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## ANNEX I TO VII

### ANNEX I

#### Public Health Programme - Work Programme for 2014

##### 1. INTRODUCTION

###### 1.1. Policy and legal context

This work plan sets out the priorities and actions to be undertaken, including the allocation of resources, to implement the third Programme of the Union's action in the field of health (2014-2020) <sup>(1)</sup> for the year 2014. It is based on Article 168 of the Treaty on the Functioning of the European Union (TFEU) and ensuing legal obligations and policy commitments. Article 168 of the TFEU sets out the scope of EU action in the area of public health which is to carry out actions to support, coordinate or supplement the actions of the Member States.

The EU Health Strategy <sup>(2)</sup> provides a policy framework for all the areas covered by this work plan. The 'Investing in health' Staff Working Document <sup>(3)</sup> of February 2013 linked this policy framework more closely to the broader Europe 2020 strategy. More specifically, it stressed the necessity to invest in sustainable health systems, invest in people's health and invest in reducing health inequalities.

Taken together, these three strands demonstrate that a healthy population and sustainable health systems are decisive for a smart, sustainable and inclusive growth.

The third Programme of the Union's action in the field of health (2014-2020) follows this approach and:

- Complements supports and adds value to the policies of Member States aimed at improving the health of Union citizens and reducing health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.

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<sup>(1)</sup> Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC [http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL\\_2014\\_086\\_R\\_0001\\_01&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_086_R_0001_01&from=EN)

<sup>(2)</sup> Commission White Paper *Together for Health: A strategic approach for the EU 2008-2013* (COM(2007) 630 final)

<sup>(3)</sup> Commission Staff Working Document Investing in Health. SWD(2013)43 final. Brussels; 20 February 2013. Accompanying the Communication: Towards Social Investment for Growth and Cohesion – including implementing the European Social Fund 2014-2020. COM(2013)83 final, available at: [http://ec.europa.eu/health/strategy/docs/swd\\_investing\\_in\\_health.pdf](http://ec.europa.eu/health/strategy/docs/swd_investing_in_health.pdf).

- Focuses on the key issues where Europe can deliver added value and impact positively in delivering mutual benefits across the European Union.

The programme is built around the following four specific objectives:

1. Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the ‘health in all policies’ principle;
2. Protecting Union citizens from serious cross-border health threats;
3. Contributing to innovative, efficient and sustainable health systems, and
4. Facilitating access to better and safer healthcare for Union citizens.

These specific objectives are explicitly set out in Article 3 of Regulation (EU) No 282/2014 of the European Parliament and of the Council on the establishment of a third Programme for the Union’s action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC <sup>(4)</sup> (hereinafter referred to as ‘the Programme Regulation’) and further specified in Annex I to that Regulation.

Actions proposed in this annual work programme should complement and create synergies with actions proposed in other policy areas, notably with relevant research projects funded under the 7th Framework Programme for Research and Innovation as well as with research projects which may be funded under Horizon 2020.

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 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.

In accordance with recital 23 of the Programme Regulation, 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.

## **1.2. Resources**

On the basis of the objectives given in the third Programme of the Union's action in the field of health (2014-2020), this work programme contains the actions to be financed and the budget breakdown for year 2014 as follows:

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<sup>(4)</sup> OJ L 86, 21.3.2014, p. 1.

for grants (implemented under direct management): EUR 39 993 000  
for procurement (implemented under direct management): EUR 12 279 100  
for other actions: EUR 2 184 000

The total available amounts to EUR 54 456 100 for 2014 <sup>(5)</sup>.

## 2. GRANTS

All grants are covered by written agreements.

### 2.1. Grants for projects

Under the overall operational budget reserved for grants, EUR 12 300 000 will be reserved for projects. The budget line is 17.03.01.

Project grants are calculated on the basis of eligible costs incurred. The maximum rate for EU co-financing is 60 %. However, this may be up to 80 % if a proposal meets the criteria for exceptional utility set out in Annex VII. Annex II contains the eligibility, exclusion, 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 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.

All grants for projects will be implemented through a call for proposals organised and managed by the Consumer, Health and Food Executive Agency (CHAFEA, hereafter called 'the Agency').

#### 2.1.1. Actions under thematic priority 1 - Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the 'health in all policies' principle

*2.1.1.1. Making use of the potential of innovation for the prevention and management of major chronic diseases (diabetes, cardiovascular diseases...) (Point 1.4. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The objective of the projects is to put more emphasis on new approaches to prevention of major chronic diseases, including linking prevention to healthcare interventions, with an emphasis on groups most at risk.

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<sup>(5)</sup> This amount corresponds to the amount available on budget line 17.03.01 + 3 % EFTA contribution.

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

The projects funded should concentrate on identifying innovative approaches to prevention, taking some of the most important preventable chronic diseases as an example. They will focus on: (a) diabetes prevention: improved implementation of good practice and the development of guidance on innovative and targeted prevention of diabetes type 2, in particular among people at high risk. Projects should draw lessons from research on metabolic profiles including children, and develop new targeted approaches to prevention in high risk groups; (b) cardiovascular diseases: based on the knowledge and recommendations on the prevention of cardiovascular conditions, the aim is to identify innovative and modern prevention measures tailored to reach in particular high risk populations, i.e. people with either genetic pre-disposition or unfavourable lifestyles, and to demonstrate their potential to reduce the incidence of cardiovascular conditions; and (c) the identification of good practice on linking and integrating prevention and healthcare intervention. This includes that the effectiveness of prevention measures identified in the projects above should be rigorously assessed for their uptake in the disease and care management, using standardized data systems linking primary and secondary prevention e.g. population-based disease registries, and identifying good practice for prevention interventions in different healthcare settings in Europe.

## Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	Second quarter of 2014	EUR 2 500 000

### *2.1.1.2. Promoting early diagnosis and screening of preventable chronic diseases (Point 1.4. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

Major chronic diseases, such as e.g. diabetes type 2 or cardiovascular conditions, are frequently not diagnosed until complications arise. The projects seek to explore the potential of early diagnosis in view of the control and more efficient treatment of chronic diseases. Technical developments, innovative approaches and progress in medicine lead to improved possibilities to identify the onset and to follow the progression of diseases.

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

The projects should develop an overview on where and how new or improved forms of early diagnosis (technical means, diagnostics, indicator diseases...) would be effective and efficient interventions for improved control of chronic diseases, and have an impact on the prevention and progression of major chronic diseases. The projects have two main objectives: (a) identify criteria for the use of early diagnosis in health care settings and develop implementation schemes based on an analysis of economic and medical benefits; (b) deliver a comprehensive overview and assessment of major screening and early intervention programmes, highlighting differences and strong and weak points in order to provide recommendations on steps to implement more efficient screening and early diagnosis schemes as prevention programmes in Europe.

## Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	Second quarter of 2014	EUR 1 500 000

*2.1.1.3. Developing innovative approaches to promote the professional reintegration of people with chronic diseases and improving their employability (Point 1.4. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

An increasing number of people are unable to work due to chronic diseases. This affects income, job turnover and can lead to disability. This is a concern for patients and also impacts on the sustainability of social security and labour systems across Europe. The objective of this action is hence to identify innovative strategies to adapt the workplace to the needs of people with chronic diseases and to improve their integration or reintegration into the workplace.

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

This project should deliver a comprehensive assessment of the availability of support services, educational/training programmes, resources and practical tools in Europe and beyond to address professional issues for people living with major chronic diseases and mental disorders, including improving their reintegration and/or employability into the workplace. The possibility to implement such existing tools and their transferability to a broader European context should also be assessed.

## Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	Second quarter of 2014	EUR 1 000 000

### **2.1.2 Actions under thematic priority 2 – Protecting Union citizens from serious cross-border health threats**

No action is foreseen in 2014.

### **2.1.3. Actions under thematic priority 3 - Contributing to innovative, efficient and sustainable health systems**

*2.1.3.1. Support in areas related to adherence, frailty, integrated care and multi-chronic conditions (Point 3.5. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The Commission has launched the European Innovation Partnerships within the Innovation Union, one of the flagship initiatives of the Europe 2020 strategy, with the objective of accelerating innovation to address a well-defined target within a grand societal challenge. The European Innovation Partnership on Active and Healthy Ageing has been selected as a pilot to tackle the challenge of an ageing population. The aim of this action is to facilitate the exchange of best practice between Member States, to support networks for knowledge sharing, to unlock the potential of innovation in health and to benchmark so as to ensure an informed decision-making at European level.

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

Building upon previous work conducted in this area, this action seeks to support projects encouraging the use of innovative, coordinated and comprehensive community based prevention. Activities to be addressed will include: (a) supporting the development and implementation of early diagnosis and screening programmes for frailty risk factors, including the optimisation of functional capacity tools and development of guidelines to address pre-frailty; (b) development of programmes to improve the management of multi-morbid patients, including use of medical data for optimising health and care systems. This action will focus on projects that would implement existing strategies or build on existing actions in order to achieve scalability and promote innovative solutions in health in the EU.

## Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	Second quarter of 2014	EUR 3 000 000

### *2.1.3.2. Financial support for statistical data in the area of medicinal product pricing in Member States (Point 3.6. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The overall goal of this action is to achieve a better coordination at the EU level in order to facilitate the control by the Member States of public budgets for medicinal products whilst avoiding/mitigating possible negative impacts on patient access to medicinal care.

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

This action seeks to support activities focusing on the identification of the optimal data-set (including the optimal data lay-out) to contain information on medicinal product prices in view of a better coordination of national policies in the area of external reference pricing of medicinal products. This action should also foresee the establishment of a database (or extension of an existing database) that builds on the identified data-set and data compilation lay-out.

## Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	Second quarter of 2014	EUR 300 000

### *2.1.3.3. Towards a sustainable health monitoring and reporting system (Point 3.7. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

This action is about data and health information and supports monitoring, research and policy making in all areas of EU health policy. It should create a network of relevant activities that have been run under the past health and research framework programmes, overcoming the fragmentation of projects on health information and data. The aim is to prepare the transition towards a sustainable and integrated EU health information system for both public health and research purposes while the potential of a comprehensive European health information research infrastructure consortium as a tool will be explored, as referred to in the Council conclusions of 10 December 2013 on the ‘Reflection process on modern, responsive and sustainable health systems’ <sup>(6)</sup>.

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

It is envisaged to finance one single project combining relevant horizontal activities, as well as specific activities linked to policy objectives, such as: (a) population health and health systems monitoring by using common validated indicators; (b) harmonized population based health examination surveys; (c) monitoring of impacts of environmental chemicals to health; (d) monitoring and reporting of perinatal and child health; (e) platform for population based registries for diseases; (f) platform for injury surveillance; (g) platform for Clinical and Administrative data on Health Care; (h) establishing standards and approaches for clinical and administrative health data collection and data sharing between countries; and (i) providing harmonised indicators, methods and tools to support monitoring and evaluation of health care systems in interested countries. Priority setting, planning and staging of activities will be done in close connection with the Commission Expert Group on Health Information. Synergies are expected with relevant selected projects following the calls for research infrastructure proposals under Horizon 2020 in the area of health information.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	Second quarter of 2014	EUR 3 500 000

**2.1.4. Actions under thematic priority 4 - Facilitating access to better and safer healthcare for Union citizens**

*2.1.4.1. Healthcare associated infections - Prevention and control in nursing homes and long-term facilities (Point 4.4. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

<sup>(6)</sup> [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lisa/140004.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/140004.pdf)



The objective of this action is to enhance infection prevention and control in nursing homes and long-term care facilities in the EU, with the aim to prevent and contain the spread of antibiotic resistances in the long term.

