

ANNEX

Third Programme for the Union's action in the field of health (2014-2020)

Work Programme for 2018

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1. INTRODUCTION

This work programme sets out the priorities and actions to be undertaken for the year 2018, 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').

According to Article 11 of the Programme Regulation, 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.

The drafting of the 2018 work programme was guided by the Commission's priorities as outlined in the political guidelines of the President and the mission letter of the Commissioner responsible for Health and Food Safety.

The work programme includes actions **referring to all or several programme objectives**. These are related to country-specific and cross-country knowledge in cooperation with Eurostat and the WHO, as well as work carried out with the Joint Research Centre on nutrition and health determinants and chronic diseases. Several activities are also planned in cooperation with the OECD, on antimicrobial resistance, chronic diseases, best practices and on big data and eHealth.

Two calls for projects will be launched, on promotion of health and prevention of chronic and major diseases — and quality and effectiveness of public expenditure (**Objective 1**). The first call deals with the implementation of existing best practices identified by the Member States and validated through agreed criteria and in the Steering Group for Promotion and Prevention. A second call will aim to help care authorities develop the necessary capacity to implement integrated care using a bottom-up approach. New activities will be launched under a service contract on reducing alcohol related harm, to support implementation of best practices, including those identified by the Member States under the Joint Action on Reducing Alcohol Related Harm (2014-2016). In addition, a number of studies on tobacco will be launched.

On cross-border health threats, preparedness and response (**Objective 2**), a new Joint Action will be launched on strengthening preparedness of Member States in the EU against serious cross-border threats to health – including laboratories; and support the implementation of International Health Regulations. In addition, simulation exercises are planned to strengthen Member States' capacity to coordinate response to health emergencies, implementing Decision No 1082/2013/EU on serious cross-border threats to health.

For the implementation of EU legislation on medicinal products (**Objective 3**), support will be provided for the implementation of the Regulations on medical devices and on in vitro diagnostic medical devices. These actions include the development of the EUDAMED database.

Finally on access to better and safer healthcare for Union citizens (**Objective 4**) the area of European Reference Networks will receive continuous support, in particular through multiannual grants and through operational support, as well as through the independent assessment of healthcare providers which would like to join existing ERNs.

Support to **NGOs** will continue. Major synergies can be achieved in close cooperation with the **European Solidarity Corps**. The Commission encourages non-governmental bodies to work with with the European Solidarity Corps, where appropriate.

Actions are related in general to EU Member States and countries participating in the Health Programme.

On the basis of the objectives given in the Third Programme for the Union's action in the field of health (2014-2020) this work programme contains the actions to be financed and the budget breakdown for year 2018 as follows:

for grants (implemented under direct management) (chapter 2): EUR 39 890 000

Projects: EUR 20 850 000

Joint Actions: EUR 7 900 000

Operating Grants: EUR 5 000 000

Direct Grants: EUR 6 140 000

for prizes (implemented under direct management (chapter 3): EUR 60 000

for procurement (implemented under direct management) (chapter 4): EUR 14 730 701

for other actions (chapter 5): EUR 7 399 000

The total available budget for 2018 is EUR 62 079 701.

2. GRANTS

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)

Articles 7(2) and 8(1) of the Programme Regulation

1. Introduction

Actions co-funded under the third Health Programme may receive a co-financing 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 State authorities. To receive 80% of co-financing, 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 to develop and implement effective health policies.
2. At least 30 % of the budget of the proposed action must be allocated to at least five different Member States whose gross national income (GNI) per inhabitant is less than 90 % of the EU average. This criterion is intended to promote the participation of stakeholders in the field of health 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 bodies¹ or candidate members of the non-governmental bodies must come from Member States whose GNI per inhabitant is less than 90 % of the EU average. This criterion is intended to promote the participation of non-governmental bodies from Member States with a low GNI.
2. Reducing health inequalities at EU, national or regional level must be laid down as an aim in the applicant's mission statement and annual work programme. This criterion aims to ensure that co-funded non-governmental bodies directly contribute to one of the main objectives of the third Health Programme, i.e. to reduce health inequalities (Article 2).

4. Criteria for the exceptional utility of actions co-financed with Member State authorities

1. At least 30 % of the budget of the proposed action must be allocated to Member States whose GNI per inhabitant is less than 90 % of the EU average. This criterion intends to promote the participation by Member States with a low GNI.
2. Bodies from at least 14 participating countries must participate in the action, out of which at least four must be countries whose GNI per inhabitant is less than 90 % of the EU average. This criterion promotes wide geographical coverage and the participation of Member State authorities from countries with a low GNI.

¹ 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 has 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 organisation members. Members of the applicant's members' organisations are not accepted as members of the applicant.

2.1. Projects

Under the overall operational budget reserved for grants, EUR 20 850 000 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, the rate may rise to 80 % if a proposal meets the criteria for exceptional utility.

The budget line is 17 03 01.

Essential eligibility, selection and award criteria

Eligibility criteria

Applicants² must be legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments.

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 EU, in accordance with Article 6 of Regulation (EU) No 282/2014 (the ‘Programme Regulation’). Please check the Commission/Chafea website for an updated list of countries.

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

As specific grant agreements (SGAs) for the support of a European Reference Network are implemented via a mono-beneficiary grant agreement, applicants for SGA are exempted from the requirements to have different legal entities from at least three countries.

Selection criteria

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 must be submitted. That report must certify the accounts for the last financial year available. This paragraph will apply only to the first application made by a beneficiary to an authorising officer responsible in any

² Whenever ‘applicants’ is written, this means the coordinator and the co-applicants (including sole applicants)

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 Rules of Application of the Financial Regulation.

The applicant must 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.

Operational capacity

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

Award criteria

Policy and contextual relevance (10 points, threshold: 7 points)

Sub-criteria taken into account in the assessment:

- relevance of the project for meeting the objectives and priorities set out in the annual work plan of the third 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.

Technical quality (10 points, threshold: 6 points)

Sub-criteria 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.

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.

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

Sub-criteria taken into account in the assessment:

- realistic estimation of person days per deliverable and per work package;
- reasonableness of the budget allocated for evaluation and dissemination.

2.1.1. *Implementation of best practices — promotion of good health, prevention of non-communicable diseases and scaling up integrated care*

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 1.4 of Annex I to the Programme Regulation — Chronic diseases including cancer, age-related diseases and neurodegenerative diseases

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

The priority in the area of promotion of health, prevention of and integrated care for non-communicable diseases is on transferring and/or scaling-up existing good and best practices.

The main objective is to support pan-EU collaboration between health and/or social services actors at national, regional or local levels to help Member States to reach the UN/WHO voluntary global targets on non-communicable diseases and achieve the Sustainable Development Goal 3.4.

There will be two calls for proposals for action grants under this item, one on best practices to promote good health and prevent non-communicable diseases and one on integrated care.

Expected results Call A — Implementation of best practices to promote health and prevent non-communicable diseases and to reduce health inequalities

- (1) Supporting the transfer of best practices from one Member State to a group of other Member States may lead to a number of benefits, such as increase in healthy lives of citizens, reduced burden of diseases, reduced (co-) morbidity/mortality, and reduced demand for treatment. In turn, these benefits help contain costs in health systems and increase their cost-effectiveness.
- (2) In addition, knowledge will be gained about how best practices can be transferred or scaled up. Such knowledge can help Member States implement concrete good practices to promote good health and prevent diseases on the ground. With the transfer and scale-up of innovative, digitally-enabled integrated care models, these actions will contribute to the transformation of health and care in the Digital Single Market.
- (3) This work will also produce important information to help reporting on the main indicator of Objective 1 of the Third Health Programme ('Promote health, prevent diseases and foster supportive environments for healthy lifestyles') with respect to best practices implemented by Member States.

To measure the results, indicators will be agreed with those Member States planning to participate in the project. The indicators will be published in the guide for applicants.

The implementation of the best practices will be closely monitored by the Steering Group on

Promotion and Prevention so that the lessons learned can be used for subsequent priority setting and best practice transfers.

Expected Results Call B — Integrated care

Integrated care seeks to improve patient experience, outcomes and effectiveness of health systems by linking up services and providers along the continuum of care. Integrated care aims to improve or maintain an individual's functional status, prolong life and enhance quality of life by reducing the discomfort caused by symptoms. To do this, healthcare must overcome its fragmentation and link with social care.

The action proposed aims to help care authorities reform their health and care systems. The proposed action will aim to:

- (1) Help care authorities develop the necessary capacity to implement integrated care.
- (2) Bring 'early adopters'/'pioneers' together with 'followers'/'green field' authorities that are keen to make the transition to integrated care.
- (3) Deliver 'technical assistance' to authorities wanting to make the transition to integrated care on:
 - 'what to consider' when planning and designing integrated care;
 - 'how to design' effective integrated care programmes;
 - 'how to transfer' good practices from early adopters/pioneers.

This may concern (i) how to put in place the essential design principles and building blocks for integrated care (as identified by the EU HSPA group) and (ii) implementing:

- new care models that place emphasis on empowering patients, delivering care at home and community settings, and incorporating prevention strategies to preserve the well-being and functional capacity of patients;
- organisational changes: e.g. joining up budgets from health and social care, training the healthcare workforce in new skills and roles, organising multidisciplinary care teams; and contracting approaches between purchasers and providers of care services;
- 'risk stratification' tools to focus interventions on people with the highest need;
- integrated patient pathways to achieve a continuum across health and social care;
- appropriate use of digital technologies to facilitate the delivery of care services outside hospitals;
- tools/frameworks for assessing the quality and effectiveness of integrated care.

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

These calls will be limited to organisations in charge of implementing the best practices in question.

Call A

Action grants will be awarded to support best practices selected by Member States for transfer from one Member State to others as part of the work of the Steering Group on Promotion and Prevention.

Activities to be carried out under such an action grant may include but are not limited to:

- assessments of the situation to prepare the ground for practice transfer, including a feasibility analysis;
- regional or local level activities to prepare the practice transfer (e.g. information sessions);
- twinning of services including exchange of staff with the ‘practice owner’, study visits and joint workshops with the ‘practice owner’ and experts from all countries transferring the same practice;
- translation of materials;
- monitoring of the process and assessment of the outcomes.
- support to develop sustainability measures beyond the action's term including innovative financing and public procurement possibilities

(indicative amount: 2 350 000 EUR)

Call B

The action under Call B concerns integrated care and good practices, which have not been discussed or selected by the Steering Group on Promotion and Prevention.

Activities under Call B will be bottom-up: care authorities (at national or regional level) will themselves agree to collaborate on a project. They will identify the good practices to transfer, their owners and the adopting regions. Neither the Commission’s Directorate General for Health and Food Safety (DG SANTE) nor the Steering Group will be involved in selecting the integrated care practices proposed for transfer under Call B. The only requirement is to focus on medical conditions with high prevalence, in order to increase the population segment that can benefit from the transfer and to create economies of scale.

The proposed action will aim to help care authorities develop the capacity to implement integrated care through cooperative tools, guidance and knowledge. The action will involve technical assistance to care authorities from other participating partners to develop capacity to implement and scale-up integrated care.

The projects under the Call B will use relevant input from existing initiatives, for instance:

- good practices, evidence and tools for deploying integrated care, coming from the work of the European Innovation Partnership on Active and Healthy Ageing (EIP AHA) and from relevant EU-funded projects;
- guidance and good practices produced by the Joint Actions on Chronic Diseases concerning the management of multi-morbidities;
- guidance developed by the ‘CHRODIS’ Joint Action on the transfer and scaling-up of good practices;
- suggestions on health workforce planning and skills-mix, prepared by the Joint

- Action on Health Workforce Planning and Forecasting; guidance on how to design, implement and assess integrated care, taken from the work of the Expert Group on HSPA.

