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ANNEX I TO VII

ANNEX I

Public Health Programme - Work Programme for 2015

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') ⁽¹⁾ for the year 2015.

It is based on Article 168 of the Treaty on the Functioning of the European Union (TFEU) and ensuing legal obligations and policy commitments. Article 168 of the TFEU sets out the scope of EU action in the area of public health which is to carry out actions to support, coordinate or supplement the actions of the Member States.

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:

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

The EU Health Strategy ⁽²⁾ provided a policy framework for all the areas covered by this work programme. The 'Investing in health' Staff Working Document ⁽³⁾ of February 2013

⁽¹⁾ 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

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

linked this policy framework more closely to the broader Europe 2020 strategy. More specifically, it stressed the necessity to invest in sustainable health systems, invest in people's health and invest in reducing health inequalities.

The 2015 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. Actions under the four specific objectives and the thematic priorities in the programme decision support the priorities of the Commission to boost economic growth and job creation, address crisis situations like pandemics, stimulate innovation, and attract more investment. Actions under the programme, contribute to improving the sustainability of health systems and accessibility of healthcare, and ensure that medicinal products are safe. Actions to further invest in health promotion, health protection and disease prevention, enabling people to remain productive and active and limiting the costs linked to the treatment of preventable diseases, are also considered.

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

- Complements, supports and adds value to the policies of Member States aimed at improving the health of Union citizens and reducing health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border threats to health.
- Focuses on the key issues where Europe can deliver added value and impact positively in delivering mutual benefits across the European Union.

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

(³) 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.

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 2015 as follows:

for grants (implemented under direct management): EUR 35 415 000
for prizes (implemented under direct management): EUR 60 000
for procurement (implemented under direct management): EUR 16 423 805
for other actions: EUR 3 731 000

The total available amounts to EUR 55 629 805 for 2015 ⁽⁴⁾.

2. GRANTS

2.1. Grants for projects

Under the overall operational budget reserved for grants, EUR 9 000 000 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. Gathering knowledge and exchanging best practices on measures reducing availability of alcoholic beverages (Thematic priority 1.1. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

⁽⁴⁾ This amount corresponds to the amount available on budget line 17.03.01 + 3 % EFTA contribution.

Heavy episodic drinking and youth drinking, including underage drinking, are of particular concern in Europe. 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. It should generate and promote new and innovative good practices targeting the reduction of heavy episodic drinking amongst young people and encourage networking for building EU and national capacities to successfully reduce availability of alcoholic beverages.

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 reducing heavy episodic drinking amongst young people in different settings and different Member States through measures reducing availability of alcoholic drinks. The activities would also analyse the impact of such measures reducing availability (in terms of reducing harmful alcohol use, in particular heavy episodic drinking amongst young people). Priority should be given to initiatives aiming at identifying good practices targeting young people among the lowest socioeconomic groups and 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 2015	EUR 1 700 000

2.1.1.2. Early diagnosis and treatment of viral hepatitis (Thematic priority 1.3. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

Hepatitis B/C infection is a significant health burden in Europe. New treatment schemes are available which can ensure high cure rates. The objective of this action is to support EU Member States to improve access to hepatitis testing for those at risk and access to affordable high quality treatment with antivirals and to further specify appropriate prevention methods to prevent (re-)infections.

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

The activities will support the development of national hepatitis strategies, screening and treatment guidelines, taking into account available treatment options. It will help to bridge primary, secondary care, and outreach, in the community including prison health services, to facilitate access to and uptake of testing, vaccination and treatment services particularly among key risk groups including drug users, prisoners, homeless, men who have sex with men, sex workers and people living with HIV/AIDS. It will also assess the potentially considerable economic impact of available treatment, testing strategies and vaccination options on health systems, which are under the responsibility of the EU Member States, with a view to inform decisions on balancing access to medicines and vaccines with the financial sustainability of health systems. They will build on work undertaken by the European Commission, the European Centre for Disease Control and Prevention, and the European Monitoring Centre for Drugs and Drug Addiction with the aim of reducing morbidity and mortality related to hepatitis B and C, and reducing new transmissions and the socioeconomic impact of hepatitis in the EU/EEA.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2015	EUR 1 600 000

2.1.1.3. Early diagnosis of tuberculosis (Thematic priority 1.3. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

Tuberculosis (TB) is not only a persistent public health challenge, but also a far-reaching social, economic, and cross-border health threat having substantial cross-linkages in terms of co-morbidities with other conditions particularly HIV/AIDS. The epidemiological context in the EU includes high or intermediate levels of TB in some Member States, and low levels of TB in other Member States with significantly increased incidence amongst vulnerable population groups in some urban areas of countries. The objectives of this action are to address the high disease burden particularly amongst vulnerable groups such as migrants, homeless, prisoners and people who inject drugs and to strengthen national capacities in tuberculosis prevention and control.

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

The activities aim at improving early diagnosis, strengthening integration of care, and outreach strategies in the community and in prison settings, and will draw on evidence and best practice from low- and high-incidence countries. They will furthermore strengthen national TB responses by supporting the development and implementation of national strategic plans and guidelines with a particular focus on improving the control of multi-drug-resistant (MDR) TB and the implementation of evidence based, state of the art diagnostics and treatment options. The action will facilitate collaboration amongst EU Member States particularly in relation to vulnerable groups including migrants, homeless, prisoners and people who inject drugs with a view to support access to and continuity of care. They will link to activities undertaken by the European Centre for Disease Prevention and Control to address the TB situation in high incidence countries and the work on interventions for tuberculosis prevention and control in hard to reach and vulnerable populations.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2015	EUR 1 900 000

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

No action is foreseen in 2015.

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

2.1.3.1. Support for the implementation and scaling up of good practices in the areas of integrated care, frailty prevention, adherence to medical plans and age-friendly communities (Thematic priority 3.5. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

The European Innovation Partnership on Active & Healthy Ageing ('The Partnership') was selected as a pilot to tackle the challenge of an ageing population within the Innovation Union, one of the flagship initiatives of the Europe 2020 strategy, and it is now in the implementation phase. The aim of this action is to build on the preliminary results of the Partnership, in the areas of integrated care, frailty prevention, adherence to medical plans and age-friendly communities. This action will facilitate the implementation and scaling-up of good practices at local, regional or country level or the exchange of good practices between Member States, supporting the potential of innovation in health and social care by encouraging the integration

of health and care and highlighting independent living and participation in the community. The results of this action should show the benefits of moving towards community based health and social care which enables older people to remain active and healthy for longer as well as providing efficient care and treatment when needed. The results will also contribute to an informed decision-making at European level.

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

Building upon previous work conducted in these areas, the activities to be addressed will include: (i) identification of benchmarks focusing on successful local interventions with high transferability potential and (ii) support to the twinning, coaching, and/or scaling up of identified good practices on: integrating health and social care in age-friendly community settings; community programmes implementing tools and European guidance on age-friendly communities that use a participatory approach and respond to needs of older people; integrated community-based approach programmes for the screening, assessment, prevention and management of frailty in older people, and development of interventions for adherence to treatment and medical plans, in particular involving health care professionals, patients in the community, caregivers and community pharmacies.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2015	EUR 2 500 000

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

2.1.4.1. Common assessment methodology on quality, safety and efficacy of transplantation therapies (Thematic priority 4.5. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

This action aims to build a common assessment methodology to allow academics, health professionals and authorities to assess and verify safety, quality and efficacy of (new) transplantation therapies and/or other type of clinical applications of human tissues and cells (e.g. assisted reproductive technologies). An increasing number of discussions in the area of substances of human origin (SoHO), especially in the tissue and cell transplantation sector showed that there is an acute need to improve the common understanding of safety, quality and efficacy issues. These relate not only to processes and techniques for the preparation of tissues and cells, but also to their clinical application. In addition to the safety of the donated material, appropriate methodologies/tools for establishing the relation between the quality of

tissues/cells and the efficacy of a specific application are needed. This improved and shared understanding is important for an optimal use of a limited resource such as human tissues and cells.

Therefore, in the context of a fast-paced technological progress, developing appropriate methodologies/tools for ensuring high quality, safety and efficacy standards for the tissues and cells for clinical application is of utmost importance.

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

The activities should develop a framework for assessing and verifying the quality, safety and efficacy of therapies with human tissues and cells. They should include criteria, parameters and methodologies for evaluation. An important focus will be on implementation, i.e. how these parameters and methodologies can be used by clinical actors in their daily practice to assess the quality, safety and efficacy of the tissues/cells clinical applications. The activities should include testing and validation of the proposed framework through prospective and/or retrospective studies. They should include measures to ensure that such a framework can be made available to and shared amongst the clinical actors in the field. They should consult all interested stakeholders, including professional societies and Member States competent authorities in order to ensure the acceptability of the proposed framework at all levels.

