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ANNEX

Third Programme for the Union's action in the field of health - Work Programme for 2019

Contents

1. INTRODUCTION

This work programme sets out the priorities and actions to be undertaken for the year 2019, 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, inbcluding 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.

On the basis of the objectives given in the Programme Regulation this work programme contains the actions to be financed and the budget breakdown for year 2019 as follows:

- for grants (implemented under direct management): EUR 31 750 000
  - Projects: EUR 5 800 000
  - Joint actions: EUR 15 000 000
  - Operating grants: EUR 5 000 000
  - Direct grants: EUR 5 750 000
  - Other direct grants: EUR 200 000
- for prizes (implemented under direct management): EUR 300 000
- for procurement (implemented under direct management): EUR 24 000 560
- for other actions: EUR 7 893 000

The main lines of the annual work programme 2019 are built around the following **priority areas**, while addressing the dimension of **health inequalities** as a cross-cutting issue:

(1) Country specific and cross country knowledge;

(2) Cross border health threats, preparedness and response, including antimicrobial resistance and vaccination;

(3) Structural support to health systems and link to digital single market;

(4) Promotion of health and prevention of non-communicable diseases.

The global budgetary envelope for 2019 amounts to EUR **63 943 560.**

The expected results of the work programme include:

- Support rare diseases registries and develop a comprehensive approach for rare diseases registries
- Contribute to implementing the European One-Health action plan against AMR by supporting stakeholder organisations to take forward and implement the EU guidelines on prudent use of antimicrobials in human health
- Increasing the offer of healthier options of processed food and/or reducing salt, sugar and satured fat from the processed food available in EU supermarkets
- Strengthen health preparedness an response to terror attacks
- Implementing best practices in the field of digitally enabled integrated person-centred care
- Provide support to non-governmental bodies that pursue one or more of the specific objectives of the Health Programme
- Provide reliable international expert assessment of the health situation and health systems in Member States through the State of Health in the EU cycle
- Support the development of better expertise and performance assessments of health systems through the patient-reported indicators survey
- Support Member States in increasing refugee and migrant's children level of health, nutrition and development
- Raise visibility of best practices and interventions supporting a healthy diet and a physically active lifestyle in children and young people through the health award
- Support Member States in reducing alcohol related harm
- Support Member States in the field of vaccination
- Support the activities of European Reference Networks as well as their assessment, monitoring, evaluation and quality improvement

Major synergies can also be achieved with the European Solidarity Corps. The Commission encourages non-governmental bodies to work with the European Solidarity Corps, where appropriate.

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

2. PROJECTS

Under the global budgetary envelope reserved for grants, EUR 5 800 000 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

Target Group

Legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments established in EU Member States and in countries participating in the Health Programme

An updated list of countries is available on the Commission/Chafea website.

2.1. Rare disease registries for the European Reference Networks

Target Group:

Approved ERNs not yet receiving grants for registries

LEGAL BASIS

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

Thematic Priorities 4.1. and 4.2.of Annex I to the Programme Regulation

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

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

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

Patient registries will contribute to the ERNs evaluation process foreseen in the ERN implementing decision and to the continuous monitoring and quality improvement system of the networks.

Patient registries will cover the diseases under the scope of the ERNs and may include inter alia the information of patients treated by the members of the Networks while fully respecting the data protection rules.

To support this process and in particular the interoperability of data in rare disease registries the Commission decided to set up a European Platform on Rare Disease Registration and to develop specific standards for the interoperability of such rare disease registries ("JRC standards" developed by the Commission Joint Research Centre).

The 24 European Reference Networks (ERNs) approved by the Member States within the ERN Board of Member States in December 2016 and which started their work in March 2017 are since 2018 developing their research capabilities. Moreover, several Horizon 2020 calls for proposals provide support to establish ERN clinical research infrastructures and establish

evidence with regard to efficient and validated organisation models[1].

Patient registries belong to this development, enabling to build patients cohorts at European level to follow up the natural course of diseases with sufficient data on patients. Five ERNs already benefit from Health Programme grants, awarded in 2018, to develop a comprehensive approach for rare disease registries covering their whole ERN, following JRC standards and tools. The 19 other approved ERNs are preparing their strategy on research and registries and need to be supported, similarly to the first five ERNs.

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

The activities concern the building and development of rare disease patient registries (including new "registries of registries"[2]) for ERNs, and further development and quality-control of existing registries. In doing so, the following principles should be followed

(i) strengthen coordination and cooperation and develop synergies among the Networks and their registries;
(ii) Ensure seamless cooperation with the European Platform for Rare Diseases
(iii) build on existing tools avoiding duplication of similar actions, activities and non-interoperable solutions.