Each project under Call B will bring together:

- ‘Early adopters/pioneers’: These are authorities (national or regional) which have already made progress on implementing integrated care and which possess essential know-how and good practices.
- ‘Followers/green fields’: These are authorities (national or regional) which are ready to embark on the transition to integrated care, seek support and know-how and have planned investments under the European Structural and Investments Funds (ESIF), in order to deploy the results of the project on a larger scale.
- Internationally recognised ‘experts’ in the domain of integrated care, who can facilitate the transfer of knowledge and good practices.

The projects will provide practical support for the collaboration and knowledge transfer. The support may take the form of activities to prepare the local environment for implementation or purposely designed ‘twinning actions’ such as dedicated seminars and workshops, study visits, short-term secondment visits, meetings, mentoring from the ‘experts’ etc. The activities will focus on strengthening the capacity of care authorities regarding the main design principles and building blocks for integrated care identified by the EU HSPA group.

The projects will entail pilot implementations of integrated care in the ‘followers/green field’ care authorities. They will also help ‘early adopters/pioneers’ improve their existing system design by transferring relevant know-how and elements of good practices from other ‘early adopters/pioneers’ in the same project.

The projects will also offer technical assistance to care authorities on building capacity for planning and mobilising investments to deploy their integrated care services at scale. This may concern, for instance:

- support on how to navigate available sources of financing and blend financing from various sources;
- access to investor networks;
- use of innovative procurement and links with the advisory services of the Investment Plan for Europe/European Investment Bank.

(indicative amount: EUR 3 650 000)

Implementation

Chafea

Indicative timetable and indicative amount of the call for proposals

Reference	Date	Amount
Call for proposals	First half of 2018	EUR 6 000 000

Maximum possible rate of co-financing of the eligible costs

60 % , rising to 80 % if a proposal meets the criteria for exceptional utility

2.1.2. *Supporting Member States voluntary cooperation in the area of pricing through the Euripid Collaboration*

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 3.4 of Annex I to the Programme Regulation: Setting up a mechanism for pooling expertise at Union level

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

The overall aim of this action is to support voluntary cooperation between Member States by putting in place and maintaining a cooperative tool to exchange information on national policies in the area of pricing of medicinal products.

The grant will contribute to further establishing the Euripid database as a method of effective voluntary cooperation between Member States. The aim is to increase the capacity of pricing and reimbursement authorities so that health systems can perform better in the area of pharmaceutical expenditure and on pharmaceutical policies in general.

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

The overall focus of the action is on:

- continuing to support the establishment and appropriate use of the data set on medicinal product prices (EURIPID);
- training and technical support to database users (via a helpdesk).

The action will also provide further support for the activities that help ensure that the EURIPID database and the webpage function properly:

- maintaining an adequate level of IT and web-page security and performing regular assessments of the security posture;
- validating the quality of the price data that the authorities submit to the database, in close cooperation with the Member States;
- standardising the data and price information according to the agreed methodology and international guidelines;
- ensuring that the prices collected are pertinent in terms of pharmaceutical specialties;
- managing the interoperability with other EU databases;
- collecting actual and relevant price and reimbursement information and producing

technical reports for users so as to maximise the usefulness of the data base.

Other activities to be covered:

- preparation and dissemination of regular newsletters to the users. The newsletter will focus on project news but will also give details on all major developments in the field of pricing and reimbursement at local, regional, national, EU and international levels);
- activities to support the preparation of the annual work plan, the organisation and documentation of meetings and workshops, and the dialogue with relevant EU stakeholders and other partners.

Implementation

Chafea

Indicative timetable and indicative amount of the call for proposals

Reference	Date	Amount
Call for proposals	First half of 2018	EUR 300 000

Maximum possible rate of co-financing of the eligible costs

60 %, rising to 80 % if a proposal meets the criteria for exceptional utility

2.1.3. Orpha codes Project

LEGAL BASIS

Regulation (EU) No 282/2014 —Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 4.1. of Annex I to the Programme Regulation: Rare diseases

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

Currently, only a small fraction of rare diseases have codes in international nomenclatures, making it a challenge to trace patients with rare diseases in national and international health information systems. In its 'Recommendation on Ways to Improve Codification for Rare Diseases in Health Information Systems' the Expert Group stated that Member States should consider adding Orpha Codes to their countries' health information system and explore their feasibility and resources needed to do so.

The objective of this action is to support Member States in improving information gathering on rare diseases through the implementation of Orphacodes (the rare diseases specific codification system). The implementation process should be guided by (i) the 'Standard procedure and guide for the coding with Orphacodes' and (ii) the 'Specification and implementation manual of the Master file', both of which were developed under the current RD-ACTION (Joint Action on rare diseases).

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

This action should include following activities:

- (1) develop additional necessary rules and guidelines for the codification of rare diseases;
- (2) support piloting of Orpahacodes implementation in at least four Member States that currently do not have a codification system for rare diseases);
- (3) further support cooperation and exchange of experiences between Member States on codification of rare diseases.

Implementation

Chafea

Indicative timetable and indicative amount of the call for proposals

Reference	Date	Amount
Call for proposals	Second half of 2018	EUR 750 000

Maximum possible rate of co-financing of the eligible costs

60 % rising to 80 % if a proposal meets the criteria for exceptional utility

2.1.4. Multiannual specific grant agreements for European Reference Networks

Criteria for European Reference Networks

Criteria for financial contributions to the functioning of a European Reference Network (ERN) (mono-beneficiary ERN grants) under the third Programme for the Union's action in the field of health (2014-2020)

Articles 7(2)(c) and 8(2) of the Programme Regulation

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.

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

Criteria for the award of specific grant agreements (SGAs) under the framework partnership agreements:

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

1. Consistency with the five-year work programme annexed to the FPA (10 points, threshold: 7 points)

Sub-criteria taken into account in the assessment:

- the proposal's relevance in achieving the multiannual FPA objectives.
- the clarity of the annual work plans.

2. Quality of the proposed activities for a period of 3 years (10 points, threshold: 7 points)

Sub-criteria taken into account in the assessment:

- quality of the planning of work;
- quality of the evaluation strategy;
- quality of the internal and external activities and implementation plan for the pooling of knowledge, the mobility of expertise, and the development, sharing and spreading of information, knowledge and best practices;
- quality of the implementation of the activities and the operational management.

3. Relevance of the proposed budget for a period of 3 years (10 points, threshold 7 points)

- quality and pertinence of the annual budgets.

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.

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 4.1. of Annex I to the Programme Regulation: European Reference Networks

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialised treatment and a concentration of knowledge and resources. The ERNs were set up in 2016 in line with the Directive on patients' rights in cross-border healthcare³.

The action will support the provision of highly-specialised healthcare for rare or low-prevalence complex diseases or conditions, and support the development of knowledge and expertise to diagnose, follow up and manage patients.

Specifically, the action will provide a better governance and coordination of the approved ERNs.

The aim is to ensure that ERNs:

- offer the possibility to work in multidisciplinary teams across different EU countries;
- increase the level of expertise;
- build capacity to produce good practice guidelines, to implement outcome measures and quality control;
- provide support to research coordination and teaching and training activities.

Description of the activities to be funded by the specific grants awarded under the FPA

The actions to be funded are the coordination, management and non-clinical activities of the approved ERNs. Co-financing will be provided in the form of mono-beneficiary grants to the coordinator of each ERN to help the coordinator run the ERN:

Coordinators may request support for:

- networking and coordination activities;
- administrative and logistic support;
- development of knowledge generation tools (clinical guidelines, patient pathways);

³ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L88 p.45.

- training and eLearning;
- meetings of the network members and participation in conferences or events related to the network's area of expertise;
- any non-clinical actions that help ERNs to achieve their goals.

Implementation

Chafea

Indicative timetable and indicative amount

Reference	Date	Amount
Invitation to FPA holders to apply; SGA awarded on a competitive basis	First half of 2018	EUR 13 800 000

Maximum possible rate of co-financing of the eligible costs

60 %, rising to 80 % if a proposal meets the criteria for exceptional utility

2.2. Joint Actions

Under the overall operational budget reserved for grants, EUR 7 900 000 will be reserved for Joint Actions. The maximum rate of EU co-financing is 60 %, but this can rise to 80 % if a proposal meets the criteria for exceptional utility.

The budget line is 17 03 01.

Essential eligibility, selection and award criteria

Member State authorities will be invited to nominate one competent authority responsible for the implementation of the action on behalf of that Member State.

‘Competent authority’ means the central authority of a Member State responsible for health or for a specific (public) health topic or any other authority to which that competence has been conferred. Where appropriate, the corresponding authority of a non-EU country may be included. A competent authority may also be a regional authority, depending on the governance structure of the Member State/non-EU country in question.

The competent authorities may implement activities in cooperation with other entities.

The competent ministry/government organisation must submit an official notification, duly signed by an authorised representative, which confirms that

- the participating entity is a competent authority;
- the participating entity is the eligible body to participate on behalf of the respective Member State/region and under its responsibility in the relevant action.

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

Eligibility criteria

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

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 non-EU 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.

Selection criterion

Operational capacity

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

Award criteria

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

Sub-criteria taken into account in the assessment:

- quality of the Joint Action's contribution to public health in Europe;
- consideration of social, cultural and political context.

Technical quality (10 points, threshold: 6 points)

Sub-criteria 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 with regard to promoting the dialogue with NGOs in the field;
- quality of the evaluation strategy;
- quality of the dissemination strategy and plan.

Management quality (10 points, threshold: 6 points)

Sub-criteria 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.

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

Sub-criteria taken into account in the assessment:

- budget's relevance to the activities;
- consistency of the estimated cost per applicant and the corresponding activities;
- realistic estimation of person days per deliverable and per work package;
- reasonableness of the budget allocated for evaluation and dissemination.

2.2.1. *Joint Action to strengthen preparedness in the EU against serious cross-border threats to health and support the implementation of International Health Regulations (IHR)*

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 2.2. of Annex I to the Programme Regulation: Capacity-building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

The Joint Action will help strengthen preparedness including laboratory capacities and the implementation of IHR in the EU.

In particular, the Joint Action will support:

- strengthening the scientific evidence base on effective actions to prevent and respond to cross-border health threats of biological, chemical, environmental and unknown origin;
- exchanging of information and sharing of best practices within and among Member States;
- strengthening preparedness and the implementation of IHR core capacities, supporting Member States in developing standard operating procedures, business continuity plans, and promoting the interoperability of national preparedness planning;
- improving methods, tools and criteria for monitoring, assessment and reporting under Decision 1082/2013/EU;
- improving EU Member State coordination as regards different global initiatives, and in particular the WHO's IHR Monitoring and Evaluation Framework under the Health Emergencies Programme;
- improving the core functions of public health laboratories, including biosafety and biosecurity to ensure systems for the safe referral of clinical specimens for early detection and monitoring of outbreaks, transport in-country and international shipment, which key capacities required under the IHR;
- the coordinaton, in collaboration with the European Centre for Disease Prevention and Control (ECDC), of a reference network of European microbiology laboratories specialised in highly pathogenic or newly emerging pathogens to improve laboratory capacity;

- supporting the development, implementation and sharing of strategies, tools, guidelines and procedures, and providing technical support and expertise for preparedness and response planning; and strengthening health crisis management;

Activities are expected to improve preparedness and response planning for serious cross-border threats to health. The work is part of a wider approach to strengthening health systems, while also ensuring coherence and interoperability between sectors at EU and Member States' levels. The activities are expected to:

- provide information on existing IHR implementation gaps;
- provide tailored support to strengthen core capacities and cross-sectoral capacity building;
- improve information sharing within the EU and with neighbouring countries.