To the extent possible/necessary this action should also cover blood and blood components.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Publication of the call for proposals	First semester of 2015	EUR 1 300 000

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

Under the overall operational budget reserved for grants, EUR 17 850 000 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

No action is foreseen in 2015.

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

No action is foreseen in 2015.

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

2.2.3.1. Health Technology Assessment cooperation (Thematic priority 3.1. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

The objective of this action is to support voluntary cooperation at scientific and technical level between Health Technology Assessment Bodies to validate the model for joint work to be continued after EU funding under the Health Programme ends. The cooperation between national and regional HTA Bodies is essential to meet the provisions set out by Article 15 of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare ⁽⁵⁾ and to create synergy with the strategic HTA Network set up under this Directive.

This cooperation should increase the use, quality and efficiency of joint HTA work at European level to support evidence-based, sustainable and equitable choices in healthcare and health technologies and ensure reuse in regional and national HTA reports and activities, in order notably to avoid duplication of assessments, in accordance with Article 15((2)(d) of the Directive.

The cooperation is expected to result in improving use, quality and efficiency of HTA work at national and EU level by: (i) improving joint assessment of clinical evidence and increasing production of HTA joint work, including reports produced at EU level for reuse at national and regional level; (ii) increasing the capacity and know-how in the HTA Bodies; (iii) improving shared understanding of qualitative and methodological issues of HTA; (iv)

⁽⁵⁾ OJ L 88, 4.4.2011, p. 45.

increasing the interaction between HTA and regulatory requirements; and (v) defining a sustainable model after EU funding under the Health Programme ends.

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 ⁽⁶⁾

Building on results achieved so far by the previous Joint Action (EUnetHTA 2012-2015) and the HTA Network strategy of October 2014, this action will be taken forward by national bodies mandated in this field to define a sustainable working model for all Member States willing to cooperate on HTA.

The action will:

(i) strengthen the production of scientific joint work resulting in reports, guidelines and joint scientific initiatives. This action will aim at addressing 50 health technologies/year, notably promising but high costs technologies, with lower numbers in the first years and then growing through the life of this action. Combined teams of EU and national staff within the HTA bodies would support the production of joint work;

(ii) support the generation of evidence appropriate for HTA purpose, including early dialogues scientific advice to technology developers;

(iii) ensure quality of joint work by sufficient quality management and standards and promote the use of the results of joint work, in particular reports, in national and regional HTA activities;

(iv) maintain and update relevant supporting tools, such as IT tools, training and communication material;

(v) provide administrative coordination support; and

(vi) define working processes between the participating HTA Bodies, including possible legal adaptations which may be necessary to implement a mechanism sustainable without EU funding in due consideration of article 15(7) of Directive 2011/24. The action shall explore potential options, including considerations of how to make the best use of existing bodies which could facilitate cooperation, efficiency gains and scientific synergies. The joint action is expected to associate EMA.

To support i) and ii) the joint action will aim at coordinating national activities on collection of real world clinical evidence to measure the effectiveness of technologies and treatments. The need is particularly acute for promising, but expensive technologies. The PARENT joint action is about to deliver methodological guidelines on setting up and management of patients registries which can be of major added value to collect such real world data. The guidelines will be tested in the HTA joint action through concrete well established or emerging technologies, in cooperation with the pharmaceutical and medical devices regulators, technologies developers, payers and relevant research initiatives of H2020 and IMI.

Implementation

⁽⁶⁾ OJ L 362, 31.12.2012, p. 1.

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 2015	EUR 12 000 000

2.2.3.2. Prevention of frailty (Thematic priority 3.5. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

This action builds on the results of the European Innovation Partnership on Active & Healthy Ageing, and on the Prevention of Frailty Action Group which was launched in 2012 and on the Joint Action on Chronic diseases. People in the EU are living longer, but many are living with one or more long-term medical condition and for a significant number of them, advancing age brings disability, frailty and/or chronic diseases. These terms are commonly used interchangeably to identify vulnerable older adults. However, there is a growing consensus that these are distinct clinical entities that are causally related, are often associated and overlapped but are not exchangeable. The distinction and adequate use of the three entities can improve our understanding of the chronic health problems affecting older people and lead to development of improved strategies to address them at multiple levels including primary, community, hospital and social care. Across the EU, frailty is a common and growing multidimensional health and social care challenge associated with an increased risk of physical, cognitive and functional decline and adverse health outcomes in the ageing population. The objective of this action is the identification for pre-frail conditions, such as malnutrition and lack of physical activity, and targeting frail older people for appropriate interventions, including promoting better health and reduction of avoidable hospitalizations and better long-term care. The action also responds to the 2014 Council Conclusions on 'Nutrition and Physical Activity' which sought to promote actions and strategies on Active & Healthy Ageing, and the 2014 Social Protection Committee's Long Term Care report which underlined the urgency to understand the risk factors for frailty as a pre-requisite for early detection, prevention and management to reduce future demand of long term care. This action will contribute to the reduction of disability and dependence and at large will prevent growing burden of chronic diseases in terms of health care demands. It will improve our understanding of long-term care medical conditions affecting older patients, including chronic diseases, and lead to development of improved strategies for diagnosis, care, research, and medical education for frailty, disability and multimorbidity. It will contribute to a more effective response to the needs of older people including gender sensitive aspects and reduce the burden of inefficiency in care delivery through self-management care planning and coordination, innovative organisational approaches and better combinations of professional and informal care.

The multifactorial nature of the causes of frailty is methodologically difficult and highly

resource intensive to study. Frailty has emerged as a key new topic, related to chronic diseases, which is underrepresented in current policy agendas, and continued underrepresentation could potentially undermine EU health and care systems. Neglecting frailty would be to neglect a large opportunity for the EC to support an action with clear European added value by alleviating the burden of chronic diseases in years to come.

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

Successful prevention of frailty requires knowledge about the risk factors as well as better definitions of risk groups and evidence-based interventions that can be offered earlier and tailored to individual's needs. The traditional approach to chronic diseases among older people largely ignores frailty. This Joint Action will foster a holistic approach to long-term conditions of the elderly that addresses frailty and its relationship with chronic disease. In addition, there is strong evidence of the usefulness of the concept of frailty as an important predictive factor of undesirable outcomes, (e.g: recurrent hospitalizations, disability, malnutrition, falls, death) independent of chronic diseases in populations of older adults. The activities of this action to be taken forward by national bodies mandated in this field will focus on building a common understanding on frailty, developing and validating tools, and the preparation of common guidelines or frameworks for preventing frailty and chronic diseases in hospitals, primary care and community setting. The action will identify frailty prevention actions at clinical level and population level. It should develop the concept of the 'Prevention of Frailty Approach' in health and social care services, by encouraging consensus on an evaluation tool for pre-frailty and frailty in the clinical and community settings, develop guidelines or frameworks on screening, prevention, assessment and management of frailty, and develop and support implementation of early diagnosis of frailty and screening programming of frailty risk factors, including malnutrition. It will consist of three activities: (i) building a common understanding on the concept and operative definition of frailty versus chronic diseases interventions; (ii) developing methodology and tools for assessment of pre-frail and frail people; and (iii) preparing common health care guidelines or frameworks on screening, assessing, and intervening to promote better health in older people and reduce the growing burden of health care demands related to frailty and chronic diseases.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First semester of 2015	EUR 3 500 000

2.2.3.3. Market surveillance of medical devices (Thematic priority 3.6. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

The conclusions of the Staff Working Document on the PIP (Poly Implant Prothèse) Action Plan discussed at the EPSCO Council on 20 June 2014 highlight the need for more developed and coordinated market surveillance of medical devices by Member States competent authorities. A pilot joint action with this aim was foreseen to be carried out under the 2014 Annual Work Plan. Member States have indicated their wish to develop this further with a larger scale action.

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 to be taken forward by national bodies mandated in this field will promote co-operation between Member States allowing development of best practice, training and knowledge and resource sharing concerning the implementation of the medical device legislation, in particular in relation to Member States tasks such as the market surveillance of devices.

