COMMISSION IMPLEMENTING DECISION
of 28 November 2012

concerning the adoption of the 2013 work plan in the framework of the second programme of Community action in the field of health (2008-2013), the selection, award and other criteria for financial contributions to the actions of this programme and the EU payment to the WHO Framework Convention on Tobacco Control, serving as a financing decision

(2012/C 378/07)

THE EUROPEAN COMMISSION,

Having regard 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 (2008-2013) (1), 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 (2), and in particular Articles 53(a), 75 and 110 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 (3), and in particular Articles 90 and 168(1)(c) and (f) thereof,


Whereas:

(1) It is appropriate to authorise grants without a call for proposals to the bodies identified in the work plan and for the reasons provided therein.

(2) The use of indirect centralised management is justified as per Articles 4 and 6 of Decision 2004/858/EC.

(3) Evidence of the existence and proper operation of the elements listed in Article 56 of Regulation (EC, Euratom) No 1605/2002, within the entities to be entrusted with implementation of the Union budget by indirect centralised management, has been obtained by the authorising officer by delegation.

(4) This Decision should allow for the payment of interest due for late payment on the basis of Article 83 of Regulation (EC, Euratom) No 1605/2002 and Article 106(5) of Regulation (EC, Euratom) No 2342/2002.

(5) For the application of this Decision, it is appropriate to define the term ‘substantial change’ within the meaning of Article 90(4) of Regulation (EC, Euratom) No 2342/2002.

(6) This Decision is also a financing decision for the EU payment to the WHO Framework Convention on Tobacco Control.

(7) The measures provided for in this Decision are in accordance with the opinion of the Committee of the second programme of Community action in the field of health (2008-2013) established by Article 10 of Decision No 1350/2007/EC,

HAS DECIDED AS FOLLOWS:

Article 1

The 2013 work plan for Implementing the second programme of Community action in the field of health (2008-2013) (hereinafter 'work plan'), as set out in Annex I, and the selection, award and other criteria for financial contributions to the actions of this programme, as set out in Annexes II, III, IV, V, VI and VII, and the EU payment to the WHO Framework Convention on Tobacco Control, are adopted. This constitutes a financing decision within the meaning of Article 75 of Regulation (EC, Euratom) No 1605/2002.

Article 2

The maximum contribution for the work plan is set at EUR 55 509 000 and shall be financed from the following lines of the General Budget of the European Union for 2013:

(a) budget line 17 03 06 — EU action in the field of health: EUR 49 800 000;

(b) budget line 17 01 04 02 — Expenditure on administrative management: EUR 1 500 000;

(c) budget line 17 01 04 30 — Subsidy to the Executive Agency: EUR 4 209 000.

(1) OJ L 301, 20.11.2007, p. 3.
Estimated additional contributions from the EFTA/EEA countries and Croatia for their participation in the Health programme are:

— EFTA/EEA countries: EUR 1 554 252.

— Croatia: EUR 69 000.

The total estimated contribution for budget line 17 03 06 — EU action in the field of health is EUR 51 260 900, for budget line 17 01 04 02 — Expenditure on administrative management EUR 1 544 500 and for budget line 17 01 04 30 — Subsidy to the Executive Agency EUR 4 326 852.

The maximum contribution for the EU payment to the WHO Framework Convention on Tobacco Control is set at EUR 192 000 and shall be financed from the following line of the General Budget of the European Union for 2013:

— budget line 17 03 05 — International agreements and membership of international organisations in the field of public health and tobacco control.

These appropriations shall cover interest due for late payment.

Implementation of this Decision is subject to the availability of the appropriations provided for in the draft budget for 2013 after the adoption of the budget for 2013 by the budgetary authority or provided for in the provisional twelfths.

Article 3
The budgetary implementation of tasks related to actions to be carried out by indirect centralised management, as set out in the work plan, may be entrusted to the Executive Agency for Health and Consumers identified therein.

Article 4
Cumulated changes of allocations to the specific financing mechanisms described in Annex I not exceeding 20 % of the maximum contribution set in Article 2 are not considered to be substantial within the meaning of Article 90(4) of Regulation (EC, Euratom) No 2342/2002, where those changes do not significantly affect the nature and objective of the work plan. The increase of the maximum contribution set in Article 2 may not exceed 20 %.

The authorising officer responsible may adopt such changes in accordance with the principle of sound financial management and principle of proportionality.

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

Article 5
Grants may be awarded without a call for proposals to the bodies identified in the work plan, in accordance with the conditions specified therein.

Done at Brussels, 28 November 2012.

For the Commission
Maroš ŠEFČOVIČ
Vice-President
ANNEX I

Work plan 2013 for the second programme of Community action in the field of health (2008-2013)

1. POLICY AND LEGAL CONTEXT

Article 168 of the Treaty on the Functioning of the European Union (TFEU) and ensuing legal obligations and policy commitments are the basis for action presented in this work plan. The Treaty states that EU action in the area of public health is designed to support and complement Member States’ action in improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. The EU Health Strategy set out in the Commission White Paper Together for Health: A strategic approach for the EU 2008-2013 (COM(2007) 630 final) provides a policy framework for all the areas covered by this work plan.

In addition to the Member States of the European Union, third countries can participate in the health programme if the necessary agreements are in place. The EFTA/EEA countries, Iceland, Liechtenstein and Norway, do so under the conditions specified 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, and the western Balkan countries included in the stabilisation and association process, may participate in the programme. Of these countries Croatia currently does so.

In accordance with recital 33 of the Programme Decision, collaboration should be facilitated with third countries not participating in the programme. This should not involve funding from the 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. RESOURCES

This work plan contains implementing measures for 2013.


On the basis of the objectives set out in Decision No 1350/2007/EC, the indicative breakdown of the operational budget (budget line 17 03 06 — EU action in the field of health) per financing mechanism is as follows:

Grants (all grants implemented by the EAHC under indirect centralised management):

— project grants: EUR 12 330 900,
— operating grants: EUR 5 000 000,
— grants for joint actions: EUR 13 800 000,
— conference grants: EUR 800 000 (EUR 200 000 Presidency conferences, EUR 600 000 other conferences),
— direct grants with international organisations: EUR 1 200 000.

Procurement (implemented by the Commission or by the EAHC): EUR 13 300 000.

Other actions (implemented by the Commission or by the EAHC): EUR 4 830 000.

Budget line 17 01 04 02 — Expenditure on administrative management is intended to cover expenditure on studies, meetings of experts, information, publications and technical and administrative assistance for IT systems. These are directly linked to achieving the objectives of the programme.

3. FINANCING MECHANISMS

All grants are covered by written agreements.

3.1. Project grants

Project grants 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% if a proposal meets the criteria for exceptional utility set out in Annex VII. Annex II contains the exclusion, eligibility, selection and award criteria for project grants.

A project grant should be of sufficient size, so that ambitious objectives with high European added value can be reached and an efficient European dissemination strategy implemented.

Only proposals that directly correspond to the topic and description as set out in this work plan, and where ‘project grant’ or ‘project grants’ are indicated as the financing mechanism, will be considered for funding. Proposals that only address the thematic area but do not match the specific description of a given action will not be considered for funding.

The indicative time frame for publishing the call for proposals for project grants in the Official Journal is the fourth quarter of 2012.

3.2. Operating grants

Operating grants 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 % if a proposal meets the criteria for exceptional utility set out in Annex VII. Annex III contains the exclusion, eligibility, selection and award criteria for operating grants. Annex VI contains the criteria for independence from industry, commercial and business or other conflicting interests.

Operating grants may be awarded to renew such grants awarded under the work plan for 2012. New operating grants may be awarded to non-governmental bodies and specialised networks active in areas corresponding to the three objectives of the health programme. Work under operating grants should contribute to reaching the priorities of the European Union as set out in Commission Communication COM(2010) 2020 of 3 March 2010 Europe 2020 — A strategy for smart, sustainable and inclusive growth (1). Particularly relevant issues include active and healthy ageing, sustainable health systems, health workforce, health threats and patient safety.

The indicative time frame for publishing the call for proposals for operating grants in the Official Journal is the fourth quarter of 2012.

3.3. Grants for joint actions

Joint actions allow the competent authorities of the Member States/other countries participating in the programme and the European Commission to take forward work on jointly identified issues. Public bodies or non-governmental bodies based in a Member State/another country that participates in a joint action may participate in the joint action in question. However, they have to be expressly mandated to do so by the authorities of the Member State/other 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 (see Annex VII). Exceptional utility co-financing of 70 % is envisaged for the joint action ‘Facilitating collaboration among the Member States for the effective operation of the pharmacovigilance system in the EU’ (point 4.1.5.2 below) because of its contribution to the effective implementation of EU legislation in this field. In other cases, the criteria for exceptional utility laid down in Annex VII will apply. Annex IV contains the exclusion, eligibility, selection and award criteria for joint actions. Annex VI contains the criteria for independence from industry, commercial and business or other conflicting interest.

Member States/other countries participating in the programme that intend to take part in one or more joint actions must declare their intention to the Commission prior to the expiry of the deadline for submitting proposals. With the exception of NGOs operating at EU level, only organisations established in Member States/other countries participating in the programme that have made this declaration may apply to take part in joint actions.

The indicative time frame for publishing the call for proposals for joint actions in the Official Journal is the fourth quarter of 2012.

3.4. Conference grants

For administrative reasons, conferences eligible for co-funding, apart from Presidency conferences, must take place in 2014.

