

## ANNEX I TO VII

### ANNEX I

#### Health Programme - Work Programme for 2016

##### 1. INTRODUCTION

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

This work programme 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) established under Regulation (EU) No 282/2014 (hereinafter referred to as 'the Programme Regulation') <sup>(1)</sup> for the year 2016.

The Regulation 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.

According to Article 11 of the Regulation on the third Health Programme, the Commission shall adopt, by means of implementing acts, annual work programmes which shall set out, in particular, actions to be undertaken, including the indicative allocation of financial resources. These actions should fall under the four objectives and 23 thematic priorities identified in Annex I of the Programme Regulation.

The EU Health Strategy <sup>(2)</sup> provided a policy framework for all the areas covered by this work programme. 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.

The 2016 work programme is also an important contribution – in the field of health – to the priorities of the Commission as outlined in the political guidelines of the President and the mission letter of the Commissioner responsible for Health and Food Safety.

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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).

To boost economic growth and job creation, stimulate innovation and attract more investments, and contribute to the connected digital single market, the work programme contains activities on health innovation, focusing on Health Technology Assessment, e-health, and European Reference Networks.

To contribute to the reinforcement of the internal market, the work programme proposes actions to help build the European Reference Networks, support healthcare workforce planning and aid implementing legislation on medical devices. It further contributes to ensuring that medicinal products are safe through actions related to the implementation of the legislation concerning pharmaceuticals.

To address the priority on migration and respond to the current high influx of refugees in Europe, the work programme includes procurement and grants for action in that area.

In response to the mission letter <sup>(4)</sup>, the work programme lists several activities enabling Member States to be able to respond quickly and efficiently to crisis situations like pandemics. These include reinforcing capacity building of Member States capacities for crisis management and assessing option to ensure a rapid response capacity to deploy medical counter-measures for international public health emergencies.

Actions proposed seek to complement and create synergies with actions proposed in other policy areas, notably with relevant research projects 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 candidate countries and potential candidates and European neighbourhood policy countries, 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.

All actions under this work programme shall also respect and shall be implemented in compliance with the rights and principles enshrined in the Charter of Fundamental Rights of the European Union <sup>(5)</sup>.

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<sup>(4)</sup> President Juncker's Mission Letter to Commissioner Vytenis Andriukaitis  
[http://ec.europa.eu/commission/sites/cwt/files/commissioner\\_mission\\_letters/andriukaitis\\_en.pdf](http://ec.europa.eu/commission/sites/cwt/files/commissioner_mission_letters/andriukaitis_en.pdf)

<sup>(5)</sup> OJ C 83, 30.03.2010, p. 389-403. Strategy for the effective implementation of the Charter of Fundamental Rights by the European Union, COM(2010) 573 final, 19.10.2010

## 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 2016 as follows:

for grants (implemented under direct management): EUR 36 300 000
for prizes (implemented under direct management): EUR 60 000
for procurement (implemented under direct management): EUR 14 913 112
for other actions: EUR 6 719 000

The total amount available is EUR 57 992 112 for 2016 <sup>(6)</sup>.

## 2. GRANTS

### 2.1. Grants for projects

Under the overall operational budget reserved for grants, EUR 13 050 000 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 programme 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, Agriculture and Food Executive Agency (CHAFEA, hereafter called 'the Agency').

#### **2.1.1. Actions under objective 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. Migrants' health: Best practices in care provision for vulnerable migrants and refugees (Point 1.3 and 1.4 in Annex I to Programme Regulation)*

Priorities of the year, objectives pursued and expected results

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<sup>(6)</sup> This amount corresponds to the amount available on budget line 17.03.01 + 2.73% % EFTA contribution.

In order to support effective responses to communicable diseases as well as cooperation in relation to preventing and improving the response to chronic diseases in vulnerable migrants and refugees this action aims to support activities in view of the development of community-based care models to improve health care access of vulnerable migrants and refugees. Through facilitating the transition from institutional to community-based care and integrated services, it aims to identify innovative ways of reducing inequalities in access to health services, and promote social inclusion through supporting access to social, community/home-care, cultural or recreational services – while avoiding to create any parallel structures. Community-based health clinics (hubs) offer an opportunity to create health-promoting places. These care models can also support reorientation of specialists to general practitioners, to strengthen healthcare in primary care settings. This action will deal with compiled best practices in care provision for vulnerable migrants and refugees (including pregnant women, children and older persons), with a focus on psycho-social aspects, acute and chronic diseases, including communicable diseases. Recommendations, innovative tools and methodologies developed by FP7 and Horizon 2020 projects for better care of people suffering from mental disorders should be taken into account whenever relevant (e. g. from PARADISE , RIGHTTIMEPLACE CARE , PRONIA , PSYSCAN ) as well as recommendations from the conference "Understanding and Tackling the Migration Challenge: The Role of Research (<sup>7</sup>)". Synergies should be sought with projects supported under the Asylum, Migration and Integration Fund (AMIF) and the Internal Security Fund (ISF), including the AMIF/ISF Emergency Assistance and AMIF/ISF national programmes, as well as activities of the European Asylum Support Office.

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

The activities to be carried out may cover:

- (i) review existing evidence and carry out a survey to collect information on the physical and mental health status of vulnerable migrants, including communicable and chronic diseases, and the related health and social service needs, with a view to provide evidence base for integrated, holistic and community based care approaches. Specific needs of vulnerable sub-groups should also be explored;
- (ii) review existing approaches and identify best practices and tools of community-based health care models across the EU and beyond, serving vulnerable migrants. Special attention should be paid to the effectiveness of these models in terms of health (physical and psychological) promotion, communicable and chronic diseases prevention and care. Approaches relevant for the most vulnerable sub-groups (e.g., children, pregnant women and older persons) should also be explored, including integrated services for families;
- (iii) map the legal, organizational and institutional environment across the EU, access existing capacity and feasibility of introducing integrated, community-based approaches;
- (iv) pilot test and evaluate comparative models for the provision of health care for vulnerable migrants across a selection of EU Member States, including the economic analysis of comparative practices; and

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<sup>7</sup> International Conference, 4-5 Feb 2016, Brussels, <https://ec.europa.eu/research/conferences/2016/migration-challenge/index.cfm>

(v) create a competence network on mental health –specially post-traumatic stress- of migrants and refugees, involving experts from Member States, in close collaboration with health ministries, non-governmental and health professionals’ organisations, and vulnerable migrants, with the aim of developing materials and recommendations on mental health care and medical documentation in intercultural refugee populations; organize training of health and social professionals to detect mental disorders and provide first psychological aid in refugees; and to identify efficient pathways for longer-term care programmes that could include social activities and peer support in refugee populations to prevent the onset of mental disorders; identifying ways to advise refugees on access to mental health care. eHealth services such as telemedicine and mobile health could also be considered.

## Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2016	EUR 4 500 000

*2.1.1.2 Gathering knowledge and exchanging best practices on measures reducing underage drinking and heavy episodic drinking (Thematic priority 1.1. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

Heavy episodic drinking and youth drinking, including underage drinking, are of particular concern in Europe. All age groups and both genders are affected by heavy episodic drinking. Building on previous work conducted in this area, this action should support Member States’ efforts to reduce alcohol related harm and particularly contribute to the objectives of the Member States’ action plan on Youth Drinking and on Heavy Episodic Drinking <sup>(8)</sup>. It should generate and promote new and innovative good practices targeting the reduction of heavy episodic drinking, including amongst young adults, and underage drinking. Innovative tools and methodologies e.g. developed by FP7 and Horizon 2020 projects (e.g. from BRAINTRAIN <sup>(9)</sup>, AAA-PREVENT <sup>(10)</sup>) for effective prevention and therapy of alcohol abuse should be taken into account where relevant.

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

<sup>(8)</sup> Action Plan on Youth Drinking and on Heavy Episodic Drinking (Binge Drinking) (2014-2016), Endorsed by the Committee on National Alcohol Policy and Action (CNAPA) on 16 September 2014, [http://ec.europa.eu/health/alcohol/docs/2014\\_2016\\_actionplan\\_youthdrinking\\_en.pdf](http://ec.europa.eu/health/alcohol/docs/2014_2016_actionplan_youthdrinking_en.pdf)

<sup>(9)</sup> <http://braintrainproject.eu/>

<sup>(10)</sup> <http://www.aaaprevent.eu/>

The activities should aim at testing methods/tools and at identifying good practices on reducing heavy episodic drinking including amongst young adults and underage drinking in different settings and different Member States. Priority should be given to initiatives aiming at identifying good practices of measures at population level and more targeted prevention measures like brief interventions. In addition, multi-stakeholder initiatives might be included. The activities should encourage EU networking and good practise exchange.

#### Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2016	EUR 1 200 000

#### 2.1.1.3. *Gathering knowledge and exchanging best practises to on measures to prevent illicit drug use in line with the minimum quality standards in drug demand reduction (Thematic priority 1.2. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

Illicit drug use is a major problem for individuals, families and communities. There is an increasing trend of polydrug use, including licit substances like alcohol and illicit substances. In addition, there is an increase in new psychoactive substances. Young adults are especially at risk. The aim of this action is to prevent and delay the age of onset of illicit drug use. It should generate and promote new and innovative good practices of prevention measures (in particular measures aimed at preventing polydrug use and use of new psychoactive substances), thus supporting the EU Action Plan on Drugs and the implementation of the minimum quality standard in drug demand reduction.

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

The activities should aim at testing methods/tools and at identifying good practices on preventing illicit drug use and delay onset of use. A particular focus should be given to prevention measures aimed at young adults to prevent polydrug use including alcohol and the use of new psychoactive substances. The measures considered should address risk factors such as age, gender and cultural and social factors, drug use in night life settings and work place and driving under influence. In addition, prevention measures in settings such as prisons might be included. The focus of activities should be aimed at selective preventions targeting vulnerable groups (in particular lower socio economic groups) The internet and its role in distribution and as knowledge base should be taken into account.

#### Implementation

## Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2016	EUR 600 000

### *2.1.1.4. Support to Member States and stakeholders to address the chronic disease challenge (Thematic priority 1.4. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The objective of this action is to identify and address key elements with a potential to reduce the burden of major chronic diseases and increase the sustainability of health systems. It should provide new evidence on economic and efficient means to achieve better health outcomes, including on the cost-efficiency of investments in prevention, and to alleviate the burden on health and social systems if implemented at an appropriate scale in Member States. Proposed initiatives should generate impact when implemented, be transferable to other settings and elaborate incentives for implementation. They should have the potential to become relevant elements of national chronic disease strategies and add up to an integrated response to chronic diseases. Initiatives should help to reduce avoidable costs and burden for patients and health care systems. This action will complement the action on chronic diseases referred to under 2.2.1.2.

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

Activities should concentrate on following areas:

**1) Identify, develop and put into practice evidence based measures to prevent and manage chronic diseases, also by addressing the major common risks factors (smoking, alcohol abuse, unhealthy diet, physical inactivity and others) with a focus on:** (i) early detection of major diseases and adequate timely intervention with a focus on inter-sectoral and cross cutting interventions; (ii) identification of needs and opportunities for disease prevention and targeted intervention for most vulnerable groups; (iii) effective means to facilitate access and retain chronic disease patients in the labour market and their home environment; (iv) enhancement of community care for better chronic disease prevention and management; (v) elements for more effective management of multi-morbidity; (vi) identification or development and implementation of integrated patient and care pathways; and (vii) Health Technology Assessment (HTA) for best interventions;

**2) Strengthen the evidence base for a response to prevent and manage chronic diseases through improved health information and health intelligence by:** (i) expanding data for monitoring and assessment of policies and health related actions; and (ii) improving the health literacy through better access and availability of health related information for most vulnerable

groups.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2016	EUR 2 500 000

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

No action is foreseen in 2016.