Registries should be built with the support of and according to the standards set up by the European Platform for Rare Disease Registration, implementing the infrastructure provided by the European Platform for Rare Disease Registration and provide all necessary data to the Platform (taking the relevant data protection rules into account).

Implementation

Chafea

Indicative timetable and indicative amount of the call for proposals

Reference	**Date**	**Amount**
Call for proposals	Q2 2019	EUR 3 800 000

Maximum possible rate of co-financing of the eligible costs

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

[1] http://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-health_en.pdf

[2] A "registry of registries" is a portal or database encompassing registries' specific information intended to promote interoperability and collaboration, to reduce redundancy and to improve transparency among patient registry holders.

2.2. Stakeholder actions to implement the EU guidelines on prudent use of antimicrobials in human health

Target Group
Professional organisations and other stakeholders, such as healthcare systems and institutions

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020)
Thematic priority 4.4.of Annex I to the Programme Regulation

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

The European one-health action plan against antimicrobial resistance COM(2017)339 sets out the intention of the Commission to 'engage with and support collaboration among key stakeholders in the human health, animal health, food, water and environmental sectors to encourage the responsible use of antimicrobials in the healthcare sector and along the food chain, as well as the appropriate handling of waste material'.

EU guidelines on the prudent use of antimicrobials in human health were published by the Commission in June 2017. These guidelines aim to support stakeholders and Member States in reducing unnecessary antibiotic use and combating AMR in the health sector.

This call for projects to professional organisations and other stakeholders, such as healthcare systems and institutions, contributes to implementing the European one-health action plan against antimicrobial resistance by supporting stakeholder organisations to take forward and implement the EU guidelines on prudent use of antimicrobials in human health on the ground through interventions of their respective organisations.

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

The activities should enable stakeholder organisations to take further action on AMR within the framework of the EU guidelines on prudent use of antimicrobials in human health. The action will engage with professional groups and settings which require specific attention and develop and implement packages of interventions to implement the guidelines adapted to the needs of the job roles and settings (e.g. hospital, primary care long term care) involved. Deliverables are expected to include adaptations of the guidelines to the local situation, training packages, clinical audit tools, evaluation tools, methods for assessing outcome indicators, tools and methods for providing positive and negative feedback to practitioners and incentive schemes.

Implementation

Chafea

Indicative timetable and indicative amount of the call for proposals

Reference	**Date**	**Amount**
Call for proposals	Q1 - Q4 2019	EUR 2 000 000

Maximum possible rate of co-financing of the eligible costs

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

3. GRANTS FOR ACTIONS CO-FINANCED WITH MEMBER STATE AUTHORITIES (JOINT ACTIONS)

Under the global budgetary envelope reserved for grants, EUR 15 000 000 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.

Target Group: Member State and countries participating in the Health Programme competent authorities, where applicable, in cooperation with other entities required for implementing the action.

3.1. Joint Action on implementation of validated best practices

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

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

Increasing the offer of healthier options of processed food and/or reducing salt, sugar and saturated fat from the processed food available in EU supermarkets (this can be precisely measured by introducing the reformulation monitoring system).

Description of the activities to be funded by the grant(s) awarded without a call for proposals on the basis of article 195(d) of Regulation (EU, Euratom) 2018/1046

The scope of the proposed joint action is to implement the transfer of best practices agreed for inter-country transfer by the Steering Group on Promotion and Prevention (SGPP).

Following the Member States' decision at the SGPP, the best practices selected for implementation in the area of prevention will include support for a monitoring system for reformulation initiatives, based on the successful French/Joint Action on Nutrition and Physical Activity model (supporting the EU Framework for national reformulation initiatives).

Additional best practices selected by the SGPP for implementation, namely on the framing of marketing aimed at children of foods and beverages high in fats, sugars or salt, on public procurement of food for health, will be added depending on availability of budget once the number of Member States implementing each best practice is clarified.

Implementation

Chafea

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

Reference	**Date**	**Amount**
Signature of the grant	Q2	EUR 6 000 000

agreement without a call for proposals		

Maximum possible rate of co-financing of the eligible costs

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

3.2. Joint Action to strengthen health preparedness and response to biological and chemical terror attacks

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

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

The Joint Action to strengthen health preparedness and response to terror attacks aims to improve:

- preparedness for biological and chemical attacks,
- threat detection and risk assessment for health related terrorism acts;
- bridging between the public health, security and civil protection sector partners;
- health systems response including diagnosis and treatment of patients exposed to biological and chemical agents;
- availability and rapid response including the deployment of medical countermeasures across borders;
- implementing non-pharmaceutical control measures, to avoid or mitigate the disruption to societal functions, the free movement of people and goods and economic losses;
- risk and crisis communication, including communication lines between security and other critical sectors;
- rapid information exchange, consultation and coordination within and between Member States.

