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**COMMISSION IMPLEMENTING DECISION**

**of 26.1.2017**

**concerning the work programme for 2017 in the framework of the third Programme of the Union's action in the field of health (2014-2020) and the EU financial contribution to the WHO Framework Convention on Tobacco Control, serving as a financing decision**

(Text with EEA relevance)

# COMMISSION IMPLEMENTING DECISION

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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<sup>1</sup>, and in particular Article 11(2) thereof,

Having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002<sup>2</sup>, and in particular Article 84(2) thereof,

Whereas:

- (1) In order to ensure implementation of the third Programme for the Union's action in the field of health (2014-2020), it is necessary to adopt a financing decision and the work programme for 2017. Article 94 of Commission Delegated Regulation (EU) No 1268/2012<sup>3</sup> establishes detailed rules on financing decisions.
- (2) It is appropriate to authorise award of grants without a call for proposals to the bodies identified in the work programme and for the reasons provided therein.
- (3) This Decision should allow for the payment of interest due for late payment on the basis of Article 92 of Regulation (EU, Euratom) No 966/2012 and of Article 111(4) of Delegated Regulation (EU) No 1268/2012.
- (4) For the application of this Decision, it is appropriate to specify where the changes to the allocations to specific actions are not to be considered substantial within the meaning of Article 94(4) of Delegated Regulation (EU) No 1268/2012.
- (5) The measures provided for in this Decision are in accordance with the opinion of the Programme Committee established by Article 17 of Regulation (EU) No 282/2014,

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

<sup>2</sup> OJ L 298, 26.10.2012, p. 1.

<sup>3</sup> Commission Delegated Regulation (EU, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

HAS DECIDED AS FOLLOWS:

*Article 1*  
*The work programme*

The 2017 annual work programme for the implementation of the third Programme of the Union's action in the field of health (2014-2020), as set out in Annex I, and the selection, award and other criteria for financial contributions to the actions of this programme, as set out in Annexes II, III, IV, V, VI, VII, VIII and the Union contribution to the WHO Framework Convention on Tobacco Control, are adopted.

The annual work programme constitutes a financing decision within the meaning of Article 84 of Regulation (EU, Euratom) No 966/2012.

*Article 2*  
*Union contribution*

The maximum contribution for the implementation of the Programme for the year 2017 is set at EUR 64 529 000, and shall be financed from the following lines of the general budget of the European Union for 2017:

(a) budget line 17 03 01 — Third programme for the Union's action in the field of health (2014-2020): EUR 58 820 000;

(b) budget line 17 01 04 02 — Support expenditure for the ‘Third programme for the Union's action in the field of health (2014-2020)’ : EUR 1 500 000;

(c) budget line 17 01 06 02 — Consumers, Health, Agriculture and Food Executive Agency — Contribution from the ‘Third programme for the Union's action in the field of health (2014-2020)’ : EUR 4 209 000.

Estimated additional contributions from EFTA countries for their participation in the Health Programme are: EUR 1 574 508.

Estimated additional contributions from other non-Member States for their participation in the Health Programme are: EUR 148 877.

The maximum contribution for the Union payment to the WHO Framework Convention on Tobacco Control is set at EUR 200 000 and shall be financed from the following line of the General Budget of the European Union for 2017:

budget line 17 03 13 — International agreements and membership of international organisations in the field of public health and tobacco control.

The appropriations provided for in the first, second and third paragraph may also cover interest due for late payment.

The implementation of this Decision is subject to the availability of the appropriations provided for in the draft budget for 2017 after the adoption of the budget for 2017 by the budgetary authority or provided for in the provisional twelfths.

*Article 3*  
*Flexibility clause*

Cumulated changes to the allocations to specific actions not exceeding 20% of the maximum contribution set in Article 2 of this Decision shall not be considered to be substantial within the meaning of Article 94(4) of Delegated Regulation (EU) No 1268/2012, where those

changes do not significantly affect the nature of the actions and objective of the work programme. The increase of the maximum contribution set in Article 2 of this Decision shall not exceed 20%.

The authorising officer responsible may apply the changes referred to in the first paragraph. Such changes shall be applied in accordance with the principles of sound financial management and proportionality.

*Article 4*  
*Grants*

Grants may be awarded without a call for proposals to the bodies identified in Annex I in accordance with the conditions specified therein.

Done at Brussels, 26.1.2017

*For the Commission*  
*Vytenis ANDRIUKAITIS*  
*Member of the Commission*



## ANNEX I TO VIII

### ANNEX I

#### Health Programme — Work Programme for 2017

## 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 ('the Programme Regulation') for the year 2017.

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

According to Article 11 of the Regulation on the third Health Programme, the Commission is required to adopt, by means of implementing acts, annual work programmes to 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 to 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,
4. Facilitating access to better and safer healthcare for Union citizens

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 have guided the drafting of the 2017 work programme.

In order to improve the capacity at European level to deal with crisis situations and to protect Union citizens from serious cross-border health threats, this work programme includes action on preparedness, which according to the Decision 1082/2013/EU on serious cross-border threats to health is a key element for the effective monitoring, warning and combating of such threats.

Bearing in mind that medicines are not goods like any other, the programme also covers the area of medicines and pharmaceutical products, to ensure the high quality of medicines in the EU, while focusing on a cost-effective use of medicines as a key element to increase accessibility.

The Work Programme also focuses on building up country-specific and cross-country knowledge which can inform policies at national and European level, in order to increase efforts towards evidence-based policy-making based on country knowledge in the field of health.

The work programme further addresses the priority on migration and responds to the current high influx of refugees in Europe, in line with the EU migration agenda and the skills agenda specifically in its part on integration of third country nationals. In this area, important synergies can be achieved in close cooperation with the newly created European Solidarity Corps. The Commission encourages non-governmental bodies to engage with the European Solidarity Corps, where appropriate.

Finally, a number of activities contribute to the overarching objective to address the risk of poverty and social exclusion by encouraging and supporting effective public health policies that exclude fewer people from the labour market for long-term health conditions. In addition, actions under the work programme have been developed which have a twofold impact: an improved functioning of the single market and improving public health.

## **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 2017 as follows:

- for grants (implemented under direct management): EUR 38 850 000
- for prizes (implemented under direct management): EUR 60 000
- for procurement (implemented under direct management): EUR 14 341 585
- for other actions: EUR 7 152 500

The total amount available is EUR 60 404 085 for 2017.

The budget line for all activities is 17.03.01.

## **2 GRANTS**

### **2.1 Grants for projects**

Under the overall operational budget reserved for grants, EUR 4 850 000 will be reserved for projects.

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. Annex VI contains the eligibility, exclusion, selection and award criteria for grants described under point 2.1.2.1.

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, hereinafter 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 Supporting Member States in mainstreaming health promotion and disease prevention in health and educational settings (Thematic priority 1.3 of Annex I to the Programme Regulation)*

*Expected Results and Impact*

This action aims to communicate the potential of health promotion and disease prevention and health determinants in the Member States and to increase the commitment of public authorities to this topic. A workshop (and a conference) to update knowledge and good practice will be organised, with the participation of the main medical faculties and the Chief Medical Officers of all Member States. The workshop will be preceded by the preparation of a report providing an overview of the current situation in the EU (this document will be updated after the workshop) and it will be followed by a conference.

*Description of activities (to be funded under the call for proposals)*

The actions to be funded are capacity building, promoting the benefits of health promotion and disease prevention in Member States. A workshop will be held in cooperation with the Commission to raise awareness.

*Implementation*

Chafea

*The timetable and the indicative amount of the calls for proposals*

Reference	Date	Amount (€)
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Publication of the call for proposals	First half of 2017	<b>250 000</b>
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## **2.1.2 Actions under objective 4 — Facilitating access to better and safer healthcare for Union Citizens**

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

Support will be provided to the ERN through Specific Grant Agreement (SGA) (mono-beneficiary) under the Framework Partnership Agreements (FPA), signed for each ERN after their establishment. The FPA has a duration of maximum five years — covering the operating years 2017-2021. Only applicants with whom a FPA is concluded are eligible for the specific grant agreement and will be invited to submit a specific grant application to cover their activities planned for 2018, including the annual work programme and budget. Signing of an FPA does not guarantee the signature of an SGA.

The maximum funding per ERN is EUR 200 000 and the maximum rate of EU co-financing is 60 % calculated on the basis of eligible costs incurred.

#### *Expected Results and Impact*

The expected result is the establishment and effective coordination and management activities of the approved ERN with the aim to support the provision of highly-specialised healthcare for rare or low-prevalence complex diseases or conditions, to provide a better governance and coordination, to support development of knowledge and expertise to diagnose, follow up and management of patients. ERNs are expected to enhance a multi-disciplinary approach and increase the level of expertise and the capacity to produce good practice guidelines and to implement outcome measures and quality control as well as providing support to research coordination and teaching and training activities.

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

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

## Implementation

Chafea

### *The timetable and the indicative amount of the calls for proposals*

Reference	Date	Amount (€)
Publication of the call for proposals	First half 2017	<b>4 600 000</b>

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

Under the overall operational budget reserved for grants, EUR 19 700 000 will be reserved for grants for actions co-financed with Member State authorities.

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 6or 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 enable the nominated national authorities (one nomination allowed per Member State per Joint Action) of the Member States/other countries participating in the Programme and the European Commission to take forward work on jointly identified issues.

In addition, appropriate representation of civil society organisations active in the relevant field at EU level should be ensured.

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

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

#### *2.2.1.1 Joint Action on health inequalities (Thematic priority 1.1 of Annex I to the Programme Regulation)*

### *Expected results and Impact*

The objective of the Joint Action is to develop a clear policy framework with a menu of actions and recommendations for local take up and implementation at national and regional level in order to fight health inequalities and to support health systems dealing with challenges related to integrating vulnerable groups. It includes those inequalities related to high influxes of migrants and the need of integrating these particular populations in the regular health systems.

The recommendations will include suggestions for improved monitoring, governance and evaluation of measures on health inequalities; identified factors of success, as well as barriers and challenges and measures proposed to overcome them.

### *Description of 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*

Work will focus on the identification and implementation of policies and practices that can contribute to a reduction of health inequalities. Various policy domains will be covered, including living and working conditions, social protection including access to health care, and migration. This can involve the design of new policies and best practices that have potential to be implemented in the countries, regions or localities involved. It can also involve the modification of existing policies to ensure that they are more effective in making a contribution to levelling up the socioeconomic gradient in health. It can include concrete pilots as well as an in-depth case study to explore how more complex challenges can be addressed, including the socioeconomic or political determinants of health.

The work will build on the existing evidence, including the conclusions of the Marmot report<sup>1</sup> and the recommendations of the World Health Organization (WHO) Commission on Social Determinants of Health, insofar as they can support the implementation of related international strategies. Synergies will be explored with ongoing work and initiatives at global level such as the UN Sustainable Development Goals (SDGs), other EU initiatives and work of the the International Organization for Migration (IOM)/WHO on health inequalities.

### *Implementation*

Chafea

### *The timetable and the indicative amount*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Signature of the grant awarded without a call for proposals	Second half 2017	<b>2 500 000</b>

<sup>1</sup> Health inequalities in the EU — Final report of a Consortium; Consortium lead: Sir Michael Marmot, 2013.

*2.2.1.2 Joint Action — Innovative Partnership on Action against Cancer (Thematic priority 1.4 of Annex I to the Programme Regulation)*

*Expected Results and Impact*

Making use of recent scientific advances, this Joint Action is expected to reinforce prevention of cancer via population based programmes on cancer screening, further developing the principles of the 2003 Recommendation on Cancer Screening, paying particular attention to genetic screening and personalised medicine.

Specific recommendations for early detection and registration of cancers for which classical prevention measures are not effective will contribute substantially to the fight against cancer. In addition, the development of a Road Map for the use of the Member States will operationalise previous work of the Comprehensive Cancer Control Joint Action (CANCON)<sup>2</sup> for the implementation of the European Guide on Quality Improvement in Comprehensive Cancer Control at national and regional level.

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

The Joint Action will formulate a proposal of consensual recommendation for the consideration of the Expert Group on Cancer Control, incorporating new scientific advances to the population based national screening plans on the basis of a scientific and political consensus, specifically regarding genetic screening and personalised medicine.

The action will map all the existing guidelines on innovative treatments on cancer and create a database accessible for professionals.

Furthermore, an analysis of the ongoing generation of National Cancer Control Plans in view of improving this tool is envisaged.

Finally, the action will monitor the accuracy of the recommendations of the European Code Against Cancer in a long-term perspective, collecting the information reinforcing or contradicting recommendations (e.g. red meat, sunbeds), map treatment guidelines and select validated protocols with particular attention to innovative treatments (immunotherapies).

*Implementation*

Chafea

*The timetable and the indicative amount*

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<sup>2</sup> CanCon Joint Action — European Guide on Quality Improvement in Comprehensive Cancer Control (2014-17)

Reference	Date	Amount (€)
Signature of the grant awarded without a call for proposals	Second half 2017	4 500 000

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

### 2.2.2.1 Joint Action on vaccination (Thematic priority 2.2 of Annex I to the Programme Regulation)

#### *Expected Results and Impact*

This Joint Action will establish sustainable cooperation of Member State authorities dealing with vaccination, with a focus on cooperation on vaccine demand planning and forecasting, and other issues related to preparedness, while fully respecting Member State responsibilities. The Joint Action will define commonly basic principles for vaccine demand forecasting and develop a concept and prototype of a data-warehouse for an EU-wide central repository on vaccine supply and demand data.