### **2.1.3. Actions under objective 3 – Contributing to innovative, efficient and sustainable health systems**

No action is foreseen in 2016.

### **2.1.4. Actions under objective 4 – Facilitating access to better and safer healthcare for Union citizens**

#### *2.1.4.1. European Reference Networks (Thematic priority 4.1. of Annex I to the Programme Regulation)*

Support will be provided through the conclusion of framework partnership agreements (FPA) for a duration of maximum five years – covering the operating years 2017, 2018, 2019, 2020 and 2021 – and, subsequently, of specific grant agreements for the financial year 2017. The FPA will include a multi-annual work programme for the period 2017-2021 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.

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 V contains the eligibility, exclusion, selection and award criteria for these actions.

Priorities of the year, objectives pursued and expected results

The Directive on the application of patients' rights in cross-border healthcare <sup>(11)</sup> requires the Commission to support Member States in the development of European Reference Networks (ERN). ERN are groups of highly specialised providers across the EU, institutionally approved – following a transparent and formal selection procedure – to perform in an exclusive way the goals and task established in the Commission Delegated Decision 2014/286/EU <sup>(12)</sup> and the Commission Implementing Decision 2014/287/EU <sup>(13)</sup>. ERNs are addressing a group of highly specialised and complex diseases and treatments.

By pooling knowledge and expertise across the EU, ERNs will facilitate access to diagnosis, treatment and provision of affordable, high quality and cost-effective healthcare contributing to the economy of scale and the sustainability and efficiency of the healthcare systems in the EU.

Setting up an ERN implies a complex work in which the clinician and scientific community have to reach an agreement in a common approach and this bottom up solid proposal is the origin of all Networks. Only national authorities of Member States have the capacity to endorse their providers to participate in an ERN. That implies a legal recognition to the capacity to address the group of diseases an ERN will deal with.

An ERN has to fulfil a list of basic requirements which are listed in the Commission Delegated and Implementing Decisions. Expected benefits to patients and healthcare systems are improvements in services delivery, working systems, patient pathways, clinical tools, earlier adoption of scientific evidence, etc.

The objective of this call is to provide financial support to ERNs, once established. Therefore, only approved ERNs are eligible for co-funding.

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

The actions to be funded are coordination, management and non-clinical activities of an approved ERN. Co-funding will be provided in the form of mono-beneficiary grants to the ERN Coordinator to run the ERN and implement all actions in order to fulfil the goals as provided for in the legal basis on ERNs: (i) each ERN shall provide highly specialised healthcare for rare or low prevalence complex diseases or conditions; (ii) have a clear governance and coordination structure; (iii) have knowledge and expertise to diagnose, follow up and manage patients with evidence of good outcomes; (iv) follow a multi-disciplinary approach; (v) offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control; (vi) make a contribution to research; (vii) organise teaching and training activities; and (viii) collaborate closely with other centres of expertise and networks at national and international level.

#### Implementation

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<sup>(11)</sup> OJ, L 88/45, 4.4.2011

<sup>(12)</sup> OJ, L 147/71, 17.5.2014

<sup>(13)</sup> OJ, L 147/79, 17.5.2014

## Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2016	EUR 2 500 000

### 2.1.4.2. Rare diseases - Support for new registries (Thematic priority 4.2. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

Patient registries and databases constitute key instruments to develop clinical research in the field of rare diseases, to improve patient care and healthcare planning. They are the best way of pooling data to achieve a sufficient sample size for epidemiological and/or clinical research. Indeed, registries serve as a recruitment tool for the launch of studies focusing on disease etiology, pathogenesis, diagnosis or therapy.

In the Council Recommendation of 8 June 2009 on an action in the field of rare diseases <sup>(14)</sup>. Member States committed themselves to consider supporting at all appropriate levels, including the EU level, for epidemiological purposes, registries and databases, whilst being aware of independent governance.

In order to support this process and in particular the interoperability of data in rare diseases registries the Commission decided to set up a European Platform on rare diseases registration.

As laid down in Article 12 of the Directive on the application of patients' rights in cross-border healthcare <sup>(15)</sup>, registries will be a one of the objectives of the European Reference Networks to be set up. Therefore, only approved ERNs are eligible to be co-funded.

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

The activities to be carried out concern the creation of 3-4 new registries on rare diseases. These registries should constitute key instruments to increase knowledge on rare diseases and develop clinical research. Collaborative efforts to establish data collection and maintain them will be considered, provided that these resources are open and accessible. Registries should be built with the support and according to the standards set up by the European Platform on rare diseases registration and provide all necessary data to the Platform (taking the relevant data protection rules into account).

Implementation

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<sup>(14)</sup> OJ L 151, 3.7.2009, p. 7.

<sup>(15)</sup> OJ L 88, 4.4.2011, p. 45.

## Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2016	EUR 1 200 000

### 2.1.4.3. Donor selection and protection (Point 4.5 in Annex I to Programme Regulation)

Priorities of the year, objectives pursued and expected results

The priority for this action is to increase the safety of donation and clinical application of tissues and cells and/or blood by optimising the procedures for donor selection and protection. While EU legislation defines the donor selection criteria in general terms, standardised procedures for gathering the necessary donor information are not developed at EU level. This is a high priority for these sectors because the success of transplantation, assisted reproduction and transfusion programmes relies heavily on achieving robust procedures for both the selection and protection of donors.

The objectives are: (i) to explore existing practices for the selection and protection of donors, including the gathering of donor medical and behavioural history, with particular emphasis on the design of effective questions for donors or their families, and (ii) to reach agreement on best practice for donor selection and protection procedures and questionnaires and develop tools to support its implementation.

This action should result in the development of common EU guidance on the selection and protection of donors and model questionnaires for use when interviewing prospective donors and/or donor families. The questions should be tested and validated to demonstrate that they are effective in terms of eliciting the information required for the application of exclusion criteria as defined in the EU legislation.

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

This action will bring together individuals and organisations from the tissues and cells and/or blood sectors with donor-facing expertise in those fields (e.g. physicians, key donation personnel from hospital to authority level) to address the following activities: (i) collect and compare EU and national donor selection and protection criteria based on a thorough evaluation of risks for donors and recipients; (ii) identify the information needed from donors or their families to allow the application of appropriate donor deferral or exclusion criteria for the protection of recipients; and (iii) propose approaches to control and minimize these risks, particularly by developing, testing and validating procedures that should gather complex and often sensitive information through an easily understood series of questions taking into account socio-economic, cultural and emotional factors. These approaches should include guidelines for screening donors, a proposal for a standardised donor and donor family

questionnaire and proposals for short and long-term care and follow-up of living donors.

This action should build on previous EU-funded projects across the area of substances of human origin, in particular in organ donation/transplantation (e.g. DOMAINE, ELIPSY, ELPAT, and ACCORD). Involvement of relevant professional associations and competent authorities is strongly encouraged.

## Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2016	EUR 550 000

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

Under the overall operational budget reserved for grants, EUR 13 800 000 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 objective 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. *Quality of HIV/AIDS/STI, viral Hepatitis and tuberculosis prevention and linkage to care (Point 1.3. in Annex I to 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) <sup>(16)</sup> and the ‘Action Plan on HIV/AIDS in the EU and neighbouring countries: prolongation 2014-2016’ <sup>(17)</sup>. The Communication and Action Plan provide the framework for prevention and integrated treatment of HIV/AIDS and co-infection (viral hepatitis, tuberculosis and sexually transmitted infections), with the main objective to target priority groups (e.g. men-who-have-sex-with men and drug users) and deliver an evidence based reduction of new cases of HIV infection and of the co-infections for these groups. This action is in line with the overall policy objectives of the Commission to ensure better preparedness. It contributes to safeguarding the quality and productivity of the EU workforce.

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 <sup>(18)</sup>

This action will build upon the results obtained by the Improving Quality in HIV Prevention – ‘Quality Action’ initiative (co-financed as a joint action under the health programme<sup>19</sup>). In particular, it will take into account the ‘Charter for Quality in HIV Prevention’ with the main objectives: 1) to ensure that the cross-border aspect of HIV/AIDS and co-infections is considered when planning national strategies; 2) to develop behavioural approach to testing and prevention activities and possible links with the Horizon 2020 longer-term research objectives; 3) to use the available materials developed by EU-level technical expertise from several agencies for direct country support and capacity building (e.g. ECDC and EMCDDA) specifically targeted to vulnerable groups for all the diseases mentioned before; and 4) to provide a platform – linked with the EU HIV/AIDS Think Tank and the Civil Society Forum – for exchange of best practice and discussions on innovations, on innovative issues such as self-testing, pre-exposure prophylaxis for HIV and other additional challenging emerging issues. The action will gear up the operational phase of the ‘Charter’ on the basis of agreed quality principles and criteria and will extend the coverage to sexually transmitted diseases, hepatitis and tuberculosis prevention, testing and care.

Deliverables are expected to include innovative tools and information packages based on new achievements in the areas of prevention, testing and linkage to treatment. It is expected to promote high quality prevention and to strengthen the essential links between prevention strategies, testing and treatments and will address the needs of the most affected and vulnerable groups as cited above. This work will include specific activities to involve stakeholders.

## Implementation

Implementation by the Agency

Indicative timetable and indicative amount

<sup>(16)</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:sp0016>

<sup>(17)</sup> [http://ec.europa.eu/health/sti\\_prevention/docs/ec\\_hiv\\_actionplan\\_2014\\_en.pdf](http://ec.europa.eu/health/sti_prevention/docs/ec_hiv_actionplan_2014_en.pdf)

<sup>(18)</sup> OJ L 362, 31.12.2012, p. 1.

<sup>(19)</sup> <http://ec.europa.eu/chafea/projects/database.html?prjno=20122102>

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	Second semester of 2016	EUR 2 000 000

### 2.2.1.2. Action on chronic diseases (Point 1.4. in Annex I to Programme Regulation)

Priorities of the year, objectives pursued and expected results

This action co-financed with Member State authorities will select and finance activities that help to identify efficient means to reduce the burden of chronic diseases, increase the sustainability of health systems and develop human capital. The focus will be on tangible activities with a potential to trigger health and chronic disease policies in Member States with a potential to improve health outcomes. This action will support Member States in developing and refining national plans and strategies to address chronic diseases and will facilitate and intensify the exchange of good practices and knowledge with regard to the prevention and management of chronic diseases. This action will complement the action on chronic diseases referred to under 2.1.1.4.

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 <sup>(20)</sup>

Along the priorities identified for taking action on chronic diseases this joint action will contribute to the identification and development of pilot actions in response to the chronic diseases challenge with a focus on the following areas: (i) integrated approaches in screening and early detection of preventable diseases; (ii) integrated approaches to address the main common risks factors (smoking, alcohol abuse, unhealthy diet, physical inactivity and others) as to strengthen prevention across health and social care services; (iii) approaches to overcome health system silos towards a better integration of prevention and health care; (iv) approaches to address multi-morbidity and polypharmacy effectively through evidence-based interventions; (v) identification of essential elements for national chronic disease strategies, including communication elements <sup>(21)</sup>; (vi) means to reduce avoidable costs and increase efficiency of health care system management; and (vii) the timely integration of research findings for prevention and management of chronic diseases. This work will involve stakeholders.

#### Implementation

Implementation by the Agency

<sup>(20)</sup> OJ L 362, 31.12.2012, p. 1.