Description of the activities to be funded by the grant(s) awarded without a call for proposals on the basis of article 195 (d) of Regulation (EU, Euratom) 2018/1046

The Joint Action will focus on biological and chemical agents, considering the EU list of high risk biological agents, including those which are known to have been weaponised as well as risk/threat assessments indicating agents that terrorists are interested in.

An effective response requires preparedness in terms of coordination between the health and

other sectors; clear command and control mechanisms regularly tested; and the capacity to rapidly mobilise health workers, health-care providers, emergency responders, law enforcement and security services.

Health systems have to be prepared for early and reliable detection, contact tracing, testing, diagnosis, triaging, treatment, and prophylaxis for large numbers of people after a biological or chemical attack, including mass casualty management, and for implementing necessary public health control measures.

The Joint Action is expected to closely collaborate with the 2018 Joint Action (SHARP) Strengthened International HeAlth Regulations and Preparedness in the EU.

Implementation

Chafea

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

Reference	**Date**	**Amount**
Signature of the grant agreement without a call for proposals	Q1	EUR 5 000 000

Maximum possible rate of co-financing of the eligible costs

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

3.3. Joint Action on implementation of digitally enabled integrated person-centred care

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

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

In the recently adopted Communication on "*enabling the digital transformation of health and care in the Digital Single Market*", the Commission commits to measures for improving capacity building and technical assistance to Member States and regional authorities, to address the demand side of health reforms and digital transformation of healthcare. This is in recognition of the fact that the transformation of health systems is complex, one of the pre-conditions to achieve it is having the required knowledge and capacity on how to design, and successfully implement digitally enabled person-centred care solutions.

The Steering Group on Health Promotion and Prevention and Management of Non-Communicable Diseases (SGPP) will be involved in the selection of best practices in digitally enabled integrated person-centred care to be transferred between Member States, with financial support from the Health Programme in the form of a Joint Action.

Description of the activities to be funded by the grant(s) awarded without a call for proposals on the basis of article 195(d) of Regulation (EU, Euratom) 2018/1046

A number of best practices in digitally-enabled integrated person-centred care will be presented to SGPP members and countries participating in the Third Health Programme, offering them the opportunity to identify the most interesting and promising practices to transfer to their jurisdictions.

The Joint Action will support the best practice transfer with practical means, for example, activities to prepare the local environment for implementation and purposely designed "twinning actions" such as dedicated seminars and workshops, study visits, short-term secondment visits, face to face meetings, mentoring from experts in the domain, availability of tools and knowledge resources etc. In doing this, the Joint Action will utilise relevant input and products from earlier work in the Health Programme, EU-level initiatives, such as the European Reference Networks, and the EU Framework Programmes for Research and Innovation.

The activities will focus on reinforcing the capacity of care authorities to address successfully

important aspects such as: change management and re-organisation of the care model, embedding digital technologies and tools in care services, re-organisation of patient pathways, health workforce roles and skills with digital technologies and data, building the capacity of individuals and communities to participate in the care process, citizen empowerment, use of patient reported data, new payment methods, and performance assessment of new care models.

Implementation

Chafea

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

Reference	**Date**	**Amount**
Signature of the grant agreement without a call for proposals	Q3 2019	EUR 4 000 000

Maximum possible rate of co-financing of the eligible costs

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

4. FINANCIAL CONTRIBUTION TO THE FUNCTIONING OF NON-GOVERNMENTAL BODIES (OPERATING GRANTS)

Target Group

Non-governmental bodies holding a Framework Partnership Agreement for the period 2018-2021.

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

Under the global budgetary envelope 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.

No call for proposals will be organised in 2019 as a result of the conclusion of FPAs.

FPA recipients being eligible for a specific grant agreement (SGA) ('operating grant') will be invited to submit an application for an SGA to cover their operating costs for 2020. This will include the annual work programme and the budget.

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.

Implementation

Chafea

Indicative timetable and indicative amount of the grant(s) awarded on a competitive basis to the FPA holders

Reference	**Date**	**Amount**
Invitation to FPA holders to apply; SGA awarded on a competitive basis	Q1 2019	EUR 5 000 000

Maximum possible rate of co-financing of the eligible costs

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

5. DIRECT AWARD OF GRANTS (INTERNATIONAL ORGANISATIONS)

The global budgetary envelope reserved for actions implemented via direct award of grants to international organisations is EUR 5 750 000. Other direct award of grants amount to EUR 200 000.