Furthermore, it will define common stages and criteria for priority-setting of vaccine R&D and develop a concept and prototype for a vaccine R&D priority-setting framework.

It will also define specifications for data requirements to establish and interlink a sustainable infrastructure to foster electronic documentation and enable sharing of vaccination-related data.

The Joint Action also provides a framework to practically address further issues related to vaccination and preparedness.

In this way, Member States could strengthen their vaccine supply management, avoid shortages and increase vaccine safety and effectiveness surveillance capacities for improved monitoring of the impact of national vaccination programmes.

A strengthened vaccine supply would mitigate the risk of vaccine shortages and thereby strengthen preparedness of Member States, with the final overall impact of improving protection of Union citizens from serious cross-border health threats.

This action contributes to the priority of strengthening cooperation and coordination of national preparedness planning and at the same time contributes to efficient and sustainable health systems while respecting the competences of Member States in area of health.

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

The Joint Action will

- (1) Establish sustained cooperation of relevant Member State authorities
- (2) Define basic principles for vaccine demand forecasting;
- (3) Develop a concept and prototype for a data warehouse for EU-wide sharing of vaccine

- supply and demand data/information among dedicated stakeholders;
- (4) Define common stages and criteria for priority-setting of vaccine research and development;
  - (5) Develop a concept and prototype for a vaccine R&D priority setting framework;
  - (6) Define structural, technical and legal specifications as regards data requirements for electronic vaccine registries/databases/immunisation information systems.
  - (7) Provide a framework to cooperate on further issues related to vaccination and preparedness

### *Implementation*

Chafea

### *The timetable and the indicative amount*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Signature of the grant awarded without a call for proposals	Second half 2017	<b>3 000 000</b>

### *2.2.2.2 Joint Action on preparedness and action at points of entry (air, maritime and ground crossing (Thematic priority 2.2 of Annex I to the Programme Regulation)*

#### *Expected Results and Impact*

This Joint Action will develop catalogues of tested best practice and guidelines, including validated action plans for the use of the Member States' health authorities, to be implemented at operational level through agencies and stakeholders in the field of transport. These catalogues of tested best practice and guidelines are expected to provide the basis for coordinated cross sectoral actions to control infectious disease transmission and possible vectors for pathogens on ground transportation, on ships, and in aircrafts in case of a serious cross-border threat to health affecting or inherently coming from the transport sector.

The action has as its aim to prepare the transport sector for immediate and adequate response to serious cross-border threats to health. A network will be put in place to communicate and notify rapidly in case of cross-border risks to health including coordination of concerted actions.

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

The focus of this Joint Action will be on the implementation of requirements of Article 4 on preparedness and response planning of Decision No 1082/2013/EU. It will provide advice for

the management of public health events in the maritime, air and land transport area for all types of health threats. Guidelines will be drafted in cooperation with international organisations and other transport authorities and lessons learnt from previous public health emergencies of international concern, e.g. lessons learnt from the Ebola outbreak.

Implementation will be facilitated and core capacities evaluated and monitored (for example guidance for contingency planning, risk communication) at points of entry and best practice documents provided for coordinating and executing hygiene inspections on conveyances.

The coherent implementation of temporary recommendations issued by the WHO during possible future public health emergencies of international concern (implementation of international health regulations) will also be supported.

### *Implementation*

Chafea

### *The timetable and the indicative amount*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Signature of the grant awarded without a call for proposals	Second half 2017	<b>3 000 000</b>

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

### *2.2.3.1 Joint Action supporting the eHealth Network (Thematic priority 3.2 of Annex I to the Programme Regulation)*

#### *Expected Results and Impact*

This Joint Action is expected to further facilitate cross-border healthcare across the EU and overcome barriers in the implementation of digital solutions in Member States' healthcare systems and provide the necessary policy support to the eHealth Digital Service Infrastructure (eHDSI) with view to implementing the Commission's Digital Single Market Strategy as regards interoperability and standardisation.

eHealth and health services based on digital solutions are essential for implementing innovation in healthcare and are broadly recognised as an essential element to achieve sustainable healthcare systems. For this reason the eHealth Network was set up by Directive 2011/24/EU on patient rights in cross-border healthcare. It works for the implementation of the objectives for EU cooperation in eHealth.

*Description of 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*

Building on the results of the Joint Action supporting the eHealth Network (JAseHN), the Joint Action will provide the technical and scientific support to the eHealth Network, which works towards delivering sustainable economic and social benefits of European eHealth systems and services, and their interoperable application.

The Joint Action will coordinate the Member State's positions and support activities with regard to the exchange of health data between the Member States and investigate a sustainable solution supporting the continuous data exchange when the funding from the Connecting Europe Facility runs out after 2020.

It will support the implementation of the updated eHealth Action Plan 2012-2020 and update the eHealth interoperability framework for the implementation of the Digital Single Market Strategy.

It will also offer a possibility to coordinate Member States' actions for cross-border eHealth services going beyond cross-border e-Prescriptions and patient summaries.

*Implementation*

Chafea

*The timetable and the indicative amount*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Signature of the grant awarded without a call for proposals	Second half 2017	<b>2 700 000</b>

*2.2.3.2 Joint Action on Health Information towards a sustainable EU health information system that supports country knowledge, health research and policy-making. (Thematic priority 3.7 of Annex I to the Programme Regulation)*

*Expected Results and Impact*

The Joint Action is expected to build on previous projects and initiatives on EU health information and lead to the establishment of a European Research Infrastructure Consortium (ERIC) on Health Information. It will coordinate all expert networks on health information developed by the Bridging Information and Data Generation for Evidence-based Health Policy and Research Project (BRIDGE) ensuring their transition to an ERIC on Health Information. It will also facilitate Member States' involvement in the ERIC and will liaise

with Member States who are not currently part of the process. Finally, the Joint Action would support the start-up phase of the ERIC once established.

The major impact expected is a sustainable solid infrastructure on EU health information (ERIC) facilitating research and evidence-based health policy-making across Member States through improving the availability of comparable, robust and policy-relevant health data and information. This will strengthen the basis for monitoring the health status of EU citizens and the performance of EU health systems, such monitoring being of key importance for effective and efficient policy-making and evaluation.

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

The concrete activities of the Joint Action on Health Information, leading up to the launch of the ERIC, will be to keep the already established expert networks and knowledge alive to ensure their incorporation in the ERIC. In this way, it is also expected that the Joint Action will increase Member States' participation in the ERIC, which is necessary to enable the ERIC to deliver its objectives. Setting up a Joint Action on Health Information would also reassure Member States of the Commission's continued commitment towards a sustainable EU health information system, and would facilitate a smooth transition towards such a system by offering the opportunity to involve in the process those Member States, which could not yet participate for financial or administrative reasons.

This action will contribute to provide data which are required for the establishment of the health profiles and Health at a glance report which are subject of action 2.4.1.2 and 2.4.1.3.

*Implementation*

Chafea

*The timetable and the indicative amount*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Signature of the grant awarded without a call for proposals	Second half 2017	<b>4 000 000</b>

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

*No action is planned under this objective.*

### **2.3 Financial contribution to the functioning of non-governmental bodies (operating grants) (related to all programme objectives)**

Under the overall operational budget reserved for grants, EUR 5 000 000 will be reserved for operating grants.

Operating grants may be awarded to non-governmental bodies that pursue one or more of the specific objectives of the Health Programme. Operating grants are awarded according to the eligibility criteria established by Article 8(2) of the Programme Regulation and repeated again in Annex III to the present decision.

It is expected that these non-governmental bodies assist the Commission with the information and advice necessary for the development of health policies and the implementation of the Programme objectives and priorities. It is also expected that non-governmental bodies will work on increased health literacy and promotion of healthy life styles, the organisation of science policy conferences and contribute to the optimisation of healthcare activities and practices by providing feedback from and facilitating communication with patients thus empowering them. The Commission also encourages these non-governmental bodies to work together with the European Solidarity Corps, where appropriate.

In 2017, a call for proposals will be organised for the conclusion of four-year framework partnership agreements (FPA) covering the years 2018, 2019, 2020 and 2021, in particular, but not limited to, the following priority areas:

- Prevention and health determinants;
- chronic diseases;
- cancer;
- dementia;
- rare diseases;
- HIV/AIDS, Tuberculosis, Hepatitis;
- access to healthcare;
- substances of human origin.

FPA recipients are eligible for a Specific Grant Agreement (SGA) (Operating Grant). These FPA recipients will be invited to submit an application for an SGA to cover their operating costs for 2018. This will include the annual work programme and the budget. This procedure for SGA invitations will be repeated each subsequent year until the end of the FPA. Having received an FPA does not guarantee annual co-funding.

Operating grants (SGA) 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 V contains the criteria for independence from industry, commercial and business or other conflicting interests. Annex III contains the eligibility, exclusion, selection and award criteria for these actions.

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
call for proposals	First half 2017	5 000 000

## **2.4 Direct grant agreements with international organisations**

The overall budgetary allocation reserved for actions implemented via direct grants to international organisations amounts to EUR 9 300 000.

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 will be reimbursed either as actual costs incurred by the international organisation 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 organisation concerned authorises and determines the use of reimbursement on the basis of unit costs and flat rates.

Funding through direct grants will be awarded to the international organisations below because of their specific competence and high degree of specialisation in the areas covered by the direct grants as set out in the respective sections of this work programme.

### **International Organisation for Migration (IOM)**

IOM is the leading inter-governmental organization in the field of migration and works closely with governmental, intergovernmental and non-governmental partners. With 165 member states, a further 8 states holding observer status and offices in over 100 countries, IOM promotes humane and orderly migration for the benefit of all, by providing services and advice to governments and migrants. IOM is currently working on the RE-HEALTH project, with the PHR, and the direct grant will be built on it.

### **World Health Organisation (WHO)**

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

### **Organisation for Economic Cooperation and Development (OECD)**

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

Council of Europe

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.

#### **2.4.1 Actions under objective 1 — Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the health in all policies principle**

*2.4.1.1 Support to IOM for the Implementation of the Personal health Record as a tool for integration of refugees in EU health systems (Thematic Priority 1.1 of Annex I to the Programme Regulation)*

##### *Expected Results and Impact*

The aim of this action is to consolidate the use of the personal health record as a single tool for health assessments in EU countries and to develop a revised version after the first phase of piloting it.

In line with the EU migration agenda and the skills agenda in its part related to integration of third countries nationals, one of the tools mentioned is the personal health record for reconstructing medical history of recent migrants and refugees.

A unified tool at EU level, also used for relocation of refugees, can provide a single identity for the collection of medical records and facilitate the transit of refugees from reception to destination countries.

##### *Description of activities (grant awarded without call for proposals on the basis of Art. 190(1)f of the Rules of Application)*

Continue the first phase of piloting of the personal health record, that due to finish in January 2017 and develop a version 2.0 after evaluation.

##### *Implementation*

Chafea

##### *The timetable and the indicative amount of the calls for proposals*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Signature of the grant awarded without a call for	First half 2017	<b>1 000 000</b>

proposals		
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*2.4.1.2 State of Health in the EU — World Health Organization as the host of the European Observatory on Health Systems and Policies (Thematic priority 1.6 of Annex I to the Programme Regulation)*

*Expected Results and Impact*

The ‘State of Health in the EU’ package consists of four elements: the Health at a Glance: Europe report, country health profiles for EU Member States, a Commission policy paper and voluntary best practice exchanges. The package will be implemented by the Commission working in partnership with the OECD and the WHO as host of the European Observatory on Health Systems and Policies.

For the ‘Health at a Glance: Europe’ report the Commission continues its collaboration with the OECD. The OECD and the Observatory will contribute jointly to the health profiles for the 28 EU Member States and Iceland and Norway, including quality assurance and checking of factual accuracy with the countries concerned. In addition, OECD and the observatory will also jointly contribute to the best practice exchanges in line with their specific expertise, which is complementary. For technical as well as practical reasons the action is funded through separate direct grant agreements with each organisation.

The aim of the State of Health in the EU cycle is to create a means for mutual learning, which can be used as a basis for policy dialogue. The State of Health in the EU cycle will (1) contribute to country-specific and cross-country knowledge to inform policies at national and European level; (2) provide Member States with a reliable benchmarking on the performance of health systems; (3) enable policy dialogues with Member States on a voluntary basis; and (4) feed into a 2019 staff working paper to further explore value added for EU actions.

*Description of activities (grant awarded without call for proposals on the basis of Art. 190(1)f of the Rules of Application)*

The two-year recurring cycle covers both public health and health systems. The grant will cover the Observatory’s remaining activities under the first State of Health in the EU cycle (2016-2017) that were not covered by the corresponding grant in the 2016 Work Programme, as well as all the Observatory’s activities under the second State of Health in the EU cycle (2018-2019).