<sup>(21)</sup> Taking into account the findings of the "scoping study on communication to address and prevent chronic diseases", carried out by ICF International for DG SANTE, final report published under: [http://ec.europa.eu/health/major\\_chronic\\_diseases/docs/2015\\_chronic\\_scopingstudy\\_en.pdf](http://ec.europa.eu/health/major_chronic_diseases/docs/2015_chronic_scopingstudy_en.pdf)

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	Second semester of 2016	EUR 5 000 000

2.2.1.3. Tobacco control (Point 1.5. in Annex I to Programme Regulation)

Priorities of the year, objectives pursued and expected results

This action will ensure effective implementation and application of the existing tobacco legislation and deliver concrete results in practice. Reporting, assessing and regulating tobacco ingredients are important aspects of an effective and comprehensive tobacco control policy which contributes to the broad objective of promoting good health, reducing tobacco related disease and deliver real benefits to citizens.

This action co-financed with Member States authorities mandated in this field will strengthen cooperation between interested Member States and the Commission in the area of tobacco control. In particular, it will focus on the reporting of ingredients and the notification of e-cigarettes, including laboratory capacity, analysis and assessment.

On tobacco products, the revised Tobacco Products Directive (TPD) 2014/40/EU provides for submission of extensive data by industry both under Articles 5 and 6 (tobacco) and 20 (e-cigarettes) of the Directive. The new reporting obligations represent a challenge both in terms of quantity and the type of the data as some of the collected data are completely new, and neither collected previously in the EU nor in other jurisdictions. The action should process data on ingredients submitted by the industry as well as the results of comprehensive studies on priority additives which will have to be conducted and submitted by the tobacco industry. The system to be put in place should facilitate the peer-review and assessment of comprehensive studies conducted by the industry on priority additives as well as the assessment of the data submitted on ingredients.

These assessments are also relevant for the regulatory tasks foreseen under Article 7 of the TPD. Furthermore, they should support the monitoring of the quality of the information submitted with a view to adapting the data submission system if necessary.

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 <sup>(22)</sup>

Regulatory capacities vary considerably between Member States. Effective mobilisation of the limited resources available at both national and EU level can generate significant synergies, in particular for peer review and assessment of comprehensive studies on priority additives.

The activities should also include an assessment of data on ingredients in tobacco products submitted for the first time under the new reporting format in 2016 and building up of

<sup>(22)</sup> OJ L 362, 31.12.2012, p. 1.

appropriate laboratory capacity to verify the submitted data and support the enforcement. The data assessment can subsequently lead to further improvement of the submission platform to further enhance comparability of the submitted data.

Data submitted shall also serve the purpose of supporting regulatory decisions on tobacco ingredients in line with Article 7 of the TPD.

At the same time regulators will receive notifications of all e-cigarettes currently available in the EU, and will begin to receive prior notification of e-cigarettes still to be launched.

This action should also provide for efficient work-sharing in this area, including on assessment and verification of the notified data, which will contribute to enforcement and lead to further improvement of the submission platform and enhancement of comparability of the submitted data on e-cigarettes. The issue of comparability of submitted data in areas where testing methods have not yet been standardised/agreed, such as the measurement of e-cigarette emissions, should also be addressed.

This work will include specific activities with regard to dissemination and networking.

### Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	Second semester of 2016	EUR 2 000 000

#### **2.2.2. Actions under objective 2 – Protecting Union citizens from serious cross-border health threats**

No action is foreseen in 2016.

#### **2.2.3. Actions under objective 3 – Contributing to innovative, efficient and sustainable health systems**

No action is foreseen in 2016.

#### **2.2.4. Actions under objective 4 – Facilitating access to better and safer healthcare for Union citizens**

##### *2.2.4.1. Antimicrobial resistance and Health Care Associated Infections (Thematic priority 4.3. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The objective of this action co-financed with Member State authorities is to increase the level and effectiveness of activities at EU, national and local levels to improve EU health security by addressing the increasing threats to health from antimicrobial resistance (AMR) and the linked but separate issue of healthcare-associated infections (HCAI). The action aims to strengthen health systems and improve health security by strengthening coordinated action between EU Member States to address the global threat on AMR. It will aim to contribute towards reducing inappropriate consumption of antibiotics, raising awareness amongst health professionals and the public and developing and promoting the uptake of mechanisms and tools to promote and maintain behaviour change towards more appropriate use of antimicrobials. It will be an important mechanism to take forward EU and Member State action on AMR in the period following the end of the current EU AMR action plan 2011-2016.

This action will specifically aim to: (i) support the development of national strategies and action plans on antimicrobial resistance; (ii) support strategy development at national, local, and health care setting level (hospital, long term care, community) in the field of health-care associated infections, including optimising the implementation at national level of work done by the ECDC; (iii) develop and enhance the implementation of evidence-based tools, including those prepared by the ECDC and through training, organisational change and/or other methods to enable sustainable improvements in practice by health care staff and teams in hospitals, as well as in long term care and community settings; (iv) strengthen the ‘one health’ approach and coordination with relevant sectors – including for AMR with animal health, food safety, agriculture, environmental and research and the Joint Programming Initiative (JPI) on AMR ; (v) contribute to the implementation of relevant research findings and identify priorities for research; and (vi) promote awareness and commitment by governments and stakeholders.

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 be taken forward in close collaboration with ECDC and other Commission services involved in the ‘one health’ approach to responds to the threats of AMR and HCAI. It will include the following actions: (i) exchange of information and good practice in relation to strategy development and implementation of actions to address AMR and HCAI, including the involvement of national focal points; (ii) activities to promote the ‘one health’ approach and foster inter-sectoral action; (iii) state of the art reviews and development of tools, guidelines and training for supporting and maintaining good practice in clinical care in relation to AMR and HCAI in the hospital, long term care and community settings; (iv) consultation and development of activities to support the implementation of EU policy on AMR and HCAI; (v) activities linking research results to policy, and contributing to the research agenda from a policy perspective; (vi) activities to promote awareness and involvement of stakeholders in dissemination and networking, including a final conference; and (vii) other relevant activities on AMR and HCAI.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	Second semester of 2016	EUR 4 000 000

*2.2.4.2. Authorisation of preparation processes in blood and tissues and cells (Point 4.5 in Annex I to Programme Regulation)*

Priorities of the year, objectives pursued and expected results

Blood and tissue establishments are subject to continuous medical progress and innovation. Each of these innovations brings changes in the operational set-up of the processes in the establishments, calling for assessment and authorisation by the competent authorities. In addition, such changes might lead to changes in the clinical outcomes for patients who benefit from transfusion or transplantation.

Such authorisations therefore require access to specific technical knowledge and clinical expertise. These are not always immediately available in each of the national and regional competent authorities in the EU 28 Member States. This action aims to bring together this combination of skills from different EU Member States to facilitate the development of a common and optimal approach to assess and authorise innovative preparation processes in blood and tissue establishments.

The results should include a manual and training for competent authorities on the assessment and authorisation of new or modified preparation processes.

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 co-financed with Member State authorities should help national authorities with their assessments and authorisations by: (i) identifying groups of innovative processes and their risks and benefits, as well as the need for assessment before authorisation, mainly in terms of safety, quality and clinical outcome; (ii) mapping and assess existing national procedures and resources (e.g. centres/sources of different expertise consulted by competent authorities) to assess and authorise (innovative) processes in tissue and blood establishments; (iii) developing common guidance for the assessment and authorisation of preparation processes in the blood and tissue and cell sectors, with a particular focus on cross-border exchange of data and expertise, including potential joint assessments; and (iv) preparing a manual and organising training courses, to disseminate the agreed optimal approach.

This action should take into consideration other EU-funded actions in the area of substances of

human origin.

#### Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	Second semester of 2016	EUR 800 000

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

Under the overall operational budget reserved for grants, EUR 4 800 000 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 VI contains the criteria for independence from industry, commercial and business or other conflicting interests. Annex III contains the eligibility, exclusion, selection and award criteria for these actions.

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>(23)</sup>.

In 2016, no call for proposals will be organised as a result of the conclusion of framework partnership agreements (FPA) for a duration of three years based on the work programme for 2014 – covering the operating years 2015, 2016, 2017. FPA recipients are eligible for a specific grant agreement. In 2016 they will be invited to submit an application for a specific grant agreement for 2017. This will include the annual work programme and the budget. Having received an FPA does not guarantee annual co-funding.

#### Implementation

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<sup>(23)</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF>

Implementation by the Agency

Indicative timetable and indicative amount

<b>Reference</b>	<b>Date</b>	<b>Amount</b>
Invitation to FPA holders, SGA awarded on a competitive basis	Second semester of 2016	EUR 4 800 000

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

According to Article 190(1)(c) of Delegated Regulation (EU) No 1268/2012 <sup>(24)</sup>, 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.

The Presidencies of the European Union may receive up to EUR 100 000 to organize high-level conferences during their term. The maximum rate of EU co-financing is 50 % of eligible costs incurred per conference.

The Presidency conferences to be financed under this work programme are a conference on ‘Prevention of chronic non-communicable diseases and healthy lifestyles’ and a conference on ‘Alzheimer’s disease - the epidemic of the third millennium. Are we ready to face it’ planned under the Slovakian Presidency and a conference on ‘Structured Cooperation between Health Care Systems’ under the Maltese Presidency.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

<b>Reference</b>	<b>Date</b>	<b>Amount</b>
Direct award	Second semester of 2016 and First semester of 2017	EUR 200 000

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<sup>(24)</sup> OJ L 362, 31.12.2012, p. 1.

## **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 4 450 000. 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 exclusively 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 or under the procedure described in section 2.2. The maximum rate for EU co-financing is 60 % of the eligible costs actually incurred. The eligible direct costs shall be reimbursed either as actual costs incurred by the international organization or on the basis of unit costs and flat rates, as long as the Commission Decision approving the Framework agreement between the European Commission and the international organization concerned authorizes and determines the use of reimbursement on the basis of unit costs and flat rates.

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.

— Organisation for Economic Cooperation and Development (OECD)

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

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 objective 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. EU contribution to the WHO Observatory on dementia – Grant to WHO (Thematic priority 1.4. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

This action will contribute to the follow up of the WHO Ministerial Conference on Dementia and support WHO in the creation of the observatory on dementia. It would enable the observatory to support EU Member States to base their health service planning on good practice, scientific evidence and public health needs, and would contribute to regular reporting on the development of dementia, and related actions and policies in EU countries. . Due consideration should be given to the knowledge base generated by research projects supported under the Seventh Framework Programme (FP7, 2007-2013) and Horizon 2020 (2014-2020) in the field of healthcare services for dementia. The scope of the Action should take into account to the mapping<sup>25</sup> of neurodegeneration research activities carried out by the Joint Programming Initiative on Neurodegenerative Disease Research (JPND) in JPND Member countries.

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 activities that will be carried out consist in: (i) monitoring information on disease prevalence, promotion and prevention efforts, dementia care system, governance and service availability and accessibility and policy strategies on dementia in EU Member States; (ii) following scientific developments and identifying good practice; and (iii) developing regular reports on the dementia situation in EU Member States.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

<sup>25</sup> <http://www.neurodegenerationresearch.eu/initiatives/mapping-exercise/>

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First semester of 2016	EUR 500 000

*2.5.1.2. Grant to the WHO/FCTC (Thematic priority 1.5. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The Framework Convention on Tobacco Control (FCTC) Illicit Trade Protocol <sup>(26)</sup> has been ratified by 8 parties (Austria, Congo, Gabon, Mongolia, Nicaragua, Spain, Turkmenistan and Uruguay). The EU signed the Protocol on 20 December 2013, which is the first step towards becoming a party to the agreement (through ratification). On 4 May 2015, the Commission proposed that the Council concludes the Protocol on behalf of the European Union. In total 40 ratifications are needed for the Protocol to enter into force. If the EU and its Member States are joined by a sufficient number of third countries ratifying the Protocol, it may realistically enter into force in 2016. It is important for the EU that the Protocol enters into force as soon as possible, in particular as there are important synergies between the EU law (Tobacco Product Directive <sup>(27)</sup>, TPD) and the Protocol.

