the Health Programme which have made this declaration can apply for participation in joint actions. The Commission, assisted by EAHC, will offer help to participating Member States/other countries participating in the Health Programme to ensure a transparent procedure to designate national NGOs to participate in joint actions.

The indicative timetable for publishing the call for proposals for joint actions in the Official Journal is the first quarter of 2011.

### 2.4. Conference grants

The total indicative amount for conferences is EUR 800 000: EUR 200 000 for Presidency conferences, and EUR 600 000 for other conferences. For administrative reasons, conferences eligible for co-funding, apart from Presidency conferences, must take place in 2012.

#### 2.4.1. Presidency conferences – De jure monopoly

According to article 168(1) point (c) of the IR, grants can be allocated without a call for proposals to organisations in a *de jure* or *de facto* monopoly situation, duly substantiated in the award decision.

Presidency conferences which are highly political in nature and which involve representation at the highest level both from National Authorities and European representatives are to be organised exclusively by the Member State holding the Presidency of the EU. Given the unique role of the Presidency in the framework of EU activities, the Member State responsible for the organisation of the event is considered as having a *de jure* monopoly.

Two conferences organised by the Presidencies of the European Union, one for the Presidency in the second half of 2011 and the other for the Presidency in the first half of 2012, may receive up to EUR 100 000 each. The maximum rate of EU co-financing is 50 % of eligible costs incurred.

The Presidency shall submit a request for a grant to EAHC, via the Permanent Representation, for the conference concerned at least 4 months before the event. The request for a grant shall specify the topic of the conference, the draft programme, the provisional budget and the composition of the scientific and organisational committees.

The Presidency conferences to be financed under this work plan are: 'European Brain Policy Forum; Ageing, Stroke and Alzheimer — finding innovative solutions' to be held in November 2011 under the Polish Presidency, and a conference to be held in the first half of 2012 under the Danish Presidency which will be the object of a separate financing Decision once the details become known.

#### 2.4.2. *Other conferences*

Conference grants may be awarded to the organisation of conferences which directly correspond to the priorities of the Health Programme and to the priorities of this work plan as set out below in point 3 Priorities for 2011 and which have a wide European dimension. They have to be organised by a public or non-profit making body which is established in a country participating in the Health Programme and which has relevant experience of cooperation at EU level. Conferences may receive up to EUR 100 000 (maximum 50 % of the total budget). Annex V contains the exclusion, eligibility, selection and award criteria for conferences other than Presidency conferences.

The indicative timetable for publishing the call for proposals for conferences in the Official Journal is the first quarter of 2011.

#### 2.5. **Direct grant agreements with international organisations**

The total indicative amount for direct grants is estimated at EUR 3 200 000. These will be based on effective collaboration with the Commission.

For this work plan, an international organisation is defined as a form of intergovernmental cooperation established by states through the signature of an international agreement that is registered or submitted to be registered at the Secretariat of the United Nations, has a permanent organisational structure and is endowed with a legal status based on the relevant international agreement that enables the exercise of its functions and the fulfilment of its purpose.

According to Article 168(1) point (f) of the IR, funding for actions with international organisations will be allocated through grant agreements without a call for proposals on topics specifically identified in this work plan. International organisations and their national or regional offices are not eligible for funding as main or associated beneficiaries under any calls for proposals. The maximum rate for EU co-financing is 60 % of the eligible costs effectively incurred. In accordance with recital 33 of the Programme Decision, activities involving third countries not participating in the Health Programme shall not be considered eligible costs. However, travel and subsistence expenses for experts invited from or travelling to such countries can be considered eligible costs in duly justified, exceptional cases, where this directly contributes to the objectives of the Health Programme.

Funding can only be awarded to the following international organisations in 2011:

- Council of Europe (CoE),
- European Observatory on Health Policies and Health Systems,
- International Agency for Research on Cancer (IARC),
- Organisation for Economic Cooperation and Development (OECD),
- World Health Organisation (WHO).

#### 2.6. **Procurement**

The total indicative amount for procurement is estimated at EUR 17 753 028.

Calls for tenders are envisaged to be published in the first semester of 2011 in the Official Journal. Framework contracts and new service contracts will be used as indicated in this work plan.

#### 2.7. **Other actions**

The total indicative amount for other actions is estimated at EUR 870 000.

These cover contributions paid by the EU as subscriptions to bodies of which they are members in the meaning of Article 108(2) point (d) of the FR, and an administrative agreement with the Joint Research Centre (JRC) and special indemnities paid to experts for their participation in meetings and work on scientific opinions in accordance with Commission Decision 2008/721/EC<sup>(1)</sup>: special indemnities.

<sup>(1)</sup> OJ L 241, 10.9.2008, p. 21.

### 3. PRIORITIES FOR 2011

In its Communication COM(2010) 2020, the European Commission presents a strategy for reinvigorating Europe in the next 10 years. Actions presented in this work plan are based in particular on two of the priorities of that strategy: Smart growth and Inclusive growth. They seek to address, among others, the challenge of promoting an active and healthy ageing population, and reducing health inequalities.

The Smart Growth priority builds on knowledge and innovation. Its flagship initiative Innovation Union seeks to focus policies to address the demographic change in the EU post the baby-boom generation. By 2050 the number of people over 50 will rise by 35 % and that over 85 will triple. This will place an increasing strain on health systems. In the *European Innovation Partnership in the field of active and healthy ageing* set out in Commission Communication COM(2010) 546 final of 6 October 2010 on Europe 2020 Flagship Initiative Innovation Union the Commission calls for measures to prevent and address diseases which affect older people with a particular focus on chronic and rare diseases. This work plan seeks to do so by addressing factors such as nutrition, tobacco and alcohol which underlie many of these age-related chronic diseases, and by taking work forward on cancer and rare diseases. EU cooperation on health technology assessment supports this objective. The work plan also supports work on the safety of blood, tissues, cells and organs which contributes to improving health across the lifecycle thereby contributing to healthy ageing.

Another Smart Growth flagship initiative, A Digital Agenda for Europe, seeks to deliver economic and social benefits from a Digital Single Market. This work plan contributes to this objective by supporting measures that apply information and communication technologies in the area of health.

The goal of the Inclusive growth priority of the Europe 2020 Strategy is a high employment economy which delivers economic, social and territorial cohesion. Ensuring a healthy workforce with less absenteeism can contribute to Europe's productivity. This work plan further aims to contribute to growth through action aimed at bridging health inequalities to ensure better health for all and better access to health care systems. In turn, this improves citizens' capacity to contribute to society and reduces poverty and social exclusion, thus contributing to the Flagship Initiative against poverty.

The work plan for 2011 focuses on five main areas. These are: Health Information and advice; Diseases; Health determinants; Health systems; and Legislation on products and substances.

#### Health information and advice

The work plan supports generating the data and scientific opinions that health stakeholders from policy makers to individuals need to be able to make informed decisions. However, generating the information is not enough. In order for it to be effective, it must reach its targets. This requires setting up efficient and user-friendly dissemination channels. These include in particular the setting up and running a knowledge management system.

#### Diseases

Work on diseases in the 2011 work plan focuses on cancer and rare diseases. Cancer is the second biggest cause of death of men and women. The aim of the Commission as set out in Commission Communication COM(2009) 291 final of 24 June 2009 on Action Against Cancer: European partnership is to reduce cancer incidence by 15 % by 2020. This work plan supports activities that are designed to help reach that goal. EU action on rare diseases pools fragmented resources across the Member States. This contributes to improved diagnostics and treatment. Commission Communication COM(2008) 679 final of 11 November 2008 on Rare diseases: Europe's challenges and Council Recommendation 2009/C 151/02 of 8 June 2009 on an action in the field of rare diseases <sup>(1)</sup> set the framework for activities supported by this work plan. Pandemic preparedness has become evermore important in the wake of recent avian flu and H1N1 crises. Work supported by this work plan focuses on applying lessons learnt from the H1N1 pandemic. This work plan also finances work on prevention strategies for HIV and co-infections.

#### Health determinants

Many of today's debilitating diseases, such as cancer and diabetes, have a direct link to what and how people eat and drink and what kind of lifestyles they have. Work on health determinants is essential in promoting health and thereby preventing disease, thus contributing to active and healthy ageing. This work plan supports activities on a number of key health determinants: social determinants and health inequalities; nutrition and physical activity; and alcohol and tobacco.

<sup>(1)</sup> OJ C 151, 3.7.2009, p. 7.



## Health systems

Action under this heading aims at ensuring high-quality, safe and efficient cross-border healthcare. The use of new technology has a key role in making cross-border health care a success. This work plan supports work on patient safety, health technologies and their assessment as well as on health work force.

## Legislation on products and substances

Activities with regard to the quality and safety of human substances support the implementation of Commission Communication COM(2008) 819 final of 8 December 2008 on an Action Plan on Organ Donation and Transplantation (2009 to 2015): Strengthened Cooperation between Member States and Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC <sup>(1)</sup>. The other two areas where this work plan finances work related to EU legislation is tobacco and medicinal products.

In addition to actions in the above areas, funding is provided for the organisation of conferences focusing on the above priorities and to organisations active in the area of health in the above areas. The work plan also finances horizontal measures which support the implementation of the Health Programme.

The second Health Programme aims to promote synergies with other Community Programmes active in the field of health, notably the 7th Research Framework Programme under its Health Theme. Proposals submitted under the second Health Programme should not contain significant elements which relate to research. Efforts will be made to avoid overlap and duplication between the second Health Programme, FP7 and other Community programmes. Where appropriate, actions will be implemented with close regard to other policy areas, notably information society.

### 3.1. Actions under the first objective 'Improve citizens' health security'

Actions under this section aim to improve citizens' health security by protecting them against health threats and by improving their safety.