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 2015	EUR 850 000

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

2.2.4.1. Rare cancer (Thematic priority 4.2. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

Around 4.3 million people in the EU are affected by rare cancers and around 500,000 new cases (22% of all cancers diagnosed) are diagnosed every year from the 186 identified rare cancers. Childhood cancer is the main cause of disease-related death in children. In contrast to cancer in adults, virtually all cancers in children are rare, but severe. Approximately 40,000 children are diagnosed with cancer every year in the EU. These tumours pose special burdens on patients, requiring diagnostic and treatment expertise. The first objective of the proposed

action is to establish methodologies for consensus guidelines on multi-disciplinary treatment on a selected pilot list of rare cancers (for children and adults). These methodologies should be complementary to the work developed by the FP7 RAREBESTPRACTICES project ⁽⁷⁾ as well as with the European Expert Paediatric Oncology Reference Network for Diagnostics and Treatment (ExPO-r-NeT) ⁽⁸⁾ Health Programme Project. The second main objective is to formulate recommendations to introduce rare cancers into the National Cancer Plans and the National Rare Diseases Plans. Other objectives should be to develop a definition of rare cancers based on incidence and to map resources. The action should make recommendations and develop strategies to overcome difficulties related to rare cancers like finding clinical expertise and accessing appropriate treatments, carrying out clinical studies due to the small number of patients, possible lack of interest in developing new therapies, high uncertainty in clinical decision-making, and the scarcity of available registries and tissue banks. It should be also considered that the existing EU frameworks on prevention and screening are normally not applicable to rare cancers.

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 provide a platform for competent national authorities, involving specialised institutions, scientific and professionals bodies and patient's organisations in Member States with the mission to produce recommendations on policy developments in order to: (i) recommend a consensual and operational definition on rare cancers analysing the impact of this in aspects related to registers, orphan medicinal products policy, etc.; (ii) spread knowledge and good practice guidelines on rare cancers with a view to ensure timely and appropriate diagnoses and care and to reflect this in the National Plans for cancer and rare diseases; (iii) address obstacles to patients' access to appropriate therapies; (iv) involve the disease-oriented communities (of both researchers and patients) in the development, approval and assessment of new therapies; (v) development of a European reference network concept for the treatment of patients with rare cancers across the EU; and (vi) provide tools and establish frameworks that are appropriate for supporting a joint patient-physician decision-making process in conditions of high uncertainty, which often occur in the treatment of rare cancers. The findings of the action should be presented and largely disseminated in a European Conference on Rare Cancers at the end of the action.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Signature of the grant awarded without a call for	Second semester of 2015	EUR 1 500 000

⁽⁷⁾ http://www.rarebestpractices.eu/pagine-1-project_description

⁽⁸⁾ <http://www.siope.eu/activities/eu-projects/expor-net/>

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

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

Operating grants are calculated based on eligible costs incurred. The maximum rate for EU co-financing is 60 %. However, this may go up to 80 % if a proposal meets the criteria for exceptional utility set out in Annex VII. Annex VI contains the criteria for independence from industry, commercial and business or other conflicting interests.

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 ([¹]).

In 2015, no call for proposals will be organised as a result of the conclusion of framework partnership agreements (FPA) for a duration of maximum 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 2015 they will be invited to submit an application for a specific grant agreement for 2016. This will include the annual work programme and the budget. Having received an FPA does not guarantee annual co-funding.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Invitation to FPA holders, SGA awarded on a competitive basis	Second semester of 2015	EUR 4 650 000

(¹) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF>

2.4. Presidency conference grants – De jure monopoly

According to Article 190(1)(c) of Delegated Regulation (EU) No 1268/2012 ⁽⁹⁾, grants can be allocated without a call for proposals to organisations in a de jure or de facto monopoly situation, duly substantiated in the award decision.

Presidency conferences, which are highly political in nature and involve representation at the highest national and European levels, are to be organised exclusively by the Member State holding the Presidency of the European Union. Given the unique role of the Presidency in the framework of EU activities, the Member State responsible for organising the event is considered as having a de jure monopoly.

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

The Presidency conferences to be financed under this work plan are a conference on ‘Personalised medicine’ planned under the Luxembourg Presidency and a conference on ‘Antimicrobial resistance’ under the Dutch Presidency.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
Direct award	Second semester of 2015 and First semester of 2016	EUR 200 000 (total amount available)

2.5. Direct grant agreements with international organisations

The overall budgetary allocation reserved for actions implemented via direct grants to international organisations amounts to EUR 2 715 000. 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.

⁽⁹⁾ OJ L 362, 31.12.2012, p. 1.

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.

— 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. 'Economics of prevention' – Grant to the OECD (Thematic priority 1.1. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

<p>This action deals with the cost-effectiveness analysis of health prevention policies. It aims to contribute to the fine tuning of existing actions and initiatives addressing major health determinants including lifestyle (nutrition and physical activity, sexual health, accidents and injuries), addiction-related (tobacco, alcohol, drugs), socio-economic and environmental</p>
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determinants.

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

This action deals with the development of a conceptual framework on the economics of health prevention policies. It will also explore the scope and potential for government intervention as well as methods for assessing prevention programmes with focus on nutrition and alcohol.

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 2015	EUR 600 000

2.5.1.2. EU Health Report 2016 – Grant to the OECD (Thematic priority 1.6. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

The European Commission will publish a report on the European health every second year. The objective for this action is to provide updated and objective health information and analysis on the health status of the EU citizens. This publication will provide updated health data and health information based on the European Core Health Indicators (ECHI).

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 Directorate General in charge of health matters will lead the initiative at the Commission level. The OECD will contribute to the Health Report 2016 with its analytic expertise in order to ensure continuity with the Health at a Glance Europe 2014. Other Commission services may be involved.

Implementation

Implementation by the Agency

Indicative timetable and indicative amount

Reference	Date	Amount
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Signature of the grant awarded without a call for proposals	Second semester of 2015	EUR 375 000
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2.5.2. Actions under objective 2 – Protecting Union citizens from serious cross-border health threats

No action is foreseen in 2015.

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

2.5.3.1. Health workforce – Grant to the OECD (Thematic priority 3.3. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

Building on the findings of Action 2013 52 01 (OECD: Co-operation on key areas for work of the Health Committee of the OECD), this study would explore the feasibility of carrying out a sector-specific survey of the skills of health professionals. Previous research by the OECD finds that while available data point to significant levels of skills mismatch, currently no data source provides a sufficient sample size to analyse in depth the level of skills mismatch of different types of health professionals in a way that would allow for robust comparisons between different countries. Given the high political interest signalled by both EU and OECD member states and stakeholder organisations to improve policy analysis in this area, a specific survey of health professionals' skills would add value to policymakers across EU and OECD 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 feasibility study would assess the potential benefits and costs of various options for a health sector-specific skills survey, begin to identify possible contents (modules and questions) for a short, medium and long versions of the survey, and identify possible next steps to move towards implementation.

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 2015	EUR 150 000

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

Priorities of the year, objectives pursued and expected results

This activity 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

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

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

2.5.4.1. *Antimicrobial resistance – Grant to the OECD (Thematic priority 4.4. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

Antimicrobial resistance (AMR) is not solely a public and animal health threat. It has also an economic impact 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 affecting labour productivity, output and economic growth ⁽¹⁰⁾. Better estimates of AMR's current and estimated economic impact are needed to provide an appropriate base for determining the proper level and balance of required investments and measures to address AMR by governments and society. Moreover, better estimates will help to evaluate the cost-effectiveness of measures to address AMR. The overall objective of the study will be to: 1) assess the economic burden and health impact of AMR infections and 2) evaluate the cost/effectiveness of the potential prevention and control measures.

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 will be divided in three phases, during which the following activities will be carried out: Phase I: (i) discussion and selection of most suitable economic models to evaluate the repercussions of AMR (literature review, discussion of the different economic models, adaptation of models); (ii) identification of key parameters to measure the direct cost of AMR infections; and (iii) identification of key parameters to establish the indirect economic burden of AMR including the societal impact. Phase II: (i) selection of the sources of the relevant data to measure direct and indirect cost of AMR, starting from the European Antimicrobial Resistance Surveillance Network (EARS-Net), but ensuring the applicability of the WHO AGISAR and other relevant official approaches for the collection of data. Phase III: (i) identification of potential prevention and control measures, general ones and ones targeted at particular microorganisms and estimation of costs; and (ii) evaluation of the cost-effectiveness of the prevention and control measures. Furthermore, a web-platform for OECD members to participate in this project should be developed (allow possible future extension to non OECD members in the future).

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 2015	EUR 340 000

⁽¹⁰⁾ In 2009, ECDC and the EMEA published a joint technical report with initial estimates of the direct and indirect costs for the EU, Iceland and Norway of healthcare-associated infections due to five types of multidrug-resistant bacteria (http://www.ecdc.europa.eu/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf)

2.5.4.2. *Data and analysis of data on patient safety, within the OECD 'Health Care Quality Indicators' Project – Grant to the OECD (Thematic priority 4.6. of Annex I to the Programme Regulation)*

Priorities of the year, objectives pursued and expected results

The objective of OECD work on patient safety has been to develop and test international comparable indicators on patient safety. The OECD project 'Health care quality indicators' (patient safety) is related to data collection and analysis of patient safety indicators. The work on patient safety indicators is envisaged by the Council Recommendation 2009/C 151/01 (point 5b) and the participation of the Commission in the work on patient safety indicators at the OECD is the response to this.