The Joint Action is expected to closely collaborate with the 2017 Joint Action on preparedness and action at points of entry (air, maritime and ground crossing).

Description of the activities to be funded by the grant awarded without a call for proposals on the basis of Article 190 (1)(d) of Delegated Regulation (EU) No 1268/2012

Specific activities under the Joint Action will:

- facilitate sharing of best practices:
 - ensuring interoperability between Member States' preparedness plans promoting inter-sectoral cooperation
 - ensuring that related standard operating procedures and business continuity plans are in place;
- help ensure more effective coordination of national crisis response systems in case of public health emergency, through testing and evaluation;
- support assessment, planning and implementing targeted actions to help Member States implement fully the core capacity standards in accordance with IHR;
- help Member States build capacity for public health professionals to be achieved through
 - facilitating the networking of stakeholders and exchange of expertise
 - targeted exercises, training and seminars at Member States and EU level;
- contribute to the development, implementation and sharing of guidelines, plans and procedures in preparedness and response;
- sustain the coordination of a reference network of European microbiology laboratories for highly pathogenic agents dedicated to strengthening laboratory preparedness and supporting less-equipped Member States through technological transfer, staff training, establishment of safe inter-laboratory sample referral procedures and the performance

of regular External Quality Assessments.

Implementation

Chafea

Indicative timetable and indicative amount of the grant awarded without a call for proposals

Reference	Date	Amount
Signature of the grant awarded without a call for proposals	First half of 2018	EUR 7 900 000

Maximum possible rate of co-financing of the eligible costs

60 %, rising to 80 % if a proposal meets the criteria for exceptional utility

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

Essential eligibility, selection and award criteria

Eligibility criteria

For a body to be eligible for the financial contribution, it needs to be:

- non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests;
- working in the public health area, playing an effective role in civil dialogue processes at Union level;
- pursuing at least one of the specific objectives of the third Health Programme;
- active at Union level and in at least half of the EU Member States (i.e. it has members⁴ in at least half of the Member States);
- engaged in an activity 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.

Selection criteria

- Financial capacity

Applicants must have the financial resources necessary to ensure that they can function for the four year duration of the framework partnership agreement.

An audit report produced by an approved external auditor must be submitted covering the last two financial years available before the framework partnership agreement was signed or the framework partnership decision was notified.

- Operational capacity

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

- Geographical coverage

Organisations must have a balanced geographical coverage with at least four of their members based in Member States which joined the EU after 2004.

Award criteria for specific grant agreements

Consistency with the four-year work programme annexed to the FPA (10 points, threshold: 6 points)

Sub-criteria taken into account in the assessment:

- relevance of annual objectives;

⁴ 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.

- contribution to achieving the multiannual objectives.

Quality of the proposed activities in the year of funding (10 points, threshold: 6 points)

Sub-criteria taken into account in the assessment:

- quality of the planning of annual work;
- quality of the implementation of the activities and the operational management.

Quality of the proposed budget for the year of funding (10 points, threshold 6 points)

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

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

(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.

It is expected that these non-governmental bodies assist the Commission by providing the information and advice necessary to the develop health policies and implement 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, organise science policy conferences and help optimise healthcare activities and practices by providing feedback from patients and facilitating communication with them, 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 was organised for the conclusion of four-year framework partnership agreements (FPAs) covering the years 2018, 2019, 2020 and 2021. The call covered in particular, but was 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'). The 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-financing.

Operating grants (SGA) are calculated based on eligible costs incurred. The maximum rate for EU co-financing is 60 %. However, this may rise to 80 % if a proposal meets the criteria for exceptional utility.

No call for proposals will be organised in 2018 as a result of the conclusion of FPAs.

Implementation

Chafea

Indicative timetable and indicative amount

Reference	Date	Amount
Invitation to FPA holders, SGA awarded on a competitive basis	First half of 2018	EUR 5 000 000

Maximum possible rate of co-financing of the eligible costs

60 % rising to 80 % if a proposal meets the criteria for exceptional utility
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2.4. Direct grant agreements (international organisations)

The overall budgetary allocation reserved for actions implemented via direct grants to international organisations is EUR 2 700 000. Other direct grants amount to EUR 3 440 000. The budget line is 17 03 01.

In accordance with Article 190(1)(f) of Delegated Regulation (EU) No 1268/2012, funding for actions with international organisations will be allocated exclusively through grant agreements without a call for proposals on topics specifically identified in this work plan. International organisations and their national or regional offices are not eligible for funding as main or associated beneficiaries under any calls for proposals or under the procedure described in sections 2.1 and 2.3.

The maximum rate for EU co-financing is 60 % of the eligible costs actually incurred. The eligible direct costs are reimbursed either on the basis of actual costs incurred by the international organisation or on the basis of unit costs and flat rates, as long as the use of reimbursement on the basis of unit costs and flat rates is authorised and provided for by the Commission Decision approving the framework agreement between the European Commission and the international organisation concerned.

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:

— Council of Europe

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

— World Health Organisation (WHO)

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

— Organisation for Economic Cooperation and Development (OECD)

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

Award criteria

Award criteria for these direct grants are:

Technical quality of the proposal

- quality of the content (clear objectives, appropriate methodology, well defined deliverables, pertinent outcomes);
- quality of the evaluation strategy (a logical framework method is used, process, output and outcome/impact indicators are well defined and pertinent);
- quality of the dissemination actions planned.

Management quality

- quality of the planning and implementation (logical timetable with milestones set, and adequate risk analysis and contingency planning);
- management structure and competences of staff are clearly described;
- technical and financial reporting procedures and quality controls are well described and appropriate.

2.4.1. Direct grant to the WHO/FCTC (Framework Convention on Tobacco Control)

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 1.5 of Annex I to the Programme Regulation: Tobacco legislation

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

The EU tracking and tracing system (developed under the Tobacco Products Directive 2014/40/EU) will be one of the key tools in fighting illicit trade in tobacco products and is expected to contribute to a reduction in the artificially cheap supplies of tobacco products and thus to lower the uptake and general prevalence of smoking. This EU system will be part of the global tracking and tracing regime created under the auspices of the FCTC (Framework Convention on Tobacco Control) Illicit Trade Protocol. In this respect, the FCTC Secretariat, given its central status, has been entrusted with establishing an information-sharing focal point.

This grant will support the work carried out by the FCTC Secretariat on the system design and functioning of the global information-sharing focal point.

The overall action executed by the FCTC Secretariat in this context is expected to deliver the rules of procedure and necessary IT tools to efficiently handle requests for traceability information. Among others, this should include the standard IT documentation necessary for establishing any new system, such as business process flow description and data dictionary documents.

A properly designed and timely developed global information-sharing focal point will enable the competent authorities of EU Member States fight the flows of illicit products of non-EU origins directed towards the EU market more effectively and efficiently. The penetration of illicit trade in cigarettes is estimated at 11.3 % of overall consumption.

Description of the activities to be funded by the grant awarded without a call for proposals on the basis of Article 190(1)(f) of Delegated Regulation (EU) No 1268/2012

The FCTC Secretariat will be asked to submit a proposal presenting a coherent programme of actions to establish the global information-sharing focal point, in particular specifying the needs for system design and software development.

Implementation

Chafea

Indicative timetable and indicative amount of the grant awarded without a call for proposals

Reference	Date	Amount
Signature of the grant agreement without a call for proposals	Second half of 2018	EUR 400 000

Maximum possible rate of co-financing of the eligible costs

60 %

2.4.2. Direct grant to the OECD

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priorities 1.5, 3.2, 3.7 and 4.1 of Annex I to the Programme Regulation:

- chronic diseases including cancer, age-related diseases and neurodegenerative diseases
- innovation and eHealth
- health information and knowledge system including support to the Scientific Committees
- patient safety and quality of healthcare

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

Digital strategy:

This action is directly relevant to the Commission Digital Single Market strategy goal of developing digital solutions to promote better care models (people-centred integrated care). This approach can not only result in better health outcomes but potentially lowers direct and indirect costs, particularly for people with complex needs

Antimicrobial resistance:

This work will deliver important analytical results and further develop an antimicrobial resistance (AMR) modelling framework to enable estimates to be made of the costs and impacts of AMR with different policy scenarios. It will also provide tools, information and technical support to help Member States use the results to inform policy decisions.

Outputs of the model will include projections of AMR prevalence rates, healthcare system and wider societal costs associated with AMR as well as estimates of the effectiveness and cost-effectiveness of selected AMR prevention and control policies in EU countries.

Selection and implementation of best practices to promote health and prevent and manage non-communicable diseases:

The objectives of this direct grant to the OECD are to:

- (1) assess actions in order to select 'best' practices,
- (2) monitor and evaluate subsequent implementation of best practices especially from an economic point of view, and
- (3) support the development of effective processes for the transfer of best practices between Member States.

The results will be used in the Steering Group on Promotion and Prevention which will select major best practices for changing health policies. The deliverables will not only support Member States directly but also national, regional and local stakeholders who will be involved in the implementation process.

Support to OECD to develop and implement patient-reported measures

The action has the following aims:

- develop expertise on performance assessments of health systems;
- help build lessons from recent experience and from EU-funded research projects;
- build up country-specific and cross-country knowledge to feed into policies at national and European level.

Deliverables will be used by Member States to assess their capacity to deliver positive health outcomes, and to identify policy action to improve it. The comparability of the indicator will also enable other stakeholders to assess and exchange best practices and share information and experiences with peers.

Description of the activities to be funded by the grant awarded without a call for proposals on the basis of Article 190(1)(f) of Delegated Regulation (EU) No 1268/2012

Digital strategy

This action will support the Commission Digital Single Market Strategy through analytical work how to use digital technology to create more integrated, people-centred care delivery models. Such models empower individuals to manage their own health, enable feedback and collection of real world data, and facilitate more productive interaction between people and their care teams.

AMR

This activity will extend the OECD's previous work on AMR (with the support of the EU Health Programme) which produced a model to assess the economic impact of AMR under a range of different policy scenarios which can be used by Member States to develop and implement measures to address AMR. The work will both extend the economic model and include activities to support the use of the model by Member States and stakeholders.

The current model assesses the effectiveness and cost-effectiveness of policy options to promote rational use of antimicrobials and preserve their effectiveness. It focuses on prevention policies to promote prudent use of antimicrobials and to promote hygiene in healthcare settings. It covers virtually all EU countries.

The scope of the model will in a next step be enlarged to assess policies in a 'One-Health' approach. This entails including specific modules to replicate the transmission dynamics from animals, animal products and the environment to humans. Additional prevention strategies will also be considered in the model. The model will also be developed to assess the potential return on investment associated with vaccination and other health technologies as alternatives to antibiotics extended to include a range of indirect costs for the economy as a whole as well as costs to the health sector. This will enable the model to produce information to enable more detailed estimates of the economic impact of AMR, on the health system and on the wider economy including via loss of contributions to the labour market and other factors.

Workshops, training and technical support will be provided to help staff from Member States use the economic model as an input to policy making. A web-based user friendly version will also be produced.