The grant is intended to focus on aspects of illicit trade of relevance for the EU, in particular in terms of Articles 15 and 16 of the TPD and secondary legislation to be adopted under these Articles in 2017. The rapid development of a track and trace system under the TPD might allow the EU based companies to export our track and trace model to other parties that ratified the Protocol. Also the Illicit Trade Protocol is expected to protect the EU against import of illicit products.

Successful deployment of the track and trace system (Art. 15 TPD) and of a new security feature (Art. 16 TPD) will lead to a decrease in the availability of cheap illegal cigarettes. It will have a direct impact on the prevalence of smoking, which represents the most serious avoidable health threat. Successful deployment of the system among others depends on the awareness of numerous stakeholders. Intensified actions by the FCTC Secretariat, given its status as one of the key stakeholders involved in facilitating the fight against illicit trade, can provide for valuable support in improving the awareness of other stakeholders and hence will contribute to the successful deployment of the system within 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

The grant will be earmarked specifically for facilitating actions in the form of stakeholder workshops, study visits and targeted public awareness actions focused on key opinion leaders

<sup>(26)</sup> <http://www.who.int/fctc/protocol/about/en/>

<sup>(27)</sup> OJ L 127, 29.4.2014, p. 1.

with a specific interest for the EU which could bring added value to the TPD implementation. The activities will have to take place within the EU territory and to be focused on stakeholders who are important from the perspective of (i) the deployment of the TPD system within EU and (ii) promoting a maximum level of compatibility of the similar systems (developed under the FCTC Protocol) with the EU system.

#### Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First semester of 2016	EUR 400 000

*2.5.1.3. Migrants health: Best practices in care provision for vulnerable migrants and refugees – Grant to WHO (Thematic priority 3.7 of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

This action aims to support common and joint activities in support to Member States efforts to integrate migrant population in national health care systems.

Common objectives are to develop migrant-sensitive health systems, strengthen the collection of evidence and information to support policy formulation, and ensure equitable access to services and inter-sectorial collaboration.

Insufficient knowledge in many aspects of migration and health has hampered efforts to more effectively plan and implement strategies to address the issue of migration and health.

The objective of this action is to help Member States integrate relevant health information and data gathering mechanisms regarding migration and to analyse the information collected in hotspots and arrival points. The analysis should help identify and disseminate best practices in health care and health promotion towards migrant populations across Europe.

Expected results include a better knowledge of vulnerable migrants' health status and mapping of best practices regarding vulnerable migrants' integration in health systems, from which other vulnerable groups (e.g. Roma) could also benefit.

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 activities to be supported under this action will consist in: (i) collecting and analysing information provided by the personal health records used in hotspots and reception centres; (ii) identifying good quality regular information collection on migrants' health with a view of

dissemination; (iii) developing guidelines for data collection on migration and health.

#### Implementation

Implementation by the Agency

#### Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First semester of 2016	EUR 500 000

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

No actions foreseen under this priority.

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

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

Priorities of the year, objectives pursued and expected results

This action aims at: (i) the harmonisation of quality standards vested in the EU pharmaceutical legislation; (ii) the facilitation of the placing on the market of medicinal products in all the Member States; and (iii) the 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

<b>Reference</b>	<b>Date</b>	<b>Amount</b>
Signature of the grant awarded without a call for proposals	First semester of 2016	EUR 1 100 000

*2.5.3.2. Preparation of EU Health Report – ‘State of health in the European Union’ and Country specific analysis – Grant to OECD (Thematic priority 3.7. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The Commission is bringing together country specific information on public health and health systems in the EU Member States. The OECD will provide data and analysis in specific areas related to health systems which will be agreed with the Commission. Information will be used for the preparation of EU health reports and to identify tools and mechanisms to support countries in addressing health challenges and for sharing good practices. This includes preparation of regular reports on health in the EU, possible thematic reports focusing on specific policy areas and targeted consultation with all EU 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

This action is a direct grant to the OECD to support the preparation of country specific data, analysis with regard to economic impacts and economics of prevention of major health issues in EU Member States and for the first thematic report foreseen in 2017. In addition, the OECD should, in collaboration with the Commission, prepare and organise Dialogue and Validation Meetings with every EU Member State on their specific health profiles. Cluster meetings involving several Member States to identify ways forward to address the key issues nationally and at the EU level may also be organised by the OECD as needed. This activity will be done in close collaboration with the European Observatory on Health Systems and Policies (action 2.5.5.1) and it will be coordinated by the Commission.

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	First semester of 2016	EUR 1 200 000

proposals		
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#### **2.5.4. Actions under objective 4 – Facilitating access to better and safer healthcare for Union citizens**

Please see below under Horizontal Action.

#### **2.5.5. Horizontal action related to objectives 3 and 4**

*2.5.5.1. Direct grant to the World Health Organization as the host of the European Observatory on Health Systems and Policies on country specific knowledge and anti-microbial resistance (Thematic priorities 3.4, 3.7 and 4.4 of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

Through this action the European Observatory on Health Systems and Policies, a partnership hosted by the World Health Organization of which the Commission is a member, will provide technical support to the Commission in two thematic areas:

##### **(1) Country-specific and cross-country knowledge**

The European Observatory on Health Systems and Policies will support the Commission in its work of profiling Member States, providing data, specific analysis and synthesis on the EU Member States in view of supporting them to strengthen access, effectiveness and resilience of health systems and public health. The Observatory will provide data and analysis in specific areas such as health care and public health policies which will be agreed with the Commission. This analysis should provide identification of the challenges in health at national and European level and exploring sustainable solutions towards the improvement of those systems, based on economic and social benefits. This activity will be done in close collaboration with the OECD (action 2.5.3.2) and coordinated by the Commission.

##### **(2) Antimicrobial resistance**

Antimicrobial resistance (AMR) is not solely a human and animal health threat, but it also has an economic impact locally and globally. Firstly, AMR impacts on health systems by increased morbidity and mortality from untreatable or difficult to treat infections. Secondly, by its impact on human health, AMR affects labour productivity, output and economic growth.

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

##### **(1) Country-specific and cross-country knowledge**

The activities to be carried out are: (i) preparing synthesis reports for selected Member States, including health systems and public health policies information, in the format agreed with the Commission; (ii) creating a network of experts in the Member States, available for

consultation on different aspects of health systems and public health policies; (iii) participating in policy dialogues requested by the Commission, on specific topics or countries, related to the health systems and public health policies.

## **(2) Antimicrobial resistance**

Complementary to activities carried out by the Commission on AMR and on prevention of health care associated infections, including on research and the joint programming initiative on AMR; as well as the ongoing work with OECD supported under the 2015 Health Programme work programme; the European Observatory on Health Systems and Policies will carry out the following activities:

(i) an analysis of EU and OECD Member State policies on AMR including a mapping exercise on EU governance structures and actions to combat antimicrobial resistance, leading to recommendations for strengthening policies and developing targets for EU level action and coordinated governance;

(ii) work on a book on AMR, to be published jointly with the Commission and the OECD, which will: take stock of the state of knowledge with respect to the effectiveness and cost-effectiveness of actions aimed at tackling AMR; present case studies of good practices; and discuss the challenges that may hinder the scaling up at the national level of local good practices and their transferability across countries.

### 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 semester of 2016	EUR 750 000

## **3. PRIZES**

The overall budgetary allocation reserved for prizes in 2016 amounts to EUR 60 000. The budget line is 17.03.01.

Annex VIII contains the eligibility, exclusion and award criteria.

### 3.1. Horizontal action (related to the 4 objectives) - Health Award

Description, objectives pursued and expected results

In the context of the EU Health Policy (Forum) Platform, as one of the three axes, a Health Award will be organized. The award will reward and highlight good practices of European, national and/or sub-national non-governmental bodies which have made a significant contribution towards promoting a healthier EU and fairer access to healthcare for EU citizens, preventing diseases and protecting EU citizens' health.

The overall objective is to raise awareness of the vital role non-governmental bodies play in strengthening participative democracy and active citizenship for a healthier EU and fairer access to healthcare.

European, national and sub-national stakeholders will be identified with this award. Thus, the award will continue to raise awareness of the EU Health Policy (Forum) Platform and further increase its number of participants. This will, in turn, allow national and sub-national non-governmental bodies to be better informed of EU developments in the field of public health and how they relate to other policies thanks to the continuous flow of information and debate within the platform.

Since the award will recognize a good practice, the EU Health Policy (Forum) Platform will contain a reservoir of good practices from international, European, national and sub-national non-governmental bodies for other users to be able to re-create.

Implementation

Implementation by the Commission

Indicative timetable of the contest and indicative amount of the prize

Reference	Date	Amount
Call for applications for the EU Health Award	First semester of 2016	EUR 60 000

### 4. PROCUREMENT

The overall budgetary allocation reserved for procurement contracts in 2016 amounts to EUR 14 913 112. 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.

**4.1. Actions under objective 1 – Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the ‘health in all policies’ principle**

*4.1.1. Monitoring of EU Platform for Action on Diet, Physical Activity and Health and the stakeholder commitments concerning reduction of alcohol related harm (Thematic priority 1.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Evaluation and monitoring:** The objective of this action is to obtain an independent analysis of the implementation and achievements of the Platform for Action on Diet, Physical Activity and Health the stakeholder commitments concerning reduction of alcohol related harm. The estimated period for producing the deliverables is three years. This action will include work related to the Platform and stakeholder commitments concerning the reduction of alcohol related harm: (i) providing an analysis of the annual progress and the actions of members/stakeholders, resulting in annual reports; (ii) facilitating plenary discussions on commitments to improve and increase the impact of individual initiatives; (iii) providing individual support and feedback; and (iv) providing recommendations on ways to further improve the current monitoring and reporting.

Type of contract and type of procurement

Specific contract based on an existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Commission

*4.1.2. EU Health Policy Forum (Thematic priority 1.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** The aim of this action will be to update and ensure the maintenance of the Health Policy Forum IT Platform aimed at easing multilateral communication and active involvement amongst stakeholders, and between the different stakeholder groups and the Commission. It will also serve as a tool to allow cross-sectoral in-depth debates, creating synergies amongst stakeholders, and leading to discussion on topics of interest for the health community. It will further create a direct bridge to citizens’ organizations on some of the topics that most directly matter to them.

Type of contract and type of procurement

Specific contracts based on existing framework contracts

Indicative number of contracts envisaged: 1-2

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Commission

*4.1.3. Support to the report to the Council on the implementation of the Action Plan on Childhood Obesity (Thematic priority 1.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Evaluation:** The work will support the Commission obligation to report on the interim (2017) status of the implementation of the Action Plan on Childhood Obesity and also on relevant related action on Nutrition and Physical Activity. This action includes: (i) collecting data from 28 EU Member States; (ii) analysing the collected data; (iii) reporting to the Commission on the interim implementation of the Action Plan on Childhood Obesity in close cooperation with WHO Europe; and (iv) supporting in the dissemination of the results via relevant channels. The estimated period for producing the deliverables is 1.5 years.

Type of contract and type of procurement

Specific contract based on an existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Agency

*4.1.4. EU framework for national initiatives on selected nutrients: new developments feasibility study (Thematic priority 1.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:** The study will support the Commission's work on action to implement the EU framework for national initiatives on selected nutrients. This action includes: (i) collecting data on food reformulation in the 28 EU Member States plus EEA/EFTA associated countries; (ii) analysing the cost-benefit of food reformulation; (iii) reporting to the Commission; (iv) supporting the dissemination of the results via relevant channels; and (v) developing proposals for supporting new interventions and public health policies in this area. The estimated period for deliverables is 1.5 year.