#### 3.1.1. *Protect citizens against health threats (Point 1.1.1 in Annex to the Health Programme)*

##### 3.1.1.1. Project on multi-sectoral preparedness and health-security: public health preparedness and response planning in the field of pandemic influenza and other serious cross-border health threats, including bio-threats.

This action will study preparedness and response planning at European level for pandemic influenza preparedness and other serious cross-border health threats. It will support the Council Conclusions of 13 September 2010 on lessons learnt from the A/H1N1 pandemic and health security. Monitoring of progress in Member States will be a key element of the measures proposed under this action. The potential benefits of lessons learnt and tools developed for pandemic preparedness for other health emergencies should be explored as well as the experiences gained from multi sectoral work (e.g. the One-Health approach). The action seeks to (a) raise awareness of the need to strengthen robust, continued and coordinated functioning of sectors beyond the health sector; (b) support Member States in planning for enhanced and robust functioning of crucial sectors in society in a pandemic based on best practice exchange; and (c) provide guidelines for preparedness for other health emergencies, in particular caused by biological and/or chemical threats based on pandemic influenza preparedness; and (d) assist in developing an effective information forum on best practices in counteracting bio-threats by the existing European networks, including on the safety of laboratories and responders.

This action should establish an inventory of existing structures, procedures and mechanisms that Member States have already put in place to enhance coordinated functioning of sectors in the event of a pandemic and any other type of major cross-border health threat; identify criteria for the selection of prioritised sectors of critical importance; identify best practice; identify gaps that still exist in response capacities and provide advice and recommendations for further measures to enhance preparedness and response planning to health threats. The action should encourage Member States to share their experiences and propose models for peer learning exchanges. A monitoring tool to assess and evaluate progress made in preparedness and response planning for both pandemic influenza and other health threats (generic preparedness) has also to be provided.

[Project grant]

Indicative amount: EUR 500 000

<sup>(1)</sup> OJ L 33, 8.2.2003, p. 30.

### 3.1.1.2. Project on crisis communication in the area of risk management

This action will support the implementation of improved communication to the public during a major health emergency and build on the lessons learnt from the response to the H1N1 pandemic that has been reviewed by the Belgian Presidency conference held in July 2010. Monitoring of progress in Member States related to communication whilst managing a crisis will be a key element of the measure. The potential benefit of lessons learnt and tools developed for pandemic preparedness for other health emergencies should be explored as well as the experiences gained from multi sectoral work (e.g. the One-Health approach). The action covers crisis communication in the area of risk management with key stakeholders, in particular health professionals/healthcare workers and with the general public and specific target groups. The objectives of the action are to seek support from key stakeholders at EU level, in particular health professionals/healthcare workers organisations and social partners in developing and delivering coherent messages to the public; to enhance public confidence in medical interventions for pandemic preparedness (e.g. prevention methods, vaccines); and to provide guidance for crisis communication related to other health threats based on experience with pandemic preparedness.

The action should identify key stakeholders at EU level, in particular health professionals/healthcare workers' organisations, social partners and Member State authorities, and use results of evaluations and reports on H1N1 pandemic to analyse reasons for different reactions in the public to measures taken to control H1N1, particularly vaccination measures, and suggest strategies and actions to enhance public confidence in medical interventions for pandemic preparedness and response (e.g. prevention methods, vaccines); create partnerships with key stakeholders' organisations to prepare for and improve public communication in a health crisis; develop guidelines for crisis communication at EU level related to other health threats based on experience with pandemic preparedness and organise exercises and training with the EU Health Security Committee and Communicators Network; develop a common communication system during crisis and strengthen common communication capacities in preparation for a pandemic; develop tools and mechanisms for monitoring the impact in real time of public health messages; and create an implementation report including guidance for crisis communication that can also be transferred to other health emergencies.

[Project grant]

Indicative amount: EUR 300 000

### 3.1.1.3. Study on the environmental risks of medicinal products

This action is intended to provide the Commission with an assessment of the environmental risks of medicinal products and the impact on public health. This assessment could moreover be used in a Commission report on this topic as proposed in the first reading agreement on a Commission proposal to amend pharmaceutical legislation in the area of pharmacovigilance<sup>(1)</sup>. The objectives of the action are to examine the scale of the problem of the pollution of waters and soils with pharmaceuticals and their residues, to assess the scale of the impacts of that pollution on the environment and public health, to identify the causes of the problem, and to make recommendations. This should result in a thorough assessment enabling the Commission to consider any necessary action in this area and contributing to the above mentioned report. In particular, the study should allow the collection of data from a broad range of sources (pharmaceutical competent authorities, environmental competent authorities, economic operators and other stakeholders) in order to provide the Commission with a detailed analysis of the situation on the ground. The study should be completed in 2012.

[Existing framework contract]

### 3.1.1.4. HIV and co-infections prevention strategies — concepts for the future

The objective of this action is the implementation of Commission Communication COM(2009) 569 final of 26 October 2009 on Combating HIV/AIDS in the European Union and neighbouring countries, 2009-13. It seeks to develop novel and integrated HIV and associated infections prevention strategies focusing on the needs of eastern European neighbourhood countries with high HIV/AIDS prevalence; to provide support for the implementation of these prevention strategies in these priority regions; and help disseminate and promote them.

The action should cover a detailed analysis of the parameters to be included in tailor-made HIV prevention strategies with a particular focus on medical, social and political aspects; an assessment of the benefit of effective and integrated HIV and associated infections prevention policies, in combination with tailor-made recommendations for efficient procurement of HIV medicines; and a set of evidence based prevention strategies for HIV and co-infections transmission with a particular focus on the needs of priority regions and priority groups mostly affected by HIV and associated infections. The action

<sup>(1)</sup> Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC. See amendment of Article 59(3) of Directive 2001/83/EC.

should produce a guide on efficient and integrated HIV (and associated infections) prevention strategies for implementation in priority regions with a particular focus on priority groups mostly affected by HIV and associated infections (as set out in COM(2009) 569 final).

[Call for tenders]

3.1.2. *Improve citizens' safety — Scientific advice (Point 1.2.1 in Annex to the Health Programme)*

3.1.2.1. Special indemnities to Scientific Committees

This objective of this action is to provide the Commission with high quality, independent advice on health risks by ensuring the functioning of Scientific Committees in accordance with Decision 2008/721/EC. The special indemnities are paid to experts for their work on scientific opinions.

[Other actions]

Indicative amount EUR 270 000

3.1.2.2. Technical and organisational assistance for the functioning of the Scientific Committees and communication on risks

The objective of this action is related to the task of providing the Commission with high quality, independent advice on consumer and public health risks by operating three independent Scientific Committees. The Committees deliver scientific opinions on request of the Commission in order to provide the independent and authoritative scientific elements needed by the Commission for establishing science-based policies and proposals.

The functioning of the Scientific Committees requires technical support by qualified bodies. This support includes the search, analysis and synthesis of scientific literature, preparation of summaries, data search, establishment of bibliography of topics addressed by the Committees, revision of texts for completeness and consistency. As part of the transparency and communication policy on scientific advice set up by Decision 2008/721/EC, and in order to increase the part of science in EU policy debate and inform citizens on risk matters, layman versions of the opinions of broadest interest for the public are prepared within the framework of this action. This action also covers the organisation of scientific hearings and scientific working meetings or thematic workshops related to the preparation of certain opinions.

[Existing framework contract]

3.1.3. *Improve citizens' safety — Safety of blood, tissues, cells and organs (Point 1.2.2 in Annex to the Health Programme)*

3.1.3.1. Ad hoc cooperation with the Council of Europe on specific matters relating to substances of human origin

The Council of Europe and its Directorate for the Quality of Medicines and HealthCare (EDQM) is a key European organisation involved in the harmonisation and coordination of standardisation, regulation and quality control of medicines, blood transfusion, organ transplantation, pharmaceuticals and pharmaceutical care. It is regarded as an expert, trustworthy and neutral organisation within the field of substances of human origin, providing continuous expert advice and support to the Commission.

In order to promote and protect human health, the Commission cooperates on an ongoing basis with the Council of Europe on quality standards for collection/procurement, testing, processing, preservation, storage and distribution of blood and blood components. The Council of Europe assists the Commission in implementing Directive 2002/98/EC and subsequent implementing directives). Specific topics are identified yearly depending on scientific and technical needs. For 2011 this covers consistent testing methods to ensure blood safety across the Member States. This action will support the development and use of validated testing methods through proficiency testing. The proficiency testing would involve laboratories of all 27 Member States, by performing double blind preparation and distribution of samples.

[Direct grant to CoE]

Indicative amount: EUR 100 000

3.1.3.2. Organisation of training sessions for inspectors in the field of blood and blood components

As set out in Article 8 of Directive 2002/98/EC, all Member States shall ensure that the competent authority organise inspections and appropriate control measures in blood establishments to ensure that the requirements of the Directive are met. The objective of this action is to organise training sessions in the field of blood and blood components for a defined number of inspectors. The action seeks to achieve a uniform knowledge and way of undertaking inspections across the EU, and increase the numbers of trained professionals in this field.

In line with Directive 2002/98/EC, such training sessions will contribute to ensuring the quality and safety of blood and blood components in the EU. Moreover, the alignment of inspection practices will improve mutual trust and stimulate collaboration among Member States. The action is in accordance with the Health Strategy objectives of fostering good health in an ageing Europe and supporting dynamic health systems and technologies. Further training of inspectors of blood establishments will positively impact the quality and safety of blood and blood components, benefiting patients all across the EU. The duration of the action will be 18 to 24 months. At least two inspectors per Member State will be trained. This will produce a multiplying effect, as these trained inspectors are expected to train more national inspectors within their own Member State. The training tools and materials produced will be reused at national level. A final evaluation will include measurement of the outcomes of the action and of the multiplication effect.