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

The action will assess whether further refinements to the definition and exclusion criteria are justified in order to improve the international comparability of data on patient safety indicators and whether the broadening from hospital based PSI's towards safety indicators related to outpatient care based on medication prescription data can be assured. Although significant progress has been made in ensuring the reliability of the data, underlying differences in the reporting 'culture' of a country and differences in administrative databases still affect comparable reporting on patient safety as part of Health System Performance reporting. In addition, detailed analysis of potential differences in the coding systems and practices remains essential for enhancing comparability. Likewise, the growing evidence on the validity of Patient Safety Indicators, both hospital and outpatient based, is systematically monitored, taking into account ongoing research in EU member states. Progress is regularly presented and discussed in OECD's Health Care Quality Indicator expert group and reported in Health at a Glance.

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 2015	EUR 150 000

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

The overall budgetary allocation reserved for actions implemented through grant procedures via a cross sub-delegation to Eurostat amounts to EUR 1 000 000. The budget line is 17.03.01.

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

These grants are calculated on the basis of eligible costs incurred. In 2015, the maximum rate for EU co-financing may be up to 70 % due to the exceptional utility of the actions 2.6.1. and 2.6.3. as justified hereinafter. Annex V contains the eligibility, exclusion, selection and award criteria for these grants.

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

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

- Non-expenditure health care statistics: Methodological work has already started and a list of potential compulsory variables should be selected for compulsory reporting. However, further assistance to Member States is needed to prepare the implementation of non-expenditure health care statistics on a mandatory basis.

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

2.6.1.1. Morbidity statistics – Cross sub-delegation and Service Level Agreement with Eurostat Services (Thematic priority 1.6. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

The Regulation on health statistics (No 1338/2008) ⁽¹²⁾ gives an overall legal framework for health data including morbidity. This action is a follow-up of previous Eurostat projects since 2005 on implementing morbidity statistics within the European Statistical System (ESS) and will contribute to the generation and dissemination of health information and knowledge within the third Health Programme.

⁽¹¹⁾ OJ L 87, 31.3.2009, p. 164.

⁽¹²⁾ OJ L 354, 31.12.2008, p. 70.

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 deal with the inventory of the sources and methods in view of producing best national estimates for predefined morbidity indicators. The inventory on the current national situation will have to include the identification of major national obstacles (data accessibility and ownership, conflicting confidentiality rules, lack of expertise in modelling or data linkage, etc...) as well as the possible solutions for overcoming them.

Implementation

Implementation by the Commission

Indicative timetable and indicative amount

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

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

No action foreseen in 2015.

2.6.3. Actions under objective 3 – Contributing to innovative, efficient and sustainable health systems

2.6.3.1. Non-expenditure health care statistics – Cross sub-delegation and Service Level Agreement with Eurostat Services (Thematic priority 3.7. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

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

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

This action will deal with the testing of the feasibility of providing core non-expenditure health care variables (covering health employment and education, health care activities and physical and technical resources) according to agreed definitions and recommendations for best estimates at national level.

Implementation

Implementation by the Commission

Indicative timetable and indicative amount

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

2.6.4 Actions under objective 4 – Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the ‘health in all policies’ principle

No action foreseen in 2015.

3. PRIZES

The overall budgetary allocation reserved for prizes in 2015 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 Health Policy Forum, as one of the three axis, a Health Award will be organized. The award will reward and highlight good practices of international, 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.

International, European, national and sub-national stakeholders will be identified with this award. Thus, the award will continue to raise awareness of the 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 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	Second semester of 2015	EUR 60 000

4. PROCUREMENT

The overall budgetary allocation reserved for procurement contracts in 2015 amounts to EUR 16 423 805. 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. Tobacco prevention and passive smoking (Thematic priority 1.1. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

This action has two aspects. **1) Communication:** Capitalising on the communication strategies and instruments of the previous EU anti-tobacco campaign, the activities proposed should support events and other communication activities to promote smoking cessation targeting in particular young adults aged 25-34. The contractor should propose a comprehensive and coherent communication plan, based on a coherent and creative concept adapted to the topic and the target group and taking into account specific circumstances within Member States. The particular background of EU-wide communication action in the field should also be considered as well as smoking cessation activities being undertaken by different actors in Member States. **2) Technical assistance:** iCoach is an innovative web-based tool, tailored to individuals, to accompany and help them to give up smoking. It is an interactive smoking cessation tool provided to obtain the overall goal of the anti-tobacco campaign. All campaign activities were conducted to get people to sign-up to the programme.

Hence, iCoach is the central element of the campaign and the most important key performance indicator. The contractor should build on the more than 430.000 registrations and the data base generated to date and provide the services needed to run this tool. The contractor should also analyse the iCoach data as a source of information supporting/guiding EC policymaking.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2015

Implementation

Implementation by the Commission

4.1.2. EU Health Policy Forum or similar cross cutting stakeholder activities (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 the development and maintenance of a new format of the Health Policy Forum. The new platform will ease multilateral communication and active engagement amongst stakeholders, between the different stakeholder groups and also with the Commission. It will also serve as a way to allow cross-sectorial in-depth debates, creating synergies amongst stakeholders, leading to a more cohesive discussion on topics of interest for the health community. This will further create a direct bridge to citizens' organizations in some of the topics that most directly matter to the public. This action includes: (i) development and maintenance of IT Platform; (ii) preparation of the EU Health Policy Summit; and (iii) preparatory work for the contest in the field of health to be implemented via this platform.

Type of contract and type of procurement

Specific contracts based on existing framework service contracts

Indicative number of contracts envisaged: 4

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Commission

4.1.3. Surveys and target prevention projects for training of health professionals in the area of HIV/AIDS (Thematic priority 1.3. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Studies: The objective of this action is to improve knowledge about the prevention needs of priority groups, to identify barriers for access to prevention and health services and to develop targeted prevention programmes and training of health professionals. The action will support the performance of European surveys and studies on behavioural surveillance and prevalence of HIV/AIDS and STIs, as well as co-infections among the most at risk groups (men who have sex with men, intravenous drug users, migrants, sex workers, prisoners, people living with HIV/AIDS and co-infections such as hepatitis and tuberculosis). The results of the surveys and studies will support the definition of strategies and capacity building to tackle HIV/AIDs and co-infections as well as drug harm health related issues, through the implementation of targeted and integrated prevention actions. These will include the development of training programmes for health professionals in order to: increase early diagnosis and treatment of HIV/AIDS, decrease stigma and discrimination in health care setting, improve access to health services for migrants and ethnic minorities including Roma, and improve the availability and quality of counselling services for people living with HIV/AIDS.

Type of contract and type of procurement

Direct service contracts

Indicative number of contracts envisaged: 2

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Agency

4.1.4. Conceptual and structural work towards the development of a European approach on chronic diseases (Thematic priority 1.4. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

The Commission intends to establish cooperative structures that support the development of an EU approach on chronic diseases. Thus, as follow-up to the ‘Reflection process’ and the ‘EU summit on chronic diseases’, the intention is to steer the response to chronic diseases at the EU level, actively react to the requests of Member States and stakeholders to step up work on chronic diseases and to underpin the Commission’s political determination at international level, building upon the UN political declaration on non-communicable diseases, the Council conclusions on chronic diseases and sustainable health systems, the Chronic diseases reflection process as well as at conclusions of the chronic disease summit. **Technical assistance:** This action will deal in particular with the organization of meetings, the development of concept and background materials and the provision of reports and information. Work under this action will: (i) support cooperative structures at EU level to implement pilot activities to highlight the potential of simple and cost-effective interventions to address selected major chronic diseases. Such activities shall be transferable and applicable in EU Member States and have the potential to reduce the burden of chronic diseases at sub-European levels; (ii) furthermore support the development of reports and background material. This action will build upon the results of the Joint Action on Chronic Diseases and Active and Healthy Ageing across the life cycle.

Type of contract and type of procurement

Specific contracts based on an existing framework service contract

Indicative number of contracts envisaged: 3

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Commission

4.1.5. Tobacco legislation - Provision of technical and scientific input and tailor-made tools to prepare and adopt cost-effective measures against smoking on the EU level, as well as to support the implementation of the existing policies (Thematic priority 1.5. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Following its entry into force, the new Tobacco Products Directive (TPD) 2014/40/EU ⁽¹³⁾ shall be made fully operational by means of delegated and implementing acts. The implementation of the new TPD and its transposition by the Member States should be supported by appropriate technical and scientific input in form of reports, studies and/or other relevant forms.

⁽¹³⁾ OJ L 127, 29.4.2014, p 1.