Type of contract and type of procurement

Specific contract based on an existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Agency

*4.1.5. Pilot specific training modules for health professionals, border guards and trainers in migrants' and refugees' health (Thematic priority 1.3. and 1.4 of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Pilot training modules:**

In previous years, the Health Programme has focused on developing training modules for health professionals and front line professionals working with migrants and refugees. Those modules aimed to provide a general knowledge about general problems and specificities of migrants' health. During the piloting and implementation of the training, the need of specific training modules in some areas was identified, for example on communicable diseases, mental health or vulnerable groups' health.

Although most migrants and newly arriving refugees are not posing a special challenge in term of communicable diseases, the evidence points out that additional work is needed to cover existing knowledge gaps, in particular for communicable diseases according to the country of origin of migrants and refugees, since prevalence rates and burden of diseases differ considerably by country of origin, and to take into account the specific vulnerability for individuals. This knowledge could help to quickly identify potential cases of communicable diseases in need of treatment, either for acute and for chronic diseases. Good practice gained from the activities coordinated by the ECDC and other networks funded under the Health Programme, might also be of added value in implementing the rapid diagnosis of communicable diseases, which are rarely seen in the EU and for which the EU capability could be reinforced.

Chronic mental health problems including post-traumatic stress could also be a problem in newly arrived migrants and refugees. Identifying such problems by the front line health professionals and border guards could help to early diagnosis, treatment, and better integration. Recommendations, innovative tools and methodologies developed by FP7 and Horizon 2020 projects for earlier diagnosis of at-risk individuals and better care of people suffering from mental disorders should be taken into account whenever relevant (e.g. from PARADISE <sup>(28)</sup>, RIGHTTIMEPLACECARE <sup>(29)</sup>, PRONIA <sup>(30)</sup>, PSYSCAN <sup>(31)</sup>).

The available training modules created by the International Organisation for Migration in EQUI HEALTH and the Migrant and ethnic minority health training package (MEM-TP) contract should be complemented with these specific training modules, not duplicating the already existing ones.

The objective of the action will be the design and the development of pilot training modules for health professionals, border guards and the trainer of trainers' package on mental health and post-traumatic stress detection and on implementation of triage and screening for communicable diseases in migrants and refugees.

The design and the development of the pilot training will take stock of the EQUIHEALTH, MEM-TP material, and the ECDC on-going work on 'Preparedness for disease control for sudden influx of migrants' project (expected results March 2016) and the outcome of the consultations of the Advisory Group on 'Evidence-based guidance on prevention of infectious diseases among newly arrived migrants in the EU and EEA'.

The action will be developed in synergy with action 4.2.1.

Type of contract and type of procurement

Direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2016

Implementation

Implementation by the Agency

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<sup>(28)</sup> [http://ihrs-en.ibe.med.uni-muenchen.de/biopsychosocial/completed/icf\\_paradise/index.html](http://ihrs-en.ibe.med.uni-muenchen.de/biopsychosocial/completed/icf_paradise/index.html)

<sup>(29)</sup> [http://cordis.europa.eu/result/rcn/57319\\_en.html](http://cordis.europa.eu/result/rcn/57319_en.html)

<sup>(30)</sup> <http://www.pronia.eu/>

<sup>(31)</sup> [http://cordis.europa.eu/project/rcn/110572\\_en.html](http://cordis.europa.eu/project/rcn/110572_en.html)

4.1.6. *Assessment of the socio-economic impact of the future initiatives on HIV/AIDS, viral hepatitis and tuberculosis (Thematic priority 1.3. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:** The aim of this study is to provide evidence reviews, and develop further evidence through scenario development and modelling on the basis of existing survey data and models. This will include assessment of the cost-effectiveness of screening and treatment and its economic impact on health systems taking also into account existing EU level instruments such as the Joint Procurement Agreement and actions under the EU Health Programme.

Type of contract and type of procurement

Specific contract based on an existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Agency

4.1.7. *Baseline study on dementia and other neurodegenerative diseases in EU Member States (Thematic priority 1.4. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:** The objective of this action is to provide a baseline mapping on dementia and other neurodegenerative diseases in EU Member States plus EEA and candidate countries. Consequently, it is necessary to describe the epidemiology of these diseases, the policy context, the healthcare services for patients and family carers, including the level of their integration with social services, as well as include relevant health promotion and prevention activities, before or after diagnosis for each EU Member State and EEA/candidate country. The work of the JPND Actions Groups on Assisted Ambient Living <sup>(32)</sup> and Palliative Care <sup>(33)</sup> should be taken into account. The study should identify the strengths and challenges of Member States and EEA/candidate country and good practices. It should support countries in the planning of their policies and the exchange at European level. It contributes to the follow-up to the First WHO Ministerial Conference on Dementia (March 2015).

Type of contract and type of procurement

<sup>(32)</sup> <http://www.neurodegenerationresearch.eu/initiatives/jpnd-alignment-actions/assisted-living-technologies/>

<sup>(33)</sup> <http://www.neurodegenerationresearch.eu/initiatives/jpnd-alignment-actions/palliative-care/>

Specific contract based on existing framework contracts

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Agency

*4.1.8. Provision of technical and scientific input to support the implementation of the new Tobacco Products Directive and further development of existing tobacco control measures on the EU level (Thematic priority 1.5. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** Following its entry into force, the new Tobacco Products Directive (TPD) 2014/40/EU <sup>(34)</sup> shall be made fully operational by means of delegated and implementing acts. The implementation of the TPD and its transposition by the Member States should be supported by appropriate technical and scientific input in form of reports, studies, market data and/or other relevant forms.

This action will focus in particular on the implementation of the TPD with the following priority areas:

- (i) further development of the ingredients regulation, in particular determination of tobacco products with a characterising flavour and reporting of ingredients and other information provided for by the Directive, including enhanced reporting obligations for priority additives;
- (ii) regulation and monitoring of e-cigarettes, in particular risk assessment and mitigation, product notification, and follow up of technical and market developments;
- (iii) further development of tracking and tracing systems and security features as outlined in Article 15 on traceability and Article 16 on security features;
- (iv) implementation of labelling and packaging provisions of TPD, in particular as regards product presentation including misleading or promotional elements (such as 'light', 'organic' or discounts), prohibited by Article 13 TPD; and
- (v) general monitoring of the market, scientific, technical and international developments including studies that will allow the Commission to comply with its reporting obligations pursuant to Article 28 TPD.

In parallel the Commission will further continue to monitor related tobacco control policies

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<sup>(34)</sup> OJ L 127, 29.4.2014, p 1.

through appropriate reports or studies, in particular advertising and sponsorship of tobacco products (regulated by Directive 2001/33/EC<sup>35</sup>, smoke-free environments (Council Recommendation 2009/C296/02 (<sup>36</sup>) and other initiatives to improve tobacco control (as outlined by Council Recommendation 2003/54/EC (<sup>37</sup>).

Type of contract and type of procurement

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

Indicative number of contracts envisaged: 5-6

Indicative timeframe for launching the procurement procedure

First and second semesters of 2016 (2 procedures in the first semester, 3 procedures in the second semester of 2016)

Implementation

Implementation by the Commission and the Agency

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

*4.2.1 Training programme for first-line health professionals, border officers and trainers working at local level with migrants and refugees (Thematic priority 2.2. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Training:** Training programmes for professionals, border officers and their trainers working at local level will be implemented with the view to upgrade and strengthen the skills and capabilities of first line health professionals, and promote a holistic approach to health care of migrants and refugees at first points of arrival in the receiving countries. Professionals from public and non-governmental organisations working at regional and local level as first line professionals will be trained as well as national and regional health professionals and border officers' trainers.

The training modules developed under EQUIHEALTH, MEM-TP and the action 4.1.5 will be used.

The Implementation and the roll out of the training will take place at two levels: first line professionals, border officers and trainers working at local level with migrants and refugees for the general and specific modules; and general practitioners and university students for the

<sup>(35)</sup> OJ L 127, 9.5.2001, p. 42.

<sup>(36)</sup> OJ C 296, 5.12.2009, p. 4.

<sup>(37)</sup> OJ L, 22, 25.1.2003, p. 31.

general modules.

The implementation will need to cover at least all Member States under extraordinary migratory pressure.

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 2016

Implementation

Implementation by the Agency

#### 4.2.2. *Capacity building against health threats in Member States (Thematic priority 2.2. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Workshops and training:** In order to protect citizens from serious cross-border health threats (Decision 1082/2013/EU <sup>(38)</sup>), it is essential to identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies. The aim of the activities is to support capacity building against health threats in Member States. Sharing of information, identifying good practices, enhancing preparedness and response planning processes, testing of procedures and plans in place that are important tasks to strengthen capacities at EU level.

**The following 3 sub-actions will look at different aspects of capacity building and require different types of deliverables:**

1) a workshop on the state of play of preparedness in the EU, taking into account the Council Conclusion on the lessons learned from the Ebola outbreak and the results of the report on the state of preparedness and response planning in the Member States (under article 4 of Decision 1082/2013/EU). The workshop will: (i) take stock of preparedness capacity built by the Commission and Member States; (ii) discuss how to bridge gaps identified by the Health Security Committee especially in the areas of bio-toxins and chemical and environmental threats; and (iii) share best practice how health systems have successfully integrated inter-sectoral cooperation in their crisis management;

2) the organisation of a table top exercise bringing together the veterinary sectors and public

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<sup>(38)</sup> OJ L 293, 5.11.2013, p. 1.

health experts (including communicators) to test procedures and protocols in place and identify gaps;

3) the identification of challenges for the management of vector borne diseases outbreaks, inter-sectoral aspects of the response (best scientific evidence for decision making, innovative approaches); organisation of the workshop related to adaptation to climate change: identify new or better methods to address vector borne disease outbreaks (e.g. vector control intervention strategies, exchange of good practices, spraying techniques, larvisides, pesticides, insecticide resistance, PPE, population at risks, new strains), establish monitoring practices on insecticide resistance in vectors as well as innovative approaches to face present and future challenges.

Type of contract and type of procurement

Specific contracts based on an existing framework contract

Indicative number of contracts envisaged: 3

Indicative timeframe for launching the procurement procedure

Second semester of 2016

Implementation

Implementation by the Agency

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

#### *4.3.1. Health innovation and Health Technology Assessment (Thematic priority 3.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:** The objective of this action is to carry out a study assessing the impact and viability of different options to establish a sustainable mechanism on EU cooperation on Health Technology Assessment (HTA) and the possible need to regulate specific aspects in terms of maintaining EU cooperation post 2019.

By 2019, the Commission will have invested about EUR 50 million in supporting cooperation and research in HTA at EU level. The third Joint Action runs from 2016 to 2019, co-funded from the 2015 work programme of the Health Programme. This third Joint Action will end in 2019 and it is necessary to maintain EU cooperation on HTA to ensure inter alia joint production of HTA and reuse at national and regional level.

This study would explore different options on how to continue EU cooperation on HTA and substantiate the findings of the inception impact assessment developed in the second half of

2015. This study would serve as a basis for the development of the Impact Assessment which is expected to be finalised in 2017.

Under the 2015 work programme, a study is funded to identify and quantify key indicators to evaluate the need for EU coordination in the area of HTA. The 2016 study would build on these indicators and evaluate the impact and viability of different options for a possible future action on EU cooperation on HTA.

*Type of contract and type of procurement*

Direct service contract or specific contract based on existing framework contracts

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Agency

*4.3.2. Health innovation and e-Health (Thematic priority 3.2. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:** The objective of this action is to carry out a study providing a better understanding of obstacles to telemedicine practice in the EU countries and between them as well as options to overcome the obstacles by regulating specific aspects of telemedicine service provision. The study will assess impacts of different options for EU action.