Selection and implementation of best practices to promote health and prevent and manage non-communicable diseases

The OECD support will focus on:

- (1) assessing existing practices in a health field selected by the Steering Group on Promotion and Prevention to select the ‘best’ practices and/or to provide health economic analyses of potential best practices selected by the Steering Group on Promotion and Prevention;
- (2) developing indicators, encompassing health, social, economic and ethical aspects. The indicators can be used to monitor and evaluate the transfer and implementation of best practices in national, regional or local settings. A methodological tool kit on the use of the indicators will be provided as well.
- (3) providing support to the CHRODIS PLUS Joint Action in developing an overall implementation approach for transferring best practices. This will include considerations of enablers and barriers to transfer and implementation, and build on existing work such as the SCIROCCO⁵ maturity model and economic aspects (such as a cost-benefit analysis).

Support to OECD to develop and implement patient-reported measures

The action will build on and will further extend previous work on developing and testing new indicators on patient-reported experience (PREMs), outcomes (PROMs) and incidence measures (PRIMs). It will focus on the piloting of the survey tool and sampling methodology to be developed for patients with complex needs (“top-down” strand of the OECD Patient Reported Indicator Survey - PaRIS) and will specifically focus on the specification and finalisation of the questions to be used for these patients, and the design and beta-testing of survey methods in the field.

In addition and in complementarity, the development of a set of patient-reported indicators of safety (PRIMs) will be continued with a view of uptake within the PaRIS framework. This will focus on reaching international consensus on appropriate indicators, pilot data collections, ongoing refinement of methodology and data collections and work to strengthen capacity and information infrastructures in primary and long-term care settings in Member States.

Implementation

Chafea

Indicative timetable and indicative amount of the grant awarded without a call for proposals

Reference	Date	Amount
Signature of the grant agreement without a call for proposals	First half of 2018	EUR 1 500 000

Maximum possible rate of co-financing of the eligible costs

60 %

⁵ <http://www.scirocco-project.eu/>.

2.4.3. *Direct grant for SoHo with Council of Europe's EDQM (European Directorate for the Quality of Medicines and Healthcare)*

LEGAL BASIS

Regulation (EU) No. 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 4.5 of Annex I to the Programme Regulation: Implementation of Union legislation in the fields of tissues and cells, blood, organs

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

The expected results of this action include:

- overall better uptake and implementation by European blood and tissue establishments of EU legal requirements on safety and quality for substances of human origin;
- updated guidance on safety and quality for actors in the blood, tissue/cell and organs sectors, complemented with on-site advice for volunteering actors;
- improved quality of testing practices in EU laboratories;
- annual reports of serious adverse events and reactions for blood and for tissues and cells.

Description of the activities to be funded by the grant awarded without a call for proposals on the basis of Article 190(1)(f) of Delegated Regulation (EU) No 1268/2012

- aligning data collection activities between Council of Europe and DG SANTE, in particular on volumes of transplanted and transfused units, in order to lighten mutual workload;
- updating versions of the guides on blood, tissues and cells and organs taking account of existing and future EU activities (evaluation of the blood/T&C legislation, legal GPG reference in Commission Directive (EU) 2016/1214, work in EU-funded actions like those focusing on process qualifications and clinical follow-up);
- audits performed under the quality management programme;
- improving quality of testing protocols for blood and tissue establishments, e.g., by assessing test kits (selections, post-mortem validation), inspection of test labs, guidance on analyses and archiving;
- performing proficiency tests with a number of reference laboratories.

- Drafting annual reports of serious adverse events and reactions for blood and for tissue and cells, as reported by EU Member States to the Commission.

Implementation

Chafea

Indicative timetable and indicative amount of the grant awarded without a call for proposals

Reference	Date	Amount
Signature of the grant agreement without a call for proposals	First half of 2018	EUR 800 000

Maximum possible rate of co-financing of the eligible costs

60 %

2.5. Other direct grants

2.5.1. Orphanet (*de facto* monopoly in line with Article 190 (1) (c) of Delegated Regulation (EU) No 1268/2012)

Orphanet was established in France in 1997 to gather scarce knowledge on rare diseases so as to improve the diagnosis, care and treatment of patients with rare diseases. It is a consortium of 40 countries, within Europe and across the globe.

Orphanet produces massive, computable, re-usable scientific data that can be used to identify rare disease patients and help expand knowledge about such diseases. Orphanet produces the only nomenclature specific for rare diseases, with the aim to provide stakeholders with a common, controlled language to improve interoperability between health information systems and databases and registries.

As such Orphanet constitutes a *de facto* monopoly.

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 4.2 of Annex I to the Programme Regulation: Rare Diseases

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

The objective of this action is to provide the rare diseases community at large with interoperability tools, an inventory of rare disease, an encyclopedia in as many languages as possible, and a directory of expert services in the participating countries. The overall outcome is to serve as the reference source of information on rare diseases for European citizens.

Description of the activities to be funded by the grant awarded without a call for proposals on the basis of Article 190(1)(c) of Delegated Regulation (EU) No 1268/2012

Activities funded under the grant should contribute to areas that come under Orphanet's three main goals:

- (1) Improving the visibility of rare diseases in the fields of healthcare and research information systems by maintaining the Orphanet rare disease nomenclature (ORPHAnumbers).
- (2) Providing high-quality information on rare diseases and expertise, ensuring equal access to knowledge for all stakeholders.
- (3) Contribute to generating knowledge on rare diseases.

Implementation

Chafea

Indicative timetable and indicative amount of the grant awarded without a call for proposals

Reference	Date	Amount
Signature of the grant agreement without a call for proposals	First half of 2018	EUR 2 640 000

Maximum possible rate of co-financing of the eligible costs

60 %

2.5.2. *Direct grant to the European Reference Network on urogenital diseases and conditions (ERN eUROGEN)*

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 4.1 of Annex I to the Programme Regulation: European Reference Networks

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

The grant will help meet the goals of the European Reference Networks (ERN) established in Article 12 of the 2011 Directive on Patients' Rights in Cross-border Healthcare in the field of rare or low prevalence and complex urogenital diseases and conditions.

The action is expected to support the eUROGEN Coordinating Centre to perform effectively coordination, management and non-clinical activities for three years.

The ERN eUROGEN was approved by the ERN Board of Member States and launched in 2017. In contrast to the other 23 established ERNs, this network has not yet received any grant from the EU.

It is the only network approved by the EU in this field of expertise. It therefore constitutes a *de-facto* monopoly in line with Article 190.1(c) of the Rules of Application of the Financial Regulation and deserves a three-year direct grant.

There are a limited number of urogenital conditions that require surgical correction, often during the neonatal period or in childhood. Urinary and faecal incontinence are a heavy burden on paediatric, adolescent and adult patients. Individuals affected require life-long care provided by multidisciplinary teams of experts who plan and perform surgery, and provide postoperative physiotherapy and psychology support. eUROGEN will provide independently evaluated best practice guidelines and improve the sharing of outcomes. It will, for the first time, offer the capacity for tracking long-term outcomes for patients over a 15 to 20-year period.

The network will collect data and materials where they are lacking, develop new guidelines, build evidence of best practice, identify practice variation, develop education programmes and training, set the research agenda in collaboration with patient representatives, and share knowledge through participation in virtual multidisciplinary teams.

Ultimately, the network seeks to advance innovation in medicine and improve diagnostics and treatment for patients.

Description of the activities to be funded by the grant awarded without a call for proposals on the basis of article 190(1)(c) of Delegated Regulation (EU) No 1268/2012

The ERN eUROGEN Coordinating Centre will be asked to submit a proposal presenting a coherent programme of actions aimed to fulfill the goals of the network including interalia

- networking and coordination activities;
- administrative and logistic support;
- development of knowledge generation tools (clinical guidelines, patient pathways)
- training and eLearning;
- meetings of the network members and participation in conferences or events related to the area of expertise of the network;
- any non-clinical actions supporting the fulfilment of the goals of the ERNs.

Implementation

Chafea

Indicative timetable and indicative amount of the grant awarded without a call for proposals

Reference	Date	Amount
Signature of the grant agreement without a call for proposals	First half of 2018	EUR 600 000

Maximum possible rate of co-financing of the eligible costs

60 %

2.5.3. Presidency conference grants — *de jure* monopoly

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

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

The EU Presidencies 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 the '**Food value chain**' (**Food systems – adding value for better health in Europe**) under the Austrian Presidency and a conference on **Procurement of Medicine, medical devices, Equipment and Increasing access to therapy** under the Romanian Presidency.

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)
(related to all programme objectives)

BUDGET LINE

17 03 01

Implementation

Chafea

Indicative timetable and indicative amount of the grants awarded without a call for proposals

Reference	Date	Amount
Signature of the grant agreement without a call for proposals	Second half of 2018 and first half of 2019	EUR 200 000

Maximum possible rate of co-financing of the eligible costs

50 %

3. PRIZES

3.1. EU Health Award for NGOs

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

(related to all programme objectives)

BUDGET LINE

17 03 01

Description, objectives pursued and expected results

NGOs play an important role in identifying needs for health policy action, informing the Commission in developing its policies and also in implementing policy actions. The EU Health Award for NGOs focuses on practices and interventions which support the implementation of the Sustainable Development Goals in priority health topics chosen by the Steering Group on Health Promotion and Prevention and Management of Non-Communicable Diseases or the Health Security Committee. The award creates an incentive for European health NGOs to share their evaluated good practices/interventions and get involved in EU health policy. The knowledge of NGO practices broadens the information base for the Commission's work with Member States.

Essential conditions for participation and award criteria

1. Eligibility Criteria

1. The applicant must be a legally established non-governmental body that is non-profit-making and independent from industry, commercial and business or other conflicting interests.
2. The applicant must act 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 must be complete (application form filled in).
6. The applicant must clearly address one of the topics listed in the call for applications.

2. Selection criteria

The mission of the applicant organisation must be in line with at least one of the objectives of

the Third Health Programme

The applicant must actively seek to shape public health affairs on the basis of their own concerns, drawing from their own specific knowledge, abilities and scope of action.

3. Award Criteria

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

The applications will be assessed against the criteria to select best practices adopted by the Steering Group on Health Promotion and Prevention and Management of Non-Communicable Diseases. These criteria will be published with the call for applications.

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

Implementation

Commission

Indicative timetable of the contest(s) and indicative amount of the prize(s)

Reference	Date	Amount
Call for applications for the EU Health Award	First half of 2018	EUR 60 000

4. PROCUREMENT

The overall budgetary allocation reserved for procurement contracts in 2018 is EUR 14 480 701.

The budget line is 17 03 01.

4.1. Support to Member States in reducing alcohol related harm

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 1.1. of Annex I to the Programme Regulation: Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity

Budget line

17 03 01

Subject matter of the contracts envisaged

Technical assistance/communication services

The main expected results are:

- implementation of best practices for early screening and brief interventions as identified by the Joint Action on reducing alcohol-related harm and supported by evidence (e.g. from the OECD and WHO);
- implementation of best practices for activities in schools as identified by the Joint Action on reducing alcohol-related harm and supported by evidence;
- implementation of best practices for public communication and awareness campaigns as identified by the Joint Action on reducing alcohol-related harm;
- support to capacity building, sharing and implementing of best practices in the Member States, including via scientific networks, organising job shadowing, missions and knowledge transfer;
- organisation of thematic meetings focused on the above specific working areas and deliverables. The work would support and strengthen the work of Member States by facilitating a focus on the development of agreed deliverables and results.

Type of contract and type of procurement

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Chafea

4.2. Evaluation of the public health impact of the provisions of Article 32 of Directive 2008/118/EC

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 1.1. of Annex I to the Programme Regulation: Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity

Budget line

17 03 01

Subject matter of the contracts envisaged

Study

High limits for personal use in cross-border alcohol shopping indirectly infringe on Member States’ ability to set their own alcohol taxation and consequently set their own policy on reducing alcohol related harm. High alcohol excise duty rates and open borders lead to high unrecorded alcohol consumption, especially as a result of travellers’ alcohol imports and cross-border trade.