*Implementation*

Chafea
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*The timetable and the indicative amount of the calls for proposals*

Reference	Date	Amount (€)
Signature of the grant awarded without a call for proposals	First half 2017	<b>1 600 000</b>

*2.4.1.3 State of Health in the EU cycle (OECD) (Thematic priority 1.6 of Annex I to the Programme Regulation)*

*Expected Results and Impact*

The ‘State of Health in the EU’ packages consists of four elements: the Health at a Glance: Europe report, country health profiles for EU Member States, a Commission policy paper and voluntary best practice exchanges. The package will be implemented by the Commission working in partnership with the OECD and the WHO as host of the European Observatory on Health Systems and Policies.

For the ‘Health at a Glance: Europe’ report the Commission continues its collaboration with the OECD. The OECD and the Observatory will contribute jointly to the health profiles for the 28 EU Member States and Iceland and Norway, including quality assurance and checking of factual accuracy with the countries concerned. In addition, OECD and the observatory will also jointly contribute to the best practice exchanges in line with their specific expertise, which is complementary. For technical as well as practical reasons the action is funded through separate direct grant agreements with each organisation.

This exercise will (1) contribute to country-specific and cross-country knowledge to inform policies at national and European level; (2) provide Member States with a reliable benchmarking on the performance of health systems; (3) enable policy dialogues with Member States; and (4) feed into a 2019 Staff working paper to further explore value added for EC actions.

The aim of the State of Health in the EU cycle is to create a means for mutual learning, which can be used as a basis for policy dialogue. The two-year recurring cycle covers both public health and health systems.

*Description of activities (grant awarded without call for proposals on the basis of Article 190(1)f of the Rules of Application)*

In the framework of the second State of Health in the EU cycle (2018-2019) the OECD will prepare (1) the 2018 ‘Health at Glance: Europe’ report prepared by OECD; (2) 28 individual country health profiles; and (3) ex-post policy dialogues organised with the Member States on a voluntary basis.

*Implementation*

Chafea

*The timetable and the indicative amount of the calls for proposals*

Reference	Date	Amount (€)
Signature of the grant awarded without a call for proposals	First half 2017	1 500 000

## 2.4.2 Actions under objective 2 — Protecting Union citizens from serious cross-border health threats

*No action is planned under this objective.*

## 2.4.3 Actions under objective 3 — Contributing to innovative, efficient and sustainable health systems

2.4.3.1 *European Pharmacopoeia– Grant to the Council of Europe — European Directorate for the Quality of Medicines and Healthcare (EDQM) (Thematic priority 3.6 of Annex I to the Programme Regulation)*

### *Expected Results and Impact*

The European Union is a party to the Convention on the European Pharmacopoeia of the Council of Europe. The action aims at ensuring the harmonisation of quality standards vested in the EU pharmaceutical legislation, facilitating the placing on the market of medicines in all the Member States, and availability of medicines for the whole European population by contributing to the work on the European Pharmacopoeia.

Furthermore, it aims at the development of best practices that are shared between Official Medicines Control Laboratories (OMCLs) responsible for controls on medicines and verification of their composition according to the established quality standards.

The development and harmonisation of quality standards in Europe for medicines contribute to an efficient regulatory framework for medicines in Europe by reducing the burden and workload needed for applicants to develop and validate their own standards.

*Description of activities (grant awarded without call for proposals on the basis of Article 190(1)f of the Rules of Application)*

This action has a duration of 3 years and covers three areas:

- (1) Biological Standardisation Programme: Development of new methods and Reference Standards for all groups of biological medicines and replacement of expired or ‘out of stock’ Biological Reference Standards for the quality control of biological medicines. Studies are conducted in relation to the 3Rs (Reduce, Refine and Replace) concept to

for animal testing in routine controls of biological medicines in line with the EU legislation on the protection of animals used for experimental and other scientific purposes

(2) Official Medicines Control Laboratories (OMCL) Network: annual meeting and thematic meetings, coordination of a specific OMCL network capable of detecting falsified medicines and development and maintenance of databases for exchange of information, data and results within the Network.

(3) Terminology: Development of Standard Terms and a database and participation in the development of the Identifier for Medicinal Products (IDMP).

### *Implementation*

Chafea

### *The timetable and the indicative amount of the calls for proposals*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Signature of the grant awarded without a call for proposals	First half 2017	<b>3 300 000</b>

### *2.4.3.2 Support to the OECD to develop patient-reported measures (Thematic priority 3.7 of Annex I to the Programme Regulation)*

#### *Expected Results and Impact*

The action will support the OECD in developing and testing in a pilot phase new indicators on patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs). These measures will serve to define new and more reliable indicators of health outcomes and health system effectiveness.

The action will develop expertise on performance assessments of health systems. It will also help build lessons from recent experience and from EU-funded research projects. Finally it is explicitly meant to build up country-specific and cross-country knowledge which can inform policies at national and European level.

Deliverables are expected to be used by Member States to assess their capacity to deliver positive health outcomes, and identify policy action to improve it. The comparability of the indicator will allow the exchange of best practice cases and the share of information and experiences with peers.

*Description of activities (grant awarded without call for proposals on the basis of Article 190(1)f of the Rules of Application)*

The OECD, in coordination with the Commission will develop a methodology for the collection and calculation of PREMs and PROMs, which will include a questionnaire, guidelines to collect the information, and metadata to read it.

The OECD will then submit the questionnaire to a sample of volunteer Member States, collect the information and calculate the related indicators. The figures will be checked with the countries that are concerned.

*Implementation*

Chafea

*The timetable and the indicative amount of the calls for proposals*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Signature of the grant awarded without a call for proposals	First half 2017	<b>500 000</b>

*2.4.3.3 Support to the OECD's work on building trust and strengthening cooperation for addressing the challenges of access to medicines (Thematic priority 3.4 of Annex I to the Programme Regulation)*

*Expected Results and Impact*

The grant will contribute to developing policy documents and analysis in the OECD context that will be useful for OECD members to reflect on their policy processes with a view to ensuring that health systems can perform better in the area of pharmaceutical expenditure and on pharmaceutical policies in general. The cost-effective use of medicines is indeed one of the elements to increase accessibility, as presented in the Commission Communication on 'effective, accessible and resilient health systems' (2014).

*Description of activities (grant awarded without call for proposals on the basis of Art. 190(1)f of the Rules of Application)*

The OECD work can provide a platform where EU Member States that are OECD members can exchange information and practices. It can identify tools and methodologies to increase transparency and better coordination to minimise any unintended effects that current national pricing systems have in terms of accessibility and affordability for the patients and costs for the health systems. The EU funding will make sure that the EU Member States that are not OECD members can benefit from the discussion. The action will support the work that the

OECD is developing in this area.

It will ensure the continuation of the discussion initiated within the OECD, with a series of meetings and publications.

#### *Implementation*

Chafea

#### *The timetable and the indicative amount of the calls for proposals*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Signature of the grant awarded without a call for proposals	First half 2017	<b>600 000</b>

#### *2.4.3.4 Support to the OECD's work on Trends and Policies affecting the international migration of doctors and nurses (Thematic priority 3.7 of Annex I to the Programme Regulation)*

#### *Expected Results and Impact*

The action will examine recent trends in the international migration of foreign trained doctors and nurses in European countries, the emerging agreements and arrangements between countries, and the impact of health and migration policies on these migration patterns. The resulting analysis will help to better inform policy dialogues between source and countries receiving health professionals and provide useful insights to shape national and regional policy responses.

#### *Description of activities (grant awarded without call for proposals on the basis of Art. 190(1)f of the Rules of Application)*

The action will support the work that the OECD is continuing to develop in the area of improving data and analysis on international migration of health professionals and in undertaking systematic review of agreements among countries. It will respond to the recommendation made by the Joint Action on health workforce planning and forecasting to improve the monitoring of health workforce migration and provide a 'map' of recent trends.

The action will draw on available documentation from the Joint Action on health workforce planning and forecasting, EU and international research.

#### *Implementation*

Chafea

#### *The timetable and the indicative amount of the calls for proposals*

Reference	Date	Amount (€)
Signature of the grant awarded without a call for proposals	First half 2017	200 000

#### **2.4.4 Actions under objective 4 — Facilitating access to better and safer healthcare for Union citizens**

##### *2.4.4.1 Support to implementation of national action plans on Antimicrobial Resistance (AMR) — World Health Organization (Thematic priority 4.4 of Annex I to the Programme Regulation)*

##### *Expected Results and Impact*

The aim of this action is to increase awareness among policy advisers in EU Member States and contribute to strengthened implementation of measures leading to reducing the rate of increase of AMR and to the long-term reductions in AMR. The WHO will provide support to Member States in the development and implementation of one-health action plans to address AMR.

Work with stakeholders and with Member States will lead to a suite of tools to support antimicrobial stewardship — including audit tools which will supplement the EU Guidelines on Prudent Use of Antimicrobials in Human medicine expected to be published at the end of 2016. The contribution of WHO to awareness raising will assist in ensuring synergy between WHO and EU activities around antibiotic awareness day/week. The evaluation component will provide information which can be used to better inform future awareness raising activities.

Awareness raising activities, education and activities aiming at behaviour change will be used to support Member States actions to raise awareness and support behaviour change among professionals and public in the direction of more prudent use of antimicrobials thereby assisting in implementation of their plans.

##### *Description of activities (grant awarded without call for proposals on the basis of Art. 190(1)f of the Rules of Application)*

This action comprises three areas:

- (1) Training and policy support to EU/EEA Member States and other countries participating in the Programme on AMR policy implementation and infection prevention and control
- (2) Development and implementation of antimicrobial stewardship including audit tools and guidance to measure performance.

(3) Development and implementation of antibiotic awareness activities including education, activities aiming at behaviour change and evaluation.

### *Implementation*

*Chafea*

### *The timetable and the indicative amount of the calls for proposals*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Signature of the grant awarded without a call for proposals	First half 2017	<b>600 000</b>

## **3 PRIZES**

### **3.1 Horizontal action (related to the four objectives) — Health Award (related to all programme objectives)**

#### *Description of activities results and impact*

The EU Health Award is part of the EU Health Policy Platform.

It will be organised annually to recognise the vital role of European, national and/or sub-national non-governmental bodies. It will highlight their significant contributions to promoting a healthier EU and fairer access to healthcare for EU citizens, preventing diseases and protecting EU citizens' health. This award will identify European, national and sub-national non-governmental bodies carrying out good practices in a different area of health every year.

These non-governmental bodies will also be invited to join the EU Health Policy Platform, an innovative tool to keep national and sub-national non-governmental bodies better informed of EU developments in the field of public health.

The EU Health Policy Platform will include a database of good practices from European, national and sub-national non-governmental bodies starting with those recognised by the EU Health Awards, to inspire other users.

## *Implementation*

Commission
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### *The timetable and the indicative amount*

<b>Reference</b>	<b>Date</b>	<b>Amount (€)</b>
Call for applications for the Health Award	First half 2017	<b>60 000</b>

## **4 PROCUREMENT**

The overall budgetary allocation reserved for procurement contracts in 2017 amounts to EUR 14 341 585.

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. These activities are implemented through service contracts based on existing framework contracts, service contracts or new framework contracts (see below the detailed information on the implementation of each activity).

### **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 Pilot on reformulation support and monitoring (Thematic priority 1.1 of Annex I to the Programme Regulation)**

##### *Subject matter of the contracts envisaged*

<p>Building on the consultations of the High Level Group and the Platform on Nutrition and Physical Activity as well as on the work of the relevant Joint Action a detailed comprehensive, effective and efficient monitoring process will be elaborated on reformulation initiatives for salt, sugars and fat. Their functioning will be pilot tested in key areas.</p>
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<p>Member States are expected to make use of the proposed monitoring system in reinforcing and protecting public health in the field on nutrition.</p>
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<p>It will include a feasibility analysis (usefulness, cost, sustainability) of further action to standardise harmonise related data collection and allow for direct comparisons that are currently not possible (from many points of view, e.g.: age groups, methods of dietary</p>
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assessment, different food composition databases).

Many countries do not have updated food and nutrition surveys and/or lack the capacity to launch them regularly and/or do not have data that cover key sectors of the population (e.g. the elderly) or topics (e.g. water intake).

This means that there is limited comparability in an essential area for decision-making despite the ongoing efforts of EFSA's EU Menu project. Any practical solution to improve monitoring will be a substantial improvement enabling the Member States to efficiently implement reformulation activities.

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

**4.1.2 Support to the design and implementation of public procurement guidelines for food (Thematic priority 1.1 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

This action focuses on the way the public sector buys food in order to support the reinforcement of the work of the Member States through action plans for prevention measures, and best practice sharing to better protect public health in the field on nutrition,.

The objective of this action is to provide a report compiling the guidance documents at EU and national level and a summary of their commonalities. An analysis will be provided on the implications and potential (including public health impact) for the wide implementation of such voluntary guidelines in Europe.

It will include a draft consensus text of Member States' authorities on this topic, and an analysis of the implications and potential (including public health impact) of wide implementation of such voluntary guidelines in Europe.

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

**4.1.3 Support to the design and implementation of measures to reduce the exposure of children to marketing of foods high in fat, sugar or salt (Thematic Priority 1.1 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

This action will produce a report on the targeting of minors and their exposure to marketing of foods high in salt, sugar or fat. The aim is to encourage its the reduction of such practices, including by the use of the (voluntary) instruments.