[Call for tenders]

### 3.1.3.3. Assisting Member States in reaching the full potential of deceased and living organ donation

Article 15 of 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 <sup>(1)</sup> requires Member States to ensure that a register or record is kept for living donors. This joint action seeks to support Member States in setting up and running living donation programmes through the development of guidelines for living donor registries/record systems; the development of registries/record systems for living donation; and the provision to the Member States of a practical tool for registries/record systems. A well-developed registry/record system for living donations is not only key to assessing the health and safety of living donors, but also to combating organ trafficking as it allows Member States to closely monitor and evaluate the practice of living donation within the EU and across borders.

In accordance with Directive 2010/53/EU and Communication (COM)2008 819 final, this joint action seeks to support the Member States in reaching the full potential of deceased organ donation by strengthening the relationship between intensive care units and transplant donor coordinators; providing Member States with a training module for better coordination; facilitating the identification of potential organ donors; and increasing the number of available organs across Europe.

The joint action also seeks to enhance the efficiency and accessibility of organ transplantation systems by the twinning of transplantation systems and peer reviews.

The action will facilitate consistent implementation of Directive 2010/53/EU within the 27 Member States; provide concrete assistance to Member States in meeting the objectives of the Action Plan; enhance cooperation between Member States in the field of organ donation and transplantation through twinning; and contribute to reaching the full potential of deceased donation by making donor detection more efficient and to enhanced safety for living organ donors across the EU.

[Joint action]

Indicative amount: EUR 1 440 000

### 3.1.3.4. Supporting registers for the European single coding system for human tissues and cells

The objective of this action is to set up and maintain (a) a European register that will aggregate the information contained in the national registers of tissue establishments in a suitable format to ensure access to operators and the public, and proper use in the context of the European Coding System for tissues and cells; and to set up and maintain (b) a second European register with reference nomenclature of human tissues and cells for use in the European Coding System for tissues and cells in accordance with Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells <sup>(2)</sup> and Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells <sup>(3)</sup>.

The action seeks to set up (a) a single access point for collecting, consolidating and making available information related to the EU tissue establishments such as coordinates, contact details and authorised activities to users and to the public. The initial set up and maintenance of the register will require significant work bringing together Member States, stakeholders and the Commission. The action seeks also to set up (b) a single access point with jointly agreed definitions and descriptions of various types for human tissues and cells. Consensus building discussions on definitions and the set-up/maintenance of the nomenclature register will require significant work bringing together Member States, stakeholders and the Commission.

<sup>(1)</sup> OJ L 207, 6.8.2010, p. 14.

<sup>(2)</sup> OJ L 294, 25.10.2006, p. 32.

<sup>(3)</sup> OJ L 102, 7.4.2004, p. 48.

These two registers will be pivotal in ensuring the proper functioning of the European coding system for human tissues and cells. The European register of tissue establishments will help Member States and the Commission to meet their obligations stemming from Directive 2004/23/EC. This action will contribute to ensuring the quality and safety of tissues and cells in the EU.

[Call for tenders]

3.1.4. *Improve citizens' safety — Improving patient safety through high-quality and safe healthcare (Point 1.2.3 in Annex to the Health Programme)*

3.1.4.1. Patient safety and quality of healthcare

This action seeks to contribute to the provision of safe and high quality healthcare for all EU citizens. It contributes to the implementation of (1) Council Recommendation 2009/C 151/01 of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections, in particular with regard to gathering and sharing comparable data and information on patient safety outcomes; sharing knowledge, experience and best practice on patient safety strategies; and sharing knowledge on the effectiveness of patient safety interventions and the evaluation of their transferability as well as the (2) Agreement in the Working Party on Public Health at Senior Level to enhance collaboration between Member States and the Commission on healthcare quality and (3) to help Member States exchange good practice in the field of patient involvement.

The action should result in a sustainable, strengthened collaborative network of Member States in patient safety and quality of health care; an agreed set of terminology/categories of patient safety topics, adverse events and contributing factors; an interactive platform (e.g. website) of sharing good practices on patient safety solutions, quality assurance systems and patient involvement; the implementation of selected good practices in a limited number of health care settings in Member States and evaluation by means of related patient safety indicators and quality indicators; a complete, comprehensive and accessible database of safety and quality systems in place in the EU with information about their transferability within the EU; and a EU guide on evaluation of quality and safety assurance systems, focusing on specified aspects, such as objectives, organisation, transparency and patient involvement.

[Joint action]

Indicative amount: EUR 3 600 000

3.2. **Actions under the second objective 'Promote health'**

Actions under this section aim to foster healthier ways of life and reduce health inequalities, as well as to promote healthier ways of life and reduce major diseases by tackling health determinants.

3.2.1. *Identifying the causes of, addressing and reducing health inequalities and promoting investment in health in cooperation with other EU policies and funds (Point 2.1.2 in Annex to the Health Programme)*

3.2.1.1. Reducing health inequalities: preparation for action plans and structural funds projects

The objective of this action is to assist Member States to develop action plans on reducing health inequalities, which would also support them in the context of the structural funds activities in the next programming period beginning in 2013. The action contributes towards the implementation of Commission Communication COM(2009) 567 final of 20 October 2009 on Solidarity in health: reducing health inequalities in the EU which sets out the Commission's intention to '... review the possibilities to assist Member States to make better use of EU Cohesion policy and structural funds to support activities to address factors contributing to health inequalities.' The activity will prioritise those Member States and regions where premature mortality exceeds the EU average by 20 per cent (defined by under 65 years standardised mortality rates).

The activities should include an analysis of health inequalities and preparation of outline actions to reduce health inequalities within and between regions or sub regions; information exchange and sharing of good practice between Member States and regions in relation to action to tackle health inequalities and the development of plans to address inequalities in (a) access to health care and health prevention services, with special attention to vulnerable groups and communities and underserved regions, (b) causes of health inequalities relating to health related behaviours and (c) causes of health inequalities related to living and working conditions, including access to basic needs such as water and sanitation.

The action should produce analyses of needs and costed plans to meet needs with the aim of reducing health inequalities in relation to access to health care, health related behaviours and living and working conditions; integration of outputs into the overall processes for use of the structural funds; and a synthesis report analysing good practice at EU level with case studies from participating regions and Member States. This action should also support Member States and regions in developing integrated approaches to health inequalities as part of overall programmes for economic and social development supported by the structural funds; and underpin efforts to overcome regional and socioeconomic inequalities in health.

[Project grant]

Indicative amount: EUR 1 200 000

3.2.1.2. European Review of Social Determinants and the Health Divide: collaboration with WHO to produce policy guidelines and tools for addressing health inequalities

The objective of this action is to contribute to the implementation of Communication COM(2009) 567 final and to take forward the close collaboration between WHO and the European Commission in developing initiatives to address health inequalities. This contribution is essential to facilitate synergies in information collection and interaction with Member States on this issue and strengthen coherence in health inequalities policy approach between WHO and the EU. This direct grant for the World Health Organisation Regional Office for Europe would support work on the 'European Review on Social Determinants and the Health Divide' (European Marmot Review) and the development of policy guidelines and tools for addressing health inequalities in Europe. The grant will contribute to the second and third phases of the work begun by WHO EURO to follow up the WHO Global report on social determinants of health entitled 'Closing the Gap in a Generation'. The action will produce policy guidelines on action on health inequalities linked to the 'European Review on Social Determinants and the Health Divide'; and develop tools for collecting and disseminating statistical information on health inequalities. It will also cover dissemination activities.

[Direct grant to WHO]

Indicative amount: EUR 400 000

3.2.2. *Addressing health determinants to promote and improve physical and mental health and taking action on key factors such as nutrition and physical activity, tobacco, and alcohol (Point 2.2.1 in Annex to the Health Programme)*

3.2.2.1. Monitoring the implementation of the European Strategy for Nutrition and Physical Activity jointly with WHO

The aim of this action is to further develop a solid EU information and reporting system capable of describing the progress in the 2007-13 Strategy for Europe on Nutrition, Overweight and Obesity related health issues and to illustrate a good practice system relying on a WHO led network of 27 National Focal Points. This work was launched by a previous direct grant to the WHO. This action will provide information regarding the level of implementation of the European Strategy in all Member States against the 2007 and 2009 benchmarks for 2011 and 2013 at the end of the strategy; animate and provide assistance to a EU27 National Focal Points network in close collaboration with the EU High Level Group on Nutrition and Physical Activity and relevant Commission services; maintain a comprehensive database on Member States and EU policy developments and activities; and ensure exchange of information and good practice between the 27 Member States. The action will further produce an annual update of the public database developed in the first period for the 27 Member States (2007 to 2010); reports on the implementation of the Strategy by Member States and contribution to the Commission evaluation report of the strategy; and a consolidation of the WHO nutrition and physical activity Focal Points network with capacity building development in data gathering and steering of the network.

The action will contribute to producing sound information on the efforts of the EU Member States to counter ill health due to poor nutrition, overweight and obesity. The information gathered over the 6 years considered will serve as a base for the evaluation of that strategy in 2013.

[Direct grant to WHO]

Indicative amount: EUR 700 000

### 3.2.2.2. Communication campaign on tobacco prevention

The objective of this action is support for Europe-wide smoking cessation activities in the form of an anti-tobacco campaign. This anti-tobacco campaign invites citizens to reflect about smoking, encourage cessation and make clear that support to stop smoking is available. The campaign focuses primarily on young adults between 25-34 years of age. Particular attention will be given to disadvantaged groups and groups with higher smoking prevalence. The themes and the scale of various actions will take into account particular situations of individual Member States. Specific actions will be developed and implemented as appropriate in cooperation with Member States' health authorities in order to secure coordination and synergies with tobacco cessations efforts undertaken within Member States. The campaign will have a distinct EU identity. This communication campaign will contribute to building knowledge and changing attitudes and behaviour in support of a tobacco free society.