Due to such high limits for personal use, consumers in high-taxation Member States might not just replace their existing alcohol consumption with cheaper alcohol, but also increase their total alcohol consumption level. The societal costs of high limits are borne by high-taxation countries: health inequalities in these countries may increase, since lower socioeconomic groups experience higher levels of alcohol related harm than wealthier groups. Setting lower limits would be relatively easy to implement and could reduce some of the harm experienced by ‘importing’ Member States (traditionally high-taxation countries).

Article 32 of Directive 2008/118/EC deals with the guide levels for travellers buying alcohol and tobacco products and then carrying them personally to another Member State for their own personal use, i.e. not for resale.

This evaluation study will provide an assessment of the impact of future potential changes to the Directive and best practice identification evaluation and sharing with a view of implementation.

The main deliverables will be the support to national prevention strategies and to the Member States so that they can attain the WHO non-communicable diseases objective on 10% reduction of alcohol related harm that the Member States have agreed to meet.

Type of contract and type of procurement

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Chafea / European Commission Directorate-General for Taxation and Customs Union (DG TAXUD)

4.3. Framework contract: support services to manage expert groups

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

(related to all Programme Objectives)

Budget line

17 03 01

Subject matter of the contracts envisaged

Administrative/communication services

This framework contract will help DG SANTE achieve a more streamlined and effective management of formal and informal Commission expert groups. This will allow for a better up-take and implementation the outputs of these Expert Groups, such as recommendations and consensus statements.

The framework contract holder would provide services in the following areas:

- a) managerial e.g. coordinating the experts' contributions to a discussion paper,
- b) administrative e.g. organising expert groups' meetings,
- c) technical e.g. writing minutes and reports from the expert groups' meetings,
- d) scientific e.g. providing scientific background analysis to the expert groups,
- e) dissemination e.g. drafting information to the public after an expert group meeting.

These services will support both formal and informal Commission expert groups and ad hoc groups which may be established to accomplish a specific task.

After the conclusion of the framework contract in 2018, it is estimated that up to three expert meetings may be organised by the contractor in the second half of 2018/1st quarter of 2019.

Type of contract and type of procurement

New framework contract (without re-opening of competition)

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Chafea

4.4. Provision of technical and scientific input to support the application, enforcement and monitoring of the Tobacco Products Directive 2014/40/EU

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 1.5 of Annex I to the Programme Regulation: Tobacco legislation

Budget line

17 03 01

Subject matter of the contracts envisaged

The application and enforcement of the Tobacco Products Directive (TPD) 2014/40/EU⁶ should be supported and monitored by appropriate technical, scientific and legal input in form of reports, studies, market statistics and/or other relevant forms.

Action to achieve the main objectives of the Tobacco Products Directive in 2018 will focus on the following priority areas:

(i) Further development of ingredients regulation:

Assessment of flavours in tobacco products (specific contract under existing framework contract): The contractor's task is to put in place and run the technical group of sensory and chemical assessors who carry out the practical sensory and chemical testing of tobacco products (i.e. the mechanism set up via Commission Implementing Decision 2016/786). The work carried out by the technical group will be used by the independent advisory panel to deliver opinions on whether or not a tobacco product contains a characterising flavour in line with the TPD.

The technical group provides support to the process of deciding whether tobacco products placed on the EU market contain a characterising flavour. This action contributes to the implementation of the TPD regarding its requirement to prohibit tobacco products with a characterising flavour.

Further development of the EU-CEG reporting tools: The EU-CEG (Central Entry Gate) is an IT tool developed to:

- facilitate and harmonise the submission of data from manufacturers or importers to the Member States;
- disseminate data from the Member States to the Commission and to other Member States;
- disseminate data from the Member States to the general public, as required under the TPD.

Additional technical support is required so that submitted data can be assessed more easily

⁶ OJ L 127, 29.4.2014, p 1.

and presented to the general public in an appropriate manner.

(ii) Establishment and operation of a tracking and tracing system as required under Article 15

The work will focus on monitoring and analysing the data generated and collected by the EU tracking and tracing system.

It will contribute to the task of collecting data on movements of tobacco products across the supply chain and help equip competent national authorities with the necessary means to exploit such data in order to fight illicit trade effectively. This is crucial given the high level of penetration of illicit trade in tobacco products (11.3 % for cigarettes).

This will involve the use of a surveillance tool which forms part of the tracking and tracing system.

In this context, an expert **study on monitoring tools** is expected to provide technical advice on how to configure the surveillance tool to:

- run effective database queries that help Member States identify and investigate possible fraudulent activities by tracing back supply-chain activities;
- design effective automatic alerts that will help Member States to discover fraudulent activities, such as duplicates, based on pre-defined risk-assessment rules.

The results of the study will be used by competent authorities in a way that meets their national enforcement strategies. The results of the study are expected to be of relevance for EU and Member State activities alike.

(iii) Collection of information for the Commission report on the application of Directive 2014/40 on tobacco products

When the Commission drafts its report on the application of the Tobacco Products Directive, it is assisted by scientific and technical experts, as laid down in Article 28 of the Directive.

This action will provide input to the Commission on the application of the TPD in the Member States and underlying information on new market developments in tobacco and e-cigarettes. It will involve producing an **expert study** that will feed into the Commission report **on the implementation of the TPD in the areas outlined in Article 28(2):**

- (1) experiences of plain packaging in Member States;
- (2) market developments for novel tobacco products;
- (3) market developments which constitute a substantial change of circumstances;
- (4) the feasibility of introducing a positive or negative list of ingredients in tobacco products;
- (5) market developments for slim cigarettes;
- (6) the impacts of the EU database on ingredients and emissions;
- (7) market developments and cessation potential of e-cigarettes; and
- (8) market developments for water pipe tobacco.

The final report should provide information to the Commission on the tobacco market in the EU and will allow the Commission to draw conclusions on the impact of the Directive in regulating tobacco and related products in the EU.

To analyse market developments effectively, a robust set of **market sales and marketing data** is essential. In this respect, the contractor should provide DG SANTE with access to the relevant market data. The data must be provided in a comprehensible and fully retrievable

way. The contractor must also provide DG SANTE with the necessary initial trainings and continuous technical support related to tobacco products and electronic cigarettes.

Type of contract and type of procurement

Direct service contracts or specific contracts under existing framework contract.

Framework Contract with a single contractor to provide services to support the assessment of flavours in tobacco. The contract also provides for service orders for product assessment.

Indicative number of contracts envisaged: 5

Indicative timeframe for launching the procurement procedure

Two contracts in the first half of 2018, three contracts in the second half of 2018

Implementation

Chafea (four contracts) and Commission (one contract)

4.5. Actions under Multiple Framework Contract for the ‘Scripting, planning, conduction and evaluation of exercises, training and assessment implementing the Decision No 1082/2013/EU on serious cross-border threats to health’

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 2.2 of Annex I to the Programme Regulation: Capacity-building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries

Budget line

17 03 01

Subject matter of the contracts envisaged

Simulation exercises/training seminar

The overall scope of the activities is to support Member States in their implementation of Decision 1082/2013/EU on serious cross-border threats to health and the International Health Regulations (IHR, 2005⁷). Participants from Member States should be involved in preparedness and response planning, risk and crisis management related to serious health threats.

The activities target existing gaps between the knowledge and skills required to achieve effective preparedness and response through testing national preparedness plans and crisis management operations, building cross-sectoral capacity and improving information sharing within EU and neighbouring countries.

Activities are expected to

- improve preparedness and response to serious cross-border threats to health, ensuring coherence and interoperability among sectors at EU level and between Member States;
- strengthen and enhance coordination between Member States at EU and international level, to create and facilitate shared and coordinated communication strategies.

Planning and organisation of actions will be implemented in close collaboration with the European Centre for Disease Prevention and Control (ECDC), while participants from relevant Commission departments, EU agencies, and international organisations (WHO) will also be invited.

(1) Simulation exercises

The exercises will:

- test crisis management and communication plans and procedures in response to a major public health event, allowing for comparisons of interoperability in the responses and identify gaps for further improvements;
- examine and strengthen risk and crisis communication capacities to better integrate them into the coordinated overall responses.
- support cross-sectoral capacity building and improve information sharing between

⁷ <http://www.who.int/ihr/publications/9789241580496/en/>

the health sector, and other relevant critical sectors at national and EU level.

Two-day simulation exercises (one table top and one command post) will be organised to help Member States improve preparedness and strengthen capacity to coordinate the response to health emergencies.

The exercises will test structures, procedures and protocols for crisis management and risk and crisis communication, based on fictitious scenarios involving the combination of cross-border threats of biological, chemical and/or environmental origin for early warning and response.

The command post exercise will use surveillance and intelligence-gathering tools and real communications methods, and an online simulation exercise platform, involving players operating from their own emergency operating centres or command and control facilities. The exercises will involve participants from public health and other relevant sectors at national level.

(2) Training seminar

- The one-day training seminar should support public health professionals working on preparedness, early warning and crisis management by helping them to improve their knowledge and skills that are critical to sustaining a public health response to cross-border health threats and to the effective implementation of the IHR, in line with Decision 1082/2013/EU.
- The training is expected to improve participants' awareness of health crisis management operations, tools and relevant policies at EU level.

The training materials and sessions will be designed and implemented so as to enable participants from the different Member States to reach the same level of understanding of issues and competencies.

Type of contract and type of procurement

Multiple framework contract No CHAFEA/2016/Health/05 with the reopening of competition for the 'Scripting, planning, conduction and evaluation of exercises, training and assessment implementing the Decision No 1082/2013/EU on serious cross-border threats to health'

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Chafea

4.6. Health innovation and eHealth — support to the implementation of the Digital Single Market

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 3.2. of Annex I to the Programme Regulation: Innovation and eHealth

Budget line

17 03 01

Subject matter of the contracts envisaged

Study

The contractor will provide support for the development of eHealth and mHealth policies to ensure continued innovation in the EU and respond to the tasks set under the Digital Single Market Strategy, which are:

- (1) Citizens’ secure access to electronic health records and the possibility to share it across borders;
- (2) building data infrastructure in particular rare, infectious and complex diseases;
- (3) setting up an EU framework for digital feedback and interaction between patients and healthcare providers, supporting prevention and citizen empowerment.

The activities include:

- developing specific proposals for cross-border access to health data and electronic health records and their use and to improve interoperability in the EU and develop telemedicine cooperation;
- support implementation of EU legislation relevant to access and use of health data across borders, in particular General Data Protection Regulation and cybersecurity for health;
- providing the background information for the development of proposals for digital health and care policies.

Type of contract and type of procurement

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Chafea

4.7. Scientific and technical assistance for the Expert Panel on effective ways of investing in health

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 3.4. of Annex I to the Programme Regulation: Setting up a mechanism for pooling expertise at Union level

Budget line

17 03 01

Subject matter of the contracts envisaged

Technical assistance

The Expert Panel on effective ways of investing in health supports the Commission in its efforts towards evidence-based policy-making on country-specific and cross-country knowledge in the field of health. The Panel supports DG SANTE’s new ‘State of Health in the EU’ cycle and more broadly DG SANTE’s agenda on effective, accessible and resilient health systems.