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

The project should create a network bringing together regional and national public health experts, Member States health authorities and relevant stakeholders in the area to analyse the current situation on healthcare associated infections and design a sustainable EU approach to help control healthcare associated infections in hospitals and long-term care facilities. The project should consider the use of tailored guidelines and best practices. More specifically, the project will focus on how regional (including cross-border) infection control networks applying harmonized infection control measures can contribute to prevent the spread of antimicrobial resistances.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	Second quarter of 2014	EUR 500 000

## 2.2. Grants for actions co-financed with Member State authorities

Under the overall operational budget reserved for grants, EUR 18 593 000 will be reserved for grants for actions co-financed with Member State authorities. The budget line is 17.03.01.

Grants for actions co-financed with Member State authorities (in short ‘Joint Actions’) are, according to Article 7.2(a) of the Programme Regulation, *‘actions having a clear Union added value co-financed by the competent authorities that are responsible for health in the Member States or in the third countries participating in the Programme pursuant to article 6, or by public sector bodies and non-governmental bodies, as referred to in Article 8(1), acting individually or as a network, mandated by these competent authorities.’*

Hence, they allow the nominated national authorities of the Member States/other countries participating in the Programme and the European Commission to take forward work on jointly identified issues.

Grants for such actions are calculated on the basis of eligible costs incurred. The maximum rate of EU co-financing is 60 %. This may be up to 80 % if a proposal meets the criteria for exceptional utility set out in Annex VII. Annex IV contains the eligibility, exclusion, selection and award criteria for these actions.

**2.2.1. Actions under thematic priority 1 - Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the ‘health in all policies’ principle**

*2.2.1.1. Facilitating the sharing of good practices between the EU Member States on national policies related to unbalanced dietary habits and physical inactivity (Point 1.1. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The objective of this action is to take forward the work on common priorities identified in the EU strategy on nutrition, overweight, and obesity-related health issues [COM(2007)279]<sup>(7)</sup> between national bodies mandated in this field. It should lead to increased attention at national level on the necessity to develop action to counter obesity, in particular childhood obesity.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

The activities should include: (a) capacity building for the development and the implementation of effective public health policies related to nutrition, dietary habits and physical activity; (b) the identification of comparable data across the Member States on the reduction of the levels of fat, saturated and trans fats, salt and sugar in manufactured foods and the development of common tools such as a methodology for food reformulation surveys; (c) the reflection on the monitoring of national policies related to nutrition, dietary habits and physical activity, including those promoting healthier environments, especially in schools and pre-schools; and (d) the production of guidelines related to these policies as well as print and online instruments for information dissemination. Work should take into account social inequalities and be taken forward in cooperation with WHO.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

<b>Reference</b>	<b>Date</b>	<b>Amount</b>
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 1 200 000

<sup>(7)</sup> White Paper COM(2007) 279 of 30 May 2007 on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues.

2.2.1.2. *Improvement of HIV and co-infection prevention and treatment in priority regions and priority groups in the European Union (Point 1.3. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

This action supports the implementation of the Commission Communication on ‘Combating HIV/AIDS in the European Union and neighbouring countries, 2009-2013’ [COM(2009) 569 final of 26 October 2009] and the ‘Action Plan on HIV/AIDS in the EU and neighbouring countries: prolongation 2014-2016’<sup>(8)</sup>. The Communication and Action Plan provide the framework for evidence based prevention and integrated treatment of HIV/AIDS and co-infection (viral hepatitis, tuberculosis and STIs), which will be focused on priority groups.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

The activities taken forward by national bodies mandated in this field should particularly address the growing HIV/AIDS epidemic among drug users, their sexual partners and offspring in East and Southern European countries, some of which are most affected by the economic crisis. This action will build on best practice models of several EU networks, which bring together health authorities, civil society and patient organisations. Furthermore, collaboration between social services, health services and security sectors will be facilitated, and the capacity of professionals in these sectors to use cost effective prevention methods will be supported. In addition, outreach work and referral systems will be bridged, by bringing together low threshold services to deliver primary health care interventions and specialised care for the management of HIV/AIDS and co-infections in the community and prison health settings. The action will promote: quality of services by fostering integration of care for HIV/AIDS and co-infections; integration of care between prison health and community public health services; use of European standards in evidence for drug prevention, and the scaling up of harm reduction by improving access to drug treatment and harm reduction programmes. In addition the action will aim to develop guidance on the utilization of funding mechanisms for actions on HIV/AIDS and co-infections, and also address discrimination in relation to HIV/AIDS.

Implementation

Implementation by the Agency

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<sup>(8)</sup> Commission Staff Working Document SWD(2014) 106 of 14 March 2014 on an Action Plan on HIV/AIDS in the EU and neighbouring countries: 2014-2016.

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 3 000 000

*2.2.1.3. Promoting the implementation in Member States of coordinated actions to improve the situation of people with dementia and their carers (Point 1.4. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The purpose of this action is to build on the outcomes of the ALCOVE Joint Action, to further develop knowledge and recommendations and to tackle important aspects related to dementia which have not been sufficiently addressed so far.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

The activities to be undertaken by national bodies mandated in this field will include: improved post-diagnostic support services, improvement of care pathways, assessment of the use of medicinal products and of psychotropic substances, the health of family carers, the qualification of the personnel involved in the care chain, and the availability and the quality of day-care homes for people with dementia.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 1 500 000

**2.2.2. Actions under thematic priority 2 - Protecting Union citizens from serious cross-border health threats**

*2.2.2.1. Efficient response to highly dangerous and emerging pathogens at EU level - Phase II (Point 2.3. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

Against the background of the entering into force of Decision No 1082/2013/EU on serious cross-border threats to health there is need of efficient, rapid and coordinated responses to emerging threats caused by new pathogens. The objective of this action is hence to ensure an efficient response to serious cross-border events caused by new and dangerous pathogens through reinforcing the existing EU network of Risk Group 3 and Risk Group 4 laboratories which are already active in the field of identification of dangerous bacterial and viral human pathogens. This action will enable an efficient and coherent EU level response to potentially devastating cross-border events. This is of particular value for Member States with less capacity and expertise to respond to threats caused by emerging and dangerous pathogens and it will also support Member States in implementing the International Health Regulations. It will be fully linked to the existing mechanisms and structures developed and put in place in other sectors, such as the network operating under the FP7 for research and development and the existing initiative developed by the European Centre for Disease Prevention and Control and in the context of the WHO Reference Laboratory Networks.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

The action will in phase II build on previous work of the '*Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens*' (QUANDHIP) consortium and will integrate activities of two different networks (Establishment of Quality Assurances for Detection of Highly Pathogenic Bacteria of Potential Bioterrorism Risk – EQADeBa and European Network of level 4 laboratories- EuronetP4). It will be taken forward by national bodies mandated in this field and be extended to the 28 EU Member States and EEA Countries offering the following specific services: (a) rapid identification of pathogens causing serious cross-border threats to health (bacterial and viral); (b) rapid mechanisms for sample sharing in case of an event to be managed under Decision No 1082/2013/EU; (c) confirmation of laboratory diagnosis; (d) quality assurances for detection of highly pathogenic bacteria of potential bioterrorism risk; (e) training, capacity building in the infection control area and in the biosafety/biosecurity quality management; (f) consolidation of biodiverse repository of reference materials; and (g) promotion of interoperability with other relevant EU and international research and public health networks/projects/organizations in the field of emerging infection.

#### Implementation

Implementation by the Agency

Indicative timetable and indicative amount

<b>Reference</b>	<b>Date</b>	<b>Amount</b>
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 3 500 000

### 2.2.3. Actions under thematic priority 3 - Contributing to innovative, efficient and sustainable health systems

#### 2.2.3.1. Technical and scientific co-operation allowing improved coordination and resource sharing between Member States (Point 3.1. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

This action is about the technical and scientific co-operation allowing improved coordination and resource sharing between Member States following the adoption by the legislators of new Regulations on medical devices and in vitro diagnostic medical devices.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

Co-operation between Member States allowing development of best practise, training and knowledge and resource sharing in the operation of the medical device legislation, in particular in relation to Member States tasks such as the designation of notified bodies, assessment of clinical studies, the operation of the Vigilance system and market surveillance.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 203 000

#### 2.2.3.2. eHealth support for the eHealth Network by national competent authorities (Point 3.2. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

eHealth and health services based on eHealth applications are broadly recognized as an essential element to support sustainability of health care systems. Directive 2011/24/EU on patients' rights in cross-border healthcare sets broad objectives and deliverables for EU cooperation in eHealth and sets up the eHealth Network. For the Network to deliver, a preparatory structure to work on policy and technical aspects is a prerequisite. This will support the eHealth Network by producing the required policy documentation and making the necessary arrangements for technical support to the work programme and decisions of the Network.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

The activities of this action to be taken forward by national bodies mandated in this field will be based on: (1) the deliverables mentioned in Directive 2011/24/EU (e.g. guidelines on ePrescription, the use of medical information for public health and research); (2) the priorities identified in the eHealth Action Plan 2012-2020; and (3) the strategic aspects of the interoperability agenda as agreed by the Network. The action will also contribute to the sharing of good practises between Member States on how eHealth tools are used in health promotion and disease management.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 2 400 000

#### **2.2.4. Actions under thematic priority 4 - Facilitating access to better and safer healthcare for Union citizens**

*2.2.4.1. Support to the implementation of Council Recommendation and Commission Communication on Rare Diseases, in particular to an EU wide rare diseases information database (Point 4.1. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

Developments in science and policy require continuous improvements. Therefore the aim of this action is to continue implementation of priorities identified in the Commission Communication COM(2008) 679 on Rare Diseases: Europe's challenges and in the Council Recommendation (2009/C 151/02) on an Action in the field of rare diseases <sup>(9)</sup>.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

This action which will be taken forward by national bodies mandated in this field will focus in particular on the implementation of actions in the areas of information provision, codification, European reference networks, gathering expertise and provision of support for the Commission expert group on rare diseases.

<sup>(9)</sup> Council Recommendation (2009/C 151/02) of 8 June 2009 on an action in the field of rare diseases, OJ C 151 (3.7.2009).

In respect to the information and inventorying of rare diseases it will aim to support the further development of the Orphanet database on rare diseases which is run by a large consortium of European partners and is the biggest global repository of information about rare diseases.

#### Implementation

Implementation by the Agency

#### Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 4 290 000

#### 2.2.4.2. *Strengthening the Member States' capacity of monitoring and control in the field of blood transfusion and tissue and cell transplantation (Point 4.5. of Annex I to the Programme Regulation)*

#### Priorities of the year, objectives pursued and expected results

This action aims to support Member States in their efforts to improve the implementation of the EU requirements for the safety and quality of blood and blood components and tissue and cell products.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

This action will promote further cooperation between Member States competent authorities in the area of blood transfusion and tissue and cell transplantation. The action, to be taken forward by national bodies mandated in this field, should build on the outcome of previous EU-funded projects (e.g. EUBIS, CATIE, EUSTITE, SOHO V&S, etc.) and should provide support in various aspects like managing national vigilance systems, traceability and implementation of the Single European Code for tissues and cells, and training of inspectors. Common practical concerns and best practices should be identified, allowing for cross-fertilisation between the transfusion and transplantation sectors.

#### Implementation

Implementation by the Agency



## Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 2 500 000

### 2.3. Financial contribution to the functioning of non-governmental body (Operating grants)

Under the overall operational budget reserved for grants, EUR 4 650 000 will be reserved for operating grants. The budget line is 17.03.01.

Operating grants are calculated based on 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.

The call for proposals 2014 aims at providing financial contributions (operating grants) to the functioning of non-governmental bodies, including networks, through the conclusion of framework partnership agreements (FPA) for a duration of maximum three years – covering the operating years 2015, 2016, 2017 – and, subsequently, of specific grant agreements for the financial year 2015. The FPA will include a multi-annual work programme for the period 2015-2017 as an annex, including a budget plan.

Applicants who receive a FPA are eligible for the specific grant agreement. They will be invited to submit a simplified grant application. This will include an annual work programme and budget. Signing an FPA does not guarantee annual co-funding.