3.4.1. Presidency conferences — De jure monopoly

According to Article 168(1)(c) of the Implementing Rules, 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 involve representation at the highest national and European levels, are to be organised exclusively by the Member State holding the Presidency of the European Union. Given the unique role of the Presidency in the framework of EU activities, the Member State responsible for organising the event is considered as having a de jure monopoly.

Two conferences organised by the Presidencies of the European Union may receive up to EUR 100 000 each. The maximum rate of EU co-financing is 50% of eligible costs incurred.

The Presidency must submit to the EAHC a request for a grant for the conference concerned, via the Permanent Representation, using a form provided by the EAHC. This has to be done at least four months before the event.

The Presidency conferences to be financed under this work plan are an eHealth conference planned for May 2013 under the Irish Presidency and a conference 'Mental Health: Challenges and Possibilities' planned for October 2013 under the Lithuanian Presidency.

3.4.2. Other conferences

Conference grants may be awarded for the organisation of conferences that correspond to the three objectives of the health programme. To be awarded funding, conferences should promote the priorities of the European Union as set out in Commission Communication COM(2010) 2020 of 3 March 2010 — A strategy for smart, sustainable and inclusive growth. Particularly relevant issues include active and healthy ageing, sustainable health systems, health workforce, health threats and patient safety.

Conferences must have a broad European dimension. They have to be organised by a public or non-profit-making body established in a country participating in the 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 time frame for publishing the call for proposals for conferences in the Official Journal is the fourth quarter of 2012.

3.5. Direct grant agreements with international organisations

According to Article 168(1)(f) of the Implementing Rules, 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 actually incurred. In accordance with recital 33 of the Programme Decision, activities involving third countries not participating in the 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 programme.

Funding through direct grants will be awarded to the international organisations below because of their specific competence and high degree of specialisation in the areas covered by the direct grants set out in Sections 4.1, 4.2 and 4.3:

— Council of Europe (CoE)

The Council of Europe has specific expertise in the harmonisation and coordination of standardisation, regulation and quality control of medicines, blood transfusion, organ transplantation, pharmaceuticals and pharmaceutical care.

— Organisation for Economic Cooperation and Development (OECD)

The OECD promotes policies to improve the economic and social well-being of people. The OECD works to strengthen health indicators and data, and analyse the organisation and performance of health systems, including on the health workforce.

— World Health Organisation (WHO)

The WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

3.6. Procurement

Procurement covers activities such as the evaluation and monitoring of actions and policies; studies; provision of advice, data and information on health; scientific and technical assistance; communication, awareness-raising and dissemination of results; and information technology applications in support of policies. Calls for tenders are expected to be published in the Official Journal during the first half of 2013. Framework contracts and new service contracts will be used.
3.7. Other actions

Other actions cover contributions paid by the EU as subscriptions to bodies of which it is a member in the meaning of Article 108(2)(d) of the Financial Regulation, administrative agreements with the Joint Research Centre (JRC), subdelegation to Eurostat, system inspections on medicinal products and special indemnities paid to experts for participating in meetings and for work on scientific opinions and advice on health systems.

3.8. EU payment to the WHO Framework Convention on Tobacco Control

The European Union is a full party to the WHO Framework Convention on Tobacco Control (FCTC). Payment of the 2013 EU contribution to the FCTC will be made under budget line 17 03 05 — International agreements and membership of international organisations in the field of public health and tobacco control, and not from the programme. The amount of this payment is based on the decision on the work plan and budget for the financial period 2012-2013 taken by the Fourth Conference of the Parties to the Convention in November 2010 (FCTC/COP/4/20).

The EU contribution is set at USD 145,225 for 2013. To cover exchange rate fluctuations, the maximum amount is set at EUR 192,000 for 2013. The FCTC Secretariat will manage the funds according to WHO financial rules.

4. PRIORITIES FOR 2013

People’s health is a key asset for society and for the economy. A healthy population will play an important role in achieving the Europe 2020 targets for smart, sustainable and inclusive growth. The current economic and financial crisis underscores the need to invest effectively in health, in order to deliver better services with sustainable health budgets. This work plan supports action that seeks to help build modern, responsive, inclusive and cost-effective health systems that are sustainable. Effective ways to invest in health will be researched in order to provide Member States with advice and information in support of their efforts to arrive at and maintain efficient and sustainable health care systems.

Improved living conditions and advances in medicine and health care enable people to live longer. This leads to increased demand for health care. This work plan supports action that contributes to reaching the aims of the Pilot Innovation Partnership on active and healthy ageing under the Flagship Initiative Innovation Union (1). Specific emphasis is placed on multimorbidity, adherence to treatment and the prevention of falls. The work plan also addresses the rising burden of chronic conditions and diseases by supporting action to improve best practice exchange, learning from a case study on diabetes and focusing on the complex area of multimorbidity. A further specific action on health promotion for older people will also be supported.

Given growing concerns about shortages of skilled health professionals and with demographic change increasing service demand, EU Member States have to find ways to ensure the sustainability of their health workforce. This work plan will support action to find effective ways of doing so. Such action supports the objectives of the Agenda for new skills and jobs (2), aiming in particular to equip people with the right skills for employment.

A safe and secure society is a prerequisite for the well-being of citizens and economic growth. Past events, such as the E. coli outbreak and the PIP silicone breast implant problem, have clearly demonstrated the added value of effective EU-level action. This work plan takes forward cooperation to improve responsiveness and preparedness in regard to cross-border health threats and to prepare and implement legislation on the safety and quality of organs and substances of human origin, blood and blood derivatives; pharmaceuticals and medical devices. The aim is ultimately to obtain and maintain the trust of EU citizens in effective EU-level action in these areas. Implementing legislation in the area of cross-border health care will also be supported.

Action related to inequalities supports the target of the European platform against poverty and social exclusion (3) to reduce poverty and social exclusion by at least 20 million by 2020. Such action aims at improving the access of vulnerable populations to health care and supporting their social inclusion.

Finally, a number of activities will be supported to comply with the programme’s third objective to ‘generate and disseminate health information and knowledge’. A series of activities are envisaged to collect data and information, to produce scientific evidence and to provide citizens, stakeholders and policy-makers with information helping them to take decisions on a range of issues affecting individual and collective health.

All actions to be funded under this work plan seek to generate European added value in supporting Member States’ efforts in areas where national action is not feasible or effective. The value added sought is both economic, entailing lower health care costs through more effective investment in health, and non-economic, entailing increased well-being of citizens.

The health programme aims to promote synergies with other EU programmes active in the field of health, notably the 7th Research Framework programme under its health theme. Whilst avoiding any duplication, actions funded from this work plan should capitalise on on-going research and innovation projects or on those funded in the past, foster their implementation in clinical practice and make use of their results and outcomes. A regularly updated list of on-going research and innovation projects can be found on the health research website at: http://ec.europa.eu/research/health/index_en.html

All activities funded from the health programme have to respect the rights and principles set out in the Charter of Fundamental Rights of the EU.

4.1. Actions under the first objective ‘Improve citizens’ health security’
4.1.1. Develop strategies and mechanisms for preventing, exchanging information on and responding to health threats from communicable and non-communicable diseases (point 1.1.1 in Annex to Programme Decision)
4.1.1.1. Improve access to early diagnosis of HIV/AIDS and timely treatment and care of most vulnerable groups and in priority regions

This action seeks to improve the early diagnosis of HIV/AIDS and provide timely treatment and care for vulnerable groups and in priority regions. The high prevalence of HIV/AIDS in populations most at risk is a major problem from the public health and social perspectives. Reaching out to these groups with appropriate prevention, diagnosis and treatment is important to reduce the transmission of HIV/AIDS.

This action will develop strategies to improve early diagnosis and to design tools for timely treatment for priority groups and regions. It will look into how best to reach people in need of testing and treatment. It will also promote, disseminate and implement good practice guidelines and manuals in cooperation with health professionals, people living with HIV/AIDS and health and social service providers. This action will contribute to increasing the uptake of available prevention, treatment and care options. It supports the implementation of Commission Communication COM(2009) 569 final of 26 October 2009 Combating HIV/AIDS in the European Union and neighbouring countries, 2009-2013 (1), which puts particular emphasis on populations most at risk and priority regions.

[Project grants] Indicative amount: EUR 1 500 000

4.1.2. Develop risk management capacity and procedures, improve preparedness and planning for health emergencies (point 1.1.3 in Annex to Programme Decision)
4.1.2.1. Public health emergency preparedness and planning

The objective of this action is to assess the preparedness of Member States to face public health emergencies. This action responds to lessons learned from previous health emergencies, such as the E. coli outbreak in 2011. The outcome of the action will be four studies: (a) a study on the state of play as regards the availability of plans in the area of generic preparedness in the Member States, including a gap-analysis of areas not covered by preparedness planning and the identification of incompatibilities between Member States’ plans, especially concerning cross-border interaction; (b) a study on intersectoral coordination focusing on the identification and prioritisation at European level of key sectors other than health that need to be prepared for emergencies; (c) a mapping exercise to improve preparedness for risk and crisis communication; and (d) a study addressing new health risks due to increased mobility in the context of globalisation (tourism, trade, travel, traffic) and global warming. The indicative number of contracts envisaged is 4.