The budget line is 17 03 01.

Under article 195(f) of Regulation (EU, Euratom) 2018/1046, for activities with specific characteristics that require a particular type or body on account of its technical competence, its degree of specialisation or its administrative powers, on condition that the activities concerned do not fall within the scope of a call for proposals[3]. 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 programme. 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, 4 and 7.

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 award of 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 award of grants, as set out in the respective sections of this work programme:

— 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)

[3] Financial Regulation, Art. 195 (f)

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.

— UNICEF

UNICEF is the United Nations agency in charge of promoting the rights and wellbeing of children. UNICEF is the only organisation that has the mandate and capacity to act in the area of children in an integral approach and that is already doing it in the context. It focuses on reaching the most vulnerable and excluded children, to the benefit of all children, UNICEF has been in the forefront of the refugee and migrant response when it comes to the provision of vaccination, specific health and nutritional needs and provision of psychosocial support and mental health services to children and their caregivers, as well as building the capacities of frontline workers, social services and national authorities in establishing more predictable, sustainable and quality services for children on the move, stranded or seeking asylum.

5.1. State of Health in the EU cycle - direct grant for the European Observatory on Health Systems and Policies to the World Health Organisation (host of 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

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

In 2020-21 the State of Health in the EU cycle will be in its third iteration. The cycle is a recurring two-year series of analytical products on country-specific and cross-country knowledge in the field of health initially launched in 2016. With it, the Commission brings together internationally recognised expertise and provides Member States with the evidence relevant to their specific context, without judging on their comparative performance.

The cycle has a direct bearing on best practice exchange between Member States and supports knowledge sharing and mutual learning. Furthermore, it provides a reliable international expert assessment of the health situation and health systems in Member States providing benchmarks to facilitate health sector reforms and allow informed decision-making at national level.

Description of the activities to be funded by the grant(s) awarded without a call for proposals on the basis of article 195(f) of Regulation (EU, Euratom) 2018/1046

As far as the European Observatory on Health Systems and Policies is concerned, the State of Health in the EU cycle consists of

(1) 30 individual country health profiles covering the EU-28, as well as Iceland and Norway; and

(2) ex-post policy exchanges organised with these EU/EFTA Member States on a voluntary basis.

The two actions will be carried out jointly between the European Observatory on Health Systems and Policies and the OECD in order to use the high-quality expertise of both organisations for each individual output, for which both organisations will also assume joint responsibility.

This grant will cover the Observatory's activities under the third State of Health in the EU cycle (2020-21).

Implementation

Chafea

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

Reference	**Date**	**Amount**
Signature of the grant agreement without a call for proposals	Q4 2019	EUR 950 000

Maximum possible rate of co-financing of the eligible costs

60 %

5.2. State of Health in the EU cycle – 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 priority 3.7. of Annex I to the Programme Regulation

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

In 2020-21 the State of Health in the EU cycle will be in its 3rd iteration. The cycle is a recurring two-year series of analytical products on country-specific and cross-country knowledge in the field of health initially launched in 2016. With it, the Commission brings together internationally recognised expertise and provides Member States with the evidence relevant to their specific context, without judging on their comparative performance.

The cycle has a direct bearing on best practice exchange between Member States and supports knowledge sharing and mutual learning. Furthermore, it provides a reliable international expert assessment of the health situation and health systems in Member States providing benchmarks to facilitate health sector reforms and allow informed decision-making at national level.

Description of the activities to be funded by the grant(s) awarded without a call for proposals on the basis of article 195(f) of Regulation (EU, Euratom) 2018/1046

As far as the OECD is concerned, the State of Health in the EU cycle consists of,

(1) the 'Health at a Glance: Europe' 2020 report,

(2) 30 individual country health profiles covering the EU-28, as well as Iceland and Norway; and

(3) ex-post policy exchanges organised with these EU/EFTA Member States on a voluntary basis.

The actions 2 and 3 will be carried out jointly between the European Observatory on Health Systems and Policies and the OECD in order to use the high-quality expertise of both organisations for each individual output, for which both organisations will also assume joint responsibility.

This grant will cover the OECD's activities under the third State of Health in the EU cycle (2020-21).