Operating grants may be awarded to non-governmental bodies, including networks, active in areas corresponding to the four objectives of the Health Programme, according to the eligibility criteria established by Article 8(2) of the Programme Regulation and in Annex III to the present decision. Work under operating grants should contribute to achieving 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<sup>(10)</sup>.

Priorities for the year 2014

Operating grants can be awarded to non-governmental bodies working at the EU level in any priority covered by the third Health Programme. However, for 2014, special attention will be given to non-governmental bodies working at the EU level in the fields of chronic diseases, cancer, HIV/AIDS, rare diseases and smoking prevention.

<sup>(10)</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF>

Description of the activities to be funded by a specific grant awarded under a framework partnership

All activities within the scope of Annex I of the Programme Regulation can be funded by a specific grant awarded under a framework partnership. In 2014, among these operating grants, support will be given in priority to work supporting the dissemination of the European Cancer Code, the secretariat of the HIV/AIDS Civil Society Forum, to activities linked to rare diseases in general, smoking prevention and the prevention and management of chronic diseases.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of a call for proposals for a framework partnership 2015-2017 and for the specific grant for the financial year 2015	Second quarter of 2014	EUR 4 650 000 (total amount available)

#### 2.4. Presidency conference grants – De jure monopoly

According to Article 190(1)(c) of Delegated Regulation (EU) No 1268/2012, 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 conferences to be financed under this work plan are a conference ‘Health in the Mediterranean area’ planned under the Italian Presidency and a conference ‘Healthy Lifestyles’ under the Latvian Presidency.

Implementation

Implementation by the Agency

## Indicative timetable and indicative amount

Reference	Date	Amount
Direct award	Second half of 2014 and First half of 2015	EUR 200 000 (total amount available)

### 2.5. Direct grant agreements with international organisations

The overall budgetary allocation reserved for actions implemented via direct grants to international organisations amounts to EUR 2 750 000. The budget line is 17.03.01.

In accordance with Article 190(1)(f) of Delegated Regulation (EU) No 1268/2012, 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 23 of the Programme Regulation, activities involving third countries not participating in the programme shall not be considered eligible. 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 the respective sections of this work programme:

— Council of Europe (CoE)

The Council of Europe has specific expertise in the harmonisation and co-ordination of standardisation, regulation and quality control of medicines, blood transfusion, transplantation of organs, tissues and cells, pharmaceuticals and pharmaceutical care.

— 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.

In accordance with Article 190(1)(f) of Delegated Regulation (EU) No 1268/2012, funding through grants will also be awarded to the Secretariat of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) because of its unique competence and high degree of specialisation in the area of Good Manufacturing Practice (GMP). PIC/S is composed of 44 pharmaceutical inspections authorities (28 from EU Member States) which develop and promote harmonised GMP standards and guidance documents, train competent authorities, in particular inspectors, assess

(and reassess) inspectorates, and facilitate the co-operation and networking for competent authorities and international organisations.

International organisations and their national or regional offices are not eligible for funding as main or associated beneficiaries under calls listed in section 2.1 and under the procedure described in section 2.2.

Award criteria for these direct grants are:

- Technical quality of the proposal
  - Quality of the content (clear objectives, adequate methodology, well defined deliverables, pertinent outcomes);
  - Quality of the evaluation strategy (a logic framework method is used, process, output and outcomes/impact indicators defined and pertinent);
  - Quality of the dissemination actions planned.
- Management quality
  - Quality of the planning and implementation (logic timetable with milestones defined, adequate risk analysis and contingency planning);
  - Management structure and competences of staff are clearly described;
  - Technical and financial reporting procedures and quality controls are well described and adequate.

**2.5.1. Actions under thematic priority 1 - Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the health in all policies principle**

*2.5.1.1. Monitoring of the national policies related to nutrition, physical inactivity overweight- and obesity-related diseases in all the Member States – Grant to WHO (Point 1.1. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

This action supports the consolidation of a solid EU information and reporting system capable of describing the progress in the Strategy for Europe on Nutrition, Overweight and Obesity-related Health issues [COM(2007)279] relying on a WHO led network of 28 National Focal Points. It shall contribute to producing sound information on the efforts of the EU Member States to counter ill health due to poor nutrition, overweight and obesity.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(f) of the Rules of Application

The work was launched by two previous direct grants to the WHO. This action will: (a) provide information regarding the level of implementation of the European Strategy in all Member States against the 2007, 2009, 2011 and 2013 benchmarks for 2014, 2015 and 2016; (b) animate and provide assistance to the EU 28 National Focal Points network in close collaboration with the EU High Level Group on Nutrition and Physical Activity and relevant Commission services; (c) maintain a comprehensive database on Member States and EU policy developments and activities; and (d) ensure exchange of information and good practice between the 28 Member States. The action will further produce: (a) an annual update of the public database developed in the first two periods for the 27 Member States (2007 to 2013); (b) reports on the implementation of the Strategy by Member States and a contribution to the Commission evaluation report on the strategy; and (c) a consolidation of the WHO nutrition and physical activity focal points network with capacity building development in data gathering and steering of the network.

#### Implementation

Implementation by the Agency

#### Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 600 000

#### 2.5.1.2. Monitoring of the national policies related to alcohol consumption and harm reduction – Grant to WHO (Point 1.1. of Annex I to the Programme Regulation)

##### Priorities of the year, objectives pursued and expected results

This action supports the implementation of key Commission Strategies for promoting health, preventing diseases and reducing inequalities in health, specifically the EU health strategy Together for Health [COM(2007)630] and the EU Strategy to support Member States in reducing alcohol related harm [COM(2006)625]. The aim of this action is to continue collecting data and maintaining a database of alcohol related key indicators and national alcohol policies in all Member States.

##### Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(f) of the Rules of Application

The action shall continue improving the knowledge base on alcohol-related trends and ensuring an effective surveillance of alcohol consumption. It shall also support policy making with valid data and through exchange of good practices on key areas of alcohol policy such as health services' response, community action, drink-driving policies and countermeasures, availability and marketing of alcohol and pricing policies. A survey with key indicators and EU specific questions is expected (updated country profiles based on these data will be ready

for on-line publishing during February 2015). Besides, one meeting with national focal points to discuss information system and relevant topics related to alcohol policy will be held.

#### Implementation

Implementation by the Agency

#### Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 500 000

### **2.5.2. Actions under thematic priority 2 – Protecting Union citizens from serious cross-border health threats**

No action is foreseen in 2014.

### **2.5.3. Actions under thematic priority 3 – Contributing to innovative, efficient and sustainable health systems**

#### *2.5.3.1. European Pharmacopoeia – Grant to CoE (EDQM) (Point 3.6. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

This activity aims at: (a) the harmonisation of quality standards vested in the EU pharmaceutical legislation; (b) the facilitation of the placing on the market of medicinal products in all the Member States; and (c) availability of medicinal products for the whole European population.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(f) of the Rules of Application

The grant will contribute to the Council of Europe work on the European Pharmacopoeia. The European Union is a party to the Convention on the European Pharmacopoeia of the Council of Europe, in line with Council Decision 94/358/CE. Directives 2001/83/EC and 2001/82/EC provide that the monographs developed by the European Pharmacopoeia are applicable to all substances, preparations and pharmaceutical forms listed therein.

The Pharmacopoeia contributes to the implementation of the EU legislation on medicinal products, to the development of monographs (i.e. technical specifications on obligatory standards for medicinal products) and analytical testing methods. It also coordinates the network of national control laboratories that verify the composition of medicinal products, as required by the EU legislation.

## Implementation

Implementation by the Agency

### Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 1 100 000

*2.5.3.2. Training in the area of active pharmaceutical ingredients (Direct Grant to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) (Point 3.6. of Annex I to the Programme Regulation)*

### Priorities of the year, objectives pursued and expected results

The aim of this action is to foster the correct implementation of Article 46b of Directive 2001/83/EC on the Community code relating to medicinal products for human use requiring that imported active substances are accompanied by a written confirmation by the third country authorities that the active substance was manufactured according to standards at least equivalent to those of the EU. The correct application of this provision requires that third countries regulators, inspectors and manufacturers are aware and knowledgeable about EU manufacturing standards. This will be achieved by the means of ad hoc training sessions organised by PIC/S in key countries exporting active substances to the EU, such as China, India, Brazil, Mexico and Argentina. The expected outcome is an increased knowledge of and compliance to EU Good Manufacturing Practices rules by targeted third countries, leading to better quality and safer active substances being imported into the EU.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(f) of the Rules of Application

This action deals with the training of regulatory authorities and manufacturers from third countries exporting active substances for medicinal products for human use into the EU on EU rules and manufacturing standards for active substances.

## Implementation

Implementation by the Commission

### Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	Second semester of 2014	EUR 50 000

#### **2.5.4. Actions under thematic priority 4 - Facilitating access to better and safer healthcare for Union citizens**

*2.5.4.1. Integration of the EU legislation on substances of human origin and the outcomes of EU funded project actions in this area into the Council of Europe actions – Grant to CoE (Point 4.5. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

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 seeks to align and support the Council of Europe with this work. It will contribute to a better implementation of the safety and quality requirements set out in the Blood, Tissues and Cells and Organs Directives.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(f) of the Rules of Application

Council of Europe activities include proficiency testing of reference laboratories, auditing and advising individual establishments active in the field of transfusion and/or transplantation and further development of best practice guidelines on the safety and quality of substances of human origin.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

<b>Reference</b>	<b>Date</b>	<b>Amount</b>
Signature of the grant awarded without a call for proposals	First quarter of 2015	EUR 500 000

#### **2.6. Cross sub-delegation to Eurostat implemented through grants procedures**

The actions referred to hereunder under Morbidity statistics and Health expenditures (sub-delegation to Eurostat) will be implemented through grants, without a call for proposals in accordance with Article 5 of Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics. The beneficiaries will be the National Statistical Institutes and the other national authorities responsible for the development, production and dissemination of European statistics as designated by Member States, included in the list referred to in paragraph 2 of this article.

These grants are calculated on the basis of eligible costs incurred. In 2014, the maximum rate for EU co-financing may be up to 70 % due to the exceptional utility of the actions 2.6.1. and



2.6.2. as justified hereinafter. Annex V contains the eligibility, exclusion, selection and award criteria for these grants.

Justification for exceptional utility: There is a crucial need for EU wide sound, comparable and accessible evidence, statistics and indicators for areas contributing to the achievement of an 'inclusive growth' in particular and of the EU 2020 objectives in general: financial sustainability of the health systems, maximisation of health systems efficiency, sustainability of EU health workforce by promoting effective forecasting and planning, reduction of inequalities in health, and the European Innovation Partnership on Active and Healthy Ageing, etc. Morbidity statistics and health expenditures are part of these data which are needed.

- Morbidity statistics: Further harmonization and increased sustainability in the process of data collection in this area among Member States is highly needed. Morbidity statistics constitute an important element of a health system knowledge system and contribute to evidence-based decision making. A coordinated approach by Member States is required towards morbidity statistics as part of the European Statistics System (ESS).

- Health expenditures: With a new Regulation on the collection of health expenditure data coming soon into force, financial support is needed to help the Member States which were not reporting this type of data to Eurostat to implement the new Regulation.

#### *2.6.1. Morbidity statistics – Cross sub-delegation and Service Level Agreement with Eurostat Services (Point 1.6. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The Regulation on health statistics (No 1338/2008) gives an overall legal framework for health data including morbidity. This action is a follow-up of previous Eurostat projects since 2005 on implementing morbidity statistics within the European Statistical System (ESS) and will contribute to the generation and dissemination of health information and knowledge within the third Health Programme.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

Beneficiaries will have to provide inventories in view of data availability, access and coverage for best morbidity estimates from different sources, and potential ways for fixing existing problems.