The contractor will provide scientific and technical assistance for the Expert Panel on effective ways of investing in health. This includes:

- organising scientific hearings, working group meetings and thematic workshops;
- providing direct scientific support for the drafting of documents, such as literature searches;
- editing;
- translation of scientific texts into publications for the general public and their dissemination.

Type of contract and type of procurement

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Commission

4.8. Scientific Committees and provision of targeted risk assessment in case of a chemical and environmental incident of cross border relevance

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic priorities 2.4 and 3.7 of Annex I to the Programme Regulation

- Health information and knowledge system to contribute to evidence-based decision-making
- Health information and knowledge system including support to the Scientific Committees

Budget line

17 03 01

Description and objective of the implementing measure

When preparing its policy and proposals relating to consumer safety, public health and environment, the Commission relies on independent Scientific Committees to provide sound scientific advice and raise awareness about new and emerging problems.

The work of the Scientific Committees also includes the rapid risk assessment for health threats other than communicable diseases (i.e. chemical and environmental threats), as stated in the Council and European Parliament Decision 1082/2013 on ‘serious cross border threats to health’ addressing the need to have ‘ad-hoc risk assessments and monitoring’ prepared by independent experts in case of need, and in particular in case of acute events of cross-border relevance.

The advice is provided by the Scientific Committees as laid down by Commission Decision C(2015) 5373 of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment.

The activity of the Scientific Committees impacts mainly on the Commission’s regulatory work in the areas of consumer safety, public health and environment. However, opinions of the Committees are taken as a reference by EU and Member States’ risk assessment bodies, international organisations, and non-EU countries’ national risk assessment bodies for their policies. Moreover, the opinions impact on the scientific community and on risk communication with citizens.

The expected results of this action are:

- the administrative support necessary to facilitate the efficient functioning of the Scientific committees;
- organisation of meetings of the Scientific Committees and their working groups (including reimbursement of travel and accommodation, and daily allowances);
- expertise for the production of scientific opinions;
- expertise for the production of rapid risk assessment opinions for chemical, environmental and other threats other than communicable diseases;
- search and retrieval of scientific studies and editorial support;
- providing support for implementing transparency requirements as laid down by

Decision C(2015) 5383, mainly via maintaining a dedicated website;

- providing support to the Secretariat in preparing communication material about scientific opinions.

This action comprises:

- (1) scientific and technical assistance for the functioning of the Scientific Committees and risk communication;

Scientific and technical assistance for the functioning of the Scientific Committees and risk communication is necessary, as members of the Committees do not benefit from any support from their organisations. This action also covers the organisation of scientific hearings, working meetings and thematic workshops.

- (2) Rapid risk assessment in case of a chemical and environmental incident of cross border relevance.

4.9. Clinical trial EU portal and database

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 3.6. of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Subject matter of the contracts envisaged

IT

Under the new Clinical Trials Regulation (EU) No. 536/2014 the European Medicines Agency (EMA) is required to set up an EU portal and database for clinical trials. The finalisation of this IT tool is a legal requirement and will determine the date from which the Regulation will apply. The activities will consist of:

- (1) formulating IT recommendations to EMA; and
- (2) testing the IT system to confirm that the system is user friendly and functional from the Commission's perspective.

Type of contract and type of procurement

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Commission

4.10. Translations, info campaigns, publications etc. related to medical devices

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 3.6 of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Subject matter of the contracts envisaged

Translation, publications and communication services

The contractor is expected to provide communication and publication services to promote understanding and correct implementation of the requirements and risks relating to medical devices of the new Regulation 2017/745 on medical devices and Regulation 2017/746 on in vitro diagnostic medical devices.

The contractor will produce information material and organise other actions that help stakeholders, Member States and other parties concerned apply and understand the new legislation.

A good understanding by stakeholders and other parties concerned of the requirements of the new Regulations 2017/745 and 2017/746 is the basis for ensuring a high level of patient safety and making sure that devices fulfil the legal requirements.

Type of contract and type of procurement

Specific service contract under existing framework contract (contract managed by the European Commission’s Directorate-General for Communication (DG COMM))

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Chafea

4.11. Development of the future EUDAMED (the European medical devices database for the new Regulations on medical devices and in vitro diagnostic medical devices)

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 3.6. of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Subject matter of the contracts envisaged

IT

The database is required under Article 33 of Regulation 2017/745 on medical devices and Article 30 of the Regulation 2017/746 on in vitro diagnostic medical devices. The database should accommodate all information laid down in the new legislation.

The contractor is expected to carry out consultations to decide on the new content and technical developments for the new EUDAMED database. The database will notably have the following electronic systems: UDI (unique device identification), registration certificates, clinical investigation, vigilance and market surveillance.

Type of contract and type of procurement

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Commission

4.12. Maintenance and required developments of the existing Eudamed

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 3.6 of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Subject matter of the contracts envisaged

IT

The objective of this action is to ensure the maintenance and, if required, developments of the EUDAMED European medical devices database, which is an information system that the Commission and the competent authorities in the Member States can use to exchange legal information on the application of EU Directives on medical devices. The contractor is expected to carry out the maintenance and ensure the developments needed before the launch of the new EUDAMED under the new Regulation 2017/745 on medical devices and Regulation 2017/746 on in vitro diagnostic medical devices.

Type of contract and type of procurement

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Commission

4.13. Assessment of healthcare providers wishing to join established European Reference Networks (ERN) by Independent Assessment Bodies

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 4.1 of Annex I to the Programme Regulation: European Reference Networks

Budget line

17 03 01

Subject matter of the contracts envisaged

Technical assistance and assessment of healthcare providers

European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialised treatment and a concentration of knowledge and resources. The ERNs were set up in 2016 in line with the Directive on patients’ rights in cross-border healthcare.

In 2018 there will be a new opportunity for highly specialised healthcare providers to join the existing ERNs, in particular to complete their coverage and clinical capacity. Independent assessment bodies will evaluate membership applications as provided for in the Commission Implementing Decision of 10 March 2014⁸. The contractor will provide the necessary technical assistance and perform the assessment.

In particular, for each application, it will verify

(i) whether the contents of the membership application are complete, in line with the requirements in the Commission Implementing Decision;

(ii) whether the healthcare provider concerned fulfils the criteria and conditions in Annex II to Delegated Decision 2014/286/EU⁹ and detailed in the assessment manual developed by the European Commission (‘operational criteria’). The assessment should include the specific criteria further developed by the ERNs.

The deliverables (assessment reports) will provide the basis for the ERN Board of Member States to decide on the approval of the new members.

Type of contract and type of procurement

Specific service contracts under existing Framework Contract

Indicative number of contracts envisaged: 1

⁸ Commission Implementing Decision of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (2014/287/EU), OJ L 147, 17.5.2014, p.79.

⁹ Commission Delegated Decision setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (2014/286/EU, OJ L 147, 17.5.2014, p.71).

Indicative timeframe for launching the procurement procedure

Second half of 2018

Implementation

Chafea

4.14. ERN implementation, including coordination, capacity building, communication, exchange of information and best practices, and other networking support actions

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 4.1 of Annex I to the Programme Regulation: European Reference Networks

Budget line

17 03 01

Subject matter of the contracts envisaged

Administrative support/conferences/workshops/technical support/training

European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialised treatment and a concentration of knowledge and resources. The 24 ERNs were set up in 2016 in line with the Directive on patients’ rights in cross-border healthcare¹⁰.

This action comprises several parts addressed through multiannual contracts:

(1) Networking, communication and coordination between the networks

a) Organisation of ERN meetings, workshops and seminars complementing the activities and thematic areas developed and financed under the previous annual work plan (2017): these technical meetings will contribute to addressing specific organisational and technical challenges and specific issues linked to the effective work of the ERNs and in particular to improve the ERNs’ clinical performance and the quality of their activities. The workshops will also help to prepare the yearly work plan and evaluate their outcomes and performance during the previous year. The workshops and seminars will contribute to implementing better practices, making the networks more efficient and therefore improving the quality of care and the access to highly specialised healthcare for the targeted patients with rare or complex conditions. The contractor is expected to provide administrative support and the secretariat for the organisation of the meetings and the work of the ERN coordinators group.

b) Communication and coordination: support to the Commission in arranging practical coordination and communication tasks of the ERNs.

(2) Development of clinical guidelines and clinical decision support tools:

a) Further to the previous actions and based on the agreed methodology, the contractor should continue supporting the ERNs in the development of specific disease oriented clinical guidelines and decision-making tools (at least one per ERN). This will result

¹⁰ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare, OJ L 88, 4.4.2011, p.45.

in:

- enhanced effectiveness in terms of number of patients treated;
- the production of guidelines and clinical decision tools;
- higher quality in 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.

b) **Crosscutting technical and disease related issues of ERNs.** The action should support the 24 approved ERNs in the analysis and coordination of technical and disease related issues. In addition to the disease-specific work of each ERN, a system needs to be built, to address common issues and support best practices in aspects of care that cut across the different ERNs areas of expertise.

This work will be carried out in close cooperation with the ERN coordinators and experts and with the participation and involvement of patients' representatives of the ERNs. The contractor will analyse and systematise the most pressing needs related to the coordination of the healthcare of patients suffering from those diseases or conditions.

- (3) **Promote the exchange of information and knowledge transfer to patients** as beneficiaries of ERN cooperation (2018-2020): The contractor will adapt ERNs scientific and technical outcomes (including clinical guidelines, protocols and fact sheets) into information tailored for non-specialised audience (patients and families). This will include technical support and guidelines implementation as well as specific training activities for healthcare providers and patient representatives (including eLearning and training and workshops). The aim is provide patients with information on their diseases and to promote the benefits of ERN collaboration.
- (4) **Support for the reduction of health inequalities in the field of rare or complex diseases and conditions** through capacity building of affiliated partners (AP) and selected healthcare providers in Member States without a full member in any given ERN.

This activity should be organised in coordination with and under the technical supervision (clinical content) of the coordinators and managers of the approved ERNs. The contractor will organise training focusing on managerial skills and clinical competences in order to improve capacity to better engage with the ERNs and to improve technical competence in dealing with rare or low prevalence and complex diseases and conditions. The result will be that affiliated partners and selected healthcare providers will have better capacity for enhanced clinical competences and to implement of effective methods of communication and team building. This in turn will result in better outcomes for the ERNs' effectiveness and equal access to expert advice.

The action will include twinning or exchange programmes between Members of ERNs and healthcare providers in Member States without any full member or affiliated partners. This action will contribute to reduce inequalities of EU citizens in access to highly specialised healthcare for rare and complex diseases.

Type of contract and type of procurement

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 3

Indicative timeframe for launching the procurement procedure

Second half of 2018

Implementation

Commission

4.15. Communication on the Health Programme and dissemination

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

(related to all programme objectives)

Budget line

17 03 01

Subject matter of the contracts envisaged

Communication services

The objective of this action is to provide accurate and timely information on EU public health. It also aims to disseminate widely the results of the Health Programmes both at EU level and at national, regional and local levels and to demonstrate the added value of European cooperation. This action will help obtain broad coverage for EU health policy activities, and in so doing gain support for them.

Activities to be funded include:

- preparing and disseminating graphic material and publications (in electronic format and on paper);
- updating the DG SANTE websites;
- media activities (including media seminars and visits by journalists);
- audio-visual productions on health policy priorities;
- support to conferences and other stakeholder-related events (including promotional material);
- (paid) promotion on social media;
- other web 2.0 activities.

Part of the activities will be co-delegated to the Commission's Directorate-General for Informatics (DG DIGIT).