[Framework contract]

4.1.2.2. Preparedness and response training and exercises

This action seeks to improve and reinforce preparedness in the EU to respond to potential risks. Past events have shown that there are gaps in understanding the respective roles, structures and capacities in place. Therefore, there is a need to
enhance knowledge and understanding of cross-border risks and the management of public health response to these, including identifying gaps in and obstacles to the effective management of a crisis. This action has two work packages. The first relates to exercises for Member States’ officials on preparedness for and response to serious cross-border health threats. These will cover the responsibilities and roles of different stakeholders in the existing structures and their interaction in managing an emergency. The second work package relates to training and continues the exchange programme for Member States’ experts/stakeholders with the aim of improving knowledge of crisis management through the sharing of best practices and experiences. The indicative number of contracts envisaged is 3.

[Framework contract]

4.1.3. Scientific advice and risk management (point 1.2.1 in Annex to Programme Decision)

4.1.3.1. Scientific and technical assistance for the functioning of the EU Scientific Committees and communication on risks, including special indemnities

The objective of this action is to provide the Commission with independent and high-quality advice on health risks. This helps obtain a robust scientific basis for EU policies and measures in line with better regulation. The advice is provided by the Scientific Committees in accordance with Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts on consumer safety, public health and the environment and repealing Decision 2004/210/EC (1). This action contributes to increasing the role of science in EU policy debate, and it helps to inform citizens of risks. It also enables stakeholders and citizens alike to better understand EU policies. This action has two components: (a) special indemnities paid to experts for their work on scientific opinions; and (b) scientific and technical assistance for the functioning of the Scientific Committees and risk communication.

Special indemnities are paid to experts for their work on scientific opinions as provided for in Decision 2008/721/EC.

[Other actions] Indicative amount: EUR 270 000

Scientific and technical assistance for the functioning of the Scientific Committees and risk communication includes:
(a) search, analysis and synthesis of scientific literature; (b) preparation of layman versions of scientific opinions; (c) preparation of summaries; (d) data search; (e) compilation of the bibliography of topics addressed by the Committees; and (f) revision of texts. This support is necessary, as members of the Committees do not benefit from any support from their organisations. This action also covers the organisation of scientific hearings, working meetings and thematic workshops. The indicative number of contracts envisaged is 20.

[Framework contract]

4.1.4. Safety and quality of organs and substances of human origin, blood and blood derivatives (point 1.2.2 in Annex to Programme Decision)

4.1.4.1. Good practices on donation, collection, testing, processing, storage and distribution of gametes for assisted reproductive technologies and haematopoietic stem cells for transplantation

This joint action seeks to develop and promote good practices on the donation, collection, testing, processing, storage and distribution of gametes for assisted reproductive technologies and haematopoietic stem cells for transplantation. This action consists of two main work packages. The first will develop guidelines to provide knowledge and guidance for actors in the field on the donation, collection, testing, processing, storage and distribution of gametes for assisted reproductive technologies. The aim is to ensure the safety and quality of different procedures in assisted reproductive technology establishments. The second work package will develop guidelines to provide knowledge and guidance for actors in the field on the donation, collection, testing, processing, storage and distribution of haematopoietic stem cells for transplantation. The aim is to ensure the safety and quality of different procedures in bone marrow registers and in cord blood banks. Supporting work includes setting up a network of dedicated inspectors and authorities in each field, and providing training on good practices to authorities and actors in the field. These activities will help to fulfil the safety and quality requirements laid down in 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 (2) and its implementing legislation.

[Joint action] Indicative amount: EUR 1 000 000

4.1.4.2. Integration of EU legislation on substances of human origin and the outcomes of actions funded in this area into the Council of Europe expert guides

This action seeks to help develop Council of Europe guides on the safety and quality of substances of human origin, and to ensure that these take full account of EU legislation and EU-funded projects in this area. These guides are the main reference tools for professionals and authorities in the field of tissues and cells, blood and organs. Currently the 17th edition of the blood guidelines and the 5th edition of the organs guidelines are under preparation. A new set of guidelines dedicated to tissues and cells will be developed. Owing to its outreach and structure, the Council of Europe can significantly contribute to the dissemination of best practice and reach out to different audiences in the EU as well as in countries from/to which EU Member States regularly import/export human substances. This action will contribute to better implementation of the safety and quality requirements set out in 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 (1), Directive 2004/23/EC and 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 (2).

[Direct grant to the CoE] 
Indicative amount: EUR 100 000

4.1.4.3. Good practices in the field of blood transfusion

The objective of this action is to ensure the efficient use of blood and blood components and to help hospitals reach self-sufficiency therein through the implementation of best practices. This action will: (a) develop a guide on the criteria, parameters and material for the implementation of best practices and for the evaluation of the process; (b) develop a Web-portal as a forum for the exchange of best practices and national outcomes and consultation; (c) establish a network of benchmark hospitals in the EU on efficient blood transfusion management; and (d) develop a training programme for trainers. This action will help Member States comply with the requirements of Directive 2002/98/EC. The indicative number of contracts envisaged is 1.

[Call for tenders]

4.1.5. Promote measures to improve patient safety through high-quality and safe health care (point 1.2.3 in Annex to Programme Decision)

4.1.5.1. Patient safety taxonomy guide

The objective of this action is to develop a minimal toolkit for patient safety incident reporting in the EU, including a common set of terms (taxonomy) for the most common types of adverse events being tracked in European reporting and learning systems. It will also include recommendations on the minimal structure of reporting systems adapted to the needs of European hospitals and patient safety institutions. The ability to measure adverse events systematically and consistently across all EU Member States is essential for comparable data collection and the sharing of best practice.

The WHO is considered as the most suitable institution to carry out this action, as it has considerable expertise in the area. The WHO patient safety programme has developed a framework for an International Classification for Patient Safety (ICPS) in 2009 and it can make use of its international group of experts with the Global Community of Practice on Reporting and Learning Systems. The work of other important multinational initiatives should also be taken into account.

This action contributes to the implementation of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border health care (3). The Directive promotes cooperation and exchange of best practice on patient safety between the Member States, for which a common patient safety language is a prerequisite. It also responds to the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of health care associated infections (2009/C 151/01) (4), calling on the Member States and the European Commission to develop common definitions and terminology, taking into account international standardisation activities, such as the International Classification for Patient Safety carried out by the WHO.

[Direct grant to the WHO] 
Indicative amount: EUR 200 000

4.1.5.2. Facilitating collaboration among the Member States for effective operation of the pharmacovigilance system in the EU

This action seeks to support Member States in achieving the optimal organisation and operation of the pharmacovigilance system in the EU and in fulfilling the requirements set out in Directive 2010/84/EU of the European Parliament and of

---

the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (1). This action will support Member States in finding ways to organise and run their pharmacovigilance systems in line with the EU pharmacovigilance legislation, focusing on: (a) exchange of best practices by the Member States for the operation of an effective system to collect information on the suspected adverse reactions of medicinal products; (b) the allocation of resources and necessary expertise, including in the area of risk communication; (c) capacity building on evaluating quality systems to supervise pharmacovigilance activities; (d) developing a methodology to establish a link between the pharmacovigilance signals and possible medication errors, overdose, misuse and abuse, and follow-up to ensure patient safety; and (e) training on pharmacovigilance inspections and on the handling of the pharmacovigilance system master file with emphasis on multiplier effects, for example training of trainers.

[Joint action] Indicative amount: EUR 3 300 000

4.1.5.3. System inspections in countries exporting active substances for medicinal products for human use to the EU

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 (2) requires compliance with the legal requirements governing medicinal products. The objective of this action is to ensure such compliance through system inspections in third countries that export to the EU active substances for medicinal products for human use and through preparatory activities in key exporting countries. This action will help ensure that the regulatory frameworks for the manufacture of active pharmaceutical ingredients, including inspection and enforcement systems, are equivalent to those of the EU. Such preparatory activities and on-site inspections in third countries will be organised in collaboration with the Member States and the European Medicines Agency. This will contribute to ensuring the safety and quality of medicinal products. Travel and subsistence expenses will be paid to Member States’ experts for their participation in system inspections.

[Other action] Indicative amount: EUR 300 000

4.1.5.4. Analysis of incident reporting

This action aims to help Member States and the EU to develop shared knowledge regarding health care quality and patient safety across the EU. The analysis to be conducted will focus on the vigilance system for medical devices. This system serves as an example of a system through which incidents relating to patient safety are reported at national level and where national reporting could be better exploited at the European level. This action should develop recommendations for mechanisms to detect signals, trends and increased incident frequency more effectively. Such mechanisms could be applied throughout the health technology sector.

[Administrative agreement with JRC] Indicative amount: EUR 260 000

4.2. Actions under the second objective ‘Promote health’

4.2.1. Promote initiatives to increase healthy life years and promote healthy ageing (point 2.1.1 in Annex to Programme Decision)

4.2.1.1. Addressing chronic diseases and promoting healthy ageing across the life cycle

This action addresses the challenge of the increased burden that chronic conditions and diseases place on the health systems and individuals, with a specific focus on multimorbidity. It also responds to the priorities of the European Innovation Partnership on Active and Healthy Ageing, the Council conclusions on active ageing of 7 June 2010 (3), the Council conclusions ‘Innovative approaches for chronic diseases in public health and health care systems’ of 7 December 2010 (4) and the reflection process on chronic diseases launched by the Member States and the Commission. This action is composed of a joint action and project grants.

The joint action will contain three work packages. The first one will develop a system for the collection, validation and dissemination of good practice focused on the prevention of chronic conditions and diseases along the life cycle with emphasis on innovative approaches to address major risk factors. The second work package will use diabetes as a case study of a classic chronic disease and will focus on the barriers to prevention, screening and treatment and on how Member States can improve coordination and cooperation. This could include monitoring the Member States’ implementation of national diabetes programmes and exchanging good practice across the EU. The third work package will seek to develop common guidance and methodologies for care pathways for multimorbidity patients. Guidance needs to focus on the design of innovative, cost-efficient and patient-centred approaches for multimorbidity patients, including secondary prevention interventions, early diagnosis and adherence to treatment and medicine regimens addressing polypharmacy. It will also include exchange of best practices and evidence data that can be scaled up.