Implementation

Implementation by the Commission

Indicative timetable and indicative amount

<b>Reference</b>	<b>Date</b>	<b>Amount</b>
Signature of the grant awarded without a call for proposals	Second semester of 2014	EUR 1 000 000

*2.6.2. Health expenditures – Cross sub-delegation to Eurostat and Service Level Agreement with Eurostat Services (Point 3.7. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The aim of this action is to foster a health knowledge system to contribute to evidence-based decision-making including collecting and analysing health data. It is about building statistical capacity in Member States before the Regulation on health care expenditure is applicable. Up to now some countries were not reporting on health expenditure data to Eurostat. They will need support to implement the new Regulation. The health expenditure data is very much needed for the thorough analysis of health systems.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

The action will be dedicated mainly to infrastructural developments such as statistical methodological developments and IT developments. Statistical methodological developments may include analysis of possible data sources and elaboration of statistical treatments to compile data according to the System of health accounts (SHA) 2011 Manual. IT developments may concern infrastructure/tools necessary for the collection, compilation, validation and data transmission to Eurostat. The action could include pilot data/metadata transmissions to Eurostat. However this will exclude the official mandatory transmissions, according to the future Regulation on health care expenditure.

Implementation

Implementation by the Commission

Indicative timetable and indicative amount

<b>Reference</b>	<b>Date</b>	<b>Amount</b>
Signature of the grant awarded without a call for proposals	Second semester of 2014	EUR 500 000

### 3. PROCUREMENT

The overall budgetary allocation reserved for procurement contracts in 2014 amounts to EUR 12 279 100. The budget line for procurement is 17.03.01.

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. Framework contracts and new service contracts will be used.

#### 3.1. Actions under thematic priority 1 - Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the 'health in all policies' principle

##### 3.1.1 Evaluation of the anti-tobacco campaign "Ex-smokers are unstoppable" and Anti-tobacco communication campaign aimed at encouraging smoking cessation (Point 1.1. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

This action has two components. **1) Evaluation** of the "Ex-smokers" campaign which ran from April 2011 until October 2013 and aimed at developing and running a campaign to make citizens aware of the dangers of tobacco and to encourage them to stop smoking. The evaluation aims therefore to focus on relevance, effects on smoking behaviour and efficiency, the added value of the campaign, and to understand which components of the current ex-smoker campaign have been working best. **2) Communication:** Capitalising on the communication strategies and instruments of the previous EU anti-tobacco campaign, the activities proposed should support events and other communication activities to promote smoking cessation targeting in particular young adults aged 25-34. The contractor should propose a comprehensive and coherent communication plan, based on a coherent and creative concept adapted to the topic and the target group and taking into account specific circumstances within Member States. The particular background of EU-wide communication action in the field should also be considered as well as smoking cessation activities being undertaken by different actors in Member States.

Type of contract and type of procurement

Specific contracts based on two different existing framework service contracts

Indicative number of contracts envisaged: 2

Indicative timeframe for launching the procurement procedure

Second quarter of 2014

Implementation

Implementation by the Commission

3.1.2. *Monitoring of the EU Platform for Action on Diet, Physical Activity and Health (Point 1.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Evaluation/monitoring:** The objective of this action is to obtain an independent analysis of and information about the progress of the Platform for action on diet, physical activity and health in support to the ‘Strategy for Europe on Nutrition, Overweight and Obesity related Health issues’ [COM(2007)279]. The estimated period for deliverables is two years. This action will contribute to: (a) gaining a better understanding of the Platform’ commitments and their relevance for the aims of the Platform; (b) fine-tuning these commitments; (c) understanding what needs to be done and how to better integrate all commitments; (d) engendering wider stakeholder trust; and (e) eventually spreading good practices. This action will facilitate plenary discussions on the Platform commitments in each key area. These are consumer information, including labelling; education; promotion of physical activity; marketing and advertising; composition of foods, availability of healthy food options, and portion sizes; and advocacy, policy work and information exchange to improve the impact of individual initiatives. This action also covers annual reports on the Platform achievements including individual commitments.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2014

Implementation

Implementation by the Commission

3.1.3. *Monitoring the EU Alcohol and Health Forum (Point 1.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Evaluation/Monitoring:** The aim of this action is to assess the self-regulatory actions (i.e. commitments) of Alcohol Forum members and to complement the monitoring activities carried out by the owners of the commitments. This action will contribute to: (a) gaining a better understanding of the Forum commitments and their relevance for the aims of the Forum; (b) fine-tuning these commitments; (c) understanding what needs to be done and how to better integrate all commitments; (d) engendering wider stakeholder trust; and (e) eventually disseminating good practices. This action also covers annual reports on the Forum’s achievements including individual commitments.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2014

Implementation

Implementation by the Commission

*3.1.4. EU Health Policy Forum or similar cross cutting stakeholder activities (Point 1.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study and technical assistance:** The aim of this action is to provide scientific support to the secretariat of the EU Health Policy Forum. This action includes: maintenance of the EU health policy forum membership; assistance to the Commission in the preparation of agendas and meeting documents for two meetings per year; preparation of draft position papers and technical reports for the EU Health Policy Forum including coordinating and integrating comments from members.

Type of contract and type of procurement

Specific contracts based on a new service framework contract

Indicative number of contracts envisaged: 4

Indicative timeframe for launching the procurement procedure

First semester of 2014

Implementation

Implementation by the Commission

*3.1.5. Disseminating good practice on mental health through the European Compass for Action on Mental Health and Well-being (Point 1.4. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** The objective is to implement the invitation contained in the Council conclusions on ‘The European Pact for Mental Health and Well-being: results and future action’ of 2011 to ‘further develop the European Compass for Action on Mental Health and Wellbeing’. This action covers (a) good practice collection: further developing the existing database on good practices, including the development of a method for their collection and validation based on agreed quality criteria; (b) supporting Member States: developing a format for the regular collection of information on key developments and policy activities in the field of mental health and well-being in Member States and at EU level, based on a concise set of indicators and including a mechanism involving a panel of experts and non-governmental organisations to review the progress made towards the objectives of the Pact, and to develop recommendations to Member States; and (c) supporting and networking health and non-health stakeholders: establishing a web based Multi-Stakeholder Partnership of Leaders in Action for Mental Health and Well-being as a platform for promoting the implementation and dissemination of initiatives in the health sector and other sectors, such as educational settings, workplaces and the social sector which support the objectives of the Pact, including through the development of implementation plans.

Type of contract and type of procurement

New direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2014

Implementation

Implementation by the Agency

*3.1.6. Tobacco legislation: Provision of technical and scientific input and tailor-made tools to prepare and adopt cost-effective measures against smoking on the EU level, as well as to support the implementation of the existing policies (Point 1.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

In order to make the revised Tobacco products Directive (TPD) fully operational delegated and implementing powers are foreseen to give effect or 'shape the rules' laid down in the basic act. In this regard, technical and scientific input is required in the form of reports, studies and/or other relevant forms, which will assist the European Commission in the implementation and monitoring of the TPD and associated policies in the area of tobacco and related products.

**The 2014 action comprises studies, supporting data and services** in four priority areas: (a) further regulation of ingredients contained in tobacco products and products which do not contain tobacco, but which are closely linked to smoking or tobacco consumption, for example electronic- and herbal cigarettes. This concerns in particular the content regulation and appropriate reporting mechanisms, especially for additives put on a priority list for which more detailed information needs to be reported; (b) implementation of the labelling and packaging requirements, for tobacco products, electronic cigarettes and herbal products for smoking, as outlined in Articles 7 to 11, 18 and 19 of the revised TPD, further data on misleading elements which are forbidden according to Article 12 on product presentation; (c) public health risks from electronic cigarettes and their refillables, development of technical and safety standards for the refill mechanism; and development of a common notification format as outlined in Article 18 on electronic cigarettes; and (d) further development of tracking and tracing systems and security features as outlined in Article 14 on traceability and Article 14a on security.

Type of contract and type of procurement

Direct service contracts or specific contracts based on existing framework service contracts

Indicative number of contracts envisaged: 6

Indicative timeframe for launching the procurement procedure

Two contracts in the second quarter, two contracts in the third quarter and two contracts in the fourth quarter of 2014

Implementation

Implementation by the Agency or the Commission determined by the type of contract

### **3.2. Actions under thematic priority 2 - Protecting Union citizens from serious cross-border health threats**

*3.2.1. High level hearing/conference with stakeholders on the state of art of seasonal influenza vaccination followed by a study on cost-benefit and socio-economic impact of seasonal influenza vaccination (Point 2.2. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

This action has two components: **1) Technical assistance:** The intention of this high level hearing/conference is to discuss with stakeholders the state of play of the implementation of the Council Recommendation on seasonal influenza vaccination (2009/1019/EU). In particular, the focus will be on a consensus statement on main issues to be addressed, both at short and medium term, in order to improve the current situation. **2) Study:** This event should be complemented by a cost-benefit analysis of seasonal influenza vaccination, aiming to develop data on the direct and indirect costs associated with vaccination as well as the direct costs prevented by vaccination. Such an examination could demonstrate the cost-effectiveness of this preventive intervention.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second quarter of 2014

Implementation

Implementation by the Commission

*3.2.2. Study on cost-benefit of reference laboratories for human pathogens (Point 2.2 of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:** The overall objective of this study is to strengthen the existing coordination of reference microbiology provision in the EU in order to support the European response coordination to outbreaks of highly pathogenic infectious agents. This study will complement findings of a study on a European system of reference laboratories for pathogens for humans with a cost-benefit analysis to assess possible options for establishing such an EU wide approach.

Type of contract and type of procurement

Direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure



Second quarter of 2014

Implementation

Implementation by the Agency

*3.2.3. Organisation of a command post exercise to test emergency coordination (Point 2.2. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** A command post exercise strives to create a situation as close as possible to an actual event, i.e. using surveillance and intelligence gathering tools, risk assessment and real communications methods. The overall objective of this command post exercise will be to test the communication channels and the procedures in place in order to detect and monitor an outbreak, to examine and assess risk, to investigate the coordination and management of the response to such events and the existing crisis communication capacities. The nature and type of events will reflect the scope and the mechanisms laid down in the new Decision on serious cross-border threats to health (1082/2013/EU), and the exercise will contribute to its implementation.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second quarter of 2014

Implementation

Implementation by the Agency

*3.2.4. Support to preparedness activities under Decision No 1082/2013/EU on serious cross-border health threats including joint procurement of medical countermeasures (Point 2.2. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** Support to the implementation of Decision No 1082/2013/EU in particular as regards preparedness activities relevant to the monitoring, the assessment and the coordination of the response. It includes the following activities: (a) assessment and organisation of a seminar addressing the inter-sectorial dimension of preparedness and response planning at Union level; (b) identification of critical sectors for the preparedness and

management of health crises, including the development of criteria; (c) inventories on situational analysis and reporting capacities in the EU including possible technological support to follow up incidents involving environmental health threats and health threats from other biological agents and chemical agents; and (d) preparatory actions (assessments) and organisation of a seminar on joint procurement. This action should ensure relevant links to the Information Platform for Chemical Monitoring (IPChEM) currently under development at JRC.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second quarter of 2014

Implementation

Implementation by the Agency

### **3.3. Actions under thematic priority 3 - Contributing to innovative, efficient and sustainable health systems**

#### *3.3.1. Maintenance and development of the existing Eudamed and the PORT authentication e-services portal (Point 3.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**IT services:** The European medical devices database EUDAMED is an information system for exchanging legal information related to the application of European Union Directives on medical devices between the European Commission and the competent authorities in the European Union Member States. Additionally an authentication e-services portal is needed to access the existing EUDAMED and for this purpose the internal portal PORT is used as management tool for the access and security for EUDAMED and some other DG Health and Consumers applications.

Type of contract and type of procurement

Specific contracts based on an existing framework service contract

Indicative number of contracts envisaged: 1-3

Indicative timeframe for launching the procurement procedure

First semester of 2014

## Implementation

Implementation by the Commission

3.3.2. *Development of the future EUDAMED following the adoption by the legislators of new Regulations on medical devices (Point 3.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**IT services:** Development following the adoption by the legislators of new Regulations on medical devices and in vitro diagnostic medical devices of the future EUDAMED, the European medical devices database. This encompasses an analysis of the future EUDAMED architecture framework, usability, technology, users' administration and users' management system data modelling and mock-up.