Implementation

Chafea

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

Reference	**Date**	**Amount**
Signature of the grant agreement without a call for proposals	Q4 2019	EUR 1 500 000

Maximum possible rate of co-financing of the eligible costs

60 %

5.3. Support to OECD to develop and implement patient-reported measures

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

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

The action will help to develop better expertise on performance assessments of health systems. It will also help to draw on lessons-learned from recent experience and from EU-funded research projects. And finally it is explicitly meant to build up country-specific and cross-country knowledge which can inform policies at national and European level. The final benefit of the action (patient reported health data) 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 indicators will also allow 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(s) awarded without a call for proposals on article 195(f) of Regulation (EU, Euratom) 2018/1046

The OECD's work on the 'Patient-Reported Indicators Survey' is conducted in two work streams: Work stream 1: building on existing national instruments, OECD seeks cross-country agreement to implement comparable approaches to measurement at single diseases level (i.e. breast cancer, knee and hip replacement, mental health). Work stream 2: development of international patient survey focusing on primary care settings enabling system-level assessments in complex areas such as care continuity, functionality for patients and multiple chronic conditions. The action supports the OECD in implementing the international survey in all participating countries. It will build on and follow-up work undertaken by OECD in this field, particularly under the Health Programmes Annual Work Plans 2015, 2017 and 2018. Based on the results of the field trial carried out in all participating countries, survey instruments will be revised and translated in the languages of the countries. Where necessary, adjustments will be made in field work materials, such as code books and manuals. The work during this phase will also focus on field work preparation, data collection, processing and weighting, assessment of psychometric properties of scales, preparation of an international dataset and analysis of data. The action will also contain communication and engagement activities with the public, patients and health care providers. The action will result in the reporting of the first international results of the PaRIS-survey that will be

published in the flagship publication Health at a Glance and / or in stand-alone publications.

Implementation

Chafea

Indicative timetable and indicative amount of grant(s) awarded without a call for proposals

Reference	**Date**	**Amount**
Signature of the grant agreement without a call for proposals	Q4 2019	EUR 800 000

Maximum possible rate of co-financing of the eligible costs

60 %

5.4. Direct grant to UNICEF. Support to children migrant populations in front line and transit countries

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., 1.4. , 2.2. of Annex I to the Programme Regulation

BUDGET LINE

17 03 01

Priorities of the year, objectives pursued and expected results

Currently, it is estimated that at least 27,000 refugee and migrant children are present, as newly arrived, in South-Eastern Europe. This population group in the first line and transit countries is –according to EU policies on migration and in agreement with DG HOME, as service in the lead of this policy- as the focus population for intervention on health, according to current situation. Effective strategies are required to identify and promote the uptake of best practices for health improvement, especially related to nutrition and psychological wellbeing and to check and update the vaccination schedule to counteract possible outbreaks of vaccine preventable diseases.

UNICEF has been identified as the international organisation, already present in the field, able to perform activities in support of Member States, aimed at increasing refugee and migrant children's level of health, nutrition, and development.

Description of the activities to be funded by the grant(s) awarded without a call for proposals on article 195(f) of Regulation (EU, Euratom) 2018/1046

The countries of action will be, as a priority: Greece, Italy, Cyprus, Malta and Spain, as entry points, and Bulgaria, Serbia and Bosnia-Herzegovina as transit countries,

The areas of work will be:

- immunization, prevention/promotion, health assessment (including nutrition) on arrival and departure;

- promotion of mental health through psychosocial support and working on PTSD (post traumatic stress syndrome) and violence prevention.

- to increase knowledge of the migrant children (and mother) themselves on health issues.

The actions will be closely coordinated with national authorities and with the Joint Action (JAHEE) Health Equity Europe.

Implementation

Chafea

Indicative timetable and indicative amount of grant(s) awarded without a call for proposals

Reference	**Date**	**Amount**
Signature of the grant agreement without a call for proposals	Q1 2019	EUR 2 500 000

Maximum possible rate of co-financing of the eligible costs

60 %

6. OTHER DIRECT AWARD OF GRANTS

6.1. Presidency conference grants- de jure monopoly

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. and 4.5 of Annex I to the Programme Regulation)

BUDGET LINE

17 03 01

Under Article 195(c) of Regulation (EU, Euratom) 2018/1046 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. The objective of the presidency conferences is to increase visibility and to facilitate high level policy dialogue. 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 Economy of Wellbeing under the Finnish Presidency in the second half of 2019 and a conference on Organs transplantation under the Croatian Presidency in the first half of 2020.