The TPD related work will focus on four priority areas in 2015: (i) further development of the implementing and delegated acts in the area of the ingredients regulations, in particular concerning the reporting of ingredients, the determination of characterizing flavour and the priority list of additives; (ii) further implementation of the labelling and packaging requirements for tobacco products, electronic cigarettes and herbal products for smoking, in particular with regard to enforcement of Article 13 TPD which prohibits the use of misleading elements in product presentation, as well as characteristics and design of the products themselves; (iii) public health risks associated with use of electronic cigarettes, technical specifications and the reporting format for the products; and (iv) further development of tracking and tracing systems and security features as outlined in Article 15 on traceability and 16 on security features.

In parallel the Commission will further continue to monitor related tobacco control policies through appropriate reports or studies, in particular advertising and sponsorship of tobacco products (regulated by Directive 2001/33/EC ⁽¹⁴⁾), smoke-free environments (Council Recommendation 2009/C296/02 ⁽¹⁵⁾) and other initiatives to improve tobacco control (as outlined by Council Recommendation 2003/54/EC ⁽¹⁶⁾).

Type of contract and type of procurement

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

Indicative number of contracts envisaged: 5

Indicative timeframe for launching the procurement procedure

First and second semesters of 2015 (2 procedures in the first semester, 3 procedures in the second semester of 2015)

Implementation

Implementation primarily by the Agency

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

4.2.1. 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

⁽¹⁴⁾ OJ L 127, 9.5.2001, p. 42.

⁽¹⁵⁾ OJ C 296, 5.12.2009, p. 4.

⁽¹⁶⁾ OJ L, 22, 25.1.2003, p. 31

Training and study: In order to protect citizens from serious cross-border health threats (Decision 1082/2013/EU (17)), 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 under this lot is to support capacity building against health threats in Member States. Sharing of information, identifying best practices, enhancing preparedness and response planning processes, testing of procedures and plans in place, supporting risk and crisis communication as well as complementing immunisation policies are important tasks to strengthen capacities at EU level.

The following 7 sub-actions look at different aspects of capacity building and require different types of deliverables:

1) Development of toolkits such as best practice reports, guidelines etc. to support the assessment and ad-hoc monitoring of environmental and biological incidents other than communicable diseases;

2) Enhancement of health literacy of journalists as regards Health Security, enhancement of **media literacy for health professionals** and actions to **increase the knowledge of citizens** about serious cross-border threats to health issues by workshops, information kits, awareness and information campaigns for journalists, health professionals and civil society/citizens;

3) Review of best practices in addressing health threats by documenting EU and Member State responses to recent health threats and providing recommendations and guidance for future action;

4) Option paper for potential joint procurement procedures at European level based on a needs analysis for essential medical countermeasures and availability of production capacities for these medical countermeasures;

5) Organisation of a table top exercise on climate change, with public health experts, environmental/climate change experts and crisis communicators to test procedures and protocols in place and identify gaps;

6) Study to address shortcomings related to low vaccination coverage in health care workers to support Member States in developing national strategies for increasing vaccination coverage of health care workers. The study should address the role, understanding, education and communication of health care workers related to vaccination and propose potential measures for action.

7) Study on the added-value of a strategic and life-course approach to vaccination to provide evidence and demonstrate the impact of life-course vaccination programmes to limit the burden of vaccine-preventable diseases, the cost-effectiveness of vaccination as a preventive tool in public health and the added value of cooperation and coordination at EU level with respect to programme development and monitoring.

⁽¹⁷⁾ OJ L 293, 5.11.2013, p. 1.

Type of contract and type of procurement

Specific contracts based on an existing framework service contracts

Indicative number of contracts envisaged: 5

Indicative timeframe for launching the procurement procedure

First semester/Second semester of 2015

Implementation

Implementation by the Agency

4.2.2. The role of public health law in the control of and protection against cross-border health threats (Thematic priority 2.2. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Study: The overall objective of this action is to provide a study of national laws supporting or constraining defined issues of health threats identified under Decision 1082/2013/EU across Europe, to facilitate the exchange of information and expertise on law between specialists in public health law interested in forging closer connections, to identify gaps in national laws that could jeopardize the implementation of coherent preparedness planning in the EU Member States, and to provide a resource to support public health law reform and public health policy making in Europe. Findings of the PHLaw Flu project need to be considered ⁽¹⁸⁾.

This action will support the overall implementation of preparedness planning in the coming years, by: (i) mapping the existing provisions in national legislation that support public health preparedness (type of laws, coverage of the laws, approach to legislation in the various MS, non-public health laws impacting preparedness); (ii) filling the gaps in expertise in public health law across Europe; (iii) identifying minimum requirements in legislation for ensuring coherence and compatibility between Member States; (iv) examining if there is a legal underpinning for a range of measures such as: reporting duties in relation to serious cross border threats to health, compulsory screening, compulsory isolation and quarantine, compulsory vaccination and treatment, requisition of persons, obligation of a worker to work in a crisis, requisition of premises and goods, compensation authorised for requisition of premises, school closures, prohibition of mass gatherings, etc.; (v) providing an analysis of coherence between laws and plans; (vi) identifying the role and scope of emergency powers of authorities in the event of a serious cross border threat to health; and (vii) examining ethical and fundamental rights issues (in particular in the light of the Charter of Fundamental Rights of the EU).

Type of contract and type of procurement

⁽¹⁸⁾ <http://ec.europa.eu/chafea/projects/database.html?prjno=2006201>

Specific contract based on an existing framework service contract or direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Agency

4.2.3 Public health preparedness and response training and exercises (Thematic priority 2.2. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

The objective of this action is to support the implementation of the Decision 1082/2013/EU on serious cross-border health threats and its subsequent undertakings relevant to preparedness and response planning, risk monitoring and assessment as well as risk management and crisis communication. Hence, the organisation of the exercises, training sessions, evaluation processes and other relevant actions is an essential tool to evaluate, test, and identify gaps in the processes in place or under development. This action seeks also to increase Member States knowledge of cross-border risks and management of the public health response to them. The foreseen activities should be as follows: table top exercises, command post exercises, field exercises/demonstration exercises, case studies, training seminars/workshops/conferences, exchange of experts' modules, online training courses.

Type of contract and type of procurement

New framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2015

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 e-Health: Use of e-Health and Big Data in Healthcare Policy and Research (Thematic priority 3.2. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Study: e-Health enables Big Data to be used to analyse the prevalence or trends of a disease among different populations, to determine risk factors, to improve patient care and inform health policies. Retrospectively, Big Data analysis can evaluate the effectiveness of treatments and the efficiency gains resulting from "hospital to home" shifts. It is a new way to promote innovation, to deliver patient-centred care and to contribute to the sustainability of health care systems. This study should provide an overview about the e-Health strategies in Member States, how citizens use and contribute eHealth and mHealth (through Eurobarometer), and about the most promising trends of implementation of Big Data initiatives in the EU health care sector, including its use in secondary analysis and aspects of privacy and protection of personal data. The study aims to: (i) map the best practices in e-health policies and use of eHealth/mHealth tools, in particular the deployment of Big Data in healthcare policy and research; (ii) provide information on the use of ePrescription and mHealth tools; and (iii) provide policy recommendations to the Commission and the Member States on the use of Big Data in health care sector.

Type of contract and type of procurement

Direct service contract

Indicative number of contracts envisaged: 2

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Agency

4.3.2. Use of SNOMED Clinical Terms terminology for cross-border exchange of medical data (Thematic priority 3.2. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

The epSOS project, which ended in 2014, developed an infrastructure that demonstrates cross-border interoperability between electronic health record systems in Europe. It focused on providing important medical data for patient treatment (exchange of patient summary), and cross-border use of electronic prescriptions (ePrescription). To make sure that the services developed in the epSOS project can continue, it is necessary to secure health vocabularies used to translate and exchange the medical data across borders. One of the main vocabularies

used in the epSOS project was SNOMED CT, which is the most comprehensive, multilingual clinical healthcare terminology in the world. Such terminologies are also needed for rare diseases.

The contract will be concluded with the International Health Terminology Standards Development Organisation (IHTSDO) for two years via a negotiated procedure without publication of a contract notice. IHTSDO is the only provider that can provide the use to SNOMED CT. The contract will be based on the number of clinical terms within the subset of SNOMED CT and the number of Member States wishing to use the subset to set up the exchange patient data without being a Member of IHTSDO (Members of IHTSDO already have secured the use of SNOMED CT by paying a membership fee). An agreement with the IHTSDO, which owns and administers the rights of SNOMED CT, will allow the use of this specific terminology within a cross-border context, and in specified EU projects, such as on rare diseases.

Type of contract and type of procurement

Direct service contact via negotiated procedure

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Agency

4.3.3. Support to prepare an Impact Assessment for the coordination of the HTA work (Thematic priority 3.2. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Study: This action will contribute to the implementation of Article 15 of the Directive on Patients' Rights. An Impact Assessment is necessary to identify the most suitable existing bodies which could facilitate the coordination of scientific work between HTA Agencies, and to provide the necessary elements for the legal basis of such work. The contract will consist of a study to assist the Commission in preparing the Impact Assessment. In particular the contractor will need to make background research on the quantitative impacts of the possible options, notably in relation to economic implications and scientific synergies that can be generated.