Type of contract and type of procurement

Specific contracts based on an existing framework service contract

Indicative number of contracts envisaged: 1-3

Indicative timeframe for launching the procurement procedure

First or second semester of 2014 (depending on adoption of new regulations by legislators)

## Implementation

Implementation by the Commission

3.3.3. *Development of a data storage system for reports of assessments of notified bodies (Point 3.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**IT services:** The Commission's implementing regulation on the designation and the supervision of notified bodies under the European legislation on medical devices establishes that the Commission will manage a data storage system for the reports of the joint assessments of notified bodies. In addition there is a need for a workspace for Member States to make available to the joint assessment teams the information related to the procedure for the designation and supervision of notified bodies. Given the high economic sensitivity and confidential nature of the documents the data storage system will have to be built to ensure secure transmission of information and control of access.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2014

Implementation

Implementation by the Commission

*3.3.4. Video on National Contact Points on cross-border healthcare (Point 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Communication services:** National Contact Points which Member States need to establish under Directive 2011/24/EU on cross-border healthcare will play a vital role in ensuring that patients have the information they need to access healthcare services in another Member State. A video clip should be developed in order to raise citizens' awareness about the existence and operation of these National Contact Points.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2014

Implementation

Implementation by the Commission

*3.3.5. Assessment of implementation of Patients' Rights directive (Point 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

This action is composed of four subactions. **1) Eurobarometer on patient information - Communication services:** Eurobarometer on patient information - A Eurobarometer should be conducted in order to examine whether citizens are aware of their rights related to cross-border healthcare and whether they know that they should get information they need to access

healthcare in another Member State from National Contact Points, in accordance with Directive 2011/24/EU. The purpose of the survey is to capture the citizens' awareness of the existence of national contact points, of patients' rights in cross-border healthcare and of patients' rights more generally in the EU, one year after the end of the transposition deadline of the Directive. The results will contribute to a Commission report on the operation of the Directive, due in October 2015. **2) Study on the implementation of the Cross-border Healthcare Directive:** The Commission has to present a report on the operation of the cross-border healthcare Directive by October 2015. The report should focus in particular on patient flows, reimbursement processes and practices, implementation of prior authorisation systems, functioning of National Contact Points, and quality/safety aspects of cross-border healthcare. **3) Study on mapping of patients' rights in all Member States:** This mapping exercise should give a general overview of the laws, structures, procedures and mechanisms in place in the different Member States guaranteeing patients' rights. According to Article 6 of Directive 2011/24/EU on cross-border healthcare, Member States are obliged to provide information on which patients' rights are granted on their territory. In order to clarify which patients' rights are granted in the different Member States, a mapping of existing patients' rights legislation in all EU Member States shall be conducted. This is to increase the predictability for each citizen who wants to seek healthcare in another Member State and ease the utilisation of these arrangements. In addition to exploring the different legal provisions in place in each Member State, an assessment on if and/or how these provisions are implemented in terms of structures, procedures and mechanisms will also be undertaken. **4) Technical opinion on main difficulties for access to care – Technical assistance:** The objective of this action is to support the work on the Directive on cross-border healthcare. It consists in technical opinions on main difficulties for access to care of patients with very specific conditions.

Type of contract and type of procurement

First subaction: Specific contract based on an existing framework service contract – Second subaction: Specific contract based on an existing framework service contract – Third subaction: Direct service contract – Fourth subaction: Direct service contract

Indicative number of contracts envisaged: 4

Indicative timeframe for launching the procurement procedure

First subaction: First semester of 2014 – Second subaction: First semester of 2014 – Third subaction: First semester of 2014 – Fourth subaction: Second semester of 2014

Implementation

Implementation by the Commission for the first, second and fourth subactions – Implementation by the Agency for the third subaction

*3.3.6. Cross-border health services (Point 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:** The objective is to review potential obstacles for healthcare providers in the EU, taking into account jurisprudence of the European Court of Justice and relevant EU legislation. It will examine mobility and establishment for healthcare providers and their cross border – including via internet - health services which are not under the scope of secondary EU legislation and analyse national measures taken in the interests of public health and patient safety. Secondly, the study will investigate national systems to practice medicine, i.e. ‘right to practice’, and revalidation procedures for health professionals. It will identify and research agreements between countries aimed at improving free movement and patient safety.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2014

Implementation

Implementation by the Agency

### *3.3.7. Study on health economics (Point 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

This action comprises studies on health economics as follows: **1) Study on health-related constraints to rising effective retirement ages in the EU:** This study will evaluate to which extent targeted increases in effective retirement ages in EU Member States are constrained by population health status varied by age. In this way, the potential impact of health investments on labour market participation of the population at working age can be assessed. **2) Study on better cross-border coordination for high-cost capital investments in health:** The goal of the study is to assess the possible benefits of enhanced coordination between Member States as regards investment decision for high-cost capital investment technologies. It will evaluate the impact of a coordinated mechanism to assess high-cost capital investments in health, which have cross-border implications. **3) Study on enhanced cross-country coordination in the area of pharmaceutical product pricing:** This study seeks to gain insights into possible benefits from improving cross-country policy coordination between Member States to set the prices of pharmaceutical products. Coordination tools to be assessed will include (enhanced) sharing of price information and consensus building on price/cost standardisation methods. Benefits considered will include budget savings and patient access.

Type of contract and type of procurement

Specific contracts based on an existing framework service contract

Indicative number of contracts envisaged: 3

Indicative timeframe for launching the procurement procedure

First study: First semester of 2014 – Second study: Second semester of 2014 – Third study: Second semester of 2014

Implementation

Implementation by the Agency

*3.3.8. Communication on online pharmacies – translation support (Point 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Communication services:** The objective of this action is to ensure translation support of the online pharmacies communication tools for EU Member States. It is foreseen by Directive 2011/62/EU which provides for the development or the promotion of information campaigns aimed at the general public on the dangers of falsified medicinal products. These campaigns should raise consumer awareness of the risks related to medicinal products supplied illegally at a distance to the public by means of information society services and of the functioning of the common logo, the Member States' websites and the Agency's website.

Type of contract and type of procurement

Specific contract based on an existing service framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2014

Implementation

Implementation by the Commission

*3.3.9. Maximum Residue Limits (MRL) (Point 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** The objective will be to submit an evaluation report of Regulation (EC) No 470/2009 on procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin. Based on the legal requirement set out in Article 28 of Regulation (EC) No 470/2009, the Commission shall submit a report to the European Parliament and to the Council. The report shall, in particular, review the experience gained from the application of this Regulation, including experience with substances classified under this Regulation which have a multiple use. MRLs also provide the basis for controls of food of animal origin imported or placed on the market.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2014

Implementation

Implementation by the Commission

*3.3.10. EMP database (management of marketing authorisations for medicinal products and of maximum residue limits of veterinary medicinal products) and IT systems (Point 3.6 of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**IT services:** (a) the running of a database (the EMP database) for the preparation of Commission decisions in the area of medicinal products for human and veterinary use and of Commission regulations on maximum residue limits of veterinary medicines in food of animal origin; and (b) IT systems for the operation of a public database of all Commission decisions and their scientific annexes (Community register for medicinal products) and the management of the SANCO websites on medicinal products.

Type of contract and type of procurement

Specific contracts based on existing framework service contracts

Indicative number of contracts envisaged: 3

Indicative timeframe for launching the procurement procedure



One framework service contract for the three first quarters of 2014, and another one for the fourth quarter of 2014

Implementation

Implementation by the Commission

### *3.3.11. Studies on off-label use of medicinal products (Point 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Studies:** The aim is to ensure public health protection and the correct application of EU legislation on medicinal products by Member States. The studies will outline the implications for patient safety of off-label/non-authorised use of medicinal products by identifying the extent, the reasons and application of the off-label use within Member States, and the potential way forward if needed. The action will: (a) allow the identification of practices (legal or not in Member States); (b) determine relations with EU legislation; and (c) clarify the way to address the off-label use issue of medicinal products by considering the public health implications. The use of medicinal products under other terms (doses, indications, age groups) than the ones described by the marketing authorisation is not regulated. Such use is commonly called off-label use. Member States are more and more concerned by the off-label use of medicinal products and some of them have started to regulate such use. Others questioned their ability to regulate in view of EU harmonisation. In addition, other concerns, as such as, budget constraints and risk of shortage of medicinal products lead some Member States to recommend the off label use of medicinal products. The essential aim of the EU rules governing the production, distribution and the use of medicinal products is to safeguard public health. In view of all these elements, further knowledge on the issue is necessary in order for the Commission to ensure that it endorses its obligation (safeguard public health and respect of EU legislation).

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2014

Implementation

Implementation by the Commission

3.3.12. *Studies on the implementation of the pharmaceutical legislation (Point 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Studies:** The aim is to ensure public health protection and the correct application of EU legislation on medicinal products by Member States. The studies would map policy developments and assess the implications of certain parts of the pharmaceutical legislation (inter alia Directive 2001/83/EC and Regulation (EC) No 726/2004).

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2014

Implementation

Implementation by the Commission

3.3.13. *ICH reform and Establishment of the International Pharmaceutical Regulators Forum (IPRF) (Point 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** This action has two components. **1) Reform of ICH:** The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) brings together the drug regulatory authorities of EU, Japan and the United States along with experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. It produces standards that are applied in the three Regions (US, Japan and EU) and beyond. The financial contribution would serve to cover the costs for hosting the ICH meeting that is due to take place in the EU in November 2014. **2) Establishment of the International Pharmaceutical Regulators Forum (IPRF):** The financial contribution would serve to cover the costs for hosting the IPRF meeting that is due to take place in the EU in November 2014 in connection with the ICH meeting.

Type of contract and type of procurement

Specific contract based on an existing service framework contract

Indicative number of contracts envisaged: 1-2

Indicative timeframe for launching the procurement procedure

Second semester of 2014

Implementation

Implementation by the Commission

*3.3.14. Scientific and technical assistance for scientific committees, the Expert Panel on effective ways of investing in Health and public health policies (Point 3.7. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** This action will provide scientific and technical assistance for scientific committees, the Expert Panel on effective ways of investing in Health and various aspects of public health policy. It includes organisation of scientific hearings, working group meetings and thematic workshops, as well as direct scientific support for the drafting of documents, such as literature searches, editing, and translation of scientific texts into publications for the general public. These services will be based on the specific scientific and technical expertise of the JRC or provided by external contractors. Support will be provided for scientific aspects of impact assessments, risk communication and if necessary, vis-à-vis scientific committees whilst upholding the respective roles of the entities involved.

Type of contract and type of procurement

Direct service contracts/One specific contract based on an existing framework service contract/Administrative agreement with the JRC.

Indicative number of contracts envisaged: 6

Indicative timeframe for launching the procurement procedure

Second semester of 2014

Implementation

Implementation by the Commission

*3.3.15. Support for the definition of core competences of healthcare assistants (Point 3.8. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Establishment of a network:** Healthcare assistants (HCA) are a group of healthcare professionals whose importance is growing in response to the rise in the care needs of an ageing population. HCAs typically support the work of the registered general care nurse and do not fall under the automatic recognition procedure of the Directive 2005/36/EC. To encourage greater intra EU mobility to meet those care needs, while ensuring a high quality of

care and patient safety, the development of a common training framework according to the modernised professional qualification directive for healthcare assistants should be prepared by setting up a network to build consensus on common knowledge, core competences and skills for healthcare assistants.