(3) DOC 9489/10.
In support of the joint action, project grants will focus on the promotion of healthy lifestyles among the 65+ age group through the prevention of specific risks. Unhealthy lifestyles and social isolation are key risk factors for chronic diseases and have an adverse impact on the health of older people. This action should promote targeted innovative cost-effective health promotion approaches in older age groups.

In support of the practical implementation of innovative solutions responding to the priorities of the European Innovation Partnership on Active and Healthy Ageing, project grants will foster pilot actions at local and regional level focusing on the management of multimorbidity among elderly people through integrated care pathways, as well as on improving adherence to treatment and prevention of falls and frailty. These pilot actions will group existing and planned public and private activities of excellence in order to create innovative, practical, feasible and measurable projects centred around:

1. implementation of integrated or coordinated interventions for early identification and diagnosis of physical frailty in older persons that can be preceded by multimorbidity and followed by the development of disability. Addressing frailty will meaningfully contribute to the development of personalised integrated care, facilitate coordination among professionals and reduce unnecessary use of health care resources;

2. implementation of interventions to address polypharmacy — lack of proper indications, inappropriate dosage and subclinical toxicities of medications. Current strategies include screening tools, but interventions which combine different health professionals and care settings through electronic monitoring could also be meaningful.

This action seeks to improve access to and quality of health services for migrants and ethnic minorities through improved training of health professionals. This action will develop training packages, pilot training and disseminate good practices. It targets national authorities, providers of health services and organisations representing migrants and ethnic minorities. This action will review existing training material, identify gaps and needs, create core modules for new training material and adapt it to specific national contexts. Piloting will be conducted in at least five countries participating in the programme. This action contributes to the implementation of Commission Communication COM(2009) 567 final of 20 October 2009 Solidarity in health: reducing health inequalities in the EU(1), which calls for EU-level action and professional training tools to address health inequalities through the health programme, ESF and other mechanisms. It also responds to the EU 2020 priority of reducing health inequalities to foster inclusive growth. The indicative number of contracts envisaged is 1.

This action seeks to promote effective securing and use of funding for health by Member States and regions under the Structural Funds’ programming in the period 2014-2020, in order to enhance health systems’ effectiveness, quality and sustainability. It responds to the Council conclusions: towards modern, responsible and sustainable health systems (2011/C 202/04) of 6 June 2011 (2), and follows on from the work of the Health Systems Reflection Process Subgroup on the effective use of Structural Funds. This action aims at building knowledge about the use of Structural Funds for health in the new programming period, disseminating this knowledge; and building expertise on Structural Funds, in particular among the health ministries and other relevant health bodies. Its outcomes are expected to be: (a) mapping of the use of Structural Funds in health; (b) compilation of successful practices; and (c) a set of tools for achieving sustainable and effective investments in health, including health promotion and prevention of diseases, through the Structural Funds, for actors in the health sector and sectors impacting on health at national and regional level. The planned duration of the action is 18 months.

(2) OJ C 202, 8.7.2011, p. 10.
4.2.2.3. Information to citizens and stakeholders on the transposition of the Directive on the application of patients’ rights in cross-border health care

The objective of this action is to inform citizens about their rights related to cross-border health care. This action covers both citizens’ rights and Member States’ actions in order to ensure that patients can use their rights, namely the establishment of transparent reimbursement processes; clear definition of entitlement to health care; authorisation processes; provision of information on health systems and individual providers; and the establishment of national contact points. Information and communication activities, which should target all Member States, include electronic video clips and other innovative tools; conferences; information material in the official EU languages; a detailed guide to EU cross-border health care legislation; and an interactive Web-presence in the official languages. This action will contribute to the effective implementation of Directive 2011/24/EU.

4.2.2.4. Health technology assessment (HTA): early dialogue pilots on pharmaceuticals and medical devices

Directive 2011/24/EU sets up a voluntary network that connects national authorities or bodies responsible for health technology assessment to support and facilitate cooperation among Member States. This action contributes to such cooperation through the conduct of early dialogue pilots on pharmaceuticals and medical devices. These aim to facilitate the dialogue between industry and regulators, multiple HTA bodies and payers in the course of health technology development. The purpose is to ensure business predictability for industry as regards market access after market authorisation (MA) or CE licensing; rationalisation of requirements for various actors; complementarity with the scientific advice provided by the European Medicines Agency; and preparation of post MA or CE marking requirements. This action aims to conduct up to 10 early dialogue pilots. In addition to contributing to the implementation of Directive 2011/24/EU, this action responds to the Council conclusions on innovation in the medical devices sector (2011/C 202/03). The indicative number of contracts envisaged is 1.

4.2.2.5. Overview of the legal framework for electronic health records in the Member States

The eHealth network is working towards interoperability guidelines for eHealth providing a framework at legal, organisational, semantic and technical levels. This work aims to enhance and secure seamless eHealth services at European level, covering the electronic exchange of patient summary sets of data, ePrescription and eIdentification for health, thereby ensuring the safety and continuity of cross-border health care for citizens. The experience of the large-scale ‘European Patients Smart Open Services’ (EPSOS) project on cross-border eHealth services has demonstrated that one of the key barriers to the sustainability of piloted eHealth services is the legal interoperability challenge.

The expected outcome of this action is a study that will examine in detail and provide an overview of the regulatory frameworks at national level on electronic health records (EHR) and provide recommendations so as to facilitate the work of the eHealth network on the legal layer of eHealth interoperability. It will build on existing evidence, gathered mainly in the course of EU projects supported by the Directorate-General for Communication Networks, Content and Technology and by the Directorate-General for Health and Consumers. The indicative number of contracts envisaged is 1.

4.2.2.6. Empowering patients in the management of chronic diseases

This action seeks to help understand the concept of patient empowerment and identify inherent advantages and barriers through detailed mapping of existing initiatives in the self-management of chronic diseases. Patient empowerment is a core value of a modern patient-centred health system, as advocated by the Council conclusions on common values and principles in European Union health systems (2006/C 146/01). However, the concept of patient empowerment is not clear, and patient empowerment is often perceived only as the use of eHealth tools. There are also concerns that an empowered patient may represent an increased cost for the health system. This action should result in: (a) a catalogue of successful patient empowerment strategies and actions; (b) identification of barriers to and advantages of patient empowerment; (c) a method to validate transferability of good practices on patient empowerment; and (d) scenarios of EU collaboration on patient empowerment. The estimated time frame for delivery of the resulting study is mid-2014.

The outcomes will feed into the chronic disease reflection process based on the Council conclusions 'Innovative approaches for chronic diseases in public health and health care systems', with the aim of facilitating the provision of high-quality and sustainable health care. The indicative number of contracts envisaged is 1.

[Call for tenders]

4.2.2.7. Pilot networks of cooperation under Directive 2011/24/EU

This action seeks to pave the way for European reference networks, as provided for by Directive 2011/24/EU. European reference networks will link health care providers and centres of expertise in the Member States. The aim is to improve access to diagnosis and provide high-quality health care to patients who have conditions that require a particular concentration of resources or expertise, especially where the expertise is rare and case volume low. This action seeks to set up two pilot networks, one on paediatric oncology centres and one on highly specialised neurological, clinical neurophysiology and neurosurgery centres. Work on both networks should cover concrete goals of and proposals for the concentration of low-frequency or high-complexity diagnostic and therapeutic procedures in services that have an adequate caseload and audited results. It also covers an evaluation of outcomes.

The objective of a pilot network of cooperation between paediatric oncology centres is to implement and further develop the European standards of care for children with cancer. This is to be done on the basis of the latest developments, knowledge and best practice. This action focuses on cancer in children, such as specific types of cancer like solid tumours, for example neuroblastoma, retinoblastoma, Wilms tumour, soft tissues and bone sarcoma. This action should be based on work already carried out by following projects: European Network for Cancer Research in Children and Adolescents, ENCAA, http://www.encca.eu/; PanCare Childhood and Adolescent Cancer Survivor Care and Follow-up Studies, PANCARESURFUP, http://www.pancaresurfup.eu/; European Clinical trials in Rare Sarcomas within an integrated translational trial network, EUROSSARC; International study for treatment of childhood relapsed ALL 2010 with standard therapy, systematic integration of new agents, and establishment of standardised diagnostic and research, INTREALL, http://www.intreall-fp7.eu/; and Analysing and Striking the Sensitivities of Embryonal Tumours, ASSET, http://www.ucd.ie/therapy, systematic integration of new agents, and establishment of standardised diagnostic and research, INTREALL, lational trial network, EUROSARC; International study for treatment of childhood relapsed ALL 2010 with standard therapy, systematic integration of new agents, and establishment of standardised diagnostic and research, INTREALL, http://www.intreall-fp7.eu/; and Analysing and Striking the Sensitivities of Embryonal Tumours, ASSET, http://www.ucd.ie/therapy, systematic integration of new agents, and establishment of standardised diagnostic and research, INTREALL.

The outcomes will feed into the chronic disease reflection process based on the Council conclusions 'Innovative approaches for chronic diseases in public health and health care systems', with the aim of facilitating the provision of high-quality and sustainable health care. The indicative number of contracts envisaged is 1.