[Call for tenders]

### 3.2.2.3. Study on the tobacco industry's new marketing, sales and product strategies

The objective of this action is to get a comprehensive overview on the tobacco industry's activities in the EU in order to equip tobacco control bodies with the knowledge to adapt to changes and trends, effectively address obstacles, anticipate new strategies and where necessary, apply restructuring, and thereby increase the efficacy of tobacco control activities. This action seeks to identify changes in the tobacco industry's marketing, sales and product strategies since the adoption of Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products <sup>(1)</sup>, Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products <sup>(2)</sup>, Council Recommendation of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control and the WHO Framework Convention on Tobacco Control in 2005 <sup>(3)</sup>; and to identify how these strategies address differences in age, gender, income, education and place of living, taking into account differences between Member States as well as rural and urban areas.

This action will produce an analysis of changes in the tobacco industry's marketing, sales and product strategies; and a set of recommendations for action to tackle them.

[Existing framework contract/Call for tenders]

### 3.2.2.4. Administrative agreement with the Joint Research Centre for the provision of scientific policy support for the implementation of the Tobacco Products Directive and FCTC

The objective of this action is the provision of neutral scientific support for the implementation of Directive 2001/37/EC and Framework Convention of Tobacco Control (FCTC). This action should support the Commission in its role as Key Facilitator for the development of the Framework Convention on Tobacco Control; develop guidelines for testing and measuring tobacco products; support work on the effective functioning of the European Governmental Tobacco Laboratories Network; support work on testing and measuring of contents and emissions of tobacco products; and deliver an analysis of ingredients data.

[Other actions]

Indicative amount: EUR 100 000

### 3.2.2.5. Good practice on brief interventions to address alcohol use disorders in primary health care, workplace health services, emergency care and social services

The objective of the action is to identify and systematise good practice on brief interventions to address alcohol use disorders in primary health care, workplace health services, emergency care and social services; tailor and field-test tools, methods and materials for each of these contexts for early identification, brief interventions and referral to treatment; and make a start in further dissemination and adaptation of tailored brief intervention approaches across the EU. The work should build on existing evidence of effectiveness and experience of the implementation of brief interventions in primary health care. Special attention should be given to involving actors in Member States with lower levels of experience of the deployment of brief interventions and to opportunities for fostering cooperation between health and social services. The action should result in sets of brief intervention tools, methods and materials tailored to and evaluated in specific

<sup>(1)</sup> OJ L 194, 18.7.2001, p. 26.

<sup>(2)</sup> OJ L 152, 20.6.2003, p. 16.

<sup>(3)</sup> <http://whqlibdoc.who.int/publications/2003/9241591013.pdf>

contexts, in guidelines for developing and rolling out tailored brief intervention approaches in further countries, and in a concrete plan for dissemination across the EU. This will provide widened opportunities to deploy targeted interventions to address alcohol use disorders at an early stage in a manner to prevent the development of more serious and costly adverse consequences.

[Project grant]

Indicative amount: EUR 350 000

#### 3.2.2.6. Evaluating the structures put in place to implement the EU Alcohol Strategy

The objective of this action is to evaluate the EU Alcohol Strategy, including an evaluation of the EU Alcohol and Health Forum, and of actions and structures to support Member States, such as the Committee on National Alcohol Policy and Action (CNAPA), and work at EU level to develop common knowledge base and best practice. Updating the knowledge base and evaluating the structures for strategy implementation will contribute to the overall assessment of the value of the EU's action to tackle alcohol related harm.

[Existing framework contract]

#### 3.2.2.7. Scientific and technical support to the implementation of EU policies in the field of nutrition, alcohol and Health Forum activities

The objective of this action is the provision of scientific and technical support to the implementation of EU policies in the field of nutrition and alcohol as well as to the implementation of the activities of the European Health Forum.

With regard to nutrition, this action seeks to support the activities linked to the implementation of the Strategy for Europe on Nutrition, Overweight and Obesity related health issues, and in particular the work of the European Platform for Action 'Diet, Physical Activity and Health' and of the High Level Group on Nutrition and Physical Activity. This action covers the development of scientific summaries and analyses of key areas of the strategy, such as overweight- and obesity-related illnesses, factors influencing nutrition choices, consumer information, product reformulation, advertising; infra-structures and healthy lifestyles. With regard to alcohol, scientific support is required to the implementation of the Commission's activities in the field of alcohol related harm. This covers support the implementation of the EU Alcohol Strategy through compilations, reviews and analyses of the knowledge base available to inform the development of further action and policy. With regard to the European Health Forum, this action seeks to assist the Commission in implementing the activities of the European Health Forum. This includes organising and supporting the activities of the 'EU Health Policy Forum' and of the 'Open Forum', including the related scientific and technical work.

[Existing framework contract]

#### 3.2.3. *Prevention of major and rare diseases (Point 2.2.2 in Annex to the Health Programme)*

##### 3.2.3.1. Support to actions in line with the Commission Communication on Action against Cancer: European Partnership

The joint action 'European Partnership for Action against Cancer' launched under the call for proposals 2010 is the starting point for action in support of the European Partnership. As the collaboration develops, new needs will emerge in addition to actions identified in Communication COM(2009) 291 final but which are not covered by the above joint action. The objective of this action is to provide additional support to the European Partnership according to the needs arising in the identified areas. The focus is health promotion and cancer prevention in relation to environmental factors and cancer. The aim is to identify relevant environmental factors and demonstrate if, how and which environmental factors are specifically addressed in relation to cancer by Member States' policies. The examples of best practices existing in Member States in addressing environmental causes of cancer should lead to demonstration and proposition how a comprehensive cancer plan or strategy could best include this aspect.

[Project grant]

Indicative amount: EUR 300 000

##### 3.2.3.2. Scientific and technical support to the European Partnership for Action against Cancer and follow-up of the implementation of the Council Recommendation on Cancer Screening

The objective of this direct grant to the International Agency for Research on Cancer (IARC) is to provide high-quality scientific and technical support to the European Partnership for Action against Cancer. IARC coordinates and conducts research on the causes of human cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer prevention and control. IARC is the only organisation of its kind in the area of cancer, and it provides high-quality scientific support and technical knowledge on cancer which is essential for the effective implementation of the European Partnership for Action against Cancer.



The action ensures the necessary follow-up/up-date of earlier results (e.g.: European Code against Cancer, European Guidelines in the area of cancer screening) and feeds in to the aims of the European Partnership for Action against Cancer in the area of information on cancer burden. The activities are directly linked to the responsibilities of the Commission deriving from the Council Recommendation of 2 December 2003 on cancer screening or from requests of the EP (European Parliament resolution of 10 April 2008 on combating cancer in the enlarged European Union) and Council (Council Conclusions of 10 June 2008 on reducing the burden of cancer).

This action covers the preparation of the revised European Code against Cancer; an assessment of the implementation of the European guidelines on quality assurance in cancer screening in the context of the implementation of the Council recommendation; and Information on cancer burden to feed in directly to the aims of the European Partnership for Action Against Cancer in this area.

[Direct grant to IARC]

Indicative amount: EUR 1 300 000

#### 3.2.3.3. Support to European rare diseases information networks

The objective of this action is to provide support to the different European Rare Diseases Information Networks as mentioned in point 4.4 of Communication COM(2008) 679 final, and in the Council Recommendation of 8 June 2009 on an action in the field of rare diseases.

This action contributes to meeting the priorities established in the Commission Communication and in the Council Recommendation and to the direct benefit obtained by patients from the creation of the existing pilot European Reference Networks, European registers of rare diseases or other forms of rare diseases information networks. This action should allow to fund more than one network.

[Project grants]

Indicative amount: EUR 1 500 000

#### 3.2.3.4. Support to the implementation of the Council Recommendation and the Commission Communication on Rare Diseases

Council Recommendation of 8 June 2009 on an action in the field of rare diseases calls Member States to adopt national action plans on rare diseases before end 2013, and most Member States still require support in doing so. This action will build on the European Project for Rare Diseases National Plans Development (EUROPLAN) and on the Joint Action on Scientific support to the Rare Disease Task Force. It will provide the necessary EU support for developing and implementing national plans for rare diseases in the 18 remaining Member States as well as provide technical support to EFTA/EEA and other non-EU Countries, as set out in the above Council Recommendation and Communication COM(2008) 679 final.

The procedures for accreditation and designation of the European Reference Networks for rare diseases should be agreed with Member States and should be part of National Plans for Rare Diseases. This will be an innovative action that gives continuity and a new technical and political framework to the projects on European Reference Networks for Rare Diseases supported by EU funding between 2006 and 2009. This action will also provide the scientific support to the new European Union Committee of Experts on Rare Diseases as established in Commission Decision 2009/872/EC of 30 November 2009 establishing a European Union Committee of Experts on rare Diseases<sup>(1)</sup>. This covers in particular support for the Implementation Report of the above Council Recommendation and Commission Communication; the organisation of working groups and workshops to support activity of the Committee and to guarantee adequate technical involvement of stakeholders. The joint action will also contribute to the standardisation of nomenclatures at international level to ensure the visibility of rare diseases in health information systems, to promote quality management of diagnosis laboratories and to clarify the concepts around rarity used to define areas for action (respective value of incidence and prevalence by area for action).