Implementation

Chafea

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

Reference	**Date**	**Amount**
Signature of the grant agreement without a call for proposals	Q1-Q4 2019	EUR 200 000

Maximum possible rate of co-financing of the eligible costs

50%

7. PRIZES

7.1. Health Award

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

Stakeholder involvement is of increasing importance for health policy making and for shaping health systems, because not only the European Union is founded on democracy and requires societal participation, but also to ensure that health legislation better serves the people it affects. Stakeholders play an important role in identifying needs for health policy action, informing the Commission in developing its policies and also in implementing policy actions. Despite action at European level to reverse the rising trend in overweight and obesity, the proportion of the population who are overweight or obese remains worryingly high for adults but specially for children and young people. The implications of overweight and obesity in the European Union are stark: the prevalence of obesity has more than tripled in many European countries since the 1980s and with this rise comes a concomitant increase in rates of associated non-communicable disease. Poor diet and physical inactivity are important determinants of overweight and obesity in children and young people. The EU Health Award will focus on practices and interventions which support healthy diet and a physically active lifestyle in children and young people. This also supports 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. The award creates an incentive for European health NGOs, schools and cities to share their evaluated good practices/interventions and get involved in EU health policy. The knowledge acquired by these practices broadens the information base for the Commission's work with Member States.

Target Group

NGOs, schools and cities.

Implementation

Commission (DG SANTE)

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

Reference	**Date**	**Amount**
Call for applications for the EU Health Award	Q1-Q2 2019	EUR 300 000

8. PROCUREMENT

The global budgetary envelope reserved for procurement contracts in 2019 amounts to EUR 24 000 560.

8.1. Studies supporting the Commission report on the application of Directive 2014/40 on tobacco products (TPD)

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(study)*

Article 28(1) of the Tobacco Products Directive (TPD)[4] sets out an obligation for the Commission to submit a report on the application of that Directive. In that process the Commission is assisted by scientific and technical experts.

Those studies should provide input to the Commission's report, which should focus, in particular, on areas listed in Article 28 of the TPD. In this respect the report plans to address a wide range of issues, including various product types (e.g. e-cigarettes, slim cigarettes, waterpipes, novel tobacco products), several policy areas (e.g. ingredient reporting and regulation, labelling and packaging, measurements methods) and different types of data (e.g. marketing and scientific data) from various sources (e.g. EU-Common Entry Gate (CEG), Member States, research studies).

Technical support may be needed in order to facilitate effective assessment, including retrieval, processing, analysis and presentation of data. It should also assess the application of the TPD and identify possible needs for adaptation. The studies may assess whether there is a need for adaptation of the health warnings in line with scientific and market developments and whether Article 20(5) of TPD that sets out the rules on advertising, promotion and sponsorship for e-cigarettes achieves the policy objectives in comparison to the regulatory framework for novel tobacco products as set out in the Tobacco Advertising and the Audiovisual Media Directives.[5]

[4] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1).

[5] Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (OJ L 152, 20.6.2003 p. 16); Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 2

Indicative timeframe for launching the procurement procedure

Q2 2019

Implementation

Chafea

law, regulation or administrative action in Member States concerning the provision of audiovisual media services (OJ L 95, 15.4.2010, p. 1).

8.2. Work carried out under the framework contract to provide services to support the assessment of flavours in tobacco products

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(study)*

The framework contract contributes to the implementation of the Tobacco Products Directive in respect of the prohibition of tobacco products with characterising flavour. In order to regulate the ingredients in tobacco products, an external contractor was tasked to establish the technical group and manage its activities in accordance with Article 12 of Commission Implementing Decision (EU) 2016/786.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific contracts based on an existing framework contract

Indicative number of contracts envisaged: 3

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019 (in line with the actual need for product testing)

Implementation

Chafea

8.3. The EU tracking and tracing system for tobacco products – Member State training

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(technical assistance)*

The illicit trade in cigarettes is estimated at 13% of the overall consumption. The EU tracking and tracing system (required under the Tobacco Products Directive (TPD) 2014/40/EU) will be one of the key tools in fighting illicit trade in tobacco products and is expected to achieve a non-negligible reduction in the artificially cheap supplies of tobacco products and thus to lower the uptake and general prevalence of smoking. The system is expected to be in place by 20 May 2019. Better understanding on the part of the users in the competent authorities of how to use the tracking and tracing system should increase efficiency of the Commission's and Member States' and Norway's and Iceland's actions against illicit trade. A series of training sessions to contribute to better use of the tracking and tracing system, which is intended as a new tool aimed at fighting illicit trade, will be carried out. By improving the skills of the users of the traceability system, the project aims at achieving lower uptake and general prevalence of smoking. An external contractor independent from the parties with vested interests will be asked to carry out the training courses and prepare the training materials. The training courses will be based on the design of the tracking and tracing system as provided for in the implementing and delegated acts adopted under Articles 15 and 16 TPD of the Tobacco Products Directive.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q3 2019