Type of contract and type of procurement

Specific service contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Commission

4.3.4. ESIF support in the area of health: building knowledge and capacities for monitoring and implementation, supporting innovation and effectiveness (Thematic priority 3.4. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

This action has two main objectives: **1) Strengthening capacity of Members States' health authorities to effectively use ESIF in health**, by: (i) supporting exchange of information, innovative ideas and processes, and success factors among Member States on effective use of ESIF and other funding for health; and (ii) providing health-specific assistance and expertise to participating Member States; **2) Study: Building knowledge on, and assessment of, ESIF interventions in health within the period 2014-2020** by: (i) furthering knowledge on Member States' health-specific interventions co-financed with ESIF and, as relevant, other identifiable funding, to translate policy priorities into investments; (ii) developing lessons learned on health investments; and (iii) elaborating conclusions and recommendations on investments in health, in view of evolving policy priorities.

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 2015

Implementation

Implementation by the Agency

4.3.5. Methodological improvements to international comparisons of the technical efficiency of the hospital sector (Thematic priority 3.4. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Study: The purpose of the study is to improve the current state of the art in the area of hospital efficiency measurement, where a growing interest is noted in the literature on the cross-country comparisons of hospital system performance. There is concern that, given likely issues with the comparability of data between countries focus is put on a suspected potential for technical efficiency improvements without sufficient consideration to the structural comparability of hospital systems across countries. This study would notably highlight the potential impact on comparative efficiency assessment stemming from differences between countries as regards: (i) the role of prevention (Ambulatory Care Sensitive Conditions); (ii) the role of care substitution between hospital-based and community-based care; (iii) and the role of care specialisation by hospital site. Additional consideration should go to possible further confounders such as varying disease prevalence, etc. Concrete improvements and leads to further research in this domain will be formulated.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Agency

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 service contract

Indicative number of contracts envisaged: 1-3

Indicative timeframe for launching the procurement procedure

First semester of 2015

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 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 service contract

Indicative number of contracts envisaged: 1-3

Indicative timeframe for launching the procurement procedure

First semester of 2015

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 service contract

Indicative number of contracts envisaged: 1-3

Indicative timeframe for launching the procurement procedure

Second semester of 2015

Implementation

Implementation by the Agency

4.3.9. Clinical trials database (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 support the development of a clinical trials database and is composed of **two sub-actions: 1) Overseeing and monitoring the work of EMA for the development of an EU portal and an EU database for the submission of requests for authorization 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. **2) Update of the ‘Clinical trial module’ of the existing Eudra Vigilance database:** This update is necessary to ensure the processing of safety reports during clinical trials. This action is linked to the adoption of the new regulation on clinical trials.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2015

Implementation

Implementation by the Commission

4.3.10. 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 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 service framework contracts

Indicative number of contracts envisaged: 3

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Commission

4.3.11. Evaluation of certain provisions and instruments under the pharmaceutical legal framework (Thematic priority 3.6. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Evaluation: The pharmaceutical legislation has developed substantially over the last decade. The objective of this action will be to provide a comprehensive and in-depth evaluation of the functioning of the pharmaceutical legislation in relation to several aspects (e.g. response to unmet medical needs, timely access to patients, functioning of incentives, effect on innovation, etc.). Such an evaluation would be essential to obtain an independent view on how certain provisions and instruments under the current legal framework have been implemented and whether they have achieved their objectives.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2015

Implementation

Implementation by the Commission

4.3.12. Evaluation of the costs of the European Medicines Agency and the costs of the tasks carried out by the national competent authorities (Thematic priority 3.6. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Evaluation: The objective of this action is to carry out an evaluation of the costs of the European Medicines Agency and the costs of the tasks carried out by the national competent authorities. This is in line the ‘Regulation of the European Parliament and of the Council on fees payable to the European medicines Agency’ for the conduct of pharmacovigilance activities in respect of medicinal products for human use (Regulation 297/95 ⁽¹⁹⁾, recital 7), whereas any future revisions of the pharmacovigilance fees or other fees levied by the Agency should be based on a transparent and independent evaluation of the costs of the Agency and the costs of the tasks carried out by the national competent authorities. A review of Council Regulation 297/95 on fees payable to the agency, including a review of the pharmacovigilance fees is planned. Data gathering has started and first results are expected in the second half of 2015. The independent evaluation should begin shortly after the data gathering in order not to delay the process.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2015

Implementation

Implementation by the Agency

4.3.13. Scientific and technical assistance for scientific committees, the Expert Panel on effective ways of investing in health and public health policies (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, the Expert Panel on effective ways of investing in Health and various aspects of public health policy. It includes organisation of scientific hearings, working group meetings and thematic workshops, as well as direct scientific support for the drafting of documents, such as literature searches, editing, and translation of scientific texts into publications for the

⁽¹⁹⁾ OJ L 35, 15.2.1995, p. 1.

general public and their dissemination, including dedicated website as requested by Commission Decision 2008/721/EC ⁽²⁰⁾. 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

Direct service contracts, specific contract based on existing framework service contract and administrative agreement with the JRC

Indicative number of contracts envisaged: 13-15 (+ 1 administrative agreement with JRC)

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Commission

4.3.14. Impact of health systems on health status of the population (Point 3.7. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Study: This study will contribute to health system performance assessment in the EU taking into account the impact of determinants of health on population health status in Member States. Research funded under the 2008-2013 Public Health Programme already offered improved insights on the impact population lifestyle has on the comparative cost-effectiveness of Member State health systems. However, a clear need was identified to further improve scientific analyses on the possible impact of time lags and interactions between various lifestyle factors. In addition, this study will improve understanding of the indicators on the health status of the population given the impacts of social/economic factors and environmental factors. The identification of these factors will allow to isolate the impact of the healthcare systems on the health status of the population, and therefore to give more precise information on their efficiency.

Type of contract and type of procurement

Direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

⁽²⁰⁾ OJ L 241, 10.9.2008, p. 21

Second semester of 2015

Implementation

Implementation by the Agency

4.3.15. Health System Performance Assessment (Thematic priority 3.7. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Preparatory work to support the work of the Commission expert group on health systems performance assessment. This work will include the preparation of background material and analysis on the priority topics identified by the expert group. In particular, this will regard the identification of tools and methodologies to assess quality of care and to assess the performance of integrated care, as per the indications of the expert group.

This work will also include actions to enhance communication of the findings of the expert group, and to facilitate the exchange of experience in the field of health systems performance assessment among relevant stakeholders at national and international level.

Type of contract and type of procurement

Direct service contract or service contract based on an existing framework service contract

Indicative number of contracts envisaged: 3

Indicative timeframe for launching the procurement procedure

Second semester of 2015

Implementation

Implementation by the Agency

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

4.4.1. Implementation of Cross-border healthcare Directive and development of European Reference Networks (Thematic priority 4.1. of Annex I to the Programme Regulation)

Subject matter of the contracts envisaged

Directive 2011/24/EU on patients' rights in cross-border healthcare and Commission implementing decision 2014/287/EU are the basis for the development of European Reference Networks (ERNs) between healthcare providers and centres of expertise, by establishing the legal framework for such networks. Based on this legal framework, ERN actions for 2015 are

composed of **three main sub-actions**. **1) Selection of the independent assessment/evaluation body(ies) in charge of the assessment of the applications of Network and membership proposals - Technical assistance:** The assessment manual and toolbox currently under development will be the common instrument to assess all Networks proposals. A call for the selection of the independent assessment bodies, which will be in charge of the assessment of ERNs by using the referred manual, should be launched. The contractor should be capable of fulfilling strong requisites, have remarkable experience and technical capacity. **2) Methodology and recommendations for the development of clinical decision-making tools (CDMT) such as clinical guidelines, consensus documents and patient pathways – Study:** The aim of this action is to provide a common basis, terminology and methods for the development of the main CDMT to be used by the Network Members. The study should include: (i) terminological manual including, according to the state of the art at international level, a list, glossary and definitions of the main clinical decision-making tools used in medical practice; and (ii) guideline manual on internationally accepted standards and criteria for the development of clinical guidelines, patients pathways, consensus documents and similar tools, providing advice on the technical aspects, processes and methods. **3) Update of information material on European Reference networks:** At the end of 2015, the Commission will have to present a first report on the implementation of the Cross-border Healthcare Directive. A conference with will be organised with relevant stakeholders to take stock of the current state of implementation, not only in legal terms but also by reviewing practical cases and patients' experiences, two years after the end of the transposition deadline. **4) IT platform for European Reference Networks:** The purpose of this action is, based on the work carried out in 2014, to further develop an IT platform which will be provided to future ERNs, to support their functioning and duties required by legal acts establishing criteria for ERNs and their members. This will support the connection and communication within the networks and with other healthcare providers making information available for patients and healthcare providers. It would include inter alia the provision of tools of communication and telemedicine and for the exchange of knowledge (such as joint development of guidelines, clinical information), collaborative work at distance, patients' follow-up, training and research activities. This will include the development of a pilot IT platform.