[Joint action]

Indicative amount: EUR 3 000 000

### 3.3. Actions under the third objective 'Generate and disseminate health information and knowledge'

Actions under this objective aim to foster exchange knowledge and best practice on health issues and collect, analyse and disseminate health information.

<sup>(1)</sup> OJ L 315, 2.12.2009, p. 18.

### 3.3.1. *European Health Information System (Point 3.2.1 in Annex to the Health Programme)*

#### 3.3.1.1. Support creation of pilot network of hospitals related to payment of care for cross border patients

The objective of this action is the setting up of a network which will investigate hospitals which are receiving a significant number of patients from other Member States, with more than a third of members being hospitals located in cross border regions. Hospitals will report and exchange information on any administrative issues related to payment of care for cross border patients, including issues related to determination of tariffs for care, potential loss of revenue for the hospitals, possible use of up-front payments and delays in reimbursement to the hospitals. The network will assess main causes of problems and propose possible solutions. The network will also set up a system to receive feedback from patients on their experience related to reimbursement of their own costs for cross border care, based on informed consent. Finally, the network will compare DRG-based tariffs for a list of common types of elective surgery and propose conclusions on general cost levels between Member States and discrepancies between relative cost levels.

[Project grant]

Indicative amount: EUR 500 000

#### 3.3.1.2. Pooling of experts on health systems

The objective of this action is to provide technical and policy advice to the Commission and the Member States on the economic efficiency of health systems at national level. This covers (1) The design of 'policy matrices', identifying policy domains in health systems varying by relevant dimensions and looking to provide analysis around these; (2) The identification and recruitment of experts per Member State and per identified policy domain and the identification of and association with institutional partners (European Observatory on Health Policies and Health Systems, World Bank, the European Health Management Association, European Investment Bank, etc.) i.e. the establishment of an 'expert pool'; (3) The design of a long term governance model for structures to bring together and provide expertise at European and national level on health systems; taking into account the outcomes from proposed action under point 3.3.1.8 and (4) The development of the 'expert pool', governance model or other structure through a pilot study.

[Call for tenders/Direct grant to the European Observatory]

#### 3.3.1.3. Complementary joint action on pilot HTA's on targeted health technologies

This action seeks to complement the joint action on health technology assessment (HTA) 2010-12 through the carrying out of a significant number of pilot HTA's; with a focus on piloting and implementing the developed models and tools to support collaborative production of core HTA information, with reinforced secretariat and coordination, further development of production-related ICT infrastructure, and increase of HTA capacities. This action covers production of transferable core HTA information at the European level which facilitates the work done at national level, in line with the HTA core model developed by the EUnetHTA (European Network for Health Technology Assessment) Project and the joint action 2010-12. This includes simultaneous collaborative production of structured core HTA information at European level, i.e. facilitation of (a) specific collaborations between joint action partners on shared topics for HTA and (b); testing of the capacity of national HTA bodies to conduct single rapid HTA's together (including collection of data on the costs and efficiency gains of both production models ((a) and (b)); testing of the capacities to produce structured core HTA information across technologies (pharmaceuticals, medical devices, interventions); analysing various coordination capacities for the permanent secretariat function of the European network for HTA (such as hosting of the secretariat by Member States, by an EU institution); further testing of the involvement of stakeholders in network activities, this involvement taking place by means of leading an exchange of views as deemed appropriate by the members, and the involvement of academic researchers in the process of producing core HTA information; and support the development of stakeholders' capacities in HTA, notably patients and health professional organisations.

The action should increase the number of HTA's produced at the national level with the facilitation by the European coordinating mechanism; produce recommendations on the design and running of the EU HTA cooperation process; and facilitate an increase in the stakeholders' capacities in HTA enabling their appropriate contribution to the HTA process. The results should be published as scientific, openly accessible literature. The action should result in a better understanding for the Commission and Member States to consider the best way to establish a sustainable structure for HTA work in the EU. The results contribute to objective 3 of the EU Health Strategy 2008-13.

[Joint action]

Indicative amount: EUR 6 600 000

#### 3.3.1.4. Cross-border eHealth instruments as supporting tools for medical information and research

The joint action on eHealth aims at developing work to cover two areas of unmet needs: (1) eHealth instruments supporting research on diseases and treatments, and (2) National contact points providing information to patients. With regard to the first need, this action should deliver a number of detailed recommendations, supported by good practises that will support health information and research. With regard to the second need, this action will prepare the roll-out of national contact points for cross-border healthcare. These national contact points will disseminate appropriate information on all essential aspects of cross-border healthcare to patients. The network will also disseminate relevant information to patients at EU level. This action will benefit patient mobility by increasing clarity on patients' rights when seeking cross-border treatment; patient safety by providing information on healthcare providers; and Member State cooperation on cross-border care.

[Joint action]

Indicative amount: EUR 2 400 000

#### 3.3.1.5. Collaboration with OECD on health information

The objective of this action is to take forward work on the healthcare quality indicators project. This covers the development of the joint publishing of the 'Health at the Glance — European edition' which addresses several aspects of health in the EU; follow up on the health modelling: the effectiveness, efficiency and distributional impact of health interventions which should result in a model to be employed to explore the relative roles of different factors accounting for alternative healthcare options and associated resource requirements; follow up on the System of Health Accounts (SHA) revision, to extend collaboration among Eurostat/OECD/WHO Europe in data management, with the aim to achieve a highly integrated statistical system which is able to generate fully comparable data; and an analysis of the performance of the hospital sector: assessing the comparability of data on hospital procedures that is regularly collected by Eurostat and OECD, and coming up with recommendations to countries to improve data comparability. An evaluation of the Commission's cooperation with the OECD in the field of health in order to assess added-value and the best focus for future work will also be conducted. The results will contribute to evidence based policy making.

[Direct grant to OECD]

Indicative amount: EUR 500 000

#### 3.3.1.6. Setting up guidelines in support of ePrescription interoperability

This action will prepare the finalisation of guidelines supporting the Member States in developing the interoperability of ePrescriptions. It will draw on the expertise already established within the framework of the epSOS (Smart Open Services for European Patients) project, notably the work done on ePrescriptions. This action has two objectives. First is a feasibility analysis of ePrescription interoperability guidelines in general, seeking to find out which aspects (e.g. Privacy and confidentiality, organisational frameworks, semantic and architectural/technical interoperability) should minimally be covered by the Guidelines; and at which level of specification can the Guidelines for these minimally covered aspects be established. Secondly the outcome of the feasibility analysis will help inform the establishment of draft guidelines on selected aspects at their pre-assessed level of specification (e.g. broad, descriptive guidelines as opposed to the selection of one specific standard). This action will contribute to patient mobility by fostering access to (cross-border) healthcare; patient safety by helping to avoid prescription errors in cross-border settings; and Member State cooperation on cross-border care.

[Call for tenders]

#### 3.3.1.7. Support to the European system of health information and diffusion of innovation

The objective of this action is to provide a mechanism for pooling, presenting and updating good quality health information throughout Europe through the HEIDI European health wikipedia. The added value of this platform comes from the combination of four elements: involving the wider health community throughout Europe in providing and maintaining information; European added-value by providing a single central health reference for the EU; a technical platform which allows information to be constantly updated, rather than printed reports which inevitably go out of date; and a quality assurance mechanism to ensure that the information is reliable, through validation of updates by experts in the relevant fields in Europe. The action covers content development; diffusion of innovation; and technical assistance and rapid information support to the Member States.

[Call for tenders]

### 3.3.1.8. Commission membership of the European Observatory on Health Policies and Health Systems

The membership of the Commission in the European Observatory on Health Policies and Health Systems is intended to support the core work of the Observatory and to strengthen the integration of European and cross-border dimensions into the work of the Observatory, with the aim of making best use of their particular expertise and capacity for the implementation of the European health strategy.

Under their collaboration, the Commission and the Observatory will develop a tool for assessing the performance of European health systems. They will produce a book to assess the 'state of the art' of health system performance comparison. The emphasis will be on performance information that sheds light on comparative system performance.

[Other actions]

Indicative amount: EUR 500 000

### 3.3.2. *Dissemination and application of health information (Point 3.2.2 in Annex to the Health Programme)*

#### 3.3.2.1. Communication and promotion of policies and Health Programme results and evaluation of activities related to communication

The objective of this action is to communicate and promote health policies and the results of the Health Programme as well as evaluate communication activities. This covers: (1) Promotion of the EU Public Health Portal. The action seeks to improve the visibility of the portal and increase its users; to map and evaluate the users and their needs; to evaluate the Portal's navigability and use and user satisfaction; and to review its structure and editorial line; (2) Organisation of the EU Journalist prize. The aim is to stimulate high-quality journalism that raises awareness of issues related to healthcare and patients' rights; and to establish and maintain an informal network of national journalists interested in EU health issues in order to communicate locally in the Member States; (3) Production of publications and audiovisual material; and (4) Organisation of workshops and expert meetings, supply of stands and other communication materials.

[Existing framework contract]

#### 3.3.2.2. Maintenance, updating and management of the EU Health Portal and health websites, including in-house services

The objective of this action is to ensure the maintenance, updating and management of the Health websites (Europa website, Health EU portal together with its sub-sites such as Europe for patients, Crisis Communication, Journalist Prize and its newsletter), while enhancing their design and expanding their public, thus supporting the collection and dissemination of health information; and editing the EU-Health Newsletter.

[Existing framework contract]

#### 3.3.2.3. IT Master Plan

This action covers the development and maintenance of the IT tools and systems necessary for the development and running of health activities and policies.