[Call for tenders]

4.2.2.7. Pilot networks of cooperation under Directive 2011/24/EU

This action seeks to pave the way for European reference networks, as provided for by Directive 2011/24/EU. European reference networks will link health care providers and centres of expertise in the Member States. The aim is to improve access to diagnosis and provide high-quality health care to patients who have conditions that require a particular concentration of resources or expertise, especially where the expertise is rare and case volume low. This action seeks to set up two pilot networks, one on paediatric oncology centres and one on highly specialised neurological, clinical neurophysiology and neurosurgery centres. Work on both networks should cover concrete goals of and proposals for the concentration of low-frequency or high-complexity diagnostic and therapeutic procedures in services that have an adequate caseload and audited results. It also covers an evaluation of outcomes.

The objective of a pilot network of cooperation between highly specialised neurology, clinical neurophysiology and neurosurgery centres is to promote cooperation and to test and exchange standards and best practices on highly specialised and complex neurological and neurosurgical conditions, such as refractory epilepsy, severe craniofacial conditions, brachial plexus injuries, refractory neuropathic pain, hereditary ataxia and paraplegia, multiple sclerosis and complex cerebro-vascular conditions. Centres offering certain treatment and procedures for neurological/neurosurgical conditions, such as complex neurosurgery, movement disorders surgery and brain neuro-modulation, need enough experience and expertise as well as adequate well-qualified human and technical resources. Such centres should also have a broad range of complementary medical services since different disciplines, such as neurology, neurosurgery, neurophysiology, neuroradiology, neuropathology and intensive care, are involved. Team-work and well-developed guidelines and procedures are also essential.

[Project grant] Indicative amount: EUR 1 500 000

4.2.2.8. Overview of education and training programmes for health professionals in the EU

This action seeks to provide an overview of education and training for health professionals in the EU through a quantitative and qualitative analysis. The first aim is to provide mapping of the structure and capacity of national programmes in the EU. This covers obtaining information on the regulatory regimes for medical and nursing education and training, and their governance structures in the Member States. Secondly, this action will produce a study on the quality dimension of the programmes in order to determine if education and training programmes deliver the right amount of professionals with the right skills to meet the needs of the health care system. The study should also present options and make recommendations for potential EU action to foster partnerships between the Member States in order to make the best use of training capacities in the EU. This action will contribute to the implementation of the action plan for the EU health workforce adopted as part of the Commission Communication COM(2012) 173 final of 18 April 2012 Towards a job-rich recovery (1).

[Direct grant to the OECD] Indicative amount: EUR 200 000

4.2.2.9. Review and mapping of the continuous professional development of health workers

This action seeks to review and map the continuous professional development of health workers. Given growing concerns about shortages of skilled health professionals and with demographic change increasing the demand for services, Member...
States have to find ways to ensure sustainability of their health workforce. As highlighted in the action plan for the EU health workforce, access to lifelong learning and continuous professional development (CPD) plays an important role in keeping professional skills up to date, ensuring quality of care and also as a means to motivate and retain staff. CPD systems and regulations vary significantly across the EU and country-specific data remain scarce. European collaboration in sharing good practice on CPD approaches and accreditation systems would help improve mutual understanding between Member States and facilitate cross-border mobility. As a first step, this action will review and map national systems, governance and practices in place to ensure the continuous professional development of health workers with the aim of promoting good practice. A concluding workshop with national experts and professional organisations will also be organised. This action is part of the implementation of the action plan for the EU health workforce adopted as part of the Commission Communication Towards a job-rich recovery aiming to boost jobs in the health sector. The indicative number of contracts envisaged is 1.

[Call for tenders]

4.2.2.10. Effective recruitment and retention strategies for health workers

The objective of this action is to provide a comprehensive analysis of strategies for recruiting and retaining health workers to assist and enhance the development of human resource policies in the Member States at a time of growing labour shortages. It will examine evidence and good practices in the EU and internationally and identify options for EU initiatives to support the development and implementation of national strategies. This analysis will feed into the on-going work on workforce planning and forecasting and deepen the reflection on potential future action on recruitment and retention. This action will contribute to the implementation of the action plan for the EU health workforce adopted as part of the Commission Communication Towards a job-rich recovery aiming to boost jobs in the health sector. The indicative number of contracts envisaged is 1.

[Framework contract]

4.2.3. Address health determinants to promote and improve physical and mental health; take action on key factors such as nutrition and physical activity, and on addiction-related determinants such as tobacco and alcohol (point 2.2.1 in Annex to Programme Decision)

4.2.3.1. European Obesity Surveillance Initiative (COSI)

The objective of this action is to contribute to the reduction of overweight and obesity-related diseases among young people, and thereby help improve the health of EU citizens and lessen the burden of ill health on health systems. This action supports the implementation of the Strategy for Europe on Nutrition, Overweight and Obesity-related Health Issues set out in COM(2007) 279 final of 30 May 2007 (1). The COSI survey conducted by the WHO measures the weight and height of 6-9 year-old children. It currently covers 15 EU Member States. This action extends the survey to the remaining Member States. The extension of the survey will help provide complete data on overweight- and obesity-related diseases among children and young people. These data feed the reflection on potential future policy and action on the reduction of overweight and obesity.

[Direct grant to the WHO] Indicative amount: EUR 300 000

4.2.3.2. Communicating nutrition and physical activity

Adequate understanding of risk factors by the public can help reduce the burden of ill health from non-communicable diseases on health systems. As part of the implementation of the Strategy for Europe on Nutrition, Overweight and Obesity-related Health Issues, this initiative seeks to support Member States’ efforts to motivate action on healthy nutrition and to thereby improve the health of EU citizens. This action will also create synergies with communication initiatives of the Directorate-General for Agriculture and Rural Development and the Directorate-General for Education and Culture regarding health promotion action at EU level, such as the agricultural school fruit scheme and policies and action on youth, education, culture and sports. It will also seek to coordinate up to five information and education pilot events/initiatives targeting children, parents and local communities. The initiative will include the production of multilingual creative material with links to selected EU and Member State actions. The indicative number of contracts envisaged is 1.

[Call for tenders]

4.2.3.3. Tobacco studies

The objective of this action is to gather information and knowledge to support EU tobacco control policies in general, and tobacco product regulation in particular, with emphasis on the implementation 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 (1), in its current or future form. This action has three work packages.

The first work package concerns tracking and tracing with the aim being to analyse, describe and possibly help design the standards for a system that will ensure full traceability of tobacco products and of security features allowing the identification of 'genuine' products. The expected outcomes are: a study covering literature review; an overview and evaluation of existing technical solutions to track and trace tobacco products and to equip them with anti-counterfeit security features; identification of potential alternatives to and improvement of tracking and tracing and/or security features; an analysis of the costs and impact of alternative solutions; and recommendations for the most suitable solutions at EU level.

The second work package concerns the role of additives and packaging in determining consumer preferences. While it is widely known that packages, flavours and other additives make tobacco products more attractive for young people, evidence of the role of individual package features/additives in brand preferences and smoking initiation among young people in Europe is still growing. The expected outcomes of this work package are: an updated study covering identification of the various different factors impacting on attractiveness, consumer preferences and underlying trends and refining methods to establish which flavours give a product a characteristic taste/aroma.

The third work package concerns the further development of labelling standards for tobacco product packages.

The indicative number of contracts envisaged is 3-4.

[Framework contract]

4.2.3.4. Joint action to support Member States in taking forward work on common priorities in line with the EU alcohol strategy

The aim of the joint action is to support Member States in preventing harmful alcohol consumption and thereby improve the health of EU citizens and lessen the burden of ill health. This action will contribute to the implementation of the EU alcohol strategy set out in Commission Communication COM(2006) 625 final of 24 October 2006 An EU strategy to support Member States in reducing alcohol related harm (2). This action provides an incentive for the Member States to intensify cooperation and develop common approaches. It focuses on improving the monitoring of drinking habits and alcohol-related harm, and on good practice in the provision of information aiming to protect children and young people and to prevent alcohol-related harm among adults. This action should result in: (a) a report providing comparable data on drinking habits and alcohol-related harm; (b) guidelines for low-risk alcohol consumption in order to protect children and young people and prevent harm among adults; and (c) a good practice toolkit of print and online instruments to disseminate low-risk drinking guidelines and other self-management tools.

[Joint action] Indicative amount: EUR 1 500 000

4.2.3.5. Scientific and technical support to the EU Health Forum

The objective of this action is to provide scientific and technical support to the European Health Forum. Active involvement of health stakeholders in policy development, with a specific reference to the Health Forum, is set out in Commission Communication COM(2007) 630 final Together for Health: A strategic approach for the EU 2008-2013. This action covers organising and supporting activities of the EU Health Policy Forum and of the Open Forum. This includes communication and networking with Forum members, the organisation of meetings and other activities of the EU Health Policy Forum and Open Forum; as well as scientific and technical work related to the EU Health Forum priorities. The work of the Health Forum also helps to ensure that EU activities on health are relevant to and understood by the public health scene at large. The indicative number of contracts envisaged is 1.

[Framework contract]

4.2.4. Prevention of major and rare diseases (point 2.2.2 in Annex to Programme Decision)

4.2.4.1. Development of a European guide on quality improvement in comprehensive cancer control

The objective of this action is to develop a European guide on quality improvement in comprehensive cancer control. The guide should address various aspects of coordinated and integrated cancer control, including prevention, screening, diagnosis, treatment, follow-up, supportive care, palliative care, survivorship and research. This action will contribute to reaching the aims of the European cancer partnership set out in Commission Communication COM(2009) 291 final of 24 June 2009 on Action against Cancer: European Partnership (1), and will build both on its achievements and on the outcomes of previous EU action on cancer, such as the development of the fourth edition of the ‘European guidelines for quality assurance in breast cancer screening and diagnosis’ (2), which includes a framework for comprehensive breast cancer services.