Type of contract and type of procurement

First sub-action: new framework service contract – Second sub-action: direct service contract – Third sub-action: direct service contract – Fourth sub-action: direct service contract

Indicative number of contracts envisaged: 4

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Agency for the first and second sub-actions – Implementation by the Commission for the third and fourth sub-actions

4.4.2. *Preparatory work to set up a framework for a sustainable EU collaboration on patient safety and quality of care (Thematic priority 4.3. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

Preparatory work to set up a framework for a sustainable EU collaboration on patient safety and quality of care, including the preparation of a feasibility study on the setting up of a permanent network intended to promote the identification, the exchange and the implementation of good practices and strategies in the field of Patient Safety and Quality of Care.

This action intends to follow up the Council Conclusions on Patient Safety and Quality of Care of 1 December 2014, as well as to sustain the European Union Network for Patient Safety and Quality of Care (PaSQ Joint Action).

Type of contract and type of procurement

Direct service contracts

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Agency

4.4.3. *Comparative assessment of the accessibility of healthcare services (Thematic priority 4.3. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

Study: This initiative concerns a study with the following objectives: (i) evidence review of existing frameworks to make a comparative assessment of the accessibility of healthcare services between health systems; (ii) methodological proposals in support of possible future such frameworks; and (iii) the collection and compilation of expert feedback on (i) and (ii) above.

The study on the assessment of the accessibility of healthcare services will complement the work being done by the 'Expert panel on effective ways of investing in health' and the pilot project on access to healthcare in rural areas. The study is meant to provide the Commission with solid evidence to support the on-going debates involving also the European Parliament and other health stakeholders on this subject.

Type of contract and type of procurement

Specific contract based on an existing framework service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Second semester of 2015

Implementation

Implementation by the Agency

4.4.4. *Definition of a minimum basket of care for hospital patients (Thematic priority 4.3. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

Study: This initiative seeks to respond to an invitation to the Commission in the Council Conclusions on the ‘Economic Crisis and Healthcare’, to provide information on the healthcare services covered by Member States’ healthcare systems by delivering a feasibility study. The study should be articulated in two modules for a limited selection of pilot lists: (i) definition of a set of criteria to establish a ranking of hospital cases classified by Diagnosis-Related Groups (DRGs). The contractor shall set up a panel of experts and stakeholders (medical doctors, insurance managers, patients, hospital managers, and policy makers) to establish criteria (such as severity of diseases/illness/condition, age, gender, cost, impact on productivity, etc.) and weights to attribute relative importance to DRGs. Based on these set of criteria and their relative weights, the contractor shall establish a ranking of DRGs; and (ii) the study will then attribute the local tariff to each DRGs and calculate the cumulative expenditure (on the basis of real volumes). Two simulations will be presented. First, the study will apply different thresholds (e.g. first half of the DRGs, up to 3rd quintile, etc.) and will show how much it would cost to cover all interventions up to that threshold. Then, it will estimate how many DRGs/cases would be covered if the budget allocated to the hospital sector would reach an established percentage of the GDP. Specific scrutiny will go to assessing possible factors impacting on the comparability of data in this domain.

Type of contract and type of procurement

Specific contract based on an existing framework service contract or direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Agency

4.4.5. *Study on the uptake and impact of the 'Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States' (Thematic priority 4.5. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

Study: This initiative seeks to provide information on the set-up of organ donation and transplantation in the EU Member States and more specifically on the level of implementation (uptake and impact) of the 10 priority actions of the Action Plan (Communication of the Commission stating that a final evaluation should be carried out) and map results achieved, at Member States and European level. The study should build upon results of the mid-term review carried out in 2012-13 (ACTOR study, Commission Staff Working Document on the mid-term review of the Action Plan). It should also take into account recent and ongoing developments in the field of transplantation and assess the need for a follow-up Action Plan at EU level. The survey should include EEA and candidate countries (already captured in the ACTOR study).

The study should be articulated in two main sections: (i) state of play at Member States' level, including a general description of the transplantation activities in each of the countries considered and a detailed assessment of activities implemented and results achieved regarding the 10 priority actions of the Action Plan; (ii) state of play at European level, mapping activities implemented and results achieved at EU level along the 10 priority actions of the Action Plan and in the transplantation field, including results from EU-funded projects.

Type of contract and type of procurement

Specific contract based on an existing framework service contract or direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First semester of 2015

Implementation

Implementation by the Agency

4.4.6. *Development of open source software for the labelling of human tissues and cells for human application with the Single European Code (SEC) (Thematic priority 4.5. of Annex I to the Programme Regulation)*

Subject matter of the contracts envisaged

IT tool: This action is about the development of a computer software for labelling of tissue and cell products with the Single European Code (SEC) allowing tissue establishments and healthcare professionals from the transplantation and ART (Assisted Reproductive Technologies) sectors to ensure traceability from donor to recipient and vice-versa according to the requirements of the EU legislation. Providing an open-source software for the labelling of the tissues and cells with SEC will ensure compliance and adherence to the new EU coding regulatory requirements and will reduce the costs of application in the EU tissue establishments choosing to use EUTC as coding system. In addition, the software should also allow users to easily read the label and find back the relevant information (decoding).

Beyond regulatory compliance, more benefits are expected from the development and application of this labelling system, including: securing patient safety, ensuring product authenticity, possibility of automated product control (which would eliminate human errors related to the use of eye readable codes) including easier management of recalls.

The labelling software (both for creating labels, and for reading them) should be connected to the EU Tissue and Cell Product Compendium and ensure the labelling of the tissues and cells with the EUTC coding system. The labelling software should produce labels including an eye readable format (serial number) and a barcode/QR code allowing for automated reading of the SEC on tissue and cells distributed for human application. The label printing software should provide a process to print and verify serial numbers and barcode/QR labels. A software for reading the different formats of the codes should be also developed.

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 2015

Implementation

Implementation by the Agency

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 communication and promotion work package consists of: **1) Dissemination of information on EU health policy initiatives and related action.** Activities to be funded include amongst others preparing and disseminating audiovisual material and publications in electronic format and on paper, conferences, workshops, media activities and expert meetings, and information stands and other communication and promotional activities including web activities (web-site and e-newsletter), tools and material; **2) Dissemination of the results of the Health programme at EU level:** its aim is to provide Member States with workable tools and services for effective dissemination in the Member States of the results of actions funded by the Health programmes. These include conferences and workshops, and other appropriate means for effectively disseminating the results to different audiences. This work package responds to the recommendations of the ex-post final evaluation of the Public Health programme (2003-2007) and the mid-term evaluation of the Health programme (2008-2013).

Type of contract and type of procurement

Most communication activities will be carried out by using existing framework service contracts

Indicative number of contracts envisaged: 15

Indicative timeframe for launching the procurement procedure

First and second semesters of 2015

Implementation

Communication: Implementation by the Commission – Dissemination: 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 3rd Health Programme and in accordance with the Europe 2020 strategy. An indicative list of applications to be covered by this action is as follows: Diet, Alcohol and mental Health platforms; Health Innovation platform; applications related to tobacco 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); IDB (Injury Database), Ras-Chem (rapid alert system for information exchange on incidents including chemical agents), etc., veterinary registries and veterinary antimicrobials, Expert database, support to Scientific Committees and the Expert Panel, to communication activities, contributions for security, knowledge management, licences and maintenance for central applications and common systems technical support.

Type of contract and type of procurement

Specific contracts based on existing framework service contracts

Indicative number of contracts envisaged: 10

Indicative timeframe for launching the procurement procedure

First and second semesters of 2015

Implementation

Implementation by the Commission

4.5.3. Mid-term evaluation of the Health Programme (2014-2020)

Subject matter of the contracts envisaged

The purpose of this action is to comply with the requirement of Article 13(3) of the Regulation on the third Health Programme. This Article requires the Commission to draw up and present to the European Parliament and to the Council a mid-term evaluation report, latest by 30 June 2017. This report shall present the achievement of the objectives of the Programme, the state-of-play regarding the implementation of the thematic priorities, the efficiency of the use of resources and the Union added value of the Programme. The evaluation will use a variety of methods (document review, analysis of quantitative data bibliometric analysis, etc.) and be complemented by a stakeholder consultation.