The ongoing revision of the Audiovisual Media Services Directive (AVSMD) is expected to result in a stronger call to the Member States to better protect children from aggressive marketing of foods that are not recommended by national or international nutritional guidelines. The report will enable Member States to better react positively to these changes and to take advantage of the revised legal framework of the AVSMD to support their national nutrition and physical activity policies.

The report will reply to several research questions, for the 28 Member States, as well as Norway, Iceland including:

- how much food advertising, in particular for foods high in salt, fat or sugars, does an average minor watching linear and non-linear audiovisual media services in the EU see?
- what is the exposure of minors to non-broadcast media, especially those utilising digital technologies?
- are minors specifically targeted by such advertising?
- how does the marketing budget of food companies differently promote the different types of products in their portfolios?
- How much is food marketing expenditure in the EU? How has it changed since the EU

Pledge became active, and what is the allocation of the budget for different marketing strategies (e.g. TV advertising budget vs non-broadcast online, social network, direct/mobile marketing, etc.)

Considering that the effects of food advertising to children are already quite well established in literature, the following gaps in evidence will be addressed: what are the effects of advertising in specific and food marketing in general on the food preferences, diets and health of teenagers (13-18 years) and what are the effects of online marketing techniques on the preferences, diets and health of children and teenagers?

This action will be coordinated with and can possibly receive a financial contribution from the Directorate General for Communications Networks, Content & Technology (DG Connect).

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

**4.1.4 The EU dimension of alcohol related harm (Lot 1) (Thematic priority 1.1 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

Based on the solid results of the 2014-2016 Joint Action to reduce alcohol related harm, this initiative will scale up and reinforce the Joint Action outcomes, and at the same time substantially increase support to Member States through a specific framework contract covering the period 2017-2020.

The initiative will strengthen the EU dimension of the efforts tackling alcohol related harm by covering a wide range of specific topics identified by the Commission and the Member States. It will increase the knowledge base and provide tools that can effectively support the Member States' activities in this area.

The specific contract within this Annual work programme 2017 covers the following

activities:

Targeted activities on alcohol contributing to the WHO target of a 10 % reduction of alcohol related harm will be carried out in form of a framework service contract to support specific objectives established by the Committee on National Alcohol Policy and Action (CNAPA). The activities will include support to addressing the main challenges on alcohol related harm, lowering alcohol consumption and preventing alcohol abuse.

The actions will be carried out with CNAPA involvement where appropriate. The Commission and the CNAPA have already identified a preliminary list of themes as particularly important. These can be grouped as follows: First, identifying data gaps and further work on data and evidence, second, developing specific evidence-based input and advice contributing to the reduction of alcohol related harm. Third, there is also a need to address the consequences for European companies and the EU economy of alcohol related harm in the workplace and of alcohol and mental health and the European dimension of topics such as road safety campaigns and targeting drink-driving, as well as support to national actions on marketing of alcohol, cross-border sale of alcohol and contraband of alcoholic beverages (given their impact on the internal market and on public health). In addition, an external evaluation of the commitments presented under the European Alcohol and Health Forum, including input and advice for future work, would be conducted, with a view to re-launching this work on the basis of securing greater impact.

The contractor will also perform an external assessment and evaluation of the commitments to reduce alcohol related harm made by the members of the European Alcohol and Health Forum and will prepare input and advice for the future work of the Forum, with a view to re-launching this work on the basis of securing greater impact. The action will allow the Commission to be more targeted and efficient in chairing the Forum and will support members in better designing their future commitments. This will further allow for drafting recommendations and additional sharing of best practice.

*Type of contract and type of procurement*

Specific contract based on new framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.1.5 Action plan to fight inactivity and promote physical activity**

##### **(Thematic priority 1.1 of Annex I to the Programme Regulation)**

###### *Subject matter of the contracts envisaged*

This activity will be carried out to complement the ongoing work to promote physical activity led by the Directorate-General for Education & Culture and in cooperation with the latter. To complement the existing EU Physical Activity Guidelines and the processes set up to implement the Council Recommendation on HEPA, and in line with WHO recommendations, work will focus on developing specific guidelines for groups of relevance (i.e. groups with specific health problems, especially pre-diabetics, diabetics, obese people, people with mental health problems). Key health professionals (lifestyle medicine, General Practitioners, physiotherapists) will be involved to gather and validate the specific guidelines.

In addition, and based on existing work, a module on effective and practical schemes for measurement of kids biometrics and physical activity performance in schools (based on the Slovene experience) and ways of involving education professionals in sustainable ways will be developed.

Moreover, an overview covering the EU and a selection of good practices would be prepared on the possibility to prescribe physical activity, the coverage by health insurance and the effective Health in all Policies approach; the draft will be presented to the Member States to be endorsed.

###### *Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

###### *Indicative number of contracts envisaged: 1*

###### *Implementation*

Chafea

###### *Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.1.6 Feasibility of a European expert network for rare communicable diseases and other rare pathologies linked to globalisation/migration**

**(Thematic priority 1.1 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

Ensuring access to services, including health services, is essential to the successful integration of migrants into their new country of residence. Prevalence of different diseases diverge in different countries and health professionals lack the skills to correctly identify and treat pathologies they are not familiar with, because they are not prevalent in the countries where they are established or because they are newly emerging diseases.

The following actions will be carried out:

- (1) identify the areas on rare pathologies linked to globalisation where establishing a European expert network could be an added value
- (2) organise a series of workshops with experts to identify the European centres that could provide expertise in the identified areas
- (3) identify the feasibility of an EU expert network in those areas
- (4) identify synergies with training packages for health professionals that have been developed

The main deliverable will be an assessment on the conditions for the creation of an EU expert network on pathologies linked to migration/globalisation. The network, if assessed positively could serve as:

- Quick reference in case of newly emerging diseases
- A means to identify EU expertise in pathologies not prevalent in EU countries
- A contribution to the lack of knowledge linked to the appearance of newly emerging diseases
- A contribution to better health care for migrants and refugees with pathologies unknown by EU professionals
- A Reference network at EU level and also for national health professionals with urgent requests

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

**4.1.7 Analysis of collected health information regarding health status of refugees  
(Thematic priority 1.1 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

This action will provide information on the actual health status of the refugees by analysis of the already collected data.

As the integration of third country nationals is a priority for the EU, as approved in the skills agenda, and as access to services, including health services, integration is key to ensuring effective integration of refugees, knowing the current use of health services and actual health status will provide a more accurate knowledge of the situation and, therefore, facilitate integration.

The aim of this action is to ensure:

- (1) Contribution to the knowledge of the state of health of the EU
- (2) Better adaptation of health systems to real needs
- (3) Combat stereotypes via accurate information
- (4) Integrate different data sources
- (5) Showing the importance of coordinated data collection

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.1.8 EU Health Policy Platform (Thematic priority of 1.1 Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

The aim of this action will be to manage the implementation of the IT-based EU Health Policy Platform aimed at easing multilateral communication and active involvement among stakeholders, and between the different stakeholder groups and the Commission. It will also serve as a tool to allow cross-sectoral in-depth debates, creating synergies among stakeholders, and leading to discussion on topics of interest for the health community. It will further create a direct bridge to citizens' organisations on some of the topics that most directly matter to them. Two regular meetings of the Platform will be organised per year, including one high-level meeting in the second half of 2017.

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Commission

*Indicative timeframe for launching the procurement procedure*

First half 2017

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

*Subject matter of the contracts envisaged*

**Technical assistance:** Following its entry into force, the new Tobacco Products Directive (TPD) 2014/40/EU<sup>3</sup> will 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 and monitored by appropriate technical, scientific and legal input in form of reports, studies, market data and/or other relevant forms.

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

(i) Further development of the ingredients regulation:

**Operation of technical group supporting the assessment of flavours in tobacco products** (specific contract under new framework contract): the technical group of sensory and chemical assessors is established by Commission Implementing Decision (EU) 2016/786<sup>4</sup> to support the Independent Advisory Panel, as well as the Commission and Member States in the decision making-process regarding tobacco products on the EU market in terms of whether or not they contain a characterising flavour.

**Further development of the EU common entry gate (EU-CEG) reporting tools and data mining** to facilitate the assessment of the data collected pursuant the TPD in order to, regulate further the additives in question, if necessary;

(ii) further development of tracking and tracing systems and security features as outlined in Article 15 on traceability and 16 on security features:

**Study of illicit trade in tobacco** (possibly co-funded with other Commission departments) should establish an independent source of information that would add to the better understanding of such a dangerous phenomenon as illicit trade and eventually help in designing better, possibly cross-policy, instruments to fightit. The results of the study will be equally useful at the EU and Member State level;

(iii) transposition checks of the TPD to conclude the analysis of the alignment of tobacco products legislation in all 28 Member States with the Tobacco Products Directive 2014/40/EU and its implementing legislation;

(iv) regulation and monitoring of e-cigarettes, in particular risk assessment and mitigation, product notification, and follow-up of technical and market developments and further implementation of labelling and packaging provisions of TPD;

(v) general monitoring of the market, epidemiological, scientific, technical and international

<sup>3</sup> OJ L 127, 29.4.2014, p 1.

<sup>4</sup> OJ L 131, 20.5.2016, p. 79-87

developments including studies that will enable the Commission to comply with its reporting obligations pursuant to Article 28 of the TPD.

In parallel the Commission will further monitor related tobacco control policies through appropriate reports or studies, in particular advertising and sponsorship of tobacco products (regulated by Directive 2001/33/EC),<sup>5</sup> smoke-free environments (Council Recommendation 2009/C29 6/02)<sup>6</sup> and other initiatives to improve tobacco control (as outlined by Council Recommendation 2003/54/EC.<sup>7</sup>

*Type of contract and type of procurement*

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

*Indicative number of contracts envisaged: 4-5*

Indicative timeframe for launching the procurement procedure

First and second halves of 2017 (two procedures in the first half of the year, three procedures in the second half)

*Implementation*

Implementation by the Commission and Chafea.

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

### **4.2.1 Workshops and table-top exercises to support the implementation of Decision 1082/2013/EU on serious cross-border health threats and of the core capacities under international health regulations (IHR) (Thematic priority 2.2 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

The contractor will organise two regional workshops to identify gaps, develop knowledge and build capacity of public health professionals working on the implementation of the IHR core capacities that Member States should have in place to properly prepare for outbreaks and

<sup>5</sup> OJ L 127, 9.5.2001, p. 42.

<sup>6</sup> OJ C 296, 5.12.2009, p. 4.

<sup>7</sup> OJ L, 22, 25.1.2003, p. 31.

ensure the required response. Two 2-day regional workshops will be developed, prepared, delivered and evaluated.

The workshops should help participants to exchange and improve knowledge and skills that are critical to sustaining public health surveillance and response at all levels of the health system and to the effective implementation of the IHR, in line with Decision 1082/2013/EU on serious cross-border threats to health. Results of the workshops will contribute to further developing the reporting process and tool under Article 4 of Decision 1082/2013/EU, and better prepare Member States for the reporting exercise. Proposed activities should take into account the development of the WHO's Joint External Evaluation approach and ongoing activities of WHO and ECDC.

Participants from relevant Commission departments, EU agencies, and international organisations (WHO) will be invited to participate. Full reporting will be available on outcomes and lessons learnt.

The workshops will facilitate developing professional knowledge and sharing of experiences and learning between participants of different Member States including on surveillance systems, structures to manage and control outbreaks, preparedness plans and appropriate risk communication mechanisms.

The aim of the table-top exercises is to test the preparedness, response and communication on serious cross border health threats, aiming to improve preparedness of Member States and strengthen capacity to coordinate response to health emergencies in line with Decision 1082/2013/EU on serious cross-border threats to health.

The exercises will enable Member States authorities to work together with a view to coordinating their response to serious cross-border threats with the involvement of cross-sectoral partners, and will ultimately strengthen preparedness at EU level. The exercises are expected to improve preparedness and response planning, crisis management and communication and intersectoral cooperation.

#### *Type of contract and type of procurement*

Specific contracts based on new framework contract

*Indicative number of contracts envisaged: 2*

#### *Implementation*

Chafea

#### *Indicative timeframe for launching the procurement procedure*

First half 2017

**4.2.2 Conduct of a comprehensive analysis of vaccination schedules and on the development of technical guidance on financial planning of national vaccination programmes (Thematic priority 2.2 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

This action provides support to Member States in improving vaccine coverage with a view to reinforcing preparedness at EU level, in line with the objectives of Decision 1082/2013/EU on cross-border threats to health, in particular in regard to strengthening cooperation and coordination of national preparedness planning. The objective is to provide an analytical framework in order to assist Member States on optimal programmatic vaccine decision-making.

The contract will include two studies:

First, a review of existing evidence on the conduct of a comprehensive analysis of vaccination schedules, taking due consideration of epidemiological, economical and operational aspects and an analysis of reasons for diverging national vaccination schedules. The evidence-based key elements are to be taken into account as regards development and adaptation of vaccination schedules. The analytic framework is expected to assist countries on optimal programmatic vaccine decision-making.