Type of contract and type of procurement

Direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2014

Implementation

Implementation by the Agency

### **3.4. Actions under thematic priority 4 - Facilitating access to better and safer healthcare for Union citizens**

#### *3.4.1. Implementation of the Cross-border Healthcare Directive (Point 4.1 of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

This action is composed of four main subactions. **1) Technical assistance: Development of a manual and toolbox for the assessment of European Reference Networks.** Directive 2011/24/EU on patients' rights in cross-border healthcare requires the Commission to support Member States in the development of European Reference Networks (ERNs) between healthcare providers and centres of expertise, by establishing the legal framework for such networks. A tenderer will be contracted to develop a complete and exhaustive assessment and evaluation manual and toolbox that will be used for the assessment of candidate ERNs projects and the healthcare providers wishing to become Members of a Network as well as for their evaluation. **2) IT tools for European Reference Networks:** The purpose of this action is to develop an IT platform which will be provided to future ERNs, to support their functioning and duties required by legal acts establishing criteria for ERNs and their members. This will support the connection and communication within the networks and with other healthcare providers making information available for patients and healthcare providers. It would include inter alia the exchange of knowledge (such as joint development of guidelines, clinical information), collaborative work at distance, patients' follow-up, training and research activities. This will include the design, the development of a pilot project and the validation of concrete networking tools (such as information system on activities of ERNs, intranet, website and telemedicine solutions). **3) Identification and definition of the typology and elements of the healthcare services to be provided by the European Reference Networks:** This action seeks to support the implementation ERN and

in particular the goal “to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare;”. Due to the scope of the Networks, which should focus on providing highly specialised healthcare for patients suffering of rare or low prevalence complex diseases or conditions, there is a need to identify the activities, elements and cost drivers linked to the services to be provided by the Network and its members. This action will help to better understand and identify: a) patient cases (including patient needs relevant to the future activities of ERNs; b) activities (services) relevant to the networking dimension (coordination activities, virtual clinical or tumour boards, telemedicine, teleconsultation, professional advice etc); c) resources relevant to the defined set of activities (human resources, structure, overheads, software, hardware etc.); and d) activity cost drivers relevant to the identified activities and resources (time, square meter, number of interventions, etc.). **4) Selection of the independent assessment/evaluation body(ies) in charge of the assessment of the applications of Network and membership proposals:** After the development of the assessment and evaluation manual mentioned above, a call for the selection of the independent bodies should be launched. The contractor shall be capable to fulfil strong requisites, experience and technical capacity.

Type of contract and type of procurement

First and third subactions: Direct service contract – Second subaction: Specific contract based on an existing framework service contract – Fourth subaction: New framework service contract

Indicative number of contracts envisaged: 4

Indicative timeframe for launching the procurement procedure

First and second subactions: First semester of 2014 – Third and fourth subactions: Second semester of 2014

Implementation

Implementation by the Agency for the first, third and fourth subactions – Implementation by the Commission for the second subaction

### *3.4.2. Study on costs of unsafe care and cost-effectiveness of patient safety programmes (Point 4.3. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:** It is necessary to provide evidence to help political prioritisation in EU Member States by considering patient safety programmes not as a cost only, but as return on investment. Such approach should support the attainment of the goals set out in the Council Recommendation on patient safety, including the prevention and control of healthcare-associated infections (2009/C 151/01). The study has hence three objectives: (a) to provide a comprehensive picture of financial impact of poor patient safety on EU health systems, including costs of additional hospitalisation and absenteeism from work; (b) to provide examples of cost-effective patient

safety programmes implemented in the EU countries with analysis of their success factors; and (c) to assess efficiency of an investment in patient safety programmes. It was requested by the conclusions of the implementation report on patient safety (COM(2012) 658 final) published in November 2012. The same report identified a need for more evidence from the EU on cost-effectiveness of patient safety programmes.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2014

Implementation

Implementation by the Agency

*3.4.3. AMR – Third EU Report on the implementation of the Council Recommendation 77/2002/EC on prudent use of antimicrobial agents (Point 4.4. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Report:** In 2002, the Council adopted a recommendation with the objective to enhance the prudent use of antibiotics in the EU Member States, and the 2011 EC Action Plan on AMR includes for 2015 the publication of the third EU Report on the implementation of the Council Recommendation 77/2002/EC on the prudent use of antimicrobial agents in human medicine on the basis of the reports from Member States. The objective of the report is to reflect on the implementation of the strategies to fight antimicrobial resistance and to identify priority areas for improving measures to be taken by Member States in close cooperation with the Commission

Type of contract and type of procurement

Direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second quarter of 2014

Implementation

Implementation by the Commission

#### 3.4.4. Eurobarometer for blood, tissues and cells (Point 4.5. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

**Communication services:** This action is a survey on the awareness/opinion of EU citizens concerning practices related to donation of human blood, cells and tissues and the safety of transfusion and transplantation services. The survey will provide data on the public perception of the implementation of the principle of voluntary and unpaid donation and also on living/deceased donation for tissues and cells. It could be used as the input from general public for potential amendments of the current directives and for supporting awareness campaigns within EU Member States.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2014

Implementation

Implementation by the Commission

### 3.5. Horizontal activities (related to all previous objectives)

#### 3.5.1. Communication, promotion and dissemination of information on EU health policies and the results of the Health programmes

Subject matter of the contracts envisaged

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 to ensure their sustainability. The communication and promotion work package consists of: (a) **dissemination of information on EU health policy initiatives and related action.** Activities to be funded include amongst others preparing and disseminating audiovisual material and publications in electronic format and on paper, conferences, workshops and expert meetings,

and information stands and other communication and promotional activities, tools and material; (b) **dissemination of the results of the Health programme at EU level**: its aim is 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) and the mid-term evaluation of the Health programme (2008-2013); (c) **organisation of a contest in view of dissemination activities in the field of health**.

Type of contract and type of procurement

Specific contracts based on existing framework service contracts and direct service contracts

Indicative number of contracts envisaged: 25

Indicative timeframe for launching the procurement procedure

First and second semesters 2014

Implementation

Communication: Implementation by the Commission – Dissemination: Implementation by the Agency

### *3.5.2. Information technologies in support of public health policies*

Subject matter of the contracts envisaged

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 EU 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. The objective of the measures covered by this action is to sustain the functioning of existing IT applications supporting public health policies relevant to the 3rd Health Programme and in accordance with the Europe 2020 strategy. An indicative list of applications to be covered by this action is as follows: Diet, Alcohol and mental Health platforms; Health Innovation platform; applications related to tobacco, Rapid Alert Platform for blood, tissues and cells, applications for collecting and analysing Serious Adverse Reactions and Events (SARE) in the fields of transfusion and tissues and cells for human application, database to support the implementation of the Single European Code for tissues and cells, support for projects in the area of organ transplantation (e.g. COORENOR, FOEDUS); IDB (Injury Database), Ras-Chem (rapid alert system for information exchange on incidents including chemical agents), etc., veterinary registries and veterinary antimicrobials, Expert database, support to Scientific Committees and the Expert Panel, to communication activities, contributions for security, knowledge management, licences and maintenance for



central applications and common systems technical support.

Type of contract and type of procurement

Specific contracts based on existing framework service contracts

Indicative number of contracts envisaged: 14

Indicative timeframe for launching the procurement procedure

First and second semesters 2014

Implementation

Implementation by the Commission

#### 4. OTHER ACTIONS

The overall budgetary allocation reserved for other actions in 2014 amounts to EUR 2 184 000. The budget line for other actions is 17.03.01.

Other actions cover contributions paid by the EU as subscriptions to bodies of which it is a member in the meaning of Article 121(2)(d) of the Financial Regulation, administrative agreements with the Joint Research Centre (JRC), 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.

##### 4.1. Actions under thematic priority 1 - Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the 'health in all policies' principle

4.1.1. *Cancer information system – Administrative Agreement with JRC (Point 1.6. of Annex I to the Programme Regulation)*

Amount

EUR 200 000

Description and objective of the implementing measure

A cancer information system is seen as fundamental for facilitating EU cancer policy-making (Communication from the Commission of 24 June 2009 on Action against Cancer: European Partnership (COM (2009) 291 final)). Building on activities already developed and in collaboration with key DGs, DG SANCO and the JRC will establish common data protocols, facilitate agreement on common metadata standards and core indicators to measure and enable European comparisons of the burden of cancer, the quality of care and the impact of cancer strategies, with special emphasis on health inequalities. The resulting system will deliver timely, accurate, reliable and comparable cancer information on a permanent basis at EU

level. This information will guide and monitor the effects and benefits of cancer policy interventions and provide an invaluable resource for cancer epidemiological research allowing a greater understanding of the differences and related causes in population-based studies. As such it will be a key instrument to support and steer evidence based policy making at both EU and national levels.

#### **4.2. Actions under thematic priority 2 – Protecting Union citizens from serious cross-border health threats**

No action is foreseen in 2014.

#### **4.3. Actions under thematic priority 3 – Contributing to innovative, efficient and sustainable health systems**

##### *4.3.1. Organisation and management of the meetings of the Medical Device Coordination Group (MDCG) (Point 3.1. of Annex I to the Programme Regulation)*

Amount

EUR 624 000

Description and objective of the implementing measure

This action deals with the organisation and reimbursement of expenses for the meetings of the Medical Device Coordination Group (MDCG) the tasks of which are laid down in the proposed Regulations on Medical Devices.

##### *4.3.2. Reimbursement of experts' expenses for joint assessments (Point 3.1. of Annex I to the Programme Regulation)*

Amount

EUR 100 000

Description and objective of the implementing measure

This action deals with the reimbursement of expenses for joint assessments of notified bodies in the field of medical devices carried out by national experts of authorities of Member States, EFTA/EEA countries, Switzerland and Turkey (in accordance with respectively EEA, MRA and Customs Union agreements) together with the Commission services under the voluntary pilot joint assessment scheme under the Joint Plan for immediate action following the PIP breast implants scandal or under Article 3 of Commission Implementing Regulation (EU) No 920/2013 on the designation and supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices.

4.3.3. *Expert Panel on effective ways of investing in Health – Indemnities paid to experts (Point 3.4. of Annex I to the Programme Regulation)*

Amount

EUR 300 000

Description and objective of the implementing measure

The objective of this action is to provide the Commission with independent and high quality advice on public health and health systems. The advice is provided by the Expert Panel on effective ways of investing in Health in accordance with Commission Decision 2012/C 198/06. This action contains special indemnities paid to experts for their work on scientific opinions and reports.

4.3.4. *Development of EU requirements for the placing on the market of medicinal products for human use through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (Point 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 210 000

Description and objective of the implementing measure

ICH is an action launched to bring together the drug regulatory authorities of EU, Japan and the United States along with experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. These activities lead to an agreement between the regulators of the 3 Regions (US, Japan and EU) on the standards to be applied for the authorisation of medicinal products, thus reducing costly and time consuming repetition of tests and trials. The concrete outputs are: the adoption of guidelines for the submission of applications for authorisation of placing on the market medicinal products which are applied in the EU as well as in the US, Japan and other non ICH members; the reduction of administrative burden through replacing complex multiple submissions by a single technical dossier for the three Regions; the promotion of innovation by reducing development costs and time; a speedier access to the market for innovative medicines and earlier availability of important, life-saving treatments to patients, and the reduction of animal testing. The purpose of the EU provisions concerning the placing on the market of medicinal products for human use is to guarantee a high level of public health protection and to enable the rules of the internal market to operate effectively. As the ICH guidelines apply both for centrally and nationally authorised products, a proper representation of the EU regulatory network is essential. Since the establishment of ICH, the Commission and EMA are responsible for representing the EU. This allows both the risk managers and the risk assessors to be represented. The same level of representation is ensured by Japan (represented by both

MHLW and PMDA) and by the US (FDA is in charge of both aspects). The Commission funds travel and accommodation costs for the experts from the EU national regulatory agencies and the EMA reimburses its own experts. In view of the regulatory environment (EU legislation), it is justified that the operational funding comes from the EU rather than from the individual Member States. This provides further legitimacy of DG SANCO as representative of the EU (and thus its Member States) in the process.