Implementation

Chafea

8.4. 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

Budget line

17 03 01

Subject matter of the contracts envisaged *(technical assistance)*

The proposed actions will - carry out a study on the cross-border advertising and marketing in new media, in order to have a better understanding of these practices and on the cross-border implications and exposure of children and young people. It would also be useful to map Member States' experiences with implementing and enforcing measures at the national level concerning marketing in new media.organise workshops/capacity building activities in the areas of alcohol and workplace, production and consumption of illicit/unrecorded alcohol and application of eHealth tools particularly in coordinated national campaigns to reduce alcohol related harm; In addition, two studies should be carried out: - A study mapping consumption patterns of low and zero alcohol beverages, and analysing their impact on reduction of alcohol related harm (either positive or negative); - The study to evaluate the impact of warning labels which have existed already for some time (e.g. pregnancy, driving) on consumption patterns. - .

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q3 – Q4 2019

Implementation

Chafea

8.5. Mapping Member States' fiscal measures and pricing policies applied to food, non-alcoholic drinks and alcoholic beverages

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(technical assistance)*

Fiscal measures and pricing measures e.g. minimum unit pricing can play an important role in nutrition policies and policies reducing alcohol consumption as part of a comprehensive approach aside other measures to facilitate healthy lifestyle choices. Based on the considerable amount of existing literature on this topic, the proposed actions will - prepare a report that compiles and updates the available information into a comprehensive overview. The report will include an EU mapping of national fiscal measures and pricing policies on alcoholic beverages, non-alcoholic drinks, and food (public health taxes, nutrient-focused taxes) including also a literature review summarising the available evidence on the impacts of these measures most importantly on public health. The focus will be on developing a factual snapshot including their description, methods used, main expectations and outcomes, information on whether an impact assessment is available and its main findings, dates of entry into force and how they were further developed after entry into force. The format of the report will ensure that the report can be easily updated and maintained. - produce 6 case studies that highlight successful national approaches, of which 3 will be on food/non-alcoholic drinks and 3 will be on alcoholic beverages. 3 case studies will focus on EU Member States and three on third countries, for example Chile (food), Australia and the United States (alcohol). - organise a one-day workshop to present these findings to the national representatives active in the policy fields of nutrition and alcohol related harm.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct service contract or a specific contract based on an existing FWC

Indicative number of contracts envisaged

Indicative timeframe for launching the procurement procedure

Q3 – Q4 2019

Implementation

Chafea

8.6. Activities for tackling vaccine hesitancy

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(study)*

This action comprises: 1. a Eurobarometer survey in all EU Member States on the peoples' perceptions on infectious diseases and vaccination, and the EU policy responses in this area 2. a Report on the state of vaccines confidence in the EU, to monitor attitudes towards vaccination, including in the community of healthcare workers. Based on that report, the Commission will provide guidance that can support Member States in countering vaccine hesitancy. Close coordination and consultation with Member States will be organized before the publication of the report.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct service contract or specific contract based on an existing FWC

Indicative number of contracts envisaged: 2

Indicative timeframe for launching the procurement procedure

Q1-Q2 2019

Implementation

Commission (DG SANTE)

8.7. Options for the development of a common EU citizens vaccination card

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(study)*

The Commission Communication on strengthened cooperation against vaccine preventable diseases[6] lists among activities to be undertaken the developing a common EU citizens' vaccination card, retrievable through electronic immunisation information systems and recognised for use across borders, in view of standardising the reporting on immunisation history. Such a vaccination card could help to keep immunisation rates high, providing ownership of data by the individual and encouraging following-up vaccine updates. The project should also check the incorporation of such a portable vaccination record in an electronic system, compatible with other IT tools being developed on health data, allowing for an electronic health vaccination card. It is proposed to examine the feasibility and develop options on the design and implementation of a common EU vaccination physical and electronic card as a recognised tool for use across borders in documenting immunisation services received by individuals. It is also proposed to test the physical and the electronic prototype with volunteering at least 10 EU Member States. The activity will be implemented in close coordination and consultation with Member States.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019

Implementation

[6] COM/2018/245 final

Chafea

8.8. Report on the feasibility of options for physical stockpiling

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(study)*

The aim is to analyse the feasibility and identify options for physical stockpiling of vaccines in case of outbreaks and to develop a concept for a mechanism for exchanging vaccine supplies from one Member State to another in the event of an outbreak. Diverse options will be identified, analysed and prioritised for a physical stockpile in case of outbreaks, exploring in particular feasibility of alternative complementarity of cooperation models and exchange mechanisms, and related challenges and requirements regarding business model, operational aspects, funding, compensation modalities and aspects of liability. The activity will be implemented in close coordination and consultation with Member States.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q4 2019