Secondly, a study on the development of technical guidance on financial planning of national vaccination programmes aims at demonstrating that financial sustainability plans are a key instrument for governments to use in planning for the financial health of the immunisation programmes and to support programme expansion and improvement. It will analyse the possibilities to integrate such financial sustainability plans into broader strategic planning processes in the health sector, building on — and contributing to — discussion about health sector priorities and mechanisms for reliable and sufficient financing of those priorities.

*Type of contract and type of procurement*

Specific contracts based on new framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.2.3 Workshop on best practices on entry and exit screening (Thematic priority 2.2 of Annex I to the Programme Regulation)**

##### *Subject matter of the contracts envisaged*

The contractor will organise a two day workshop for exchange of best practices in controlling incoming and exiting passengers. The workshops will provide a valuable tool for public health and medical border authorities as well as the Health Security Committee. It will offer the opportunity to learn from actors in the field who have developed a solid experience (WHO, ECDC, US-CDC). The workshop will focus on health measures in border controls and cooperation between the public health/medical border authorities from EU Member States and border control agencies (e.g. IOM, FRONTEX). The workshop's result will be presented in a comprehensive report. A gradual follow-up will be organised to foster the creation of a network of public health/medical border authorities.

The proposed actions will enable the Member States authorities, as well as EEA countries and other countries participating in the Health Programme to better coordinate the EU responses to serious cross-border threats and ultimately enable the EU to be better prepared.

This network should form the basis of public health teams under the newly created European Medical Corps, and will require the close association with the Health Security Committee, the ECDC, the WHO and the Commission (Directorate-General for European Civil Protection and Humanitarian Aid Operations (DG ECHO)). This action will be linked to International Health Regulation (IHR) implementation.

The proposed actions will also enable the network of public health professionals at border crossings and airports to assist the WHO when responding to major communicable diseases threats and enable deployment to countries who have failed to adequately control the spread at their border crossings.

##### *Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

##### *Indicative number of contracts envisaged: 1*

##### *Implementation*

Chafea

##### *Indicative timeframe for launching the procurement procedure*

First half 2017

### 4.3 Actions under objective 3 — Contributing to innovative, efficient and sustainable health systems

#### 4.3.1 EU market access paths for medical technologies with a focus on health technology assessments (HTA) (Thematic priority 3.1 of Annex I to the Programme Regulation)

##### *Subject matter of the contracts envisaged*

The study will provide a comprehensive overview of the HTA methodologies for medical devices across the EU by identifying the responsible HTA bodies, the national requirements for assessing the various categories of medical technologies (e.g. in relation to the domains of the HTA Core Model as elaborated by the EUnetHTA Joint Action<sup>8</sup>) and the main steps of health technology assessments and their timing as carried out by the Member States HTA bodies. The study will compare the EU market access paths for medical technologies with those for medicinal products and will include a workshop with the relevant stakeholders for the validation of the final conclusions.

The study will allow for a better understanding of the current organisational and methodological framework for HTA of medical technologies across EU in order to identify the particularities of HTA by sector.

##### *Type of contract and type of procurement*

Direct service contract or specific service contracts based on framework contract

##### *Indicative number of contracts envisaged: 1*

##### *Implementation*

Chafea

##### *Indicative timeframe for launching the procurement procedure*

Second half 2017

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<sup>8</sup> [www.eunetha.eu](http://www.eunetha.eu) (2012-2015)

#### **4.3.2 Stakeholders forum on EU cooperation on health technology assessment (HTA) (Thematic priority 3.1 of Annex I to the Programme Regulation)**

##### *Subject Matter of the contracts envisaged*

The purpose of this action is to organise a conference for the presentation of an EU initiative on the future EU cooperation on HTA to all interested Member States, other countries participating in the Health Programme and stakeholders. The conference will allow for an open discussion on the implementation of the initiative for the future EU cooperation on HTA, and could address issues such as:

- (1) improving the dialogue between regulatory and HTA organisations and industry and patients representatives
- (2) achievements of EU cooperation on HTA thanks to EU-funded actions (for example the EUnetHTA Joint action, Innovative Medicines Initiative (IMI) projects);
- (3) the role of EU cooperation on HTA in stimulating innovation and improving access of innovative and effective technologies to the EU market

This conference will represent an opportunity for consulting stakeholders on their views, with the aim to build consensus on the challenges and opportunities for the implementation of a future sustainable solution for EU cooperation on HTA.

##### *Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

##### *Indicative number of contracts envisaged: 1*

##### *Implementation*

Chafea

##### *Indicative timeframe for launching the procurement procedure*

Second half 2017

#### **4.3.3 Health innovation — eHealth (Thematic priority 3.2 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

The study will map options for the sustainable implementation of the cross-border exchange of health data, make suggestions for new use cases beyond e-prescriptions and patient summaries, proposals for technical standards and systems necessary in telemedicine and electronic access to own health data, map the main health platforms and make a recommendation for policy actions, as well as provide information on the public opinion on eHealth and on the uptake of the eHealth services.

In particular the study will provide:

- (1) Proposals for further digital solutions for the exchange of health data cross borders, such as access to registers of hospitals or professionals providing cross-border treatment;
- (2) Proposals for the development of standards necessary for the development of telemedicine;
- (3) An analysis and recommendations on the role of the platforms in health;
- (4) Information about the measured uptake and use of eHealth services among EU citizens.

The study results will provide background information for support the development of concrete proposals for eHealth and mHealth actions to ensure the continued innovation in the EU's eHealth policy and respond to the tasks set under the Digital Single Market Strategy and the updated Action Plan for eHealth 2012-2020.

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

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

##### *Subject matter of the contracts envisaged*

This action will provide scientific and technical assistance for the Expert Panel on effective ways of investing in Health. The assistance will take the form of the organisation of scientific hearings, working group meetings and thematic workshops, as well as direct scientific support for the drafting of documents, such as literature searches, editing and translation of scientific texts into publications for the general public and their dissemination.

For the role and mandate of the Expert Panel, please refer to section 5.3.1.

##### *Type of contract and type of procurement*

Direct service contract or specific service contract based on framework contract

*Indicative number of contracts envisaged: approximately 5*

##### *Implementation*

Commission

##### *Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.3.5 Development of the future Eudamed, the European medical devices database, following the adoption of new Regulations on medical devices and in-vitro diagnostic medical devices by the legislators (Thematic priority 3.6 of Annex I to the Programme Regulation)**

##### *Subject Matter of the contracts envisaged*

The expected result of the action is a new Eudamed database with six electronic systems: UDI, registration certificates, clinical investigation, vigilance and market surveillance — a well-functioning database accommodating all information laid down for it in the new

legislation.

The database is required under the obligations of the Commission in Article 27 of the Commission proposal of 26.9.2012 for a Regulation on medical devices and in Article 25 of the Commission proposal of 26.9.2012 for a Regulation on in-vitro diagnostic medical devices.

A new Eudamed (with six electronic systems: UDI, registration certificates, clinical investigation, vigilance, market surveillance) is required under the forthcoming regulations on medical devices and in-vitro diagnostic medical devices. The financing through the Health Programme aims at covering the cost of consultations to decide on the new content of the database and technical developments of the new database.

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Commission (DG GROW)

*Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.3.6 Maintenance and required developments of the existing Eudamed (Thematic priority 3.6 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

The objective of this action is to ensure the maintenance and if required developments of the existing European medical devices database Eudamed before the launch of the new version. Eudamed is an information system for exchanging legal information related to the application of EU Directives on medical devices between the Commission and the competent authorities in the EU Member States. The financing aims at covering the maintenance and required developments of the existing Eudamed.

*Type of contract and type of procurement*

Specific contracts based on an existing framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Commission (DG GROW)

*Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.3.7 Translations, info campaigns, publications — on medical devices (Thematic priority 3.6 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

This activity will focus on the production of information material and the organisation of other actions facilitating the application and understanding of the new legislation by stakeholders, Member States and other parties concerned.

The communication activities and publications have the aim to promote 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.

This action will underpin and improve the implementation of Directives 90/385/EC and 93/42/EEC and the future regulations on medical devices and in-vitro diagnostic medical devices following their adoption by the legislators.

*Type of contract and type of procurement*

specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Commission (DG GROW)

*Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.3.8 Clinical Trial EU Portal and Database (Thematic priority 3.6 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

The objective of this action is to provide specialised IT and project management support to the work of the European Medicines Agency (EMA) for the development of an EU portal and database for the submission of requests for authorisation and follow-up of clinical trials on medicinal products for human use. The action covers the specific input the Commission will provide to the project.

The new Clinical Trials Regulation (EU) No 536/2014 provides for the establishment by the EMA in collaboration with the Member States and the Commission of an EU portal and database for clinical trials. A fully functional portal and database are legal requirements for the application of the new Regulation on clinical trials. As required by Article 37 (4) and 81 of the Clinical Trials Regulation (EU) No 536/2014, this database will store information on the content, start and end of clinical trials. It will facilitate on different levels the sharing of clinical trials information between approving authorities different institutions and establishments carrying out their trials in different EU Member States and the public.

*Type of contract and type of procurement*

Direct service contract or specific service contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Commission

*Indicative timeframe for launching the procurement procedure*

Second half 2017

#### **4.3.9 Study on the impact of the incentives provided in the EU legislation on innovation — accessibility of medicinal products (Thematic priority 3.6 of Annex I to the Programme Regulation)**

##### *Subject matter of the contracts envisaged*

The Council conclusions ‘on strengthening the balance in the pharmaceutical systems in the EU and its Member States’ call for an evidence based analysis of the impact of the incentives in the EU legislation on innovation, as well as on the availability and accessibility of medicinal products.

Beside the SPC study that will be conducted with DG GROW in 2016/2017, this SANTE study will cover some additional aspects of pharmaceutical legislation and will take into account the results of the SPC studies, and of the ongoing study and report on the Paediatric Regulation.

With the objective to address the request made in the Council Conclusions mentioned above, the study will provide important data and a holistic view on the impact of the incentives for pharmaceutical products on innovation, availability, accessibility and shortages of medicinal products, including high prices that pose a high burden for patients and health systems. The impact of the incentives on the availability of generic medicinal products will also be included. Where relevant, the analysis of the impacts of the incentives will address the development of medicinal products and the effects of the pricing strategies in relation to the incentives.

##### *Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

##### *Indicative number of contracts envisaged: 1*

##### *Implementation*

Commission

##### *Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.3.10 Study of centralised and decentralised procedures for pharmaceutical products (Thematic priority 3.6 of Annex I to the Programme Regulation)**

##### *Subject matter of the contracts envisaged*

The external evaluation study covering jointly the elements listed in Article 86 of Regulation (EC) 726/2004 and Art. 38(2) of Directive 2001/83/EC, will enable the Commission to adopt in 2019 a joint report covering all the elements required under both legal provisions.

The final report will provide an important evidence base and potential recommendations for improving and amending centralised and decentralised procedures for authorisation of medicinal products in the EU. Once these recommendations are implemented at the EU and Member States' level this will bring important benefits to patients, national competent authorities, pharmaceutical industry and health care professionals.

The analysis of centralised, decentralised and mutual recognition procedures for authorisation of medicinal products at least once in 10 years is a legal requirement of the EU pharmaceutical legislation.

##### *Type of contract and type of procurement*

Service contract on the basis of a framework contract

##### *Indicative number of contracts envisaged: 1*

##### *Implementation*

Commission

##### *Indicative timeframe for launching the procurement procedure*

Second half 2017

#### **4.3.11 Support to the implementation of health systems performance assessment (HSPA) (Thematic priority 3.7 of Annex I to the Programme Regulation)**

##### *Subject matter of the contracts envisaged*

In order to provide technical assistance to Member States that request it, in the framework of the activities of the Commission expert group on health systems performance assessment, the action aims to:

- (1) Provide tools for dissemination of the findings of the expert group, its conclusions and policy recommendations. — This may take the form of workshops with stakeholders, seminars, policy focus groups;
- (2) Deliver expert advice to Member States which request for it. — The advice may be in form of peer reviews and meeting with experts appointed or identified by the expert group. Advice can be both of strategic and operational nature: it can be to design policy action and plans, as well as to implement them.

The action will develop expertise on performance assessments of health systems. It will also help building on lessons from recent experience and from EU-funded research projects. Finally, it will specifically contribute to country-specific and cross-country knowledge which can inform policies at national and European level.

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Commission

*Indicative timeframe for launching the procurement procedure*

First half 2017

**4.3.12 Scientific Committees (scientific and technical assistance) (Thematic priority 3.7 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

**Technical assistance:** This action will provide scientific and technical assistance for scientific committees. This includes organisation of scientific hearings, working group meetings and thematic workshops, as well as direct scientific support for the drafting of documents, such as literature searches, editing, and translation of scientific texts into publications for the general public and updating of the scientific committees' website. These services will be based on the specific scientific and technical expertise of the Commission Departments (e.g. the Joint Research Centre or the EAC library) or provided by external contractors. Support will be provided for data analysis, scientific aspects of impact assessments and risk communication.