[Joint action] Indicative amount: EUR 3 000 000

4.2.4.2. Integrated surveillance of non-communicable diseases

The aim of this action is to allow the EU and the WHO, with the involvement of the OECD, to assess and increase the completeness and timeliness of data on chronic diseases and their collection and to identify an effective process for such work. The lack of sound data, for example on morbidity from selected diseases, risk factors and their social determinants, hampers evidence-based policy development. Chronic diseases are emerging as a priority area for action on health, and timely access to reliable data is essential. Any data collection will be linked to existing indicators and frameworks, notably the European Health Information System. In the short term, this action will map gaps and look into how to improve existing data collection. In the long term, it will help improve and better coordinate the quality, coverage and timeliness of data collection. This will contribute to improved analysis and reporting on chronic non-communicable diseases.

[Direct grant to the WHO] Indicative amount: EUR 100 000

4.2.4.3. Scoping study on communication action addressing chronic diseases

The objective of this action is to conduct a scoping study to help test different tools and methods in order to better communicate and raise awareness of health determinants and EU action to prevent chronic diseases, making use of evidence from social and behavioural science. Chronic diseases represent the largest burden of diseases in the EU, but they can be effectively prevented by taking action on common risk factors. This study will develop a number of recommendations and proposals for basic messages and will help shape effective campaigns adapted to different target groups. This action contributes to the implementation of the EU strategy on overweight and obesity, the EU alcohol strategy and EU action on tobacco. It also contributes to the implementation of the Council conclusions ‘Innovative approaches for chronic diseases in public health and health care systems’ of 7 December 2010 and to the reflection process on chronic diseases launched by the Member States and the Commission. The indicative number of contracts envisaged is 1.

[Framework contract]

4.2.4.4. Support to rare diseases registries and networks in view of their sustainability

The aim of this action is to set up a sustainable platform to coordinate and maintain registries and networks on rare diseases. Registries and networks are key instruments in increasing knowledge of rare diseases and in developing clinical research. They are the only way to pool data in order to achieve a sufficient sample size for epidemiological research and/or clinical research. This action will build on activities and experiences developed through initiatives funded by the EU health programmes and research and innovation programmes.

[Project grant/Administrative agreement with the JRC] Indicative amount: EUR 2 000 000

4.2.4.5. Support to an information network on lung mesothelioma

The aim of this action is to support the creation of an information network focusing on best practices for treatment of lung mesothelioma, which is becoming a rare disease owing to successful prevention efforts, and their dissemination. The pooling of expertise is expected to contribute to reduce costs for individual health systems. This action should exclude European Commission activities on the protection of workers from the risks related to exposure to asbestos at work.

(2) http://bookshop.europa.eu/is-bin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en_GB//EUR/ViewPublication-Start/PublicationKey=ND7306954
4.3. **Actions under the third objective 'Generate and disseminate health information and knowledge'**

4.3.1. **European Health Information System (point 3.2.1 in Annex to Programme Decision)**

**4.3.1.1. Improving timeliness and comparability of health data**

This action will be carried out by Eurostat in support of work on health systems, active and healthy ageing, eHealth and health information. There are two work packages. The first involves exploring the feasibility of producing data on expenditure by disease at EU level. The aim is to obtain patient-level data with information on patient and treatment characteristics, actual resource use and reliable price/cost data, including the provision of sound data on private expenditure. It would also address the collection of indirect costs data, such as linkage to years of life lost/loss of potential years of work. Data on expenditure by disease can contribute to health systems’ performance analysis through the provision of data on how much money is spent on preventing and treating particular diseases, differentiated by age and gender. The action should take into consideration the increasing health care needs of ageing populations in Europe.

The second work package focuses on statistics about the causes of death. It would look into establishing a modernised, integrated system for causes of death certification, processing and data sharing. The electronic certification of causes of death would also allow information on multiple causes of death to be produced, which is of growing interest given the ageing of the population. The aim is to increase timeliness and better comparability of data. This would contribute to better resource allocation in Member States through reduced multiple data coding.

**[Subdelegation to Eurostat] Indicative amount: EUR 1 000 000**

**4.3.1.2. Health at a Glance Europe 2014**

The objective of this action is to take forward work on health care quality indicators and continue to publish with the OECD the ‘Health at a Glance Europe’ edition in order to provide the latest comparable data on different aspects of the performance of health systems in the EU Member States, EFTA/EEA and EU candidate countries. This action seeks to help policy-makers through the provision of sound evidence.

**[Direct grant to the OECD] Indicative amount: EUR 300 000**

**4.3.1.3. Commission membership fee to the European Observatory on Health Care Systems and Policies**

This action implements Commission Decision (C(2009) 10213 final) of 21 December 2009 on its incorporation as a Participating Organisation of the European Observatory on Health Care Systems and Policies until the termination of the current health programme in 2013. The Decision sets the Commission’s annual membership fee at EUR 500,000. The objective of the Commission’s participation in the Observatory is to generate and disseminate quality information and actionable evidence on EU health systems. The Observatory, which is a repository of technical expertise, independent analysis and respected advice, is a partnership project of the World Health Organisation Regional Office for Europe, the governments of Belgium, Finland, Ireland, Norway, Slovenia, Spain and Sweden, the Veneto Region of Italy, the European Commission (throughout the duration of the health programme, 2009-2013), the European Investment Bank (EIB), the International Bank for Reconstruction and Development (World Bank), the French Union of Health Care Funds (UNCAM), London School of Economics (LSE) and the London School for Hygiene and Tropical Medicine (LSHTM). The Commission will be a privileged partner and topics of interest to it will be included in the work programme of the Observatory.

**[Other actions] Indicative amount: EUR 500 000**

4.3.2. **Dissemination, analysis and application of health information; provision of information to citizens, stakeholders and policy makers (point 3.2.2 in Annex to the Programme Decision)**

**4.3.2.1. Expert panel to provide advice on the efficiency and effectiveness of health systems**

The objective of this action is to set up a multisectoral and independent expert panel to provide advice, at the request of the Commission, on effective ways of investing in health in accordance with Commission Decision (2012/C 198/06) (1) of 5 July 2012. This action responds to the Council conclusions of 6 June 2011 on moving towards modern, responsive and sustainable health systems. The Member States and the Commission were invited to initiate a reflection process aiming ‘to identify effective ways to invest in health, so as to pursue modern, responsive and sustainable health systems’. The Commission is to support the process through appropriate measures, such as facilitating access to informal and independent multisectoral expert advice. Indemnities are paid to members of the panel and invited experts as provided for in Decision (2012/C 198/06).

[Other actions] Indicative amount: EUR 500 000

4.3.2.2. Communication, promotion and dissemination of information on EU health policies and the results of the health programmes

The objective of this action is to provide accurate and timely information on EU public health activities provided for in Article 168 TFEU and thereby bring Europe closer to its citizens. It also aims to disseminate widely the results of the health programmes both at EU level and at national, regional and local levels. This action will help obtain broad coverage for EU health policy activities, and thereby gain support for them. It will also contribute to optimising the impact of actions financed by the health programmes and thereby help ensure their sustainability.

The communication and promotion work package consists of: (a) organisation of the Fifth EU Journalist Prize; (b) dissemination of the results of the second health programme at EU level; and (3) dissemination of information on EU health policy initiatives and related action. Activities to be funded include preparing and disseminating audiovisual material and publications in electronic format and on paper, workshops and expert meetings, and information stands and other communication and promotional material.

The dissemination work package aims to provide Member States with workable tools and services for effective dissemination in the Member States of the results of actions funded by the health programmes. These include conferences and workshops, and other appropriate means for effectively disseminating the results to different audiences. This work package responds to the recommendations of the ex-post final evaluation of the public health programme (2003-2007) (1) and the midterm evaluation of the health programme (2008-2013) (2). The indicative number of contracts envisaged is 10 under an existing framework contract. A call for tenders for dissemination at EU level will also be launched.

[Framework contracts]

4.3.2.3. Information technology applications in support of public health policies

The objective of the measures covered by this action is to support EU public health policies as set out in Article 168 TFEU through the setting up and maintenance of relevant IT applications. These IT tools also support objectives set out in the 'Europe 2020' strategy, such as promotion of active and healthy ageing and of eHealth, reduction of health inequalities and ensuring better access to health care systems. An indicative list of applications to be covered by this action is as follows: the Public Health Portal; Eurobarometers, eLearning; IDB (Injury Database) and ECHI; MediEQ, EuroMedStat, Euphix, Health Data; Crisis Portal; EHIS (HEIDI — Health in Europe: Information and Data Interface) Wiki; HEDIS (Health Information and Diseases Information System) and Medlys (Medical Intelligence System); Ras-BICHAT (rapid alert system information exchange on health threats due to deliberate release of chemical, biological and radio-nuclear agents), Ras-Chem (rapid alert system for information exchange on incidents including chemical agents); Diet, Alcohol and Mental Health Platforms; Health Innovation Platform; applications relating to blood, cells, tissues and tobacco, including SARE and Rapid Alert Blood; Expert Database; NanoHazard; Spindex, Manif, Risk Assessors; Scoma; and cross-border health care. The indicative number of contracts envisaged is 20.