Type of contract and type of procurement

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 20

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Commission

4.16. Dissemination of the results of the Health Programme

LEGAL BASIS

Regulation (EU) No 282/2014 —Third Programme for the Union’s action in the field of health (2014-2020)

(related to all programme objectives)

Budget line

17 03 01

Subject matter of the contracts envisaged

Communication services

The objective of this action is to highlight and promote concrete results/outputs and good practices which will favour their scaling up and uptake across the EU.

The action has the aim to:

- increase the visibility and take up of the results obtained by actions funded under the Third Health Programme;
- maximise the Union’s budget effectiveness in supporting growth, jobs and stability in Europe and beyond.

The action will respond to the recommendations from the final evaluation of the Second Health Programme and the mid-term evaluation of the Third Health Programme. The activity will also increase and show the impact of the European investment in the field of public health.

Activities to be funded include:

- preparing and disseminating material and publications (in electronic format and on paper);
- updating of the Chafea website;
- audio-visual productions on health policy priorities;
- support to conferences and other stakeholder-related events;
- other web 2.0 activities.

Type of contract and type of procurement

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 12

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Chafea

4.17. ICT

LEGAL BASIS

Regulation (EU) No 282/2014 - Third Programme for the Union's action in the field of health (2014-2020)- related to all programme objectives

Budget line

17 03 01

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

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 10

Indicative timeframe for launching the procurement procedure

First half of 2018

Implementation

Commission/Chafea

5. OTHER ACTIONS OR EXPENDITURES

The overall budgetary allocation reserved for other actions in 2018 is EUR 7 399 000. The budget line for other actions is 17 03 01.

5.1. Direct agreement with the Joint Research Centre

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priorities 1.1, 1.4 and 4.2 of Annex I to the Programme Regulation:

- Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity
- Chronic diseases including cancer, age-related diseases and neurodegenerative diseases
- Rare diseases

Budget line

17 03 01

Amount

EUR 2 000 000

Description and objective of the implementing measure

(1) Rare diseases

The general objective will be to continue the development of the European Platform on Rare Diseases Registration (EU RD Platform). The platform will promote interoperability for data sharing between RD registries to overcome the enormous fragmentation of data contained in over 600 patient registries across Europe.

The actions include:

- provide and promote European-level standards for RD data collection and information exchange;
- ensure semantic interoperability for RD data via the Central Metadata Repository — a fundamental tool of the EU RD Platform;
- implement the European Directory of RD Registries;
- develop and maintain a web-hub that any stakeholder can use to find the required RD data collection;
- connecting the EU RD Platform with the ERNs: a close linkage is needed for the provision and implementation of interoperability standards and tools);
- create the conditions for linking RD patient data with other health- and health-

related data (biobanks, omics, etc.);

- use of the Platform as the central registry and sustainable data repository for two European surveillance networks: EUROCAT (European Surveillance of Congenital Anomalies) and SCPE (Surveillance of Cerebral Palsy in Europe).

(2) Cancer

The JRC will

(i) consolidate the processes and mechanisms in place 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;

(ii) Provide evidence-based recommendations for breast cancer guidelines and the piloting of the quality assurance (QA) scheme for breast cancer services.

Evidence-based recommendations for breast cancer guidelines and the piloting of the quality assurance (QA) scheme for breast cancer services includes:

- updates of recommendations issued on screening;
- new recommendations on screening and diagnosis;
- the launch of the Guidelines Platform (recommendations on treatment, rehabilitation, end-of-life care);
- manuals of the European Commission Initiative on Breast Cancer (ECIBC) QA scheme;
- piloting of the ECIBC QA scheme;
- release of a European breast cancer screening training template for radiologists and radiographers.

In parallel, work will be initiated on:

- evidence-based guidelines for colorectal cancer screening and care;
- development of a pan-European QA scheme (including release of requirements); and
- development of a web hub for the European Commission Initiative on Colorectal Cancer (ECICC) based on the ECIBC model. The hub will ensure that all stakeholders, patients and citizens have easy access to recommendations, requirements and lists of breast cancer services.

The central objective of the cancer-information activity is to ensure that a comprehensive and directly comparable set of up-to-date cancer indicators down to regional level is available

across the whole of the EU.

- agreed metadata standards, data-privacy issues, lengthy data-collection and cleaning processes;
- agreed statistical methods for data projections for estimating future trends.
- extension of the current minimal European cancer-data set to provide regional-level information for all countries;
- having in place a rolling process for submission of data;
- development of improved data-quality checking and visualisation tools.

(3) Health promotion and prevention of non-communicable diseases

Actions to be covered are:

- direct and technical support to the Member States' 'Steering Group on health promotion, prevention and management of non-communicable diseases';
- collecting and analysing evidence for health promotion, prevention and management of non-communicable diseases to inform and empower Member States so that they can implement successful policies and take effective action in this area;
- development of an online reference guide on prevention of non-communicable diseases.

(4) Initiatives in several action areas on nutrition, physical activity and alcohol related harm, focusing on the negative impact of health determinants in the economy and health inequalities

Actions to be covered are:

- scientific support to the EU strategy for Europe on nutrition, overweight and obesity-related health issues and to the action plan on childhood obesity: development of policy briefs related to its key areas;
- further development of joint European reference publications on evidence on nutrition, physical activity and alcohol related harm;
- direct scientific support to the High Level Group on Nutrition and Physical Activity and the EU Platform for Action on Diet, Physical Activity and Health;
- direct scientific support to the Committee on National Alcohol Policy and Action and the EU Alcohol and Health Forum on alcohol related harm;
- capacity building in Member States on nutrition, physical activity, support to reducing alcohol abuse, addressing alcohol-related harm, and behavioural sciences.

5.2. Direct agreement with the Joint Research Centre: support work on e-cigarettes, ingredients and security features

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 1.5 of Annex I to the Programme Regulation: Tobacco legislation

Budget line

17 03 01

Amount

EUR 100 000

Description and objective of the implementing measure

e-cigarettes

- measurement of emissions and safety assessment of e-cigarettes’ ingredients;
- analysis of ingredients in e-cigarettes.

Tobacco — ingredients in general

- Analysis of ingredients contained in tobacco products in particular in the light of the reporting obligations under the TPD. This work might include both methodological guidance (including validation of measurement methods) and actual measurements.

Tobacco – Assessment of products with characterising flavours

- independent advisory panel: follow-up/monitoring of the work of the panel;
- technical group of sensory and chemical assessors:
 - provide input to the preparation of a framework contract (by Chafea) covering the setting up of this group (e.g. support the evaluation and negotiation process);
 - follow-up/monitor the work of the technical group.

Security features:

- Analysis of security feature technologies that are/were newly introduced to the market and therefore could not yet be considered at the time when the implementing act was drafted.
- Assessment of the suitability of these individual security feature technologies in line with the requirements set out in the TPD and implementing legislation

5.3. Sub-delegation to Eurostat implemented through direct award of grants for morbidity statistics

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 1.6. of Annex I to the Programme Regulation: Health information and knowledge system to contribute to evidence-based decision-making

Article 190(1)(d) of the Commission Delegated Regulation (EU, Euratom) No 1268/2012 and Article 5 of Regulation (EC) 223/2009

Budget line

17 03 01

Amount

EUR 600 000

Description and objective of the implementing measure

This action will contribute to developing and increasing availability and comparability of data in different countries, thus providing information for evidence-based policy making.

The action on morbidity statistics will help statistical authorities in the European Statistics System (ESS) provide data on morbidity and develop the existing (or planned) sources and methods in view of producing best national estimates for the morbidity indicators included in the Eurostat prioritised shortlist.

The action aims at establishing a regular data collection on diagnosis-based morbidity at national as well as European level. A coordinated approach by Member States towards morbidity statistics is required as part of the ESS.

Essential eligibility, selection and award criteria

To be eligible, grant applications must be submitted by National Statistical Institutes or other national authorities in accordance with Article 5 of Regulation (EC) 223/2009. The National Statistical Institutes and the other national authorities included in the list referred to in paragraph 2 of this Article may receive grants without a call for proposals, in accordance with Article 190(1)(d) of the Commission Delegated Regulation (EU, Euratom) No 1268/2012.

The verification of the financial and operational capacity shall not apply to public bodies.

The award criteria are based on

- (a) the relevance of the application in relation to the objectives of the invitation and the priorities of the annual work programme; and
- (b) the quality of the proposal including an evaluation in terms of coherence, relevance and proportionality of the estimated budget in relation with the proposed action.

Indicative timetable

Reference	Date
Signature of the grant agreements without a call for proposals	Second half of 2018

Maximum possible rate of co-financing of the eligible costs

70%.

5.4. Cross sub-delegation to Eurostat implemented through direct award of grants for testing new modules/variables for future European Health Interview Survey (EHIS) waves

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 1.6. of Annex I to the Programme Regulation: Health information and knowledge system to contribute to evidence-based decision-making

Article 190(1)(d) of the Commission Delegated Regulation (EU, Euratom) No 1268/2012 and Article 5 of Regulation (EC) 223/2009

Budget line

17 03 01

Amount

EUR 800 000

Description and objective of the implementing measure

The action will deliver health data for a major part of the European Core Health Indicators (ECHI) and other European health indicators such as joint assessment framework health indicators. The action will contribute and be used in the ‘State of Health in the EU’ cycle. The deliverables will be used following Eurostat dissemination of results and the integration in the ECHI data tool.

The financial support will be given for national adaptations, testing and implementation of new variables/ modules in countries that want to integrate them on a voluntary basis in the future European Health Interview Survey (EHIS). Topics of interest could include:

- patient experience (taking into account developments carried out by the OECD);
- dietary habits including sugar intake;
- mental health-related issues;
- disability and variables related to the health of children.

Essential eligibility, selection and award criteria

To be eligible, grant applications must be submitted by National Statistical Institutes or other national authorities in accordance with Article 5 of Regulation (EC) 223/2009. The National Statistical Institutes and the other national authorities included in the list referred to in paragraph 2 of this Article may receive grants without a call for proposals, in accordance with Article 190(1)(d) of the Commission Delegated Regulation (EU, Euratom) No

1268/2012.

The verification of the financial and operational capacity shall not apply to public bodies.

The award criteria are based on

- (a) the relevance of the application in relation to the objectives of the invitation and the priorities of the annual work programme; and
- (b) the quality of the proposal including an evaluation in terms of coherence, relevance and proportionality of the estimated budget in relation with the proposed action.

Indicative timetable

Reference	Date
Signature of the grant agreements without a call for proposals	Second half of 2018

Maximum possible rate of co-financing of the eligible costs

70%

5.5. Expert Panel on effective ways of investing in health — special indemnities paid to experts

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 3.4. of Annex I to the Programme Regulation: Setting up a mechanism for pooling expertise at Union level

Budget line

17 03 01

Amount

EUR 300 000

Description and objective of the implementing measure

The objective of this action is to provide the Commission with independent and high quality advice on public health and health systems. The action covers special indemnities paid to experts for their work on the Expert Panel’s scientific opinions and reports. The Panel delivers high-quality scientific opinions on matters related to healthcare modernisation, responsiveness, and sustainability to the Commission (and to Member States). These provide the basis for policy-making by presenting the best evidence, examples and ideas from the current academic knowledge base. The Panel ensures:

- Improved cooperation and information exchange among the actors involved in health services. This can lead to increased efficiency of health and care systems, and the putting in place of conditions that can support their long-term sustainability of such systems.
- Independence from the European Commission. The Panel’s 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.
- Transparency. The requests for opinions, the opinions and minutes of the Panel’s meetings are made publicly available on its website. Stakeholders are invited to participate in public consultations organised before the final opinions are adopted.