*Type of contract and type of procurement*

Specific contracts based on existing framework contracts and low-value contracts (and one administrative agreement with the Joint Research Centre)

*Indicative number of contracts envisaged: 6 (+ 1 administrative agreement with the Joint Research Centre)*

*Implementation*

Commission

*Indicative timeframe for launching the procurement procedure*

First half 2017

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

##### **4.4.1 ERN capacity building and implementation, including communication, coordination and other support actions (Thematic priority 4.1 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

This action comprises six parts:

- (1) Conference: based on the success of the previous ERN Conferences, the fourth conference will present information on the achievements further to the approval of ERN as a result of the first and second call for ERN. The conference aims to showcase the main activities and projects of the ERNs, to investigate how the networks will contribute to better and safer healthcare, to host a high level discussion at political and strategic level on the implementation of ERNs.
- (2) ERNs working seminar: with the participation of the ERN coordinators, a representation of healthcare providers and affiliated partners of the approved ERNs, this event will share best practices developed by the ERNs, prepare the yearly work plan and evaluate the outcomes and performance of the ERN during the previous year. The event will contribute to implement better practices, make the networks more efficient and therefore improve the quality of care and the access to highly specialised healthcare for the targeted patients with rare or complex conditions.
- (3) Two types of training programmes tailored to the needs of:
  - a) the coordinators and managers of the approved ERNs. The training will focus on managerial skills and competences for improving networking capacity and the quality of the ERNs governance and coordination across the EU. Better capacity will be

achieved for the resolutions of conflicts and implementation of effective ways of communication and team building, resulting in better outcomes in terms of the ERNs effectiveness.

b) the ERN members for the development of clinical guidelines and decision-making tools. As a result, effectiveness will be enhanced in terms of number of patients treated, guidelines and clinical decision tools produced and increase the quality of the evidence gathered and methodologies used. This action will also contribute to better clinical information and transfer of knowledge to the less experienced or smaller Member States.

(4) Knowledge transfer to patients as beneficiaries of the ERN cooperation: ERNs scientific and technical outcomes will be translated into information tailored for non-specialised audience (patients and families). The aim is to empower patients by providing them with accessible information related to their diseases and to promote the benefits of ERN collaboration.

(5) Support for the functioning of the ERNs: the development of standard templates for all ERN developed tools, working documents and reports (paper or electronic) adapted to the content and clinical needs of the Networks. This action will create a complete taxonomy and classification of products and documents such as clinical guidelines, protocols, algorithms, recommendations and research outcomes. An analysis will be carried out based on the ERN experts' consensus of their schemes, contents and structures and a repository of the templates to be integrated in the everyday work of the Networks. The expected impact will help ensure the increased use and application of the knowledge generated in a consistent way.

(6) Support for the external communication of ERNs: to raise awareness on the benefits offered by ERNs to address complex and rare clinical cases through centrally coordinated media and online actions, and the development of a multilingual communications toolkit for ERN members. The expected impact will be the recognition of ERNs and their results.

#### *Type of contract and type of procurement*

Specific contracts based on existing framework contract and service contracts. Restricted and open call for tenders.

*Indicative number of contracts envisaged: 3*

#### *Implementation*

Chafea/Commission

*Indicative timeframe for launching the procurement procedure*

First half 2017

**4.4.2 Assessment of healthcare providers wishing to join established European Reference Networks (ERN) by Independent Assessment Bodies (Thematic priority 4.1 of Annex I to the Programme Regulation)**

*Subject matter of the contracts envisaged*

Independent assessment bodies will evaluate the membership proposals applying to join existing European Reference Networks which were set up in 2016. The ERN rules offer a possibility for further healthcare providers to join also after the call launched by the Commission but they must also be assessed in order to join. The contract will include the necessary technical assistance and the assessment.

The deliverables (assessment reports) will provide the basis for the ERN Board of Member States for the eventual approval of the membership of the healthcare providers positively assessed to join and existing Network.

The contractor will perform the eligibility check, documentation assessment of all the received applications and on-site visits, with the aim of producing an assessment report of all Healthcare Providers, participating in the open call for interested healthcare providers to join existing approved Networks

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

## 4.5 Horizontal action

### 4.5.1 Implementation assessment on uptake of recommendations (on cancer, and rare diseases) and their implementation in the Member States

#### *Subject matter of the contracts envisaged*

The implementation assessment will analyse recommendations developed by previous Joint Actions and expert groups and their use in the Member States. For instance, the use of the CANCON guide on National Cancer Control Plans or the Rare Diseases Expert Group Recommendation on Ways to Improve Codification for Rare Diseases in Health Information Systems could be assessed.

The study should provide advice and expertise to the Commission and its departments in relation to the impact of Expert Group Recommendations and selected Joint Action deliverables concerning cancer and rare diseases.

Expert Groups essentially are a forum for discussions, providing high-level input from a wide range of sources and stakeholders in the form of opinions, recommendations and reports.

The Expert Groups assists the Commission by drawing up legal instruments and policy documents and by providing guidelines and recommendations. They advise the Commission on international cooperation, provide an overview of EU and national policies and organise exchanges of relevant experience, policies and practices between the Member States and the various parties involved. This study will assess the outcomes of the work of the expert groups in the area of cancer and rare diseases in the past years and order to ensure a continuous high quality work of these groups. It will take into account that suggestions stemming from expert groups may have been taken-up by the Member States in various ways. It will aim neither to standardise nor rank.

The results of this assessment will also help identify the best future orientation of the Health Programme, improve the efficiency of the work of Expert Groups, and help identify the best ways for the Commission's initiatives to ensure the highest possible added value for Member States.

#### *Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

#### *Indicative number of contracts envisaged: 1*

#### *Implementation*

Commission

*Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.5.2 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.

Activities to be funded include inter alia:

- preparing and disseminating graphic material and publications
- web management
- media activities
- audiovisual productions on health policy priorities
- support to conferences and other stakeholder-related events — promotion on social media

Part of the activity will be co-delegated to the Directorate-General for Informatics (DG DIGIT)

*Type of contract and type of procurement*

service contract based on existing framework contracts

*Indicative number of contracts envisaged: 10-15*

*Implementation*

Commission/Chafea

*Indicative timeframe for launching the procurement procedure*

First and second half 2017

### **4.5.3 Health reports and economic analysis**

*Subject matter of the contracts envisaged*

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

*Type of contract and type of procurement*

Framework contract

*Indicative number of contracts envisaged: 1-5*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

### **4.5.4 Evaluation of the Chafea Agency**

*Subject matter of the contracts envisaged*

Council Regulation No (EC) 58/2003 of 19 December 2002 lays down in general the statute for executive Agencies to be entrusted with certain tasks in management of Union's programmes. Under Article 25 of that Regulation the Commission has to draw up an external evaluation report every 3 years. The last evaluation (first interim evaluation of the Executive Agency for Health and Consumers) was conducted in 2010. In 2013, the Executive Agency was also underwent a second evaluation combined with the cost benefit analysis before finalising the extension of the Agency's mandate to manage the 'Promotion of the Agriculture

Product Programme’.

This new and mandatory evaluation should be conducted in 2017 and the results/recommendations generated by this evaluation will help Chafea improving its efficiency and performance as well as its accountability towards the Commission and the other European Institutions.

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.5.5 Impact assessment of the Health Programme**

*Subject matter of the contracts envisaged*

Following on the action plan for implementing recommendations from the ex-post evaluation of the second Health Programme 2008-2013, and in accordance with the last subparagraph of Article 13.3 of Regulation (EU) 282/2014, "the long term impact and the sustainability of effects of the Programme shall be evaluated with a view to feeding into a decision on the possible renewal, modification or suspension of a subsequent programme". This study will focus on health topics on which actions have been funded in the previous Programme period and continue to be funded within the third Health Programme, such as chronic diseases. This study will also analyse the impact of these actions in terms of output/deliverables and success and in particular on how these outputs are transformed into recommendations that have been or will be integrated into Member States policies. This study will assess the limitations and barriers that may prevent proper integration of the results into national/regional health policies. It will also analyse if/how best practices collected by actions have been exchanged among Member States, the effects of such exchange and potential transfer/scaling-up and use of best practices.

*Type of contract and type of procurement*

Direct service contract or specific contracts based on framework contract

*Indicative number of contracts envisaged: 1*

*Implementation*

Chafea

*Indicative timeframe for launching the procurement procedure*

First half 2017

#### **4.5.6 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. This action is also intended to sustain the functioning of existing IT applications supporting public health policies relevant to the Third Health Programme. The provisional list of applications to be covered by this action is as follows: Alcohol Platform; Platform on Workforce, European Reference Networks, Health Policy Platform, Pharmaceuticals website, 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, support for projects in the area of organ transplantation (e.g. COORENOR, FOEDUS); Injury Database (IDB), Ras-Chem (rapid alert system for information exchange on incidents including chemical agents), EU clinical trials portal and Union Database. The action also includes, contributions for security, knowledge management, licences and maintenance for central applications and common systems technical support.

*Type of contract and type of procurement*

Specific contracts based on existing framework contracts

*Indicative number of contracts envisaged: 10*

*Implementation*

Commission
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*Indicative timeframe for launching the procurement procedure*

First and second halves of 2017
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## **5 OTHER ACTIONS**

The overall budgetary allocation reserved for other actions in 2017 amounts to EUR 7.152 500.

Other actions cover contributions paid by the EU as subscriptions to bodies of which it is a member in the meaning of Article 121(2)(d) of the Financial Regulation, administrative agreements with the Joint Research Centre, 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 Administrative Agreement with the Joint Research Centre (JRC) regarding the development and maintenance of the European Platform on Rare Diseases Registration, European Guidelines for Quality Assurance in Cancer Screening and Diagnosis and scientific evidence on chronic diseases (Thematic priority 1.4 and 4.2 of Annex I to the Programme Regulation)**

*Amount*

EUR 2 200 000
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*Description and objective of the implementing measure*

(1) Rare Diseases
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The JRC will host all elements of the European level coordination and data collection of the
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two surveillance networks: the European Surveillance of Congenital Anomalies (EUROCAT)<sup>9</sup> and Surveillance of Cerebral Palsy in Europe (SCPE)<sup>10</sup> and will also link data collected by EUROCAT and SCPE surveillance networks to other sources of data collected by European institutions, for example environmental data.

The principal goal of the European Platform on Rare Diseases Registration is to enable data analysis within and across many rare diseases and to facilitate clinical trials, other studies, research and health policy guidance and support.

## (2) Cancer

The JRC will consolidate the processes and mechanisms established over 2012-2016 for the collection, harmonisation, validation, access, and inter-comparison of European cancer registry data for EU policy-making, and to develop a comprehensive knowledge-management resource for European cancer information

Furthermore the JRC will update the EU guideline on colorectal cancer screening which is urgently needed since 2010 due to the significant advances in the field of colorectal screening. A pilot Voluntary European Quality Assurance Scheme will be launched for Colorectal Cancer Services including sustainability plan, monitoring plan (including measurement of its policy impact) and strategy to ensure that what is developed will be publicly available and implemented.

Implementing colorectal cancer screening programmes only started in the 2000s, and takes years to be extensively implemented. According to data compiled by the International Agency for Research on Cancer (IARC) and the European Commission, for colorectal cancer there are currently population based screening programmes at national level in 15 Member States, while in 4 Member States population based screening programmes exist only in some regions, and in 9 Member States no programmes exist for the moment although in 6 of them several colorectal cancer screening initiatives are scheduled for 2016. Better results could be expected if new a EU guideline is prepared.

## (3) Chronic Diseases

This action builds on an ongoing action with the JRC on a reference publication on nutrition and physical activity and will enlarge the scope to cover chronic diseases. The outcome will include summaries of scientific studies and also list sources of information, the summary of existing national and international recommendations as well as guidance and evidence on the economic burden.

### **5.1.2 JRC Administrative Agreement (Laboratory work) (Thematic priority 1.5 of Annex I to the Programme Regulation)**

*Amount*

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<sup>9</sup> <http://www.eurocat-network.eu/>

<sup>10</sup> <http://www.scpenetwork.eu/>

EUR 100 000

*Description and objective of the implementing measure*

The revised Tobacco Products Directive 2014/40/EU provides for submission of extensive data by industry both under Articles 5 and 6 (tobacco) and 20 (e-cigarettes) of the Directive. These data on ingredients submitted by the industry need to be processed and verified by the Member States. This should be facilitated in the context of the joint action on tobacco set up in 2016. As laboratory capacities vary significantly between Member States the experience of JRC acting as a reference laboratory in other fields can ensure proper and uniform analysis of the submitted information.

On e-cigarettes, the JRC will work on the measurement of emissions and safety assessment of the ingredients of e-cigarettes, in order to complement the upcoming joint action with Member States that is expected to start in 2017. In addition, the JRC will provide an analysis of ingredients contained in tobacco products and e-cigarettes. This work could complement the work to be carried out by Member States.

Further development of laboratory methods will facilitate implementation of the new TPD, in particular uniform enforcement by the Member States.

**5.1.3 Cross sub-delegation to Eurostat implemented through grants procedures for pre-testing of new variables for future European Health Interview Survey (Thematic priority 1.6 of Annex I to the Programme Regulation)**

The actions will be implemented through grants, without a call for proposals as provided for in Article 5 of Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics. The beneficiaries will be the National Statistical Institutes and the other national authorities responsible for the development, production and dissemination of European statistics as designated by Member States.