[Framework contracts]

4.3.3. Analysis and reporting (point 3.2.3 in Annex to Programme Decision)

4.3.3.1. Health reports and economic analysis

The objective of this action is to produce information, in the form of reports and economic analysis, which is needed at short notice to support the development or implementation of policies or legislation and the evaluation of the effects of policy implementation. Health reports ought to provide well-structured and sound information on topical issues for EU citizens, stakeholders and policy-makers. Economic analysis will provide information on health and health-related phenomena serving as sound evidence for policy-making. The indicative number of contracts envisaged is 1-4.

[Framework contract]

4.3.3.2. Study on the economics of primary health care financing schemes

The objective of this action is to conduct a study on the economics of primary health care financing schemes. This action responds to the Council conclusions of 6 June 2011 on moving towards modern, responsive and sustainable health systems. The Member States and the Commission were invited to share experiences, best practices and expertise in order to understand and adequately respond to society's growing and changing health needs, particularly due to an ageing population. They were also invited to design health sector investments effectively and efficiently, and to cooperate on measuring and monitoring the effectiveness of those investments. The study seeks to identify existing typologies in terms

of financing individual primary health care providers, such as fee-for-service, capitation, salaried staff, mixed systems, and at higher organisational levels, such as lump-sum envelope systems and case-mix corrections. It also aims to identify best practice lessons and determine potential gains for the Member States in terms of patient outcomes and public health care budgets. The indicative number of contracts envisaged is 1.

[Framework contract]

4.3.3.3. Study on existing pricing and tariff systems in Member States in order to define cost-intensive health care

The objective of this action is to help define cost-intensive health care. It seeks to identify possible and likely objective criteria for cost calculation in health care provision and to determine how to define cost-intensive health care based on such criteria. It also seeks to see how best to define ‘highly specialised’ health care. This action will contribute to the implementation of Directive 2011/24/EU on the application of patients’ rights in cross-border health care. The indicative number of contracts envisaged is 1.

[Framework contract]

4.3.3.4. Life-table analysis: health system cost-effectiveness assessment across Member States

This action seeks to provide a health system cost-effectiveness assessment across Member States. It aims to disentangle some of the complexities inherent to health system performance measurements at population level. This action responds to the Council conclusions of 6 June 2011 on moving towards modern, responsive and sustainable health systems, which invited the Member States and the Commission to cooperate in measuring and monitoring the effectiveness of health investments. The indicative number of contracts envisaged is 1.

[Call for tenders]

4.3.3.5. Evaluation of the health programme (2008-2013)

The purpose of this action is to comply with the requirement of Article 13(3)(c) of Decision No 1350/2007/EC. The Commission is to submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions an external and independent ex-post evaluation report covering the implementation and results of the programme. This should be done no later than 31 December 2015. The report resulting from this action should assess the implementation and outcomes of the programme and provide recommendations for future programme implementation. The indicative number of contracts envisaged is 1.

[Framework contract]

4.3.3.6. Eurobarometer survey on patient safety and antimicrobial resistance

The purpose of this action is to conduct two Eurobarometer surveys, one of them focusing on patient safety. The first Eurobarometer survey on patient safety was conducted following the adoption of the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of health care associated infections (2009/C 151/01) (1). This survey will map developments in terms of patient safety perception, awareness of rights in cross-border care and experience of adverse events. The purpose is to provide a trend analysis of citizens’ perceptions and experience four years after the adoption of the Recommendation. The survey will also help assess the implementation of the Recommendation. The second survey will focus on antimicrobial resistance (AMR), as a follow-up to a Eurobarometer survey conducted in 2010. The survey will map the evolution of behaviour regarding AMR and prudent use of antimicrobials in human medicine. It is to be launched at the end of 2013 as part of the implementation of Commission Communication COM(2011) 748 of 15 November 2011 Action plan against the rising threats from Antimicrobial Resistance (2).

The indicative number of contracts envisaged is 2.

[Framework contract]

---

(2) http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf
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)

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, by way of either the beneficiary's own resources or the financial resources of third parties. (Article 113 of the Financial Regulation and Article 172 of the Implementing Rules),

— Non-profit rule: the grant may not have the purpose or effect of producing a profit for the beneficiary (Article 109(2) of the Financial Regulation and Article 165 of the Implementing Rules),

— Non-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),

— Non-cumulation rule: only one grant may be awarded for a specific project to a given beneficiary (Article 111 of the Financial Regulation).¹

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

— exclusion and eligibility criteria (Article 114 of the Financial Regulation),

— selection criteria, to assess the applicant's financial and operational capacity to complete a proposed action (Article 115 of the Financial Regulation),

— award criteria, to assess the quality of the proposal taking into account its cost.

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

4. Projects must:

— have an innovative character and not be of a recurrent nature,

— be of sufficient size to enable achievement of ambitious objectives with high European added value and to implement an efficient European dissemination strategy,

— provide added value at EU level on 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 applicable elsewhere,

— contribute to and support the development of EU policies in the field of health,

— have an efficient management structure, a clear evaluation process and a precise description of expected results,

— include a plan for using and disseminating results at EU level to appropriate target audiences.

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(1) and 94 of the Financial Regulation.

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

2. Proposals which involve only one eligible country or a region of a country will be rejected.

¹ This means that a specific action, submitted by one applicant for a grant, can be approved for co-financing by the Commission only once regardless of the length of this action.
3. Proposals received after the deadline for receipt, incomplete proposals or proposals which do not meet 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:

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

Evidence: Application content.

4. Actions that 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 meet the exclusion and eligibility criteria will be eligible for evaluation. The following selection criteria have to be met.

1. Financial capacity

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

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

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

2. Operational capacity

Applicants 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 curriculum vitae of all relevant professional staff in all organisations involved in the proposed action.

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 meet the exclusion and eligibility and selection criteria will be eligible for further evaluation on the basis of the following award criteria.

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

   (a) Project's contribution to meeting the objectives and priorities defined in the work plan for 2013 (8 points);

   (b) Strategic relevance with regard to the EU Health Strategy (1) and with regard to expected contribution to existing knowledge and implications for health (8 points);

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

       — impact on target groups, long-term effect and potential multiplier effect, such as replicable, transferable and sustainable activities,

       — contribution to complementarity, synergy and compatibility with relevant EU policies and programmes;

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

       Applicants must ensure that the geographical coverage of the project is commensurate with its objectives, and explain the role of eligible countries as partners and the relevance of project resources or the target populations they represent;

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

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

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

(a) Evidence base (6 points):

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

(b) Content specification (6 points):

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

(c) Innovative nature, technical complementarity and avoidance of duplication of other existing actions at EU level (6 points):

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

(d) Evaluation strategy (6 points):

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

(e) Dissemination strategy (6 points):

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

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

(a) Planning and organisation (5 points):

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

(b) Organisational capacity (5 points):

Applicants must clearly describe the management structure, competence of staff, responsibilities, internal communication, decision-making, and monitoring and supervision;

(c) Quality of partnership (5 points):

Applicants must clearly describe the partnerships envisaged in terms of extensiveness, roles and responsibilities, relationships between the partners, and the synergy and complementarity of partners and network structure;

(d) Communication strategy (5 points):

Applicants must clearly describe the communication strategy in terms of planning, target groups, adequacy of channels used, and visibility of EU co-financing;

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

Applicants must ensure that the budget is relevant, appropriate, balanced and consistent in itself, between partners and in relation to the specific objectives of the project. The budget should be distributed between partners at a minimum reasonable level, avoiding excessive fragmentation.

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

Any proposal which does not reach all thresholds 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-financing.
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. 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, by way of either the beneficiary's own resources or the financial resources of third parties. (Article 113 of the Financial Regulation and Article 172 of the Implementing Rules).

— Non-profit rule: the grant may not have the purpose or effect of producing a profit for the beneficiary (Article 109(2) of the Financial Regulation and Article 165 of the Implementing Rules).

— Non-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).

— Non-cumulation rule: only one operating grant may be awarded to a given beneficiary per financial year (Article 111 of the Financial Regulation) (1).

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

— exclusion and eligibility criteria (Article 114 of the Financial Regulation),

— selection criteria, to assess the applicant's financial and operational capacity to complete a proposed action (Article 115 of the Financial Regulation),

— award criteria, to assess the quality of the proposal taking into account its cost.

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

2. EXCLUSION AND ELIGIBILITY CRITERIA

1. Financial contributions awarded by the EU may relate 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 EU and does not have an image harmful to the EU 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(1) and 94 of the Financial Regulation.

Applicants working with private sector actors deemed ineligible due to the nature of their activity being incompatible with the principles of the European Union as stated in Articles 2 and 3 of the EU Treaty shall be considered unacceptable.

(1) This means that an annual work programme submitted by one applicant for an operating grant can be approved for co-financing by the Commission only once.
Proposals received after the deadline for receipt, incomplete proposals or proposals which do not meet 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 of industry, commercial and business or other conflicting interests’ will be assessed according to Annex VI.

SELECTION CRITERIA

Only proposals which meet the exclusion and eligibility criteria will be eligible for evaluation.

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 an 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 for 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 EU, conclusion of grant agreements and conclusion of contracts from the EU budget.

AWARD CRITERIA

Only proposals which meet the exclusion and eligibility criteria and the selection criteria will be eligible for evaluation.