[Existing framework contract]

### 3.3.3. *Analysis and reporting (Point 3.2.3 in Annex to the Health Programme)*

#### 3.3.3.1. Research agenda for the EU on health economic evaluations

The general objective of this action is to propose a research agenda for the EU on health economic evaluations. The specific objectives are: (1) A scanning exercise for existing health economic research (i.e. publications reporting on cost-effectiveness/utility and/or cost-benefit) in selected therapeutic fields leading to the identification of therapeutic fields where little health economic research is performed; (2) An expert-based analysis of possible reasons for the observed scarcity of research in identified fields; and (3) A proposal for a priority agenda on EU health economic research.

[Direct grant to WHO]

Indicative amount: EUR 200 000

### 3.3.3.2. Health reports and analysis

The objective of this action is to produce information in form of reports and economic analysis needed on a short notice to support policy development and the evaluation of the effects of its implementation. The objective with regard to health reports is to produce well-structured and informative reports on health topics, selected by the Commission as important for the public, stakeholders and policymakers. The objective with regard to economic analysis is to provide an economic analysis of health and health-related phenomena in order to establish sound evidence for policymaking. In addition, this heading would support data collection as necessary for the forthcoming innovation partnership on active and healthy ageing.

[Existing framework contract]

### 3.3.3.3. Feasibility study on health workforce

The objective of this action is to produce a feasibility study for EU level collaboration on monitoring health workforce trends, forecasting health workforce needs and assisting the Member States in workforce planning. The objective of the study will be to examine the benefits and costs of sharing good practice and innovation at EU level in order to promote long term workforce planning in the Member States; assess and predict current and future changes in skill mix; to match workforce to patients' needs in an ageing society; and to assess what investment is needed in training to better utilise new technology.

[Existing framework contract]

### 3.3.3.4. Study on the package leaflets and the summaries of product characteristics of medicinal products for human use

The objective of the action is to provide the Commission with an assessment on the readability of the package leaflets and the summaries of product characteristics. The action seeks to identify possible shortcomings, as regards their value as a source of information for healthcare professionals and the public, with a particular focus on older persons, the rational use of medicines and patient safety in the readability, layout and content of the summaries of product characteristics and the package leaflets; to identify the causes of such shortcomings, and their potential consequences for the health of patients; and to make recommendations for the improvement of the summaries of product characteristics and the package leaflets in order to increase their value for the healthcare professionals and the general public, their contribution to the rational use of medicines and patient safety. This action will produce a thorough assessment enabling the Commission to consider any necessary action in this area and contributing to the report to the European Parliament and the Council. The report to the European Parliament and the Council is due 24 months after publication of Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>(1)</sup>. The amending directive was published on 31 December 2010. The study should therefore be completed in the first quarter of 2012 in order for the Commission to prepare the report within the timeline foreseen.

[Existing framework contract]

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<sup>(1)</sup> OJ L 311, 28.11.2001, p. 67.

## ANNEX II

**Criteria for financial contributions to projects under the second programme of Community action in the field of health (2008-2013)**

Decision No 1350/2007/EC, Article 4(1)(a)

This document applies only to co-funding of individual actions under the Health Programme through grants following a call for proposals for projects.

**1. GENERAL PRINCIPLES**

1. The Financial Regulation and its Implementing Rules are the reference documents for the implementation of the Health Programme.

2. Grants must comply with the following principles:

- Co-financing rule: external co-financing from a source other than EU funds is required, either by way of the beneficiary's own resources or the financial resources of third parties. Contributions in kind from third parties may be considered as co-financing if considered necessary or appropriate (Articles 113 of the Financial Regulation and 172 of the Implementing Rules),
- No-profit rule: the grant may not have the purpose or effect of producing a profit for the beneficiary (Articles 109(2) of the Financial Regulation and 165 of the Implementing Rules),
- No-retroactivity rule: expenditure eligible for financing must be incurred after the agreement is signed. In exceptional cases, it may be acceptable to consider expenditure that was incurred from the date of submission of the grant application, but not earlier (Article 112 of the Financial Regulation),
- No-cumulation rule: only one grant may be awarded for a specific action carried out by a given beneficiary per financial year (Article 111 of the Financial Regulation) <sup>(1)</sup>.

3. Proposals for actions (projects) will be evaluated on the basis of three categories of criteria:

- exclusion and eligibility criteria, to assess the applicant's eligibility — Article 114 of the Financial Regulation,
- selection criteria, to assess the applicant's financial and operational capacity to complete the proposed action — Article 115 of the Financial Regulation,
- award criteria, to assess the quality of the proposal taking into account its cost.

These three categories of criteria will be considered consecutively during the evaluation procedure. A project which fails to meet the requirements of one category will not be considered at the next evaluation stage and will be rejected.

4. In respect of the Health Programme, priority will be given to projects which:

- have an innovative character in relation to the existing situation and are not of a recurrent nature,
- provide added value at European level in the field of health: projects are to yield relevant economies of scale, involve an appropriate number of eligible countries in relation to the scope of the project and be capable of being replicated elsewhere,
- contribute to and support the development of EU policies in the field of health,
- devote adequate attention to an efficient management structure, a clear evaluation process and a precise description of the expected results,
- include a plan for using and disseminating the results at European level to appropriate target audiences.

<sup>(1)</sup> This means that a specific action, submitted by one applicant for a grant, can be approved for co-financing by the Commission only once a year, regardless of the length of this action.

## 2. EXCLUSION AND ELIGIBILITY CRITERIA

1. Applicants will be excluded from participation in an award procedure under the Health Programme if they are in any of the situations of exclusion listed in Articles 93 and 94 of the Financial Regulation.

Evidence: Candidates shall provide a declaration on their honour, duly signed and dated, stating that they are not in any of the situations listed above.

2. Any proposals received after the deadline for receipt, any incomplete proposals or proposals failing to meet the formal requirements laid down in the call for proposals will not be considered for funding. This does not apply in the case of obvious clerical errors within the meaning of Article 178(2) of the Implementing Rules.

Each application must contain the documents required in the call for proposals, including the following documents:

- administrative data on the main partner and associated partners,
- technical description of the project,
- global budget of the project and the requested level of EU co-financing.

Evidence: Application content.

3. Actions which have already commenced by the date on which the grant application is registered will be excluded from participation in the Health Programme.

Evidence: The scheduled starting date and duration of the action must be specified in the grant application.

## 3. SELECTION CRITERIA

Only proposals which have met the requirements of the exclusion criteria will be eligible for evaluation. All 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-funding.

Evidence: Applicants must supply the profit and loss accounts and the balance sheets for the past two complete financial years.

The verification of financial capacity will not apply to public bodies, or to international public organisations created by inter-governmental agreements or to specialist agencies created by the latter.

2. Operational capacity:

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

Evidence: Applicants must supply the organisation's most recent annual activity report including operational, financial and technical details and the curricula vitae of all relevant professional staff in all the organisations involved in the project.

3. Additional documents to be supplied at the request of the Commission:

If so requested, applicants must supply an external audit report produced by an approved auditor, certifying the accounts for the last financial year available and giving an assessment of the applicant's financial viability.

## 4. AWARD CRITERIA

Only projects which have met the requirements of the exclusion and selection criteria will be eligible for further evaluation on the basis of the following award criteria.

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

- (a) project's contribution to meeting the objectives and priorities of the Health Programme, as defined in the Work Plan for 2011 (8 points);
- (b) strategic relevance in terms of relevance to the EU Health Strategy <sup>(1)</sup> and in terms of expected contribution to the existing knowledge and implications for health (8 points);
- (c) added value at European level in the field of public health (8 points):
  - impact on target groups, long term effect and potential multiplier effects, such as replicable, transferable and sustainable activities,
  - contribution to complementarity, synergy and compatibility with relevant EU policies and other programmes;

(d) pertinence of the geographical coverage (8 points):

Applicants must ensure that a geographical coverage of the project is appropriate with regard to its objectives, explaining the role of the eligible countries as partners and the relevance of the project resources or target populations they represent.

Proposals with national or sub-national dimension (i.e. which involve only one eligible country or a region of a country) will be rejected;

(e) adequacy of the project with social, cultural and political context (8 points):

Applicants must relate the project 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 of the project (30 points, threshold: 15 points):

(a) Evidence base (6 points):

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

(b) Content specification (6 points):

Applicants must clearly describe the 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 (6 points):

Applicants must clearly identify the progress the project intends to accomplish within the field in relation with 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 European and international level;

(d) Evaluation strategy (6 points):

Applicants must clearly explain the kind and adequacy of methods proposed and indicators chosen.

(e) Dissemination strategy (6 points):

Applicants must clearly illustrate the adequacy of the envisaged strategy and methodology proposed to ensure transferability of results and sustainability of the dissemination.

<sup>(1)</sup> COM(2007) 630 final; [http://ec.europa.eu/health/ph\\_overview/strategy/health\\_strategy\\_en.htm](http://ec.europa.eu/health/ph_overview/strategy/health_strategy_en.htm)



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

(a) Planning and organisation of the project (5 points):

Applicants must clearly describe the activities to be undertaken, timetable and milestones, deliverables, nature and distribution of tasks, risk analysis;

(b) Organisational capacity (5 points):

Applicants must clearly describe the management structure, competency 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 among the different partners, synergy and complementarity of the various project partners and network structure;

(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-funding;

(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 within partners at a minimum reasonable level, avoiding excessive fragmentation.

Applicants must clearly describe the financial circuits, responsibilities, reporting procedures and controls.

Any project failing to achieve the threshold will be rejected.

Following the evaluation, a list is drawn up of proposals recommended for funding, ranked according to the total number of points awarded. Depending on budget availability, the highest ranked proposals will be awarded co-funding.