These grants are calculated on the basis of eligible costs incurred. In 2017, the maximum rate for EU co-financing may be up to 70 % due to the exceptional utility of the actions 5.1.3. as justified hereinafter.

**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 Regulation (EU, Euratom) No 966/2012, the obligation to verify the operational capacity of public bodies or international organisations is waived.

**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 main 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.

At least the second of the main criteria will be specified by appropriate sub-criteria, like the efficiency of the proposed approach, the organisation and/or the methods proposed, etc.

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.

*Amount*

EUR 400 000
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*Description and objective of the implementing measure*

<p>The action will deliver health data for an important a major part of the European Core Health Indicators (ECHI) and other European Health Indicators and will contribute and be used in the State of Health in the EU cycle.</p> <p>Eurostat will conduct pre-testing (including qualitative testing) of some new variables in a few countries in view of their possible introduction in future waves of the European Health Interview Survey. Topics of interest to be tested could include patient experience, dietary habits including sugar intake, mental health-related issues, disability and health of children. The funds can also be used to support national adaptations.</p> <p>The action will build up country-specific and cross-country knowledge which can inform policies at national and European level by developing some variables for the European Health Interview Survey.</p> <p>The action will provide methodology for future data collections to be used for evidence-based for policy decision-making. The deliverables will be used following Eurostat dissemination of results and the integration in the ECHI Data Tool.</p>
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## **5.2 Actions under objective 2 — Protecting Union citizens from serious cross-border health threats**

### **5.2.1 Provide targeted risk assessment in case of a chemical and environmental incident of cross border relevance – expert expenses (Thematic priority 2.1 of Annex I to the Programme Regulation)**

*Amount*

EUR 70 000

*Description and objective of the implementing measure*

Article 10, (2), of the Decision 1082/2013<sup>11</sup> on serious cross-border threats to health states that: ‘Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the Health Security Committee or its own initiative, provide a risk assessment’.

The objective of this action is to provide targeted risk assessment in the short term in case of a chemical or environmental incident of cross-border relevance as provided for in Article 10(2) of the Decision cited above. In order to put this in place, ad hoc funding is needed to support the work to address specific rapid risk assessment during emergency situations. The risk assessment would be carried out via the Scientific Committees,<sup>12</sup> composed of experts whose expenses would be covered.

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

### **5.3.1 Expert Panel on effective ways of investing in Health — Special 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

<sup>11</sup> OJ L 293, 5.11.2013, p.1

<sup>12</sup> [http://ec.europa.eu/health/scientific\\_committees/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/index_en.htm)

advice on public health and health systems. The advice is provided by the Expert Panel on effective ways of investing in Health which was established by Commission Decision 2012/C 198/06. This action contains special indemnities paid to experts for their work on scientific opinions and reports on matters related to health care modernisation, responsiveness, and sustainability provided to the Commission (and Member States), which provide the basis for policy-making by presenting the best evidence, examples and ideas from the current academic knowledge base.

The opinions provide independent, non-binding advice that supports the pursuit of sustainable health systems. This advice can be used by Member States and the Commission in policy-making to achieve this goal.

The requests for scientific opinions and the opinions and minutes of the meetings are made publicly available by publication on the panel's website. Stakeholders are invited to participate in public consultations organised before adopting the final opinions.

**5.3.2 Meetings of the Medical Device Coordination Group (MDCG) and its subgroups, following the adoption of new Regulations on medical devices and in-vitro diagnostic medical devices by the legislators (Thematic priority 3.6 of Annex I to the Programme Regulation)**

*Amount*

EUR 1 217 500

*Description and objective of the implementing measure*

This action covers the reimbursement of expenses of participants of the meetings of the MDCG and its subgroups, the tasks of which are laid down in the proposed Regulations on Medical Devices and in-vitro diagnostic medical devices.

**5.3.3 Reimbursement of experts' expenses for joint assessments carried out by several Member State authorities and the Commission services (Thematic priority 3.6 of Annex I to the Programme Regulation)**

*Amount*

EUR 416 000

*Description and objective of the implementing measure*

This action will cover the reimbursement of experts' expenses for joint assessments of 80 notified bodies carried out by national experts of authorities of Member States and EFTA/EEA countries together with the Commission departments under Article 3 of

Commission Implementing Regulation (EU) No 920/2013 on the designation and supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices.

#### **5.3.4 Technical and scientific opinions and advices (Thematic priority 3.6 of Annex I to the Programme Regulation)**

*Amount*

EUR 406 000

*Description and objective of the implementing measure*

This action is an Administrative Agreement with the Joint Research Centre for the provision of technical and scientific information to form a basis for regulatory measures by Member States and the Commission. The scientific and technical data will feed into the policy meetings on medical devices.

#### **5.3.5 International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and VICH Outreach Forum (VOF) (Thematic priority 3.6 of Annex I to the Programme Regulation)**

*Amount*

EUR 43 000

*Description and objective of the implementing measure*

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products<sup>13</sup> brings together the drug regulatory authorities of the 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 for the experts from the EU national regulatory agencies to attend the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and VICH Outreach Forum (VOF) meetings. In view of the regulatory environment (EU legislation) it is justified that the funding is provided at EU level rather than by the Member States.

The expected results of this action are inter alia:

- (1) Adoption of guidelines for the submission of applications for authorisation of placing on the market medicinal products which are applied in the EU as well as in the US,

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<sup>13</sup> <http://www.vichsec.org/>

Japan and other non-VICH members;

- (2) Reduction of administrative burden through replacing complex multiple submissions by a single technical dossier for the three Regions;
- (3) Exchange of information between regulators on innovative and rapidly evolving areas such as nanotechnologies and promotion of convergences in areas such as biosimilars;
- (4) Regulatory cooperation in areas such as generics, combination products, antimicrobial resistance evaluation

The aim of this action are: international harmonisation as well as the promotion of innovation by reducing development cost and time, and a more speedy access to the market for innovative medicines and earlier availability of important and life-saving treatments for animals. The action has a further objective to provide, by means of dialogue between regulatory authorities and industry, technical guidance enabling response to significant emerging global issues and science that impact regulatory requirements.

### **5.3.6 Active pharmaceutical ingredients: system inspections in third countries (Thematic priority 3.6 of Annex I to the Programme Regulation)**

*Amount*

EUR 20 000

*Description and objective of the implementing measure*

This activity will cover the reimbursement of expenses of Member States' experts supporting the Commission (Directorate-General for Health and Food Safety Directorate F) in carrying out system inspections in third countries exporting active substances for medicinal products for human use into the EU.

The objective of this action is to ensure thorough system inspections in third countries exporting active pharmaceutical ingredients for medicines for human use into the EU. These inspections make it possible to verify whether the regulatory framework for the manufacture of active pharmaceutical ingredients, including inspection and enforcement systems, are equivalent to that of the EU.

System inspections are part of the Commission equivalence assessment of third countries' legal and regulatory framework for active ingredients of medicines. Performing such assessment at the request of the third country is a legal obligation in accordance with Article 111(b) of Directive 2001/83/EC.

The system inspections will ensure the Commission's compliance with EU legislation and will facilitate the importation into the EU of active ingredients from third countries that have a regulatory framework for active substances equivalent to that of the EU.

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

*Amount*

EUR 600 000
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*Description and objective of the implementing measure*

This action implements the Commission Decision on the participation of the Commission as founding member in the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). It covers the ICH membership fee as well as the travel costs for travel of the experts from the EU national regulatory agencies involved in ICH activities. It will also contribute to the administrative and technical support to International Pharmaceutical Regulators Forum (IPRF) activities meeting in conjunction with ICH.

The ICH Association is the international harmonisation venue responsible for standard-setting in the field of medicinal products for human use. Its objectives are inter alia to contribute to the development, registration and manufacturing of safe, effective, and high quality medicines in an efficient and cost-effective manner. The ICH guidelines are implemented by the EU, the US, Japan and an increasing number of strategic partners.

The IPRF, which meets in conjunction with the ICH has the three following objectives:

- (1) The first objective is to enable all members to identify new approaches and specific best practices, and develop smart strategies for dealing with the challenges of a rapidly evolving globalised pharmaceutical industry.
- (2) The second objective is to provide a global overview of the different regulatory developments at national and international level and enable open sharing of information and ideas among regulatory leaders with hands-on operational responsibilities.
- (3) The third objective is to support international regulatory cooperation in areas which are not covered by existing initiatives.

**5.3.8 Joint Audit Programme (JAP) on Good Manufacturing Practice (GMP) inspections and Transatlantic Trade Investment Partnership (TTIP) (Thematic priority 3.6 of Annex I to the Programme Regulation)**

*Amount*

EUR 110 000

*Description and objective of the implementing measure*

The objective of this action is to support the organisation of a number of audits in 2017 by financing the mission costs of JAP auditors. The JAP which is organised by the Heads of Medicines Agencies (HMA) is a programme that monitors the equivalence of Member State GMP inspectorates. The programme consists of audits carried out by Member States Authorities (the auditors) on a given Member State GMP system (the auditee). The JAP audits will be carried out on the basis of objective criteria based on specific requirements vested in EU legislation, guidelines and procedures.

In 2017, the JAP audits will also be used by the US Food and Drug Administration to assess the capability of Member State GMP inspectorates. The JAP will thus play a pivotal role towards the achievement of the first objective of the TTIP negotiations for the pharmaceutical sector: the mutual recognition of GMP inspections between the US and the EU.

**5.3.9 Annual Commission membership fee to the European Observatory on Health Systems and Policies (Thematic priority 3.7 of Annex I to the Programme Regulation)**

*Amount*

EUR 500 000

*Description and objective of the implementing measure*

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

### **5.3.10 Scientific Committees (Thematic priority 3.7 of Annex I to the Programme Regulation)**

*Amount*

EUR 350 000

*Description and objective of the implementing measure*

The objective of this action is to provide the Commission with independent and high quality advice on consumer safety and health and environmental risks. This contributes to obtaining a robust scientific basis for EU policies and measures in line with the better regulation requirements. The advice is provided by the Scientific Committees in accordance with Commission Decision C (2015) 5383 of 7 August 2015<sup>14</sup>. This action will cover travelling and accommodation expenses, daily allowances and 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 planned under this objective.*

### **5.5 Transversal action**

#### **5.5.1 Evaluators of calls for proposals**

*Amount*

EUR 200 000

*Description and objective of the implementing measure*

This action and budget is supporting efficient and transparent selection of proposals to be funded. The proposals submitted under different calls for proposals are evaluated by external expert (peer-review). For giving this important input into the evaluation process, these experts receive a daily remuneration of EUR 450/day of work. Chafea has published a call for expression of interest that is available on <http://ec.europa.eu/chafea/news/news311.html>. This action and budget is important for supporting efficient and transparent selection of

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<sup>14</sup> Commission Decision C (2015) 5383 of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment  
[http://ec.europa.eu/health/scientific\\_committees/docs/call\\_2015\\_5383\\_decision\\_with\\_annexes\\_en.pdf](http://ec.europa.eu/health/scientific_committees/docs/call_2015_5383_decision_with_annexes_en.pdf)

proposals to be funded. Evaluators will receive a daily fee, travel costs and subsistence allowances (if applicable) according to the standard rules of the European Commission.

### **5.5.2 Presidency conference grants — De jure monopoly (related to all programme objectives)**

According to Article 190(1)(c) of Delegated Regulation (EU) No 1268/2012<sup>15</sup> grants can be allocated without a call for proposals to organisations in a de jure or de facto monopoly situation, duly substantiated in the award decision.

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

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

The Presidency conferences to be financed under this work programme are a conference on *Cross-Border aspects in alcohol policy – Tackling harmful use of alcohol* and a conference on *Health in digital society - Digital Society for Health* planned under the Estonian Presidency and a conference on *Pharmaceutical Products* and a conference on *Healthy Nutrition* under the Bulgarian Presidency.

#### Implementation

Chafea

#### Indicative timetable and indicative amount

Reference	Date	Amount (€)
Direct award	Second half of 2017 and First half of 2018	EUR 200 000

<sup>15</sup> OJ L 362, 31.12.2012, p. 1

## 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: The following articles of the Financial Regulation apply
  - Article 105a,
  - paragraphs 1 to 4, 6 and 7, except point (b) of the first subparagraph and the second subparagraph of that paragraph, paragraphs 8, 9, 11 and 13 to 17 of Article 106 and
  - Article 108 shall apply to grant applicants and beneficiaries.
  - Article 107 shall apply to applicants. Applicants shall declare whether they are in one of the situations referred to in Article 106(1) or Article 107 and, where applicable, whether they have taken remedial measures as referred to in point (a) of Article 106(7)).
3. Selection criteria, to assess the applicant's financial and operational capacity to complete a proposed action (Articles 131 and 132 of the Financial Regulation and Article 202 of the Rules of Application),
4. Award criteria, to assess the quality of the proposal taking into account its cost (Article 132 of the Financial Regulation and Article 203 of the Rules of Application).

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

## 1. ELIGIBILITY CRITERIA

1.1. The applicants<sup>16</sup> are legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments.

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

- EU Member States;
- 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/Chafea website for an updated list of countries.<sup>17</sup>

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 and/or cover fewer countries will be rejected.