*4.3.5. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Veterinary Use (VICH) - Expert indemnities (Point 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 40 000

Description and objective of the implementing measure

The purpose of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Veterinary Use (VICH) is to bring together the drug regulatory authorities of EU, Japan and the United States along with experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose of the Union provisions concerning the placing on the market of medicinal products for veterinary use is to guarantee a high level of animal health protection and to enable the rules of the internal market to operate effectively. As the VICH guidelines apply both for centrally and nationally authorised products, a proper representation of the EU regulatory network is essential. Hence the Commission funds travel and accommodation costs for the experts from the EU national regulatory agencies (which still pay their salaries), whereas the EMA reimburses its own experts. In view of the regulatory environment (EU legislation), it is justified that the operational funding comes from the EU (or the EMA) rather than from the individual Member States.

*4.3.6. Active pharmaceutical ingredients: system inspections (Point 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 60 000

Description and objective of the implementing measure

The objective of this action will be to ensure thorough system inspections in third countries exporting active substances for medicinal products for human use into the EU. These inspections allow verifying whether the regulatory framework for the manufacture of active pharmaceutical ingredients, including inspection and enforcement systems, are equivalent to that of the EU. This action is a legal obligation in accordance with Article 111(b) of Directive 2001/83/EC.

*4.3.7. Commission membership fee to the European Observatory on Health Systems and Policies (Point 3.7. of Annex I to the Programme Regulation)*

Amount

EUR 500 000

Description and objective of the implementing measure

This action implements the Commission Decision related to the participation of the Commission in the partnership of the European Observatory on Health Systems and Policies. The objective of the Commission's participation in the European Observatory on Health Systems and Policies is to generate and disseminate quality information and actionable evidence on EU health systems. The Observatory is a repository of technical expertise, independent analysis and respected advice. It is a partnership project established between the WHO Regional Office for Europe, the Governments of Belgium, Finland, Norway, Slovenia, Spain and Sweden, the Veneto Region of Italy, the Commission, the European Investment Bank, the World Bank, the French Union of Healthcare Funds, the London School of Economics and Political Science, and the London School of Hygiene & Tropical Medicine.

The Observatory supports evidence-based health policy-making through analysis of the dynamics of health care systems in Europe.

*4.3.8. Scientific Committees – Indemnities paid to experts (Point 3.7. of Annex I to the Programme Regulation)*

Amount

EUR 150 000

Description and objective of the implementing measure

The objective of this action is to provide the Commission with independent and high quality advice on health risks. This contributes to obtaining a robust scientific basis for EU policies and measures in line with better regulation. This action also contributes to increasing the role of science in the EU policy debate and to informing citizens of risks and to better understanding EU policies. 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. This action will cover special indemnities which are paid to experts for their work on scientific opinions as provided for in Decision 2008/721/EC.

## ANNEX II

### **Criteria for financial contributions to projects under the third Programme for the Union's action in the field of health (2014-2020)**

*Regulation (EU) No 282/2014, Article 7(2) and Article 8(1)*

**The Financial Regulation and its Rules of Application are applicable for the implementation of the Health Programme.**

**Grants given to implement a project are multi-beneficiary grants.**

**Proposals for actions will be evaluated on the basis of four categories of criteria:**

1. Eligibility criteria, to assess the applicant's eligibility (Article 131 of the Financial Regulation),
2. Exclusion criteria (Articles 106(1), 107 and 131 of the Financial Regulation),
3. Selection criteria, to assess the applicant's financial and operational capacity to complete a proposed action (Articles 131 and 132 of the Financial Regulation and Article 202 of the Rules of Application),
4. Award criteria, to assess the quality of the proposal taking into account its cost (Article 132 of the Financial Regulation and Article 203 of the Rules of Application).

These categories of criteria are considered during the evaluation procedure. If a proposal fails to meet the requirements in one category it will be rejected.

#### 1. ELIGIBILITY CRITERIA

1.1. The applicants <sup>(1)</sup> are legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments.

1.2. Applicants participating in a project proposal have to be different legal entities (i.e. independent from each other) from at least 3 countries participating in the Health Programme. Proposals which involve fewer applicants will be rejected.

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<sup>(1)</sup> Whenever 'applicants' is written, this means the coordinator and the co-applicants.

## 2. EXCLUSION CRITERIA

The applicants are not in any of the situations of exclusion listed in Articles 106 and 107 of the Financial Regulation.

## 3. SELECTION CRITERIA

Only proposals which meet the eligibility and exclusion criteria will be assessed on the basis of the selection criteria.

The following selection criteria have to be met:

### 3.1. Financial capacity

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

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

### 3.2. Operational capacity

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

## 4. AWARD CRITERIA

Only proposals which meet the eligibility, exclusion and selection criteria will be further assessed on the basis of the award criteria.

### 4.1. Policy and contextual relevance (10 points, threshold: 8 points)

Sub-criteria that are taken into account in the assessment:

- Relevance of the contribution to meeting the objectives and priorities defined in the annual work plan of the 3<sup>rd</sup> Health Programme, under which the call for proposals is published,
- Added value at EU level in the field of public health,
- Pertinence of the geographical coverage of the proposals,
- Consideration of the social, cultural and political context.



#### 4.2. Technical quality (10 points, threshold: 6 points)

Sub-criteria that are taken into account in the assessment:

- Quality of the evidence base,
- Quality of the content,
- Innovative nature, technical complementarity and avoidance of duplication of other existing actions at EU level,
- Quality of the evaluation strategy,
- Quality of the dissemination strategy and plan.

#### 4.3. Management quality (10 points, threshold: 6 points)

Sub-criteria that are taken into account in the assessment:

- Quality of the planning and appropriate task distribution to implement the project,
- Relevance of the organisational arrangements, including financial management,
- Quality of the partnership.

#### 4.4. Overall and detailed budget (10 points, threshold: 6 points)

Sub-criterion taken into account in the assessment:

- Relevance and appropriateness of the budget,
- Consistency of the estimated cost per applicant and the corresponding activities,
- Realistic estimation of person days / deliverable and per work package,
- The budget allocated for evaluation and dissemination is reasonable.

Following the evaluation, all eligible proposals are ranked according to the total number of points awarded. Only proposals meeting all thresholds are eligible for co-funding. Depending on the specifications in the annual work plan and budget availability, the highest ranked proposal or proposals will be awarded co-financing.

## ANNEX III

### **Criteria for financial contributions to the functioning of a non-governmental body (operating grants) under the third Programme for the Union's action in the field of health (2014-2020)**

*Regulation (EU) No 282/2014, Article 7(2) and Article 8(2)*

**The Financial Regulation and its Rules of Application are applicable for the implementation of the Health Programme.**

Grants provided to the functioning of a non-governmental body are mono-beneficiary grants.

**Proposals for actions will be evaluated on the basis of four categories of criteria:**

1. Eligibility criteria, to assess the applicant's eligibility (Article 131 of the Financial Regulation),
2. Exclusion criteria (Articles 106 (1), 107 and 131 of the Financial Regulation)
3. Selection criteria, to assess the applicant's financial and operational capacity to complete a proposed action (Articles 131 and 132 of the Financial Regulation and Article 202 of the Rules of Application),
4. Award criteria, to assess the quality of the proposal taking into account its cost (Article 132 of the Financial Regulation and Article 203 of the Rules of Application),

These categories of criteria will be considered during the evaluation procedure. A proposal which fails to meet the requirements under one category will be rejected.

#### **1. ELIGIBILITY CRITERIA**

Financial contributions by the EU may be awarded to the functioning of a non-governmental body or to the coordination of a network by a non-profit body. In the latter case only the network coordinator can apply for an operating grant, not the members of the network.

The applicant (non-governmental body or network coordinator) must satisfy the following criterion:

1.1. Be non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests.

The network must comply with the following criterion:

1.2 Be financially independent of industry, commercial and business or other conflicting interests and transparent.

Annex VI provides details on how the criterion ‘independent of industry, commercial and business or other conflicting interest’ is assessed.

The applicant non-governmental body or the network must comply with the following criteria:

1.3. Be working in the public health area, playing an effective role in civil dialogue processes at the Union level,

1.4. Is pursuing at least one of the specific objectives of the third Health Programme

1.5. Is active at the Union level and in at least half of the EU Member States (e.g. has members<sup>12</sup> in at least half of the Member States),

1.6. Has a balanced geographical coverage of the Union,

1.7. Its activity is compatible with the principles of the European Union as stated in Articles 8 to 12 of the Treaty on the Functioning of the European Union. In case of applicants working with the private sector, this also applies to the activities of the latter.

## 2. EXCLUSION CRITERIA

The applicant organisation is not in any of the situations of exclusion listed in Articles 106 and 107 of the Financial Regulation.

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(<sup>12</sup>) Definition of ‘member’ applying to non-governmental bodies: A member is a natural person, a legal person or an entity which does not have a legal personality under the applicable national law, who became a member through a procedure laid down in the body's statutes and who have a ‘member’ status according to the body’s statutes. Only full members or candidates to become full members are considered. Members of the applicant's member organization are not accepted as members of the applicant.

Definition of ‘member’ for a network: A member of a network is a natural person, a legal person or an entity which does not have a legal personality under the applicable national law, who became member through signing the rules of cooperation (e.g. SOP, a memorandum of understanding or a collaboration agreement.) Members of a specialised network's member organisation are not accepted as members of the specialised network.

Evidence: duly signed declaration of honour

### 3. SELECTION CRITERIA

Only proposals that meet the eligibility and exclusion criteria will be assessed on the basis of the selection criteria.

The selection criteria make it possible to assess the applicant organisation's financial and operational capacity to complete the proposed work programme for the 3 years of duration of the framework partnership agreement.

Given the difference between a non-governmental body and a network, hosted by a non-profit body in terms of the legal set-up, the documentary evidence to be provided differs.

#### 3.1. Financial capacity

Applicants must have the financial resources necessary to ensure their functioning for the 3 year duration of the framework partnership agreement.

#### 3.2. Operational capacity

Only organisations with the necessary operational resources, skills and professional experience may be awarded a framework partnership agreement.

### 4. AWARD CRITERIA

#### 4.1. Criteria for the award of **framework partnership agreements (FPA)**

Only proposals that meet the eligibility, exclusion and selection criteria will be eligible for the evaluation of the award criteria.

The award criteria make it possible to select work programmes that can assure compliance with EU objectives and priorities and can guarantee proper dissemination and high visibility of the EU co-funding granted.

##### 4.1.1. Policy and contextual relevance of the operation of the non-governmental body (10 points, threshold: 8 points)

The following sub-criteria are taken into account in the assessment:

- Pertinence of the applicant in the public health area, and effectiveness of its role in civil dialogue processes at Union level,
- Pertinence of the mission, vision and overall purpose of the applicant to achieving the objectives of the 3<sup>rd</sup> Health Programme (applicant pursues at least one of the specific objectives of the Programme,
- Contribution of the multi annual work programme of the applicant to the 3<sup>rd</sup> Health Programme,
- High EU-added value of the applicant's activities,
- Pertinence of the geographical coverage.

4.1.2. Technical quality of the multi-annual work programme proposed (10 points, threshold: 7 points)

The following sub-criteria are taken into account in the assessment:

- Pertinence of the multi-annual work programme,
- Quality of the operational framework,
- Quality of the evaluation strategy,
- Quality of the dissemination strategy and plan.

4.1.3. Management Quality (10 points, threshold: 7 points)

The following sub-criteria are taken into account in the assessment:

- Quality of the planning of the work,
- Adequacy of the organisational capacity,
- Relevance and appropriateness of the budget plan for the total period of the FPA.

The applicants meeting all thresholds will be awarded a framework partnership agreement. The conclusion of a FPA does not guarantee to receive co-funding.

#### 4.2. Criteria for the award of **specific grant agreements (SGA)** under the framework partnership agreements

All FPA-holders will be invited to submit an application for annual co-funding. This application will be assessed based on the criteria below.