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## ANNEX III

**Criteria for financial contributions to the functioning of a non-governmental body or a specialised network (operating grants) under the second programme of Community action in the field of health (2008-2013)**

Decision No 1350/2007/EC, Article 4(1)(b)

**1. EXCLUSION AND ELIGIBILITY CRITERIA**

Financial contributions by the EU may be awarded to the functioning of a non-governmental body or the costs associated with the coordination of a specialised network by a non-profit body. A specialised network is a European network representing non-profit bodies active in the Member States or in countries participating in the Health Programme and promoting principles and policies consistent with the objectives of the Programme, which have a relevant track record of joint achievements (e.g. successfully completed projects and/or joint publications) and established rules of collaboration (e.g. SOPs or a memorandum of understanding). An organisation or a specialised network may receive funding if it:

- is non-profit-making and independent of industry, commercial and business or other conflicting interests,
- has members in at least half of the Member States,
- has a balanced geographical coverage,
- pursues as its primary goal one or more objectives of the Health Programme,
- does not pursue general objectives directly or indirectly contrary to the policies of the European Union or associated with an inadequate image,
- has provided to the Commission satisfactory accounts of its membership, internal rules and sources of funding,
- has provided to the Commission its annual work programme for the financial year and the most recent annual activity report and, if available, the most recent evaluation report,
- is not in any of the situations of exclusion listed in Articles 93 and 94 of the Financial Regulation.

Any proposals received after the deadline for receipt, any incomplete proposals or proposals failing to meet the formal requirements laid down in the call for proposals will not be considered for funding. This does not apply in the case of obvious clerical errors within the meaning of Article 178(2) of the Implementing Rules.

The criterion 'independent from industry, commercial and business or other conflicting interest' will be assessed as described in Annex VI.

**2. SELECTION CRITERIA**

The selection criteria make it possible to assess the applicant organisation's financial and operational capacity to complete the proposed work programme.

Only organisations with the resources necessary to ensure their functioning can be awarded a grant. As evidence of this they must:

- attach a copy of the organisation's annual accounts for the last financial year for which the accounts have been closed preceding the submission of the application. If the grant application is from a new European organisation, the applicant must produce the annual accounts (including balance sheet and profit and loss statement) of the member organisations of the new body for the last financial year for which the accounts have been closed preceding the submission of the application,
- present a detailed forward budget for the organisation, balanced in terms of income and expenditure,
- attach an external audit report produced by an approved auditor in case of operating grant applications in excess of EUR 100 000, certifying the accounts for the last financial year available and giving an assessment of the applicant organisation's financial viability.

Only organisations with the necessary operational resources, skills and professional experience may be awarded a grant. To this end, the following information must be enclosed in support of the application:

- the organisation's most recent annual activity report, or, in the case of a newly constituted organisation, the curricula vitae of the members of the management board and other staff and the annual activity reports of the new body's member organisations,
- any references relating to participation in or applications for actions financed by the European Community, conclusion of grant agreements and conclusion of contracts from Community budget.

### 3. AWARD CRITERIA

The award criteria make it possible to select work programmes that can guarantee compliance with the Community's objectives and priorities and can guarantee proper dissemination and communication, including visibility of Community financing.

To this end, the annual work programme presented with a view to obtaining EU funding must meet the following criteria:

1. Policy and contextual relevance of the non-governmental body or specialised network's annual work programme (25 points, threshold 13 points):
  - (a) Consistency of the annual work programme with the Health Programme and its annual Work Plan in terms of meeting the objectives and priorities (10 points);
  - (b) The organisation's activities <sup>(1)</sup> must be described in relation to the priorities detailed in the Work Plan for 2011 (10 points);
  - (c) Pertinence of the geographical distribution of the non-governmental body or specialised network. The annual work programme of the applicant should include activities in a representative number of participating countries. (5 points).
2. Technical quality of the annual work programme proposed (40 points, threshold 20 points):
  - (a) purpose of the annual work programme: the work programme of the applicant must clearly describe all objectives of the organisation or the specialised network and their suitability for achieving the expected results. The applicant must demonstrate that the work programme submitted gives a true and fair view of all activities planned for the organisation/specialised network in 2011, including those activities which do not fit in the Work Plan for 2011 of the Health Programme (10 points);
  - (b) operational framework: the applicant's work programme must clearly describe the activities planned, tasks, responsibilities and timetables of the part of their work programme consistent with the Work Plan for 2011 of the Health Programme and describe its relationship with the other parts of their activity (10 points);
  - (c) evaluation strategy: the applicant's work programme must clearly describe the internal and external evaluation of their activities and the indicators to be used (10 points);
  - (d) dissemination strategy: the beneficiary must clearly illustrate the adequacy of the actions and methods for communication and dissemination (10 points).
3. Management Quality (35 points, threshold 18 points):
  - (a) planning of the annual work: the applicant must clearly describe the activities to be undertaken, the timetable; the list of deliverables and provide the nature and the distribution of tasks and a risk analysis (10 points);
  - (b) organisational capacity: the applicant must clearly describe the management process, human resources and competencies of staff, responsibilities, internal communication, decision making, monitoring and supervision. The applicant must also clearly specify the working relationships with relevant partners and stakeholders (10 points);

<sup>(1)</sup> Lobbying activities exclusively targeted at EU Institutions are excluded from funding.

- (c) overall and detailed budget: the applicant must ensure that the budget is relevant, appropriate, balanced and consistent in itself and for the activities planned (10 points);
- (d) financial management: the applicant must clearly describe the financial circuits, responsibilities, reporting procedures and, where possible, controls (5 points).

Any proposal failing to achieve the threshold will be rejected.

Following the evaluation, a list is drawn up of proposals recommended for funding, ranked according to the total number of points awarded. Depending on budget availability, the highest ranked proposals will be awarded co-funding.

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## ANNEX IV

**Criteria for financial contributions to joint actions under the second programme of Community action in the field of health (2008-2013)**

Decision No 1350/2007/EC, Article 4(3)

**1. EXCLUSION AND ELIGIBILITY CRITERIA**

Joint actions may be implemented with public bodies or non-governmental bodies:

- which are non-profit making and independent of industry, commercial and business or other conflicting interest,
- which pursue as their primary goal one or more objectives of the Programme,
- which do not pursue general objectives directly or indirectly contrary to the policies of the European Union or associated with an inadequate image,
- which have provided to the Commission satisfactory accounts of their membership, internal rules and sources of funding,
- which are not in any of the situations of exclusion listed in Articles 93 and 94 of the Financial Regulation.

The criterion 'independent from industry, commercial and business or other conflicting interest' will be assessed as described in Annex VI.

**2. SELECTION CRITERIA**

The selection criteria make it possible to assess the applicant's financial standing and operational capability to complete the proposed work programme.

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

Applicants must have adequate financial resources to maintain their activity throughout the period during which the activity is being carried out and to participate in its co-funding.

Each applicant must provide:

- a clear, exhaustive and well detailed estimated budget of the expenses in relation to the corresponding activities carried out by each body taking part in the joint project,
- a copy of the annual accounts for the last financial year for which the accounts have been closed preceding the submission of the application (for non-profit bodies other than public bodies).

**3. AWARD CRITERIA**

Only joint actions which have met the requirements of the exclusion and selection criteria will be eligible for further evaluation on the basis of the following award criteria.

**1. Policy and contextual relevance of the project (40 points, threshold: 20 points):**

- (a) Joint action's contribution to meeting the objectives and priorities of the Health Programme, as defined in the Work Plan for 2011 (8 points);
- (b) Strategic relevance in terms of relevance to the EU Health Strategy <sup>(1)</sup> and in terms of expected contribution to the existing knowledge and implications for health (8 points);

<sup>(1)</sup> COM(2007) 630 final; [http://ec.europa.eu/health/ph\\_overview/strategy/health\\_strategy\\_en.htm](http://ec.europa.eu/health/ph_overview/strategy/health_strategy_en.htm)

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

- impact on target groups, long term effect and potential multiplier effects such as replicable, transferable and sustainable activities,
- contribution to, complementarity, synergy and compatibility with relevant EU policies and other programmes;

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

Applicants must ensure that a geographical coverage of the action is appropriate with regard to its objectives, explaining the role of the eligible countries as partners and the relevance of the action resources or target populations they represent.

Proposals with national or sub-national dimension (i.e. which involve only one eligible country or a region of a country) will be rejected;

(e) Adequacy of the joint action with social, cultural and political context (8 points):

Applicants must relate the action to the situation of the countries or specific areas involved, ensuring the compatibility of envisaged activities with the culture and views of the target groups.

2. Technical quality of the joint action (30 points, threshold: 15 points):

(a) Evidence base (6 points):

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

(b) Content specification (6 points):

Applicants must clearly describe the 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 (6 points):

Applicants must clearly identify the progress the joint action intends to accomplish within the field in relation with 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 European and international level;

(d) Evaluation strategy (6 points):

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

(e) Dissemination strategy (6 points):

Applicants must clearly illustrate the adequacy of the envisaged strategy and methodology proposed to ensure transferability of results and sustainability of the dissemination.

3. Management quality of the joint action and budget (30 points, threshold: 15 points):

(a) Planning and organisation of the joint action (5 points):

Applicants must clearly describe the activities to be undertaken, timetable and milestones, deliverables, nature and distribution of tasks, and risk analysis;

(b) Organisational capacity (5 points):

Applicants must clearly describe the management structure, competency 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 among the different partners, synergy and complementarity of the various project partners and network structure;

(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-funding;

(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 joint action. The budget should be distributed within partners at a minimum reasonable level, avoiding excessive fragmentation.

Applicants must clearly describe the financial circuits, responsibilities, reporting procedures and controls.

Any proposal failing to achieve the threshold will be rejected.