1.4. As Specific Grant Agreements (SGA) for the support of an European Reference Network are implemented via mono-beneficiary grant agreement, applicants for SGA are exempted from the requirements of previous article (1.3) concerning different legal entities from at least 3 countries.

## 2. EXCLUSION CRITERIA

The following articles of the Financial Regulation apply

- Article 105a,
- paragraphs 1 to 4, 6 and 7, except point (b) of the first subparagraph and the second subparagraph of that paragraph, paragraphs 8, 9, 11 and 13 to 17 of Article 106 and
- Article 108 shall apply to grant applicants and beneficiaries.
- Article 107 shall apply to applicants. Applicants shall declare whether they are in one of the situations referred to in Article 106(1) or Article 107 and, where applicable, whether they have taken remedial measures as referred to in point (a) of Article 106(7)).
- 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 of the work programme

Evidence: duly signed declaration of honour

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<sup>16</sup> Whenever 'applicants' is written, this means the coordinator and the co-applicants  
<sup>17</sup> Serbia and Moldova

### 3. 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.

Where the application concerns grants for an action for which the amount exceeds EUR 750 000, an audit report produced by an approved external auditor shall be submitted. That report shall certify the accounts for the last financial year available. This paragraph shall apply only to the first application made by a beneficiary to an authorising officer responsible in any one financial year.

The verification of financial capacity will not apply to public bodies and the international organisations referred to in Article 43 of the financial regulation.

The applicant shall indicate the sources and amounts of Union funding received or applied for the same action or part of the action or for its functioning during the same financial year as well as any other funding received or applied for the same action.

#### 3.2. Operational capacity

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

### 4. 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 project for meeting the objectives and priorities defined in the annual work plan of the 3<sup>rd</sup> Health Programme, under which the call for proposals is published,
- Added value at EU level in the field of public health,

- Pertinence of the geographical coverage of the proposal,
- 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 and complementarity of the partnership

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

Sub-criteria taken into account in the assessment:

- Realistic estimation of person days / deliverable and per work package,
- The budget allocated for evaluation and dissemination is reasonable.

Following the evaluation, all proposals meeting the above mentioned eligibility, exclusion, selection and award criteria 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 a grant or grants.

## ANNEX III

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

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

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

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

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

1. Eligibility criteria, to assess the applicant's eligibility (Article 131 of the Financial Regulation),
2. Exclusion criteria The following articles of the Financial Regulation apply
  - Article 105a,
  - paragraphs 1 to 4, 6 and 7, except point (b) of the first subparagraph and the second subparagraph of that paragraph, paragraphs 8, 9, 11 and 13 to 17 of Article 106 and
  - Article 108 shall apply to grant applicants and beneficiaries.
  - Article 107 shall apply to applicants. Applicants shall declare whether they are in one of the situations referred to in Article 106(1) or Article 107 and, where applicable, whether they have taken remedial measures as referred to in point (a) of Article 106(7)).
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 for the functioning of a non-governmental body.

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

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

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

1.2. It is working in the public health area, playing an effective role in civil dialogue processes at the Union level,

1.3. It is pursuing at least one of the specific objectives of the third Health Programme

1.4. Is active at the Union level and in at least half of the EU Member States (e.g. has members<sup>18</sup> in at least half of the Member States),

1.5. 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. If the applicant is working with the private sector, this also applies to the activities of the latter.

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<sup>18</sup> Definition of ‘member’ applying to non-governmental bodies: A member is a natural person, a legal person or an entity which does not have a legal personality under the applicable national law, who became a member through a procedure laid down in the body's statutes and who have a ‘member’ status according to the body's statutes. Only full members or candidates to become full members are considered. Members of the applicant's member organization are not accepted as members of the applicant.

## 2. EXCLUSION CRITERIA

The following articles of the Financial Regulation apply

- Article 105a,
- paragraphs 1 to 4, 6 and 7, except point (b) of the first subparagraph and the second subparagraph of that paragraph, paragraphs 8, 9, 11 and 13 to 17 of Article 106 and
- Article 108 shall apply to grant applicants and beneficiaries.
- Article 107 shall apply to applicants. Applicants shall declare whether they are in one of the situations referred to in Article 106(1) or Article 107 and, where applicable, whether they have taken remedial measures as referred to in point (a) of Article 106(7)).

Evidence: duly signed declaration of honour

## 3. 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.

### 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.

In the case of partnerships, an audit report produced by an approved external auditor shall be submitted covering the last two financial years available before signature of the framework partnership agreement or notification of the framework partnership decision.

### 3.2. Operational capacity

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

### 3.3. Geographical coverage

Organisations must have a balanced geographical coverage with at least 4 of its members in Member States which joined the European Union after 2004.

## 4. AWARD CRITERIA

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

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

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

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

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

- Pertinence of the applicant in the public health area, and effectiveness of its role in civil dialogue processes at Union level,
- Pertinence of the mission, vision and overall purpose of the applicant to achieving the objectives of the 3<sup>rd</sup> Health Programme (applicant pursues at least one of the specific objectives of the Programme,
- High EU-added value of the applicant's activities,
- Pertinence of the proposals for dissemination of Health Programme results and best practices in the priority areas mentioned in para 2.3 of Annex I
- Cover more than one area of the priorities listed in para 2.3 of Annex I

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

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

- Pertinence of the multi-annual work programme in the context of the 3<sup>rd</sup> Health Programme,
- Relevance of the operational framework for the implementation of the multi-annual work programme
- Quality of the evaluation strategy,
- Quality of the dissemination strategy and plan.

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

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

- Quality of the planning of the work programme implementation,
- Relevance and appropriateness of the budget plan for the total period of the FPA.

The applicants meeting all thresholds will be awarded a framework partnership agreement. The conclusion of a FPA does not guarantee receiving co-funding which will be awarded annually through specific grant agreements (SGA).

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

All FPA-holders will be invited to submit their applications for annual co-funding. This application will be assessed based on the following criteria:

##### 4.2.1. Coherence with the 4-year work programme annexed to the FPA (10 points, threshold: 6 points)

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

- Relevance of annual objectives.
- Contribution to achieving the multi-annual objectives,

##### 4.2.2. Quality of the proposed activities for 2017 (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 implementation of the activities and the operational management.

##### 4.2.3. Quality of the proposed budget for 2017 (10 points, threshold 6 points)

- Relevance of the annual budget to activities in the annual work plan.

**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 nominate one competent authority responsible for the implementation of the action on behalf of that Member States. The competent authorities may implement activities in cooperation with other entities.

The competent authorities shall also identify and select the civil society organisations active at EU level which can make the most valuable contribution to the action. These organisations will be invited to join the action as collaborating partners and/or to participate in advisory structures.

#### **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  
The following articles of the Financial Regulation apply
  - Article 105a,
  - paragraphs 1 to 4, 6 and 7, except point (b) of the first subparagraph and the second subparagraph of that paragraph, paragraphs 8, 9, 11 and 13 to 17 of Article 106 and
  - Article 108 shall apply to grant applicants and beneficiaries.
  - Article 107 shall apply to applicants. Applicants shall declare whether they are in one of the situations referred to in Article 106(1) or Article 107 and, where applicable, whether they have taken remedial measures as referred to in point (a) of Article 106(7)).
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, grants may be awarded to fund 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 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 Rules of Application of the Financial Regulation EU 2015/2462 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.

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

## 2. EXCLUSION CRITERION

The following articles of the Financial Regulation apply

- Article 105a,
- paragraphs 1 to 4, 6 and 7, except point (b) of the first subparagraph and the second subparagraph of that paragraph, paragraphs 8, 9, 11 and 13 to 17 of Article 106 and
- Article 108 shall apply to grant applicants and beneficiaries.

- Article 107 shall apply to applicants. Applicants shall declare whether they are in one of the situations referred to in Article 106(1) or Article 107 and, where applicable, whether they have taken remedial measures as referred to in point (a) of Article 106(7)).

### 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:

#### 2.2. Operational capacity

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

### 4. AWARD CRITERIA

#### 4.1. Contribution to public health in Europe (10 points, threshold: 7 points)

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 (10 points, threshold: 6 points)

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 and relevance of the actions to be taken to promote the dialogue with the NGOs in the field,
- Quality of the evaluation strategy,
- Quality of the dissemination strategy and plan.

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

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 (10 points, threshold: 6 points)

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 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 the core funding of the organisation from private sector organisations <sup>(19)</sup> representing a conflicting interest, or from other sources representing a conflicting interest.

Core funding shall mean financing required for the basic structure of an organisation, including salaries of full-time staff, facilities, equipment, communications, and the direct expenses of day-to-day work. Core funding also includes financing of all permanent or regularly repeated activities (e.g. annual general assembly or other statutory meetings, website, databases, newsletters). Core funding requirements are usually budgeted separately from other costs such as specific actions or projects.

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

All activities should be published in the applicant's annual report<sup>20</sup>.

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

## 4. ASSESSMENT OF INDEPENDENCE

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

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

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<sup>19</sup>The term 'private sector' covers 'for-profit' companies/enterprises/corporations, business organisations or other entities irrespective of their legal nature (registered/not registered), ownership (wholly or partially privately owned/state owned) or size (large/small), if they are not controlled by the public.

<sup>20</sup>Collaborators in a position that could lead to a conflict of interest (Article 57 of the Financial Regulation and Article 32 of the Rules of Application) shall be listed.

## ANNEX VI

### **Criteria for financial contributions to the functioning of a European Reference Network [ERN] (mono-beneficiary ERN grants<sup>21</sup>) 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.**

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

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

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

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

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

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

Relevance of the proposal to achieve the multi-annual objectives.

Purpose of the annual work plan.

**2. Quality of the proposed activities** for 2017 (10 points, threshold: 7 points)

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

Quality of the planning of annual work.

Quality of the evaluation strategy.

Quality of the internal and external activities and implementation plan regarding the pooling of knowledge, the mobility of expertise, the development, sharing and spreading information, knowledge and best practices.

Quality of the implementation of the activities and the operational management.

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

Quality and pertinence of the annual budget.

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

## ANNEX VII

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

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

#### 1. INTRODUCTION

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

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

1. At least 60 % of the total budget of the action must be used to fund staff. This criterion intends to promote capacity building for development and implementation of effective health policies.

2. At least 30 % of the budget of the proposed action is allocated to at least 5 different 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. CRITERIA FOR THE EXCEPTIONAL UTILITY OF OPERATING GRANTS

1. At least 25 % of the members of the non-governmental bodies<sup>22</sup> or candidate members of the non-governmental bodies come from Member States whose gross national income (GNI) per inhabitant is less than 90 % of the Union average. This criterion intends to promote the participation of non-governmental bodies from Member States with a low GNI.

2. The reduction of health inequalities at EU, national or regional level is stated in the mission as well as the annual work programme of the applicant. This criterion aims to ensure that co-

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<sup>22</sup> Definition of 'member of non-governmental body': A member is a natural person, a legal person or an entity which does not have a legal personality under the applicable national law, who became a member through a procedure laid down in the body's statutes and who have a 'member' status according to the body's statutes. Only full members or candidates to become full members are considered. National members are counted in the same manner as pan-European/umbrella organization members. Members of the applicant's members' organizations are not accepted as members of the applicant.

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 by Member States with a low GNI.

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 four categories of criteria:**

1. Eligibility criteria, to assess the applicant's eligibility,

2. Exclusion criteria

The following articles of the Financial Regulation apply

- Article 105a,

- paragraphs 1 to 4, 6 and 7, except point (b) of the first subparagraph and the second subparagraph of that paragraph, paragraphs 8, 9, 11 and 13 to 17 of Article 106 and

- Article 108 shall apply to grant applicants and beneficiaries.

- Article 107 shall apply to applicants. Applicants shall declare whether they are in one of the situations referred to in Article 106(1) or Article 107 and, where applicable, whether they have taken remedial measures as referred to in point (a) of Article 106(7)).

3. Selection criteria

4. Award criteria

#### 1. ELIGIBILITY CRITERIA

1. The applicant is a legally established non-governmental body, non-profit-making and independent from industry, commercial and business or other conflicting interests
2. The applicant acts at European, national or sub-national level.
3. Only applications from entities established in one the following countries are eligible:
  - a) EU Member States.
  - b) Iceland and Norway;
  - c) Countries which have a bilateral agreement with the European Union, in accordance with Article 6 of Regulation (EU) No 282/2014 on the establishment of a third Health Programme for the Union's action in the field of health (2014-

2020). Please check the Commission/Chafea website for an updated list of countries.

4. Only applications from single applicants are acceptable (with or without partners).
5. The application is complete (application form filled in).
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 following articles of the Financial Regulation apply

- Article 105a,
- paragraphs 1 to 4, 6 and 7, except point (b) of the first subparagraph and the second subparagraph of that paragraph, paragraphs 8, 9, 11 and 13 to 17 of Article 106 and
- Article 108 shall apply to grant applicants and beneficiaries.
- Article 107 shall apply to applicants. Applicants shall declare whether they are in one of the situations referred to in Article 106(1) or Article 107 and, where applicable, whether they have taken remedial measures as referred to in point (a) of Article 106(7)).

## 3. SELECTION CRITERIA

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

## 4. AWARD CRITERIA

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

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

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

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

#### 4.2. Technical quality (70 points)

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

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

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