Telemedicine services fall within the scope of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare <sup>(39)</sup> when there are health services provided by health professionals as defined in that Directive. The Directive clarifies patients' rights to be reimbursed for the provision of cross-border health services, including cross-border telemedicine services.

This study would build on the work already carried out by the Commission in the context of the 'eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century' <sup>(40)</sup>, the eHealth network and activities in the framework of the eHealth Joint Action. The findings of the study will feed into the Digital Single Market Strategy for Europe.

<sup>(39)</sup> OJ L 88, 4.4.2011, p. 45. DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011, on the application of patients' rights in cross-border healthcare , [http://eur-lex.europa.eu/legal\\_content/EN/TXT/?uri=celex:32011L0024](http://eur-lex.europa.eu/legal_content/EN/TXT/?uri=celex:32011L0024)

<sup>(40)</sup> [http://ec.europa.eu/health/ehealth/docs/com\\_2012\\_736\\_en.pdf](http://ec.europa.eu/health/ehealth/docs/com_2012_736_en.pdf)

Open aspects in relation of telemedicine which would need to be considered and evaluated through this study were identified in the Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services, accompanying the eHealth Action Plan 2012-2020. These include notably licensing and registration of healthcare professionals performing telemedicine services, data protection and legal processing of data, liability, reimbursement, and legal aspects of safety.

This study would be used to substantiate the inception Impact Assessment developed in 2015 and would serve as a basis for the development of the Impact Assessment which is expected to be finalised in 2017.

Type of contract and type of procurement

Direct service contract or specific contract based on existing framework contracts

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Agency

#### *4.3.3. Support for the health workforce planning and forecasting expert network (Thematic priority 3.3. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** This action will contribute to the sustainability of the health workforce through expertise and knowledge sharing and support anticipation of skills needs to tap into the health sector's job creation potential. Building on the previous work of the Joint Action for health workforce planning and forecasting <sup>(41)</sup>, the activities to be addressed include: (i) organising three expert network meetings to exchange knowledge in the area of health workforce planning and forecasting and providing a forum for peer support to resolve health workforce challenges; (ii) updating information on national health workforce strategies and further analysis on skills needs in the health sector; and (iii) maintaining and updating the website on health workforce planning and policies.

Type of contract and type of procurement

Direct service contract

Indicative number of contracts envisaged: 1

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<sup>(41)</sup> <http://ec.europa.eu/chafea/projects/database.html?prjno=20122201>

Indicative timeframe for launching the procurement procedure

Second semester of 2016

Implementation

Implementation by the Agency

4.3.4. *Scientific and technical assistance for the Expert Panel on effective ways of investing in Health (Thematic priority 3.4. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** This action will provide scientific and technical assistance for the Expert Panel on effective ways of investing in Health <sup>(42)</sup>. It includes assistance in the evaluation of the selection of experts, organisation of scientific hearings 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.

Type of contract and type of procurement

Direct service contracts and one specific contract based on an existing framework contract

Indicative number of contracts envisaged: 5-10

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Commission

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

Subject matter of the contracts envisaged

**IT services:** (i) 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

<sup>(42)</sup> Commission Decision of 5 July 2012 on setting up a multisectoral and independent expert panel to provide advice on effective ways of investing in health (2012/C 198/06)  
[http://ec.europa.eu/health/healthcare/docs/dec\\_panel2012\\_en.pdf](http://ec.europa.eu/health/healthcare/docs/dec_panel2012_en.pdf)

origin; and (ii) 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 Commission websites on medicinal products.

Type of contract and type of procurement

Specific contracts based on an existing framework contract

Indicative number of contracts envisaged: 3

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Commission

*4.3.6. Maintenance and development of the existing Eudamed (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**IT services:** The objective of this action is to ensure the maintenance and the development of the European medical devices database EUDAMED which is an information system for exchanging legal information related to the application of European Union Directives on medical devices between the Commission and the competent authorities in the EU Member States.

Type of contract and type of procurement

Specific contracts based on an existing framework contract

Indicative number of contracts envisaged: 1-3

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Commission

4.3.7. *Development of the future EUDAMED following the adoption by the legislators of new Regulations on medical devices (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**IT services:** This action is about the preparatory work for the development of the future EUDAMED (the European medical devices database) provided for in the proposals of new regulations on medical devices and *in vitro* diagnostic medical devices. The activities should encompass 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 contract

Indicative number of contracts envisaged: 1-3

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Commission

4.3.8. *Communication and publication actions to promote the understanding and correct implementation of the requirements and risks relating to medical devices (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Communication services:** This action deals with communication and publication activities to promote the understanding and correct implementation of the requirements and risks relating to medical devices following the adoption by the legislators of new Regulations on medical devices and *in vitro* diagnostic medical devices.

Type of contract and type of procurement

Specific contracts based on an existing framework contract

Indicative number of contracts envisaged: 1-3

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Agency

*4.3.9. Overview of certain transposition measures of the Falsified Medicines Directive (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:** A study is needed in view of the preparation of a Report to the Parliament and Council giving an overview of the transposition measures on the rules on penalties applicable to infringements of the national provisions adopted pursuant to Article 118a(3) of the Directive 2011/62/EU on falsified medicines.

Type of contract and type of procurement

Specific contract based on an existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2016

Implementation

Implementation by the Commission

*4.3.10. Clinical trials database (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**IT services:** Overseeing and monitoring the work of the European Medicines Agency for the development of an EU portal and an EU database for the submission of requests for authorisation of clinical trials and follow-up. This database will store information on the content, start and termination of clinical trials. It will facilitate the sharing of clinical trials information between different institutions and establishments carrying out these trials in different EU Member States.

Type of contract and type of procurement

Direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2016

Implementation

Implementation by the Commission

*4.3.11. Study on Cross-border cooperation (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:**

This study aims to yield a comprehensive picture of cross-border healthcare collaboration initiatives across the EU (based on Chapter IV of Directive 2011/24/EU), including a mapping of cross-border collaboration projects, e.g. bilateral agreements between insurers and providers (between neighbouring countries or between regions) and to develop scenarios for possible pilots to foster European collaboration on cross-border healthcare.

Building on the findings emanating from the study on cross-border collaboration in capital investments, this study would aim in particular at:

- (i) mapping existing projects, with an analytical categorisation/ taxonomy;
- (ii) analysing previous framework agreements where cross-border collaboration helped address local needs;
- (iii) drawing up a list of enabling factors for successful cross-border collaboration;
- (iv) estimating the resource demands on stakeholders and public authorities for conclusion of such agreements;
- (v) performing an horizon scanning for cross-border collaboration 2030: avenues for capacity building and further development.

Type of contract and type of procurement

Direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2016

Implementation

Implementation by the Agency

4.3.12. *Study on enhancing information provision to patients (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Study:** The study aims to yield an overview of good practices and enabling factors for providing information to patients via the National Contact Points (NCPs), including an analysis based on defined criteria for NCPs website accessibility for patients.

Such study would aim in particular at:

- (i) performing an in-depth survey on the operational organisation of all EU28 NCPs;
- (ii) estimating the resource demands on NCP staff (full-time equivalents) in given scenarios;
- (iii) analysing actual cases of patients who have sought information from NCPs/ alternatively conducting a mystery shopping of NCPs;
- (iv) drawing up of a list of thematic indicators for NCP service provision e.g. patient/citizen experience (reviews);
- (v) estimating the social cost of non-provision of accurate information to citizens (potentially via description of real life cases);
- (vi) horizon scanning for NCP 2030: avenues for capacity building and further development.

Type of contract and type of procurement

Direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2016

Implementation

Implementation by the Agency

4.3.13. *Conference of National Contact Points for Cross-border healthcare (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Conference:** A Commission conference on ‘National Contact Points (NCPs) for Cross-border Healthcare’ will be organized, aiming at fostering coordination and cooperation of NCPs with patient organisations, healthcare providers and healthcare insurers.

This conference on “Towards amplified awareness of EU rights to cross-border care” would aim at:

- (i) strengthening patients’ access to clear and tailored information for correctly accessing cross-border care;
- (ii) amplifying awareness of all patients in the medium term and of identified multipliers in the short term (e.g. frontline providers, patient organisations, trade unions);

- (iii) presenting the Pilot “A Learning Network of NCPs”: a member-driven network of over 33 member NCPs from across the EU that provides core tools necessary to successfully implement effective information provision and to be a gateway for accountable care (workshops with interested NCPs will lead up to this);
- (iv) presenting a preliminary list of thematic indicators for NCP service provision: patient/citizen experience (reviews), care coordination (continuity of care), record management, enquiry management, patient safety, quality of care, at-risk population/frail elderly health;
- (v) enhancing accountability for the quality of the information provided;
- (vi) developing capacity for case handling within NCPs.

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 2016

Implementation

Implementation by the Commission

*4.3.14. Scientific and technical assistance for scientific committees (Thematic priority 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. This 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 and updating of the scientific committees’ website. 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 data analysis, scientific aspects of impact assessments and risk communication

Type of contract and type of procurement

Specific contracts based on existing framework contracts and low value contracts (+ 1 administrative agreement with the JRC)

Indicative number of contracts envisaged: 11 (+ 1 administrative agreement with the JRC)

Indicative timeframe for launching the procurement procedure

First and second semesters of 2016

Implementation

Implementation by the Commission

#### **4.4. Actions under objective 4 - Facilitating access to better and safer healthcare for Union citizens**

##### *4.4.1. European Reference Networks - Assessment of applications of network and membership proposals (Thematic priority 4.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Technical assistance:** Commission implementing decision 2014/287/EU sets out the criteria for establishing and evaluating European Reference Networks (ERN) and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such networks. Accordingly, the Commission has started the process of establishing ERNs by setting up a Board of Member States, developing the assessment manual and toolbox and organising awareness and communication activities. In 2015 the independent assessment body (or bodies) in charge of evaluating the applications of network and membership proposals are selected and contracted.

The aim of this action is to contract independent assessment bodies in order to perform the evaluation of applications of network and membership proposals presented to the call for ERNs that will be launched by the Commission in 2016.

Type of contract and type of procurement

Specific contracts based on existing framework contracts

Indicative number of contracts envisaged: 15-20

Indicative timeframe for launching the procurement procedure

First semester of 2016

Implementation

Implementation by the Agency

##### *4.4.2. European Reference Networks - Support of the IT platform (Thematic priority 4.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**IT services:** A first version of the European Reference Networks (ERN) IT platform is being created in 2015. The aim of this action is to support, maintain and improve the ERN IT platform by integrating the different elements and tools in 2016 and to give support to the Commission and the approved ERNs in their functioning and duties required by legal acts.

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 2016

Implementation

Implementation by the Commission

#### 4.4.3. *European Reference Networks - Conference (Thematic priority 4.1. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

**Communication services:** The purpose of this action is to organise a conference on European Reference Networks in the framework of the implementation of the directive on patient rights in cross-border healthcare. The objective of the event is to facilitate the exchange of information and expertise on establishing and evaluating networks in order to fulfil the mandate given to the Commission as provided in the Commission implementing decision 2014/287/EU. The conference will gather all coordinators and members of the approved ERNs, national experts and authorities, stakeholders involved in the ERN implementation and Independent Assessment Bodies responsible of the assessment process.