Type of contract and type of procurement

Specific contracts based on existing framework service contract

Indicative number of contracts envisaged: 2

Indicative timeframe for launching the procurement procedure

Second semester of 2015

Implementation

5. OTHER ACTIONS

The overall budgetary allocation reserved for other actions in 2014 amounts to EUR 3 731 000. 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 ⁽²¹⁾, 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. Technical and scientific support of the Joint Research Centre to action on Nutrition, Physical Activity and Alcohol-related harm (Thematic priority 1.1. of Annex I to the Programme Regulation)

Amount

EUR 450 000

Description and objective of the implementing measure

This action deals with the scientific support of the Joint Research Centre (JRC) to the initiatives on nutrition, physical activity and alcohol-related harm. It includes support to the Member States' and stakeholders' groups (chaired by the Commission) that discuss those topics.

This action will include the production by the JRC of policy briefs related to the key areas of the Action Plan on Childhood Obesity and of the Youth Drinking and on Heavy Episodic Drinking.

It will also include reviews of scientific evidence in these mentioned areas; these should be drafted so as to allow for a possible joint reference publication on the existing scientific evidence on nutrition and physical activity.

The technical and scientific support will further contribute (with evidence summaries and drafting of expert analysis) to the monitoring updates of the Action Plans (on Childhood Obesity and of the Youth Drinking and on Heavy Episodic Drinking), related reports for the Council (on nutrition and physical activity, to be presented in 2017) and the preparations for the 2016 OECD Health Ministerial.

⁽²¹⁾ OJ L 298, 26.10.2012, p. 1.

The support of the JRC to the Member States' and stakeholders' meetings (including the High Level Group on Nutrition and Physical Activity, the EU Platform for action on diet, physical activity and health, the related working groups on monitoring and on the drafting of the annexes of the EU Framework for National Initiatives on Selected Nutrients, the Committee on National Alcohol Policy and Action and the European Alcohol and Health Forum) will include the preparation of relevant technical support documents, the update of scientific news and the participation in the events.

This action will generally contribute to the steering of existing policies, initiatives and fora and to support the long term sustainability of related action, projects and databases. It will be implemented through an administrative agreement with the JRC.

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

The objective of this action is to provide targeted risk assessment at medium term in case of a chemical or environmental incident of cross-border relevance in line with Article 10, paragraph 2 of Decision 1082/2013 on serious cross-order threats to health. At this stage only the basic needs to maintain the networking among experts is supported while a specific need remains in term of ad hoc funding to support the work to address specific emergency situations.

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

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 (²²). This action contains special indemnities paid to experts for their work on scientific opinions and reports.

5.3.2. Technical and scientific opinions and advices (Thematic priority 3.6. of Annex I to the Programme Regulation)

Amount

EUR 345 000

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. Technical and scientific support for the development of a methodology for improving the operation of the medical devices field and for exploratory work on EU reference laboratories for medical devices (Thematic priority 3.6. of Annex I to the Programme Regulation)

Amount

EUR 300 000

Description and objective of the implementing measure

The main objectives of this action are: (i) to further develop methods for improving the communication and cooperation on market surveillance and vigilance issues between EU Member States and the Commission and for the analysis of signals and trends; to monitor and identify actions taken by other jurisdictions and make this information available in the EU; (ii) to support the clinical investigation and evaluation activities in particular by contributing to the development of guidance, cooperation mechanisms and sharing of best practices in data analysis; and (iii) to start exploratory work on EU reference laboratories for Medical Devices and in vitro diagnostic Medical Devices. This action will be carried out through an administrative agreement with the JRC.

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

Amount

(²²) OJ C 198, 6.7.2012, p. 7.

EUR 200 000

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 ⁽²³⁾ and related training activities.

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

Amount

EUR 955 000

Description and objective of the implementing measure

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

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

Amount

EUR 250 000

Description and objective of the implementing measure

ICH is an action launched to bring together the drug regulatory authorities of EU, Japan and the United States along with experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The Commission funds travel and accommodation costs for the experts from the EU national regulatory agencies and the EMA reimburses its own experts. Considering the regulatory environment (EU legislation), the operational funding should come from the EU rather than from the individual EU Member States. This provides further legitimacy of the Commission as representative of the EU (and thus its Member States) in the process.

⁽²³⁾ The joint assessments are either carried out under the Commission Implementing Regulation (EU) No. 920/2013 on the designation and supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices or on specific request by a national authority.

5.3.7. *Commission membership fee to the International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 100 000

Description and objective of the implementing measure

This action will implement a Commission Decision relating to the full participation of the Commission, as a founding member of the legal entity (ICH Association), in the decision-making and financing of the ICH Association. The Decision of the Commission will lay down the status of the Commission in this ICH Association. ICH is an international collaboration between the pharmaceutical regulatory authorities of EU, US, Japan, Switzerland and Canada along with experts from the pharmaceutical industry in the EU, US, Japan to discuss scientific and technical aspects with the view to harmonise the requirements for registration of medicinal products for human use. This membership fee will support the expenses related to the establishment of the legal entity and the operation of ICH activities (secretariat/administration).

5.3.8. *The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Veterinary Use (VICH) – Experts' reimbursement of expenses (Thematic priority 3.6. of Annex I to the Programme Regulation)*

Amount

EUR 41 000

Description and objective of the implementing measure

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

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

Amount

EUR 50 000

Description and objective of the implementing measure

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

5.3.10. *Commission membership fee to the European Observatory on Health Systems and Policies (MDCG) (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.

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

Amount

EUR 150 000

Description and objective of the implementing measure

The objective of this action is to provide the Commission with independent and high quality advice on health risks. This contributes to obtaining a robust scientific basis for EU policies and measures in line with better regulation. The advice is provided by the Scientific Committees in accordance with Commission Decision 2008/721/EC. 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 2015.

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 ⁽²⁴⁾ 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:

⁽²⁴⁾ Whenever 'applicants' is written, this means the coordinator and the co-applicants.

- EU Member States;
- 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.

2. EXCLUSION CRITERIA

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

3. SELECTION CRITERIA

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

The following selection criteria have to be met:

3.1. Financial capacity

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

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

3.2. Operational capacity

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

4. AWARD CRITERIA

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

4.1. Policy and contextual relevance (10 points, threshold: 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 3rd 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 2015 only framework partnership agreement holders will be invited to submit proposals for their Annual Work Programme for 2016.

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 ² 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 members²⁵ in at least half of the Member States),

⁽²⁵⁾ 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.

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.

Definition of 'member' for a network: A member of a network is a natural person, a legal person or an entity which does not have a legal personality under the applicable national law, who became member through signing the rules of cooperation (e.g. SOP, a memorandum of understanding or a collaboration agreement). Members of a specialised network's 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 which meet the exclusion and eligibility and selection criteria will be assessed on the basis of the following award criteria.

4.1. Contribution to public health in Europe

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

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

4.2. Technical quality

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

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

4.3. Management quality

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

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

4.4. Overall and detailed budget

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

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

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

ANNEX V

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

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.

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

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

1. ELIGIBILITY CRITERIA

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

2. EXCLUSION CRITERIA

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

3. SELECTION CRITERIA

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

Based on a risk assessment and in accordance with Article 131(3) of the Financial Regulation, the obligation to verify the operational capacity of public bodies or international organisations is waived for beneficiaries included in the list referred to in paragraph 2 of article 5 of regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics. According to Article 5 of Regulation 223/2009, grants in Eurostat can be awarded directly without call for proposal to National Statistical Institutes or other national authorities responsible in each Member State for the development, production and dissemination of European statistics. Member States are responsible for designating the statistical authorities based on common criteria endorsed by the ESS Committee, thereby providing reasonable assurance about the operational capacity to carry out the proposed actions.

4. AWARD CRITERIA

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

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

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

ANNEX VI

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

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 ⁽²⁶⁾ 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 ⁽²⁷⁾.

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.

⁽²⁶⁾ 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.

⁽²⁷⁾ Collaborators in a position that could lead to a conflict of interest (Article 57 of the Financial Regulation and Article 32 of the Rules of Application) shall be listed.

ANNEX VII

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

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 and a very high EU added value.

3. CRITERIA FOR THE EXCEPTIONAL UTILITY OF OPERATING GRANTS

1. At least 25 % of the members of the non-governmental bodies ⁽²⁸⁾ or candidate members of the non-governmental bodies come from Member States whose gross national income (GNI)

⁽²⁸⁾ 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 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 an international, 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.
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 3rd 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.

4.1. Policy and contextual relevance (10 points, threshold: 7 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 3rd 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 (10 points, threshold: 7 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 and has a potential long term impact.
- Cost-efficiency: the good practice obtains results with a reasonable level of resources and time.
- 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 public health fields.
- Innovation and creativity: the good practice has an innovative and/or creative approach with regards to target audience, processes carried out or outcomes utility.