The award criteria make it possible to select work programmes that can guarantee compliance with EU objectives and priorities and can guarantee proper dissemination and communication, including visibility of EU 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 their objectives and priorities (10 points);

(b) The organisation's activities (1) must be described in relation to the priorities detailed in the 2013 work plan of the Health programme (10 points);

(c) Pertinence of the geographical coverage 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 expected results. Applicants must demonstrate that the work programme submitted gives a true and fair view of all activities planned for the organisation/specialised network in 2013, including those activities which do not fit in with the 2013 work plan of the Health programme (10 points);

Lobbying activities exclusively targeted at EU institutions are excluded from funding.
(b) Operational framework: each applicant’s work programme must clearly describe the activities planned, tasks, responsibilities and timetables of the part of their work programme that is consistent with the 2013 work plan of the Health programme and describe its relationship with other parts of their activity (10 points);

(c) Evaluation strategy: each 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: applicants must clearly illustrate the adequacy of actions and methods for communication and dissemination (10 points).

3. Management quality (35 points, threshold: 18 points):

(a) Planning of annual work: applicants must clearly describe activities to be undertaken, timetable and milestones, deliverables, nature and distribution of tasks, and provide a risk analysis (10 points);

(b) Organisational capacity: applicants must clearly describe the management process, human resources and competencies of staff, responsibilities, internal communication, decision-making, and monitoring and supervision. Applicants must also clearly specify the working relationships with relevant partners and stakeholders (10 points);

(c) Overall and detailed budget: applicants must ensure that the budget is relevant, appropriate, balanced and consistent in itself and for the activities planned (10 points);

(d) Financial management: applicants must clearly describe financial circuits, responsibilities, reporting procedures and, where possible, controls (5 points).

Any proposal which does not reach all thresholds 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-financing.
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. 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, by way of either the beneficiary's own resources or the financial resources of third parties. (Article 113 of the Financial Regulation and Article 172 of the Implementing Rules).

— Non-profit rule: the grant may not have the purpose or effect of producing a profit for the beneficiary (Article 109(2) of the Financial Regulation and Article 165 of the Implementing Rules).

— Non-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).

— Non-cumulation rule: only one grant may be awarded for a specific joint action to a given beneficiary (Article 111 of the Financial Regulation) (1).

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

— exclusion and eligibility criteria (Article 114 of the Financial Regulation),

— selection criteria, to assess the applicant's financial and operational capacity to complete a proposed action (Article 115 of the Financial Regulation),

— award criteria, to assess the quality of the proposal taking into account its cost.

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

2. EXCLUSION AND ELIGIBILITY CRITERIA

1. 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 Health programme,

— which do not pursue general objectives directly or indirectly contrary to the policies or values of the EU as set out in the Treaties,

— which have provided to the Commission satisfactory accounts of their membership, internal rules and sources of funding,

— which are designated through a transparent procedure by the Member State or the competent authority concerned and agreed by the Commission,

— which are not in any of the situations of exclusion listed in Articles 93(1) and 94 of the Financial Regulation.

(1) This means that a specific action, submitted by one applicant for a grant, can be approved for co-financing by the Commission only once regardless of the length of this action.
Applicants working with private sector actors deemed ineligible due to their activity being incompatible with the principles of the European Union as stated in Articles 2 and 3 of the EU Treaty shall be considered unacceptable.

2. Proposals received after the deadline for receipt, incomplete proposals or proposals which do not meet 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.

3. The criterion ‘independent of industry, commercial and business or other conflicting interests’ will be assessed in accordance with Annex VI.

3. SELECTION CRITERIA

Only proposals which meet the exclusion and eligibility criteria will be eligible for evaluation.

Selection criteria make it possible to assess the applicant’s financial standing and operational capability to complete the proposed action.

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-financing.

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 action,

— a copy of the annual accounts for the last financial year for which the accounts have been closed preceding the submission of an application (for non-profit bodies other than public bodies).

4. AWARD CRITERIA

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

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

(a) Joint action’s contribution to meeting the objectives and priorities defined in the work plan for 2013 (8 points);

(b) Strategic relevance with regard to the EU Health Strategy (1) and with regard to expected contribution to existing knowledge and implications for health (8 points);

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

— impact on target groups, 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 geographical coverage (8 points):

Applicants must ensure that the geographical coverage of the joint action is appropriate with regard to its objectives and explain the role of eligible countries as partners and the relevance of the joint action’s resources or the target populations they represent. Proposals which involve only one eligible country or a region of a country will be rejected;

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

Applicants must explain how the joint action relates 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 (30 points, threshold: 15 points):

(a) Evidence base (6 points):

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

(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 is expected to make in relation to the state of the art and ensure that there will be neither inappropriate duplication nor overlap, whether partial or total, between projects and activities already carried out at EU and international level;

(d) Evaluation strategy (6 points):
Applicants must clearly explain the methods proposed and indicators chosen and their adequacy;

(e) Dissemination strategy (6 points):
Applicants must clearly illustrate the adequacy of the envisaged strategy and methodology to ensure transferability of results and sustainability of dissemination.

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

(a) Planning and organisation (5 points):
Applicants must clearly describe the activities to be undertaken, timetable and milestones, deliverables, nature and distribution of tasks, and provide a risk analysis;

(b) Organisational capacity (5 points):
Applicants must clearly describe the management structure, competence of staff, responsibilities, internal communication, decision-making, and monitoring and supervision;

(c) Quality of partnership (5 points):
Applicants must clearly describe the partnerships envisaged in terms of extensiveness, roles and responsibilities, relationships between partners, and the synergy and complementarity of 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-financing.

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

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

Any proposal which does not reach all thresholds 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.
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. 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, by way of either the beneficiary's own resources or the financial resources of third parties. (Article 113 of the Financial Regulation and Article 172 of the Implementing Rules).

— Non-profit rule: the grant may not have the purpose or effect of producing a profit for the beneficiary (Article 109(2) of the Financial Regulation and Article 165 of the Implementing Rules).

— Non-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).

— Non-cumulation rule: only one grant may be awarded for a specific conference to a given beneficiary (Article 111 of the Financial Regulation) (1).

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

— exclusion and eligibility criteria (Article 114 of the Financial Regulation),

— selection criteria, to assess the applicant's financial and operational capacity to complete a proposed action (Article 115 of the Financial Regulation),

— award criteria, to assess the quality of the proposal taking into account its cost.

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

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(1) and 94 of the Financial Regulation.

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

2. Proposals received after the deadline for receipt, incomplete proposals or proposals which do not meet 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.

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

— 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.

(1) This means that a specific action, submitted by one applicant for a grant, can be approved for co-financing by the Commission only once regardless of the length of this action.
4. 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.

3. SELECTION CRITERIA

Only proposals which meet the requirements of the exclusion and eligibility criteria will be eligible for evaluation. The following selection criteria have to be met.

1. Financial capacity:

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

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

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

2. Operational capacity:

Applicants 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 curriculum vitae of all relevant professional staff in all organisations involved in the proposed action.

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

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 work plan for 2013 (15 points);

(b) Participation (15 points):

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

(c) European dimension (15 points):

Conferences must have a wide European Union dimension, with participants from 10 or more countries participating in the Health programme;

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

Applicants must clearly describe the dissemination strategy. An adequate evaluation must be provided 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):

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

(b) Organisational capacity (10 points):

Applicants must clearly describe the management structure, competence of staff, responsibilities, decision-making, monitoring and supervision;
(c) Overall and detailed budget (15 points):

Applicants 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 which does not reach all thresholds 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 interests 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, Article 4(1)(b) and Article (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 of industry, commercial and business or other conflicting interests' 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 when 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 one 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 will 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 concerned 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 undertake not to receive more than 20 % of their core funding from private sector organisations (1) representing a conflicting interest, or from other sources representing a conflicting interest during the financial years covered by the grant.

Core funding is taken to 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 such as specific actions or projects.

3. TRANSPARENCY OF THE APPLICANT'S ACTIVITIES AND FUNDING

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

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.

Applicants' existing position statements regarding the requirement on transparency are to be publicly available.

4. ASSESSMENT OF INDEPENDENCE

Assessment of legal independence and transparency is based on the latest available information provided by the applicant together with the application. Financial independence will be assessed on the basis of financial information for the

---

(1) 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.

(2) 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) must be listed.
financial year for which the grant will be awarded 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 will be recovered.
ANNEX VII

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

Decision No 1350/2007/EC, Article 4(1)(a), Article 4(1)(b) and Article 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, whether at regional or local level and across participating countries. This includes the public sector, the private sector and stakeholders in wider civil society whose primary aims are not limited to public health (for example from youth, ethnic groups and other public interest spheres such as the environment and sport).

Proposals which meet the above criteria can be considered of exceptional utility. Applicants must be able to demonstrate how the proposed action will contribute to the areas mentioned above by complying with criteria specified below.

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 ‘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 five out of eight marks must be achieved for all the award criteria under the policy relevance block mentioned in Annex II. The purpose of this criterion is to promote improvement in 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 Health programme in the past five 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 an operating grant is of exceptional utility, as specified under ‘General principles’ above. Proposals for 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.
— 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.

4. EXCEPTIONAL UTILITY OF JOINT ACTIONS

A maximum EU contribution of 70 % of eligible costs may be envisaged where a proposal for a joint action is of exceptional utility, as specified under the section 'General principles' above. Proposals for joint actions requesting more than 50 % 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 five out of eight marks must be achieved for all the award criteria under the policy relevance block mentioned in Annex IV. The purpose of this criterion is to promote 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 Health programme in the past five years. This criterion is intended to promote the involvement of new actors for health.

— Bodies from at least 10 participating countries, or bodies from three participating countries where the action is proposed by a body from a Member State which has acceded to the European Union since 1 May 2004 or by a candidate country, should participate in the joint action.