Type of contract and type of procurement

Specific contract based on an existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2016

Implementation

Implementation by the Commission

#### 4.5. Horizontal actions (related to the 4 objectives)

##### 4.5.1. *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 following actions will be carried out:

**Action 1: dissemination of information on EU health policy initiatives and related actions:** Activities to be funded include amongst others preparing and disseminating graphic and audio-visual material and publications in electronic format and on paper, web management, conferences and other stakeholder-related events, media activities (including media seminars and journalists visits) and other communication and promotional activities and material;

**Action 2: dissemination of the results of the Health Programme at EU level:** This action aims to provide Member States with working 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, info-sheets on selected health topics and clusters of projects, and other appropriate means for effectively disseminating the results to different audiences. This work will also take into account the recommendations stemming from the ex-post final evaluation of the Second Health Programme (2008-2013), especially with regards to fostering a strategic approach, the types of dissemination activities to be pursued and the target groups to be prioritized.

Type of contract and type of procurement

Service contracts based on existing framework contracts

Indicative number of contracts envisaged: 10-15

Indicative timeframe for launching the procurement procedure

First and second semesters of 2016

Implementation

Action 1: Implementation by the Commission – Action 2: Implementation by the Agency

#### 4.5.2. *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 policy/activities 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 Third Health Programme and in accordance with the Europe 2020 strategy. An indicative list of applications to be covered by this action is as follows: Alcohol and Mental Health Platforms; Health Innovation Platform; applications related to tobacco control, 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); Injury Database (IDB), Ras-Chem (rapid alert system for information exchange on incidents including chemical agents), etc., 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 contracts

Indicative number of contracts envisaged: 10

Indicative timeframe for launching the procurement procedure

First and second semesters of 2016

Implementation

Implementation by the Commission

#### 4.5.3 *Review of implementation of and follow-up to the 2010 Commission Communication and subsequent Council Conclusions on Global Health including stakeholder consultation on next steps*

Subject matter of the contracts envisaged

**Study and conference:** It is foreseen (i) to commission a study on how the 2010 Commission Communication and subsequent Council Conclusions on Global Health have been

implemented and (ii) to organise (with other Commission Services) a major stakeholders conference in November 2016 to identify whether and how the existing policy needs to be updated.

The Commission Communication and the Council Conclusion on Global Health, adopted in May 2010, laid out a series of recommendations and commitments for EU action on Global Health. Global health is one of the four pillars on which the EU Health Strategy is based and it is a crosscutting issue encompassing, inter alia, the four thematic priorities of the work programme – health promotion and diseases prevention, cross-border health threats, health systems strengthening and sustainability, and access to healthcare. It is also highly integrated with other EU policies – research, development cooperation, trade etc.

However, since 2010, the global health landscape has changed significantly e.g. lessons learned from Ebola, the adoption of the post-2015 sustainable development goals, the revision of the International Health Regulations, the high-level UN Declaration and plan of action on NCDs, the global code of conduct on recruitment of health personnel, the reform of the WHO, changes in migration patterns, increased tensions between intellectual property rights and access to medicines etc. These changes have implications inside and outside the EU.

It is time to review what has been done at Commission and other levels and to consult with the major stakeholders (civil society, international organisations, strategic partners, etc.) on whether and how Commission/EU policies need to be adapted to the new realities.

It is foreseen to engage an external entity to be charged with two tasks. Firstly, the contractor will document the actions that the Commission and other actors have undertaken that contribute to reaching the aims outlined in the Communication and towards realising the commitments of the Council Conclusions. Secondly, the contractor will be charged with organising a major stakeholder conference on global health towards November 2016 to discuss the need to recalibrate and refocus EU global health activities in light of the recent major changes in the global health landscape.

Type of contract

Direct contract or specific contract based on an existing framework contract.

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester 2016

Implementation

Implementation by the Commission

## 5. OTHER ACTIONS

The overall budgetary allocation reserved for other actions in 2016 amounts to EUR 6 719 000. 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 <sup>(43)</sup>, 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.

### 5.1. Actions under objective 1 – Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the ‘health in all policies’ principle

#### 5.1.1. European initiative on breast cancer and cancer information system (Thematic priority 1.6. of Annex I to the Programme Regulation)

Amount

EUR 1 800 000
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Description and objective of the implementing measure

<p>These actions will be implemented by the Commission Joint Research Centre (JRC) having as objectives to:</p>
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<p><b>1) Access, harmonise, enhance and use European Cancer Information for EU policy making:</b> There is the need to create a European Cancer Information System (ECIS) with accurate and comparable (harmonised) data on cancer incidence, prevalence, cure, survival rate, and mortality in the EU as advocated in Commission Communication COM (2009) 291 final of 24 June 2009 on Action Against Cancer: European Partnership <sup>(44)</sup>. These high quality, harmonised data are required for providing the basis for framing effective cancer policies in the EU;</p>
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<p><b>2) Develop a Voluntary European Accreditation Scheme for Breast Cancer Services updating existing Breast Cancer Screening Guidelines:</b> The development of the voluntary quality assurance scheme would follow the lines of the legal framework for accreditation <sup>(45)</sup>. This should be also based on updated breast cancer screening guidelines as set out in the Council Recommendation 2003/878/EC of 2 December 2003 on cancer screening <sup>(46)</sup>. Since the work of developing a quality assurance scheme also needs to touch upon the entire process of healthcare provision for breast cancer patients (such as treatment and follow-up), a new</p>
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<sup>(43)</sup> OJ L 298, 26.10.2012, p. 1.

<sup>(44)</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0291:FIN:EN:PDF>

<sup>(45)</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC), No 339/93: OJ L218/30-47 of 13.08.2008.

<sup>(46)</sup> OJ L 327, 16.12.2003, p. 34.

version of the *European Guidelines for quality assurance in breast cancer screening and diagnosis* will be integrated with a platform of existing guidelines for the other stages of care than screening and diagnosis. This scheme will be developed in such a way that the methodology and knowledge-base could be easily applied to other cancer sites in the future, especially colorectal and cervical cancers for which the European guidelines already exist; and

**3) Provide Training on Digital Mammography:** The objective is to provide a concept for training targeted at health professionals involved in screening programmes, including minimum requirements for acceptability of such training to be proposed at European level.

## **5.2. Actions under objective 2 – Protecting Union citizens from serious cross-border health threats**

### *5.2.1. Risk assessment (Thematic priority 2.1. of Annex I to the Programme Regulation)*

Amount

EUR 70 000

Description and objective of the implementing measure

Following Article 10, paragraph 2, of the Decision 1082/2013 <sup>(47)</sup> on serious cross-border threats to health: "Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide a risk assessment".

The objective of this action is to provide targeted risk assessment at short term in case of a chemical or environmental incident of cross-border relevance in line with Article 10, paragraph 2 of the Decision cited above. In order to be in such a position a specific need for ad hoc funding to support the work to address specific rapid risk assessment during emergency situations remains. The risk assessment would be carried out via the Scientific Committees <sup>(48)</sup>, composed of experts whose expenses would be covered.

## **5.3. Actions under objective 3 – Contributing to innovative, efficient and sustainable health systems**

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

Amount

EUR 320 000

Description and objective of the implementing measure

<sup>(47)</sup> [OJ L 293](#), 5.11.2013, p. 1.

<sup>(48)</sup> [http://ec.europa.eu/health/scientific\\_committees/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/index_en.htm)

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<sup>(49)</sup>. This action will cover special indemnities paid to experts for their work on scientific opinions and reports.

5.3.2. *Technical and scientific opinions and advice on medical devices (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 406 000

Description and objective of the implementing measure

This action is about the technical and scientific co-operation allowing improved coordination and resource sharing between Member States and enhanced transparency regarding medical devices on the EU market. This action will be implemented through an administrative agreement with the JRC.

5.3.3. *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) membership fees and International Pharmaceutical Regulators Forum (IRPF) (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 350 000

Description and objective of the implementing measure

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)<sup>(50)</sup> 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 develop harmonised guidelines for product registration. The “International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use” has been established as an association on 23 October 2015. The Commission is a founding member of the association. ICH may enter into cooperations with other organisations such as the International Pharmaceutical Regulators Forum (IPRF)<sup>(51)</sup>.

<sup>(49)</sup> OJ C 198, 6.7.2012, p. 7.

<sup>(50)</sup> <http://www.ich.org/home.html>

<sup>(51)</sup> <https://www.i-p-r-f.org/en/>

ICH has its own secretariat which provides all the administrative and technical support to ICH activities. This covers not only the classical tasks of a secretariat (dissemination of documents, minutes, etc.) but also establishment and maintenance of the ICH website, request of legal advice, maintenance of private website with repository of documents, contract for a system to allow teleconferences and webinars. ICH also organises two meetings per year with over 300 experts.

As ICH founding member, the Commission has to contribute to the financing of the association through membership fees in order to ensure the functioning of the association.

*5.3.4. Reimbursement of experts' expenses for joint assessments (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 416 000

Description and objective of the implementing measure

This action deals with the reimbursement of expenses for joint assessments of notified bodies carried out by national experts of authorities of Member States and EFTA/EEA countries together with the Commission services and related training activities in the field of medical devices.

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

Amount

EUR 250 000

Description and objective of the implementing measure

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (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. In 2015, the “International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use” will be established as an association under Swiss law. The Commission will be a founding member of the association.

The Commission funds travel and accommodation costs for the experts from the EU national regulatory agencies to participate in ICH meetings. Considering the regulatory environment

(EU legislation), the operational funding should come from the EU rather than from the individual EU Member States. This is in accordance with the decision of the Commission to be representative of the EU (and thus its Member States) in the process.

5.3.6. *Joint Audit Program (JAP) on Good Manufacturing Practice (GMP) inspections (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 35 000

Description and objective of the implementing measure

The Joint Audit Program (JAP) organised by the Heads of Medicines Agencies (HMA) is a programme that monitors the equivalence of Member State Good Manufacturing Practices (GMP) inspectorates. The programme consists of audits carried out by Member States Authorities (the auditors) to a given Member State GMP system. The JAP audits will be carried out on the basis of objective criteria based on specific requirements vested in Community legislation, guidelines and procedures. The objective of this action is to support the organisation of a number of audits in 2016 by financing the mission costs of JAP auditors.

The JAP has been identified as a key element that would support the mutual recognition of GMP inspections between the EU and the US. This is the most important EU priority for the TTIP negotiations in the pharmaceutical sector.

In 2016, six JAP audits (Spain, Cyprus, Malta, Croatia, Norway, and Iceland) are planned and likely to be observed by FDA.

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

Amount

EUR 42 000

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) <sup>(52)</sup> 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

<sup>(52)</sup> <http://www.vichsec.org/>

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. 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.

5.3.8. *Organisation and management of the meetings of the Medical Device Coordination Group (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 1 873 000

Description and objective of the implementing measure

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

5.3.9. *Active pharmaceutical ingredients: system audits (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 20 000

Description and objective of the implementing measure

The objective of this action is to ensure thorough system audits in third countries exporting active substances for medicinal products for human use into the EU. These audits 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 111b of Directive 2001/83/EC on the Community code relating to medicinal products for human use <sup>(53)</sup>. The expense of Member State experts participating in the audit will be covered.

5.3.10. *Clinical trials on medicinal products for human use – Union controls (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Amount

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<sup>(53)</sup> OJ L 311, 28.11.2001, p. 67.

EUR 87 000

Description and objective of the implementing measure

This action is about the reimbursement of expenses of Member State experts participating in Commission-led Union controls on both Member States and third countries, as foreseen by Article 79 of the Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use <sup>(54)</sup>. It is a legal obligation to verify whether Member States correctly supervise compliance with this Regulation, and to check the regulatory system applicable to clinical trials conducted outside the Union.

*5.3.11. Commission membership fee to the European Observatory on Health Systems and Policies (Thematic priority 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.

*5.3.12. Scientific committees – Indemnities paid to experts (Thematic priority 3.7. of Annex I to the Programme Regulation)*

Amount

EUR 550 000

Description and objective of the implementing measure

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<sup>(54)</sup> OJ L 158, 27.5.2014, p. 1.