4.2.1. Coherence with the 3-year work programme annexed to the FPA (10 points, threshold: 6 points)

The following sub-criteria are taken into account in the assessment:

- Relevance to achieving the multi-annual objectives,
- Purpose of the annual work plan.

4.2.2. Quality of the proposed activities for 2015 (10 points, threshold: 6 points)

The following sub-criteria are taken into account in the assessment:

- Quality of the planning of annual work,
- Quality of the evaluation strategy,
- Quality of the dissemination strategy and plan,
- Quality of the implementation of the activities and the operational management.

4.2.3. Quality of the proposed budget for 2015 (10 points, threshold 6 points)

- Quality and pertinence of the annual budget.

**The applications meeting all thresholds are ranked according to the number of points received. Specific grant agreements will be awarded to those ranking highest, depending on budget availability.**

## ANNEX IV

### **Criteria for financial contributions to actions co-financed with Member State authorities under the third Programme for the Union's action in the field of health (2014-2020)**

*Regulation (EU) No 282/2014, Article 7(2) and Article 8(1)*

**The Financial Regulation and its Rules of Application are applicable for the implementation of the Health Programme.**

The Member State authorities will be invited to submit proposals for co-funding.

**Proposals for actions will be evaluated based on four categories of criteria:**

1. Eligibility criteria, to assess the applicant's eligibility (Article 131 of the Financial Regulation),
2. Exclusion criteria (Articles 106 (1), 107 and 131 of the Financial Regulation),
3. Selection criteria, to assess the applicant's financial and operational capacity to complete a proposed action (Articles 131 and 132 of the Financial Regulation and Article 202 of the Rules of Application),
4. Award criteria, to assess the quality of the proposal taking into account its cost (Article 132 of the Financial Regulation and Article 203 of the Rules of Application).

#### 1. ELIGIBILITY CRITERION

According to Article 7(2)(a) of the Health Programme Regulation, applicants must be the competent authorities that are responsible for health in the Member States or in third countries participating pursuant to Article 6 of that Regulation, or public sector bodies and non-governmental bodies, as referred to in Article 8(1) of that Regulation, acting individually or as a network, mandated by those competent authorities. According to Article 8(1) of the Health Programme Regulation, the grants for actions referred to under Article 7(2)(a) may be awarded to legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments.

According to Article 190(1)(d) of the Financial Regulation grants may be awarded without a call for proposals to bodies identified by a basic act, within the meaning of Article 54 of the Financial Regulation, as beneficiaries of a grant or to bodies designated by the Member States, under their responsibility, where those Member States are identified by a basic act as beneficiaries of a grant.

‘Competent authority’ means the central authority of a Member State competent for health/specific (public) health topic or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country. A competent authority can also be one at regional level, depending on the governance structure of the Member State/third country.

If the participating entity is a competent authority, the competent ministry/government organisation shall by way of an official notification, duly signed by an authorised representative, confirm that the entity is the eligible body to participate on behalf of the respective Member State/regional entity and under its responsibility in the relevant action.

If the chosen entity is a non-governmental body or a public body other than a competent authority, the competent ministry/government organisation shall officially designate the body that will be eligible to participate on behalf of the respective Member State/regional entity and under its responsibility in the relevant action.

The competent ministry/government organisation shall confirm that the designation procedure was executed and concluded in the respect of the national legislation in force in the respective country and that all the transparency requirements for the use of public EU and national funds in the respective country have been fully met. The authorised representative signing the official notification of the designation shall confirm that the Ministry/government organisation is fully responsible for this designation and its legality.

## 2. EXCLUSION CRITERION

The applicants are not in any of the situations of exclusion listed in Articles 106 and 107 of the Financial Regulation.

## 3. SELECTION CRITERIA

Only proposals which meet the eligibility and exclusion criteria will be assessed on the basis of the selection criteria.

The following selection criteria have to be met:



## 2.1. Financial capacity

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

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

## 2.2. Operational capacity

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

## 4. AWARD CRITERIA

Only actions co-financed with Member State authorities which meet the exclusion and eligibility and selection criteria will be assessed on the basis of the following award criteria.

### 4.1. Contribution to public health in Europe

The following sub-criteria are taken into account in the assessment:

- Quality of the contribution of the Joint Action to public health in Europe,
- Consideration of social, cultural and political context.

### 4.2. Technical quality

The following sub-criteria are taken into account in the assessment:

- Quality of the evidence base,
- Quality of the content,
- Innovative nature, technical complementarity and avoidance of duplication of other existing actions at EU level,
- Quality of the evaluation strategy,
- Quality of the dissemination strategy and plan.

### 4.3. Management quality

The following sub-criteria are taken into account in the assessment:

- Quality of the planning and appropriate task distribution to implement the Joint Action,
- Relevance of the organisational capacity, including financial management,
- Quality of the partnership.

#### 4.4. Overall and detailed budget

The following sub-criteria are taken into account in the assessment:

- Relevance of the budget in relation to the activities,
- Consistency of the estimated cost per applicant and the corresponding activities,
- Realistic estimation of person days / deliverable and per work package,
- The budget allocated for evaluation and dissemination is reasonable.

Following the evaluation, only proposals which meet the eligibility, exclusion and selection criteria and all the award criteria may be considered for financing.

## ANNEX V

### **Criteria for financial contributions to grants awarded through a cross sub-delegation to Eurostat under the third Programme for the Union's action in the field of health (2014-2020)**

*Regulation (EU) No 282/2014, Article 7(2) and Article 8(1)*

**The Financial Regulation and its Rules of Application are applicable for the implementation of the Health Programme.**

**Proposals for actions will be evaluated based on four categories of criteria:**

1. Eligibility criteria, to assess the applicant's eligibility (Article 131 of the Financial Regulation),
2. Exclusion criteria (Articles 106 (1), 107 and 131 of the Financial Regulation),
3. Selection criteria, to assess the applicant's financial and operational capacity to complete a proposed action (Articles 131 and 132 of the Financial Regulation and Article 202 of the Rules of Application),
4. Award criteria, to assess the quality of the proposal taking into account its cost (Article 132 of the Financial Regulation and Article 203 of the Rules of Application).

#### **1. ELIGIBILITY CRITERIA**

Grants referred may only be allocated to institutions that are identified as National Statistical Institutes or other national authorities responsible in each Member State for the development, production and dissemination of European statistics.

#### **2. EXCLUSION CRITERIA**

Grants may not be awarded to applicants who are, at the time of a grant award procedure, in one of the situations referred to in Articles 106(1), 107 and 109(2)(a) of the Financial Regulation.

#### **3. SELECTION CRITERIA**

The selection criteria will be defined in order to assess the applicant's financial and operational capacity to complete the proposed action/project. Applicants who have not been excluded during the exclusion phase must meet the following selection criteria. Firstly, applicants must have stable and sufficient sources of funding to maintain their activity throughout the period during which the action is being carried out and to participate in its funding.

Secondly, applicants must also have the necessary operational competencies and qualifications to complete the proposed action and demonstrate their capacity to run the action/project.

The verification of financial capacity, based in particular on an analysis of the supporting documents requested from the applicants, does not apply to public bodies.

#### 4. AWARD CRITERIA

Detailed award criteria will be defined in order to assess the quality of proposals against the objectives and priorities set, so that grants are awarded to the actions which maximise the overall effectiveness.

Applications which have successfully passed the selection stage will be assessed on the basis of the following criteria:

- (a) relevance of applications in relation to the objectives of the invitation and the priorities of the annual work programme adopted by the Commission;
- (b) quality of the proposal, on the basis of criteria such as understanding of tasks, efficiency and effectiveness of approach, technical methodology, level of detail of description of the work, clarity of practical application in terms of how the project's goals and outputs are to be achieved, work schedule, organisation of methods, presentation of expected results and sustainability of the action.

## ANNEX VI

### **Criteria for independence from industry, commercial and business or other conflicting interests applicable to operating grants under the third Programme for the Union's action in the field of health (2014-2020)**

*Regulation (EU) No 282/2014, Article 7(2) and Article 8*

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

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

#### 1. LEGAL INDEPENDENCE

To be eligible for funding, a non-governmental body or a network (and its coordinating body) 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 shall not in themselves be deemed to constitute controlling relationships:

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

## 2. FINANCIAL INDEPENDENCE

A non-governmental body or a network and its coordinating body must be financially independent at the time of applying i.e. not receiving more than 20 % of their core funding from private sector organisations <sup>(13)</sup> representing a conflicting interest, or from other sources representing a conflicting interest.

Core funding shall mean financing required for the basic structure of an organisation, including salaries of full-time staff, facilities, equipment, communications, and the direct expenses of day-to-day work. Core funding also includes financing of all permanent or regularly repeated activities (e.g. annual general assembly or other statutory meetings, website, databases, newsletters). Core funding requirements are usually 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 <sup>(14)</sup>.

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.

## 4. ASSESSMENT OF INDEPENDENCE

Legal independence and transparency is assessed based on the latest available information provided by the applicant together with the application.

**Financial independence will be assessed based on the latest available financial information, in particular the financial independence form. This must be provided by the applicant together with the application based on the specification in the call text.**

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<sup>(13)</sup> The term 'private sector' covers 'for-profit' companies/enterprises/corporations, business organisations or other entities irrespective of their legal nature (registered/not registered), ownership (wholly or partially privately owned/state owned) or size (large/small), if they are not controlled by the public.

<sup>(14)</sup> Collaborators in a position that could lead to a conflict of interest (Article 57 of the Financial Regulation and Article 32 of the Rules of Application) shall be listed.

## ANNEX VII

### **Criteria to assess the exceptional utility of projects, operating grants, actions co-financed with Member State authorities applications under the third Programme for the Union's action in the field of health (2014-2020)**

*Regulation (EU) No 282/2014, Article 7(3)*

#### 1. INTRODUCTION

Actions co-funded under the third Health Programme may receive a co-funding of 80% of the total eligible cost for the action, if they are deemed to be of exceptional utility towards achieving the objectives of the Programme. This concerns projects, operating grants and actions co-financed with Member States authorities. To receive 80% of co-funding, the proposals must comply with the criteria set out below.

#### 2. CRITERIA FOR THE EXCEPTIONAL UTILITY OF PROJECTS

1. At least 60 % of the total budget of the action must be used to fund staff. This criterion intends to promote capacity building for development and implementation of effective health policies.
2. At least 30 % of the budget of the proposed action is allocated to Member States whose gross national income (GNI) per inhabitant is less than 90 % of the Union average. This criterion intends to promote the participation of health actors from Member States with a low GNI.
3. The proposal must demonstrate excellence in furthering public health in Europe and a very high EU added value.

#### 3. CRITERIA FOR THE EXCEPTIONAL UTILITY OF OPERATING GRANTS

1. At least 25 % of the members or candidate members of the non-governmental bodies come from Member States whose gross national income (GNI) per inhabitant is less than 90 % of the Union average. This criterion intends to promote the participation of non-governmental bodies from Member States with a low GNI.
2. The reduction of health inequalities at EU, national or regional level is manifested in the mission as well as the annual work programme of the applicant. This criterion aims to ensure that co-funded non-governmental bodies directly contribute to one of

the main objectives of the third Health Programme, i.e. to reduce health inequalities (Article 2).

#### 4. CRITERIA FOR THE EXCEPTIONAL UTILITY OF ACTIONS CO-FINANCED WITH MEMBER STATE AUTHORITIES

1. At least 30 % of the budget of the proposed action is allocated to Member States whose gross national income (GNI) per inhabitant is less than 90 % of the Union average. This criterion intends to promote the participation from Member States with a low GNI, and

2. Bodies from at least 14 participating countries participate in the action, out of which at least four are countries whose gross national income (GNI) per inhabitant is less than 90 % of the Union average. This criterion promotes wide geographical coverage and the participation of Member State authorities from countries with a low GNI.