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## ANNEX V

**Criteria for financial contributions for conferences under the second programme of Community action in the field of health (2008-2013)**

Decision No 1350/2007/EC, Article 4(1)(a)

**1. EXCLUSION AND ELIGIBILITY CRITERIA**

1. Applicants will be excluded from participation in an award procedure of the Health Programme if they are in any of the situations of exclusion listed in Articles 93 and 94 of the Financial Regulation.

Evidence: Candidates shall provide a declaration on their honour, duly signed and dated, stating that they are not in any of the situations listed above.

2. Any proposals received after the deadline for receipt, any incomplete proposals or proposals failing to meet the formal requirements laid down in the call for proposals will not be considered for funding. This does not apply in the case of obvious clerical errors within the meaning of Article 178(2) of the Implementing Rules.

Each application must contain the documents required according to the call for proposals, including the following documents:

- administrative data on the main partner,
- technical description of the conference,
- global budget of the conference and the requested level of EU co-financing.

Evidence: Application content.

3. Actions which have already commenced by the date on which the grant application is registered will be excluded from participation in the Health Programme. The duration of the action must not exceed 12 months.

Evidence: The scheduled commencement date and duration of the action must be specified in the grant application.

**2. SELECTION CRITERIA**

Only proposals which have met the requirements of the exclusion criteria will be eligible for evaluation. All 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-funding.

Evidence: Applicants must supply the profit and loss account and the balance sheets for the past two complete financial years.

The verification of financial capacity will not apply to public bodies, or to international public organisations created by inter-governmental agreements or to specialist agencies created by the latter.

**2. Operational capacity:**

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

Evidence: Applicants must supply the organisation's most recent annual activity report including operational, financial and technical details and the curricula vitae of all relevant professional staff in all the organisations involved in the conference.



3. Additional documents to be supplied at the request of the Commission:

If so requested, applicants must supply an external audit report produced by an approved auditor, certifying the accounts for the last financial year available and giving an assessment of the applicant's financial viability.

3. AWARD CRITERIA

1. Content of the proposal (60 points, threshold 30 points):

(a) Relevance of the content and expected results of the event in relation to the objectives and priorities described in the Health Programme and its annual Work Plan taking into account the priorities set out in the Communication COM(2010) 2020 (15 points);

(b) Participation (15 points):

The applicant must clearly describe the expected number and profile/function of the target participants in the event, making reference to distribution by Member State, organisation and type of expertise;

(c) European dimension (15 points):

The conference must have a wide European Union dimension, with participation of representations from 10 or more countries participating in the Health Programme;

(d) Follow-up and evaluation methodology (15 points):

The applicants must clearly describe their dissemination strategy.

An adequate evaluation should be foreseen based on an evaluation plan with corresponding design, method, responsibilities and timing making use of indicators.

2. Management Quality (40 points, threshold 20 points):

(a) Planning of the event (15 points):

The applicant must clearly describe the methodology, tools, timetable and milestones, deliverables, nature and distribution of tasks, risk analysis, and financial circuits;

(b) Organisational capacity (10 points):

The applicant must clearly describe the management structure, competency of staff, responsibilities, decision making, monitoring and supervision;

(c) Overall and detailed budget (15 points):

The applicant must ensure that the budget is relevant, appropriate, balanced and consistent in itself and in relation to the objective/s of the conference.

Any proposal failing to achieve the threshold will be rejected.

Following the evaluation, a list is drawn up of proposals recommended for funding, ranked according to the total number of points awarded. Depending on budget availability, the highest ranked proposals will be awarded co-funding.

## ANNEX VI

**Criteria for independence from industry, commercial and business or other conflicting interest applicable to operating grants and grants for joint actions under the second programme of Community action in the field of health (2008-2013)**

Decision No 1350/2007/EC, Articles 4.1(b) and 4.3

A conflicting interest occurs when an individual or organisation has multiple interests, one of which could possibly corrupt the motivation to act in the other.

The criterion 'independent from industry, commercial and business or other conflicting interest' refers to three requirements all of which the applicant organisation has to meet:

#### 1. LEGAL INDEPENDENCE

To be eligible for funding, an NGO has to be independent from other entities representing industry, commercial and business or other conflicting interests.

Two legal entities shall be regarded as independent of each other where neither is under the direct or indirect control of the other or under the same direct or indirect control of a third entity as the other.

Control may in particular take either of the following forms:

- (a) The direct or indirect holding of more than 50 % of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
- (b) The direct or indirect holding of decision-making powers, in fact or in law, in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:

- (c) The direct or indirect holding of more than 50 % of the nominal value of the issued share capital of the applicant organisation or a majority of voting rights of the shareholders or associates of the legal entities is held by the same public body;
- (d) The legal entities concerned are owned or supervised by the same public body.

#### 2. FINANCIAL INDEPENDENCE

In order to be considered independent, applicant organisations must unilaterally commit not to receive more than 20 % of their core funding from private sector organisations <sup>(1)</sup> representing a conflicting interest, or from other sources representing a conflicting interest during the financial years covered by the grant.

Core funding shall mean financing required for the basic structure of an organisation, including salaries of full-time staff, facilities, equipment, communications, and the direct expenses of day-to-day work. Core funding also includes financing of all permanent or regularly repeated activities. Core funding requirements are often budgeted separately from other costs like specific actions or projects.

#### 3. TRANSPARENCY OF THE APPLICANT'S ACTIVITIES AND FUNDING

All activities should be published in the applicant's annual report <sup>(2)</sup>.

Applicants working with private sector actors regarded ineligible for example by the nature of their activity which is incompatible with the basic principles of the European Union as stated in Article 2 and 3 of the EU Treaty, can be considered unacceptable.

- (a) All information on funding is to be made available to the public via the applicant's website, broken down by type (core and project funding, contribution in kind) and by funding entity.

<sup>(1)</sup> The term 'private sector' covers 'for-profit' companies/enterprises/corporations, business organisations or other entities irrespective of their legal nature (registered/not registered), ownership (wholly or partially privately owned/state owned) or size (large/small), if they are not controlled by the public.

<sup>(2)</sup> Collaborators in a position that could lead to a conflict of interest (Article 52 of the Financial Regulation and Article 34 of the Implementing Rules) shall be listed.

(b) Applicant's existing position statements regarding their requirement on transparency are to be publicly available.

#### 4. ASSESSMENT OF INDEPENDENCE

Legal independence and transparency is assessed based on the latest available information provided by the applicant together with the application. The financial independence will be assessed based on the financial information for the financial year for which the grant will be attributed at the time of the final report. This information has to be provided according to the form published with the call for proposals and must be certified by an independent auditor. If these accounts show that during any of the financial years covered by the grant, the beneficiaries have received more than 20 % of their core funding from private sector organisations representing a conflicting interest, or from other sources representing a conflicting interest, the entire amount of the grant shall be recovered.

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## ANNEX VII

**Criteria for exceptional utility for project grants and operating grants under the second programme of Community action in the field of health (2008-2013)**

Decision No 1350/2007/EC, Articles 4(1)(a), 4(1)(b) and 4(3)

**1. GENERAL PRINCIPLES**

Exceptional utility may be accorded to proposals that have very high European added value in the following areas:

- Contribution to:
  - improving the health of European citizens, as measured where possible by appropriate indicators, including the Healthy Life Years indicator,
  - reducing health inequalities in and between EU Member States and regions,
  - building capacity for development and implementation of effective public health policies particularly in areas of high need;
- involvement of new (non-traditional) actors for health in sustained, cooperative and ethically sound actions, both at regional or local level and across participating countries. This includes the public sector, the private sector and stakeholders among wider civil society whose primary aims are not limited to public health (for example among the youth, ethnic groups and other public interest spheres such as environment and sport).

Proposals which meet the abovementioned criteria can be considered of exceptional utility. Applicants must be able to demonstrate how the proposed action will contribute to the abovementioned areas by complying with criteria specified in the following sections.

**2. EXCEPTIONAL UTILITY OF PROJECTS**

A maximum EU contribution per beneficiary (i.e. per main and per associated beneficiary) of 80 % of eligible costs may be envisaged where a proposal is of exceptional utility, as specified under the section 'General principles' above. No more than 10 % of funded projects should receive EU co-funding of over 60 %. Proposals for projects requesting more than 60 % co-funding will need to comply with the following criteria:

- at least 60 % of the total budget of the action must be used to fund staff. This criterion is intended to promote capacity building for development and implementation of effective public health policies,
- at least 25 % of the budget of the proposed action must be allocated to Member States with a GDP per capita (as published by Eurostat in its latest statistical report) in the lower quartile of all EU Member States. This criterion is intended to contribute to the reduction of health inequalities among EU Member States,
- a score of at least 5 out of 8 marks must be achieved for all the award criteria of the policy relevance block mentioned in Annex II. This criterion aims at promoting the improvement of the health of European citizens, in the sense of enhancing policy relevance,
- at least 10 % of the budget must be allocated to organisations that have not received any funding under the first and the second Health Programme in the past 5 years. This criterion is intended to promote the involvement of new actors for health.

**3. EXCEPTIONAL UTILITY OF OPERATING GRANTS**

A maximum EU contribution of 80 % of eligible costs may be envisaged where a proposal for a new operating grant is of exceptional utility, as specified under the section 'General principles' above.

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Proposals for new operating grants requesting more than 60 % co-funding will need to comply with the following criteria:

- at least 25 % of the members or candidate members of the non-governmental bodies or organisations forming the specialised network come from Member States with a GDP per capita (as published by Eurostat in its latest statistical report) in the lower quartile of all EU Member States,
- the reduction of health inequalities at EU, national or regional level is manifested in the mission as well as the annual work programme of the applicant organisation/specialised network.

For operating grants which are renewed, the exceptional utility status will remain the same as under the 2010 call for proposals.

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