The objective of this action is to provide the Commission with independent and high quality advice on consumer safety and health and environmental risks. This contributes to obtaining a robust scientific basis for EU policies and measures in line with better regulation. The advice is provided by the Scientific Committees in accordance with Commission Decision C (2015) 5383 of 7 August 2015 <sup>(55)</sup>. This action will cover special indemnities which are paid to experts for their work on scientific opinions.

#### **5.4. Actions under objective 4 - Facilitating access to better and safer healthcare for Union citizens**

No action is foreseen in 2016.

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<sup>(55)</sup> Commission Decision C (2015) 5383 of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment  
[http://ec.europa.eu/health/scientific\\_committees/docs/call\\_2015\\_5383\\_decision\\_with\\_annexes\\_en.pdf](http://ec.europa.eu/health/scientific_committees/docs/call_2015_5383_decision_with_annexes_en.pdf)

## ANNEX II

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

*Article 7(2)(b) and Article 8(1) of the Programme Regulation*

**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>(56)</sup> are legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments.

1. 2. Only applications from entities established in one the following countries are eligible:

- EU Member States;

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<sup>(56)</sup> Whenever 'applicants' is written, this means the coordinator and the co-applicants.

- Iceland and Norway;
- Countries which have a bilateral agreement with the European Union, in accordance with Article 6 of Regulation (EU) No 282/2014 on the establishment of a third Health Programme for the Union's action in the field of health (2014-2020). Please check the Commission/Agency website for an updated list of countries.

1.3. 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.

1.4 Applicable **only** to the calls for proposals for projects mentioned under 2.1.4.2 "Rare diseases – support for new registries": Only those applicants whose network and membership applications to become an official European Reference Network in the meaning of Directive 2011/24/EU<sup>57</sup> have been positively assessed and approved are eligible.

## 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

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<sup>(57)</sup> Directive 2011/24/EU of the European Parliament of 9 March 2011, on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45.

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: 7 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)**

*Article 7(2)(c) and Article 8(2) of the Programme Regulation*

**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.

**A call for proposals for framework partnership agreements was launched in 2014. Based on this, framework partnership agreements have been awarded for the period 2015-2017. In 2016 only framework partnership agreement holders will be invited to submit proposals for their Annual Work Programme for 2017.**

**These proposals 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.

Only applications from entities established in one the following countries are eligible:

- EU Member States;
- Iceland and Norway;
- Countries which have a bilateral agreement with the European Union, in accordance <sup>2</sup> with Article 6 of Regulation (EU) No 282/2014 on the establishment of a third Health Programme for the Union's action in the field of health (2014-2020). Please check the Commission/Agency website for an updated list of countries.

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>(58)</sup> in at least half of the Member States),

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<sup>(58)</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 members' organizations 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

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.

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.

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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 members' organizations are not accepted as members of the specialised network.

#### 4. AWARD CRITERIA

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

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.

2. Quality of the proposed activities for 2016 (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.

3. Quality of the proposed budget for 2016 (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)**

*Article 7(2)(a) and Article 8(1) of the Programme Regulation*

**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. A deadline for the official notification will be communicated to the competent authorities.

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 who 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 the functioning of a European Reference Network [ERN] (mono-beneficiary ERN grants) under the third Programme for the Union's action in the field of health (2014-2020)**

*Article 7(2)(c) and Article 8(2) of the Programme Regulation*

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

Grants provided to the coordination, management and non-clinical activities of an approved ERN are mono-beneficiary grants to the co-ordinator of an approved ERN.

**A call for proposals for framework partnership agreements (FPA) will be launched in 2016. Based on this, framework partnership agreements will be awarded for the period 2017-2021.**

**These proposals 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 criteria under one category will be rejected.

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

Financial contributions by the EU may be awarded to the coordination, management and non-clinical activities of approved ERN. Only the network coordinator can apply, not all the members of the network.

The applicant (the ERN network coordinator) must satisfy the following criterion:

The applicant, on behalf of a network, must have applied to be approved as an European Reference Network as established in Commission implementing decision (2014/287/EU)<sup>59</sup> in compliance with the criteria and conditions of Commission Delegated Decision (2014/286/EU).

## 2. EXCLUSION CRITERIA

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

1. The applicant and its network were approved as a European Reference Network (ERN).
2. The applicant organisation is not in any of the situations of exclusion listed in Articles 106 and 107 of the Financial Regulation.

## 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 5 years of duration of the framework partnership agreement. For public organisations the financial capacity will not be checked.

### 3.1. Financial capacity

Applicants must have the financial resources necessary to ensure their functioning for the 5 year duration of the framework partnership agreement.

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

### 3.2. Operational capacity

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

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<sup>(59)</sup> Commission implementing decision (2014/287/EU

## 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 the applicable objectives of the European Reference Networks and 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 approved ERN- (10 points, threshold: 7 points)

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

- Pertinence of the mission, vision and overall purpose of the approved ERN in coherence with the scope and services to be provided by the ERN as defined in the delegated (2014/286/EU) and implementing decision (2014/287/EU).
- The European added <sup>(60)</sup> value of the proposed goals and activities has to be shown in the multiannual work programme of the approved ERN.
- Pertinence of the mission, vision and overall purpose of the ERN and contribution of the multi annual work programme of the approved ERN to achieve the specific objective 4 of the 3rd Health Programme.
- Contribution of the approved ERN to help MS with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality as provided by Directive 2011/24/EU <sup>(61)</sup>.

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<sup>(60)</sup> Commission Implementing Decision (2014/287/EU):

(5) In order to guarantee that the Network has genuine **European Union added value** and is big enough to enable the sharing of expertise and to improve access to care for patients across the Union, only applications from the minimum required numbers of healthcare providers and Member States, submitted in line with the call of interest, should be approved. If an insufficient number of healthcare providers apply or applications cover an insufficient number of Member States, the Commission should ask Member States to encourage their healthcare providers to join the proposed Network.

(11) Using a common evaluation manual, an independent evaluation body appointed by the Commission should periodically evaluate Networks and their Members. The evaluation should conclude with a technical evaluation report detailing the extent to which the objectives set out in Article 12(2) of Directive 2011/24/EU have been achieved and the criteria and conditions set out in Delegated Decision 2014/286/EU fulfilled. It should also describe the outcomes and performance of the Network and the contribution of its Members. A negative evaluation report should generally prompt Member States to approve the termination of a Network. Compliance with the requirement to have a minimum number of healthcare providers and Member States should be monitored after the evaluation so that the European Union added value of the Network can be maintained.

<sup>(61)</sup> Directive 2011/24/EU article 12, 2 (h)

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:

- Quality of the operational framework.
- Pertinence of the proposed goals and activities of the multiannual work programme of the approved ERN.
- Quality of the evaluation strategy of each ERN.
- Quality of the internal and external activities and implementation plan regarding the pooling of knowledge, the mobility of expertise, the development, sharing and dissemination of information, knowledge and best practices.

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 proposals 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.

1. **Coherence with the 5-year work programme** annexed to the FPA (10 points, threshold: 7 points)

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

- Relevance of the proposal to achieve the multi-annual objectives.
- Purpose of the annual work plan.

2. **Quality of the proposed activities** for 2017 (10 points, threshold: 7 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 internal and external activities and implementation plan regarding the pooling of knowledge, the mobility of expertise, the development, sharing and spreading information, knowledge and best practices.
- Quality of the implementation of the activities and the operational management.

3. **Quality of the proposed budget** for 2017 (10 points, threshold 7 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 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)**

#### *Article 7(2) and Article 8 of the Programme Regulation*

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>(62)</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>(63)</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>(62)</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>(63)</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, mono-beneficiary ERN grants and actions co-financed with Member State authorities applications under the third Programme for the Union's action in the field of health (2014-2020)**

*Article 7(2) and Article 8(1) of the Programme Regulation*

#### 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.

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

1. At least 25 % of the members of the non-governmental bodies<sup>(64)</sup> or candidate members of the non-governmental bodies come from Member States whose gross national income (GNI)

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<sup>(64)</sup> Definition of 'member of non-governmental body': 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. National members are counted in the same manner as pan-European/umbrella organization members. Members of the applicant's members' organizations are not accepted as members of the applicant.

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 MONO BENEFICIARY ERN GRANTS

1. At least 25 % of the members of the ERN 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 highly specialized healthcare providers from Member States with a low GNI.

2. The mission and the annual programme of the ERN include activities aiming at foster capacity building such as organising training activities, contributing to the pooling of knowledge and collaborating closely with other centres of expertise and networks.

#### 5. 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.

## ANNEX VIII

### Criteria for financial contributions in the form of prizes

#### *Article 7(1) of the Programme Regulation*

**The Financial Regulation (in particular Article 138) and its Rules of Application are applicable for the implementation of the Health Programme.**

**Applications will be evaluated on the basis of three categories of criteria:**

1. Eligibility criteria, to assess the applicant's eligibility,
2. Exclusion criteria (Articles 106 (1), 107 (1) and 138 (2) of the Financial Regulation),
3. Selection criteria, to assess the ability of the applicant (Article 132 (1) of the Financial Regulation and Article 202 of the Rules of Application).
4. Award criteria, to assess the quality of the proposal (Article 132 (2) of the Financial Regulation and Article 203 of the Rules of Application).

#### 1. ELIGIBILITY CRITERIA

1. The applicant is a legally established non-governmental body, non-profit-making and independent from industry, commercial and business or other conflicting interests
2. The applicant acts at European, national or sub-national level.
3. Only applications from entities established in one the following countries are eligible:
  - a) EU Member States.
  - b) Iceland and Norway;
  - c) Countries which have a bilateral agreement with the European Union, in accordance with Article 6 of Regulation (EU) No 282/2014 on the establishment of a third Health Programme for the Union's action in the field of health (2014-2020). Please check the Commission/Agency website for an updated list of countries.
4. Only applications from single applicants are acceptable (with or without partners).
5. The application is complete (application form filled).
6. The applicant clearly addresses one of the topics listed in the call for applications:

7. The application is submitted in English. If it is in another EU language, a translation into English is provided.

## 2. EXCLUSION CRITERION

The applicants are not in any of the situations of exclusion listed in Articles 106(1) and 107 of the Financial Regulation.

## 3. SELECTION CRITERIA

- The mission of the applicant organization is in-line with at least one of the objectives of the 3<sup>rd</sup> Health Programme
- The applicant actively seeks to shape public health affairs on the basis of their own concerns, drawing from their own specific knowledge, abilities and scope of action.

## 4. AWARD CRITERIA

Only applications which meet the eligibility, exclusion and selection criteria will be further assessed on the basis of the award criteria with a maximum of 100 points.

### 4.1. Policy and contextual relevance (30 points)

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

- The good practice contributes to at least one of the thematic priorities defined in the Annex 1 of the 3<sup>rd</sup> Health Programme,
- The good practices provides added value at EU level in the field of public health,
- The good practice considers the social, cultural and political context.

### 4.2. Technical quality (70 points)

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

- Relevance: the good practice addresses an important public health concern and corresponds to the needs of the population group.
- Effectiveness: the good practice produces expected measurable results, improved the target group situation and has a potential long term impact.
- Transferability: the good practice can be applied in another Member State or at EU level.
- Sustainability: the good practice can be prolonged over a long period of time without massive injection of additional resources.
- Intersectional collaboration: the good practice encourages synergies with other fields.

- Innovation and creativity: the good practice has an innovative and/or creative approach with regards to target audience, business processes carried out or outcomes utility.

Following the evaluation, only proposals which score a minimum of 50% of the total points under the award criteria may be considered for financing.