The Panel’s advice is provided by the Expert Panel on effective ways of investing in health in accordance with Commission Decision 2012/C 198/06.

5.6. Organisation and management of the meetings of the Medical Device Coordination Group (MDCG) and its subgroups

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 3.6. of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Amount

EUR 500 000

Description and objective of the implementing measure

This action comprises the organisation and reimbursement of expenses for the meetings of the Medical Device Coordination Group (MDCG) and its subgroups. The group's tasks are laid down in the Regulations on medical devices and in-vitro diagnostic medical devices.

This action is expected to result in the establishment of mechanisms to ensure harmonised implementation of the rules by all Member States with a sustainable, efficient and credible management at EU level with access to internal and external technical, scientific and clinical expertise, leading to improved coordination and resource-sharing between Member States.

5.7. Technical, scientific and related logistic support — on medical devices (JRC)

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 3.6. of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Amount

EUR 690 000

Description and objective of the implementing measure

The JRC will support DG GROW with regard to technical, scientific and related logistic aspects concerning implementation and management of the novel legislative framework for medical devices (Regulation 2017/745) and IVDs (Regulation 2017/746).

5.8. Medical devices: reimbursement of experts' expenses for joint assessments carried out by several Member State authorities and the Commission services assessing the application for designation of notified bodies or extension and renewal of designations

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 3.6. of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Amount

EUR 224 000

Description and objective of the implementing measure

The action will cover the expenses for national experts who participate in the joint assessments of notified bodies together with Commission departments under Article 3 of Commission Implementing Regulation (EU) No. 920/2013 and Articles 38-42 and 123(3)(a) of Regulation 2017/745 on medical devices and Articles 34-38 and 113(3)(b) of Regulation 2017/746 on in vitro diagnostic medical devices. The expected result of this action is the smooth functioning of the joint assessments with a sufficient number of experts from Member States participating, leading to continued improvement in the operation of the notified bodies under the legislation on medical devices.

5.9. Joint Audit Programme (JAP) on Good Manufacturing Practice (GMP) inspections for Mutual Recognition Agreement on GMP inspection between the EU and the US and other strategic partners

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 3.6. of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Amount

EUR 110 000

Description and objective of the implementing measure

The Joint Audit Programme (JAP) organised by the Heads of Medicines Agencies is a programme that monitors the equivalence of inspectorates of good manufacturing practices in Member States. The programme consists of audits by Member States authorities (the auditors) of a given Member State’s GMP system (the auditee).

The JAP is however under-resourced as travel and accommodation are, in the absence of Commission funding, paid for out of Member State authorities’ budgets. The JAP audits are carried out on the basis of objective criteria based on specific requirements vested in EU legislation, guidelines and procedures. The proposed action will support the organisation of a high number of audits by financing the mission costs of JAP auditors.

The Mutual Recognition Agreement (MRA) of Good Manufacturing Practices (GMP) inspections between the EU and the US was successfully concluded on 1 March 2017 (Decision No 1/2017 of 1 March 2017 (OJ L58/36 of 4.3.2017)). The EU has concluded a number of other MRAs and similar types of agreements with other strategic partners. GMP inspections, which have to be performed by Member State competent authorities, are resource intensive and an essential element of the implementation of EU legislation on medicinal products by ensuring oversight of the quality of medicinal products.

From 2018 to 2020, it is planned that JAP audits will be necessary to enable US authorities to complete the evaluation of Member State GMP inspectorates for human and veterinary medicines and to maintain the recognition of Member State GMP inspectorates.

Similarly, the MRA with Israel (ACAA) provides for Israel’s participation in the JAP in order to reconfirm the of equivalence of Israeli inspection systems.

5.10. International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and VICH Outreach Forum (VOF)

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 3.6. of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Amount

EUR 25 000

Description and objective of the implementing measure

The Commission funds travel and accommodation costs for the experts from the EU national regulatory agencies who participate in the activities of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and the VICH Outreach Forum.

The VICH is the leading international body and framework for harmonisation and regulatory cooperation in the field of veterinary medicinal products. VICH is recognised as the main body that has contributed to and will contribute to the EU-US harmonisation of applications for authorisation of veterinary pharmaceuticals.

VICH Outreach Forum (VOF) is a VICH initiative with the main objective of providing a basis for wider international harmonisation of technical requirements, improving information exchange and raising awareness of VICH and VICH guidelines with non-VICH countries/regions in conjunction with the World Organisation for Animal Health.

5.11. Active pharmaceutical ingredients: system inspections in non-EU countries

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 3.6. of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Amount

EUR 30 000

Description and objective of the implementing measure

The objective of this action is to ensure thorough system inspections in non-EU 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, is equivalent to that of the EU.

This action covers the reimbursement of Member State experts supporting the Commission in carrying out system inspections in non-EU countries exporting active substances for medicinal products for human use into the EU.

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

The system inspections will facilitate the importation into the EU of active ingredients from non-EU countries having a regulatory framework for active substances equivalent to that of the EU.

5.12. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and International Pharmaceutical Regulators Forum (IRPF)

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 3.6. of Annex I to the Programme Regulation: Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare

Budget line

17 03 01

Amount

EUR 600 000

Description and objective of the implementing measure

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and International Pharmaceutical Regulators Forum (IRPF) are the leading international organisations and global platforms for harmonisation and regulatory cooperation between all regions in the field of medicinal products.

ICH brings together the drug regulatory authorities of EU, Japan and the United States along with experts from the pharmaceutical industry in the three regions, to develop harmonised guidelines for product registration. The Commission is a founding member of the association, with the European Medicines Agency (EMA) providing technical and scientific support. ICH organises two meetings per year with over 350 experts.

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

The International Pharmaceutical Regulators Forum (IPRF) is held in conjunction with ICH. The funds will contribute to the IPRF secretariat that provides the administrative and technical support to IPRF activities.

The Commission funds travel and accommodation costs for the experts from the EU national regulatory agencies who participate in the activities of the ICH and IPRF.

5.13. Scientific Committees and provision of targeted risk assessment in case of a chemical and environmental incident of cross border relevance

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic priorities 2.4 and 3.7 of Annex I to the Programme Regulation

- Health information and knowledge system to contribute to evidence-based decision-making
- Health information and knowledge system including support to the Scientific Committees

Budget line

17 03 01

Amount

EUR 420 000

Description and objective of the implementing measure

When preparing its policy and proposals relating to consumer safety, public health and environment, the Commission relies on independent Scientific Committees to provide sound scientific advice and raise awareness about new and emerging problems.

The work of the Scientific Committees also includes the rapid risk assessment for health threats other than communicable diseases (i.e. chemical and environmental threats), as stated in the Council and European Parliament Decision 1082/2013 on ‘serious cross border threats to health’ addressing the need to have ‘ad-hoc risk assessments and monitoring’ prepared by independent experts in case of need, and in particular in case of acute events of cross-border relevance.

The advice is provided by the Scientific Committees as laid down by Commission Decision C(2015) 5373 of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment.

The activity of the Scientific Committees impacts mainly on the Commission’s regulatory work in the areas of consumer safety, public health and environment. However, opinions of the Committees are taken as a reference by EU and Member States’ risk assessment bodies, international organisations, and non-EU countries’ national risk assessment bodies for their policies. Moreover, the opinions impact on the scientific community and on risk communication with citizens.

The expected results of this action are:

- the administrative support necessary to facilitate the efficient functioning of the Scientific committees;
- organisation of meetings of the Scientific Committees and their working groups (including reimbursement of travel and accommodation, and daily allowances);
- expertise for the production of scientific opinions;

- expertise for the production of rapid risk assessment opinions for chemical, environmental and other threats other than communicable diseases;
- search and retrieval of scientific studies and editorial support;
- providing support for implementing transparency requirements as laid down by Decision C(2015) 5383, mainly via maintaining a dedicated website;
- providing support to the Secretariat in preparing communication material about scientific opinions.

This action comprises:

- (1) travel and accommodation expenses and daily allowances and special indemnities are paid to experts for their work on scientific opinions as provided for in Decision C(2015) 5373
- (2) Rapid risk assessment in case of a chemical and environmental incident of cross border relevance.

5.14. Sub-delegation to Eurostat implemented through direct award of grants for non-monetary health care statistics

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

Thematic Priority 3.7. of Annex I to the Programme Regulation: Health information and knowledge system including support to the Scientific Committees

Article 190(1)(d) of the Commission Delegated Regulation (EU, Euratom) No 1268/2012 and Article 5 of Regulation (EC) 223/2009

Budget line

17 03 01

Amount

EUR 300 000

Description and objective of the implementing measure

The action on health care non-monetary statistics will help the ESS (European Statistics System) statistical authorities in their effort to comply with the data request on health care non-monetary data and will provide support for the study of countries’ readiness to provide data under a regulation. The action will not support current routine data collections that have to be ensured by countries. The action will only support efforts with EU added value that will enable countries to report a complete data set of high quality. This will include improving the data quality already provided.

The expected result of this action is to provide reporting of health care data, that was previously missing, incomplete or not to the expected standard of quality, including a complete reporting of metadata. It will contribute to the availability and comparability of data across the EU and provide a basis for policy-making that is grounded on factual evidence. The data will be validated and disseminated by Eurostat.

Essential eligibility, selection and award criteria

To be eligible, grant applications must be submitted by National Statistical Institutes or other national authorities in accordance with Article 5 of Regulation (EC) 223/2009. The National Statistical Institutes and the other national authorities included in the list referred to in paragraph 2 of this Article may receive grants without a call for proposals, in accordance with Article 190(1)(d) of the Commission Delegated Regulation (EU, Euratom) No 1268/2012.

The verification of the financial and operational capacity shall not apply to public bodies.

The award criteria are based on

- (a) the relevance of the application in relation to the objectives of the invitation and the priorities of the annual work programme; and
- (b) the quality of the proposal including an evaluation in terms of coherence, relevance and proportionality of the estimated budget in relation with the proposed action.

Indicative timetable

Reference	Date
Signature of the grant agreements without a call for proposals	Second half of 2018

Maximum possible rate of co-financing of the eligible costs

70%

5.15. Annual Commission membership fee to the European Observatory on Health Systems and Policies

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)

Thematic Priority 3.7. of Annex I to the Programme Regulation: Health information and knowledge system including support to the Scientific Committees

Budget line

17 03 01

Amount

EUR 500 000

Description and objective of the implementing measure

This action implements Commission Decision C(2014) 4529 as regards the Commission's participation in the partnership of the European Observatory on Health Systems and Policies.

Membership in the Observatory provides technical expertise, independent analysis and advice capacity, enabling the Commission to quickly respond to emerging evidence needs of policy-makers within and outside of the Commission as well as a systematic monitoring and analysis tool for following health system reforms in EU Member States.

The three main working areas of the Observatory are:

- (1) Country monitoring and information: 'Health Systems in Transition' was the initial product of the Observatory, reviewing the country health systems reforms;
- (2) Comparative health systems studies;
- (3) Dissemination and knowledge brokering.

5.16. Expert evaluators

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union’s action in the field of health (2014-2020)

(related to all programme objectives)

Budget line

17 03 01

Amount

EUR 200 000

Description and objective of the implementing measure

This action and budget supports the efficient and transparent selection of proposals to be funded. The proposals submitted under different calls for proposals are evaluated by external experts (peer-review). The experts receive a daily remuneration of EUR 450 per day of work for their input into the evaluation process.

This action is important for supporting efficient and transparent selection of proposals for funding. Evaluators will receive a daily fee, travel costs and subsistence allowances (if applicable) according to the standard European Commission rules.