Implementation

Chafea

8.9. EU networking and support for reference laboratory functions for antimicrobial resistance.

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020) Thematic priority 4.4.of Annex I to the Programme Regulation

BUDGET LINE

17 03 01

Subject matter of the contracts envisaged

The EU AMR action plan sets out the intention of the Commission to 'improve AMR detection in the human health sector by providing EU support for networking collaboration and reference laboratory functions'. On 22 June the Commission adopted Implementing Decision (EU) 2018/945 on communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions pursuant to Decision 1082/2013/EU. The new Implementing Decision updates the list of communicable diseases and related special health issues which will be monitored through the EU's epidemiological surveillance network by using the EU case definitions to ensure comparability and compatibility of the collected data at Union level. It also includes state-of-the-art case definitions for AMR and healthcare associated infections. The purpose of this action is to pilot a strengthened framework for coordinating and supporting national reference laboratory functions for AMR. It will be implemented in coordination with ECDC. Well functioning reference laboratory functions are essential to support the implementation of effective action to combat AMR as set out in; the European one-health action plan against antimicrobial resistance COM(2017)339; Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance[7] and Decision 1082/2013 on serious cross border health threats. This action will designate a reference laboratory support structure – to be selected by competitive tender which will complement existing activities of the European Centre for Disease Prevention and Control (ECDC) and support a range of training, external quality assurance and networking activities to improve reference laboratory functioning and through this improve laboratory functioning at local and national levels across the EU as a whole. Three EU networks of reference laboratories in the area of antimicrobial resistance (AMR) will be supported over a 4 year period. The first network will cover carbapenem and colistin resistant Enterobacteriaceae; the second network will cover invasive bacterial pathogens under surveillance by the European Antimicrobial Resistance Surveillance Network (EARS-Net); and a third phase to be carried

[7] http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-antimicrobial-resistance/

out in close cooperation with existing EU reference laboratories in the animal health and food safety fields, as well as jointly with ECDC and the European Food Safety Authority (EFSA), will address food borne pathogens in humans.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged:1

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019

Implementation

Chafea

8.10. Global Summit on vaccination

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

BUDGET LINE

17 03 01

Subject matter of the contracts envisaged

Organisation of a "Global Summit on vaccination". The objective of this Summit would be to provide EU leadership for a new global commitment to vaccination, building on the Sustainable Development Goals, global vaccination targets and EU strategies on immunization. The "Global Summit on vaccination" will identify opportunities and agreement towards reducing vaccination gaps, and discuss solutions towards a lasting push for vaccination uptake at a global dimension, particularly on vaccine hesitancy and waning confidence, on modernisation of vaccines schedule, working to reduce vaccine shortages, and boosting research into development of new vaccines.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing FWC

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019

Implementation

Commission (DG SANTE)

8.11. EU Health Technology Assessment (HTA) cooperation

Legal basis

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020) Thematic priority 3.1. of Annex I to the Programme Regulation

Budget line

17 03 01

Subject matter of the contracts envisaged *(IT)*

Develop a feasibility study to identify the IT needs for supporting EU level cooperation on HTA. In particular identify the existing IT solutions developed by the Joint Action EUnetHTA and/or other relevant cooperation initiatives, and provide a comparative analysis of the different options available to answer the identified needs, taking into account the costs for implementing these options.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019

Implementation

Commission (DG SANTE)

8.12. Actions in support of the implementation of Communication 233(2018) on enabling the Digital Transformation of Health and Care in 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 and 4.1. of Annex I to the Programme Regulation

Budget line

17 03 01

Subject matter of the contracts envisaged *(study; technical assistance)*

This action relates to

- the Directive 2011/24/EU on the Application of Patients' Rights in Cross-Border Healthcare
- Commission Communication on enabling the digital transformation of health and care in the Digital Single Market (COM(2018) 233).

Four actions are envisaged:

(1) In a context of fast moving innovations and new and disruptive technologies in the e-health area (mhealth, telemedicine, e-care, genomics, big data, artificial intelligence (AI), secondary use of health data etc), there is a need to explore if there are gaps in the evidence available to the Commission. The study would map the existing legislation in the Member States in the area of digital health- eHealth, m-health, , telemedicine, AI genomics etc tackling legal and regulatory implications resulting from the digital transformation of health and care. This action would outline available evidence and experience to identify gaps and areas where further action is needed and would support the analysis for choosing the best tools to advance. It would provide a comprehensive overview as well as key policy options for the way forward, supported by quantitative data. It would also organise policy dialogues with stakeholders, feeding into the discussion.

(2) Technical assistance in competence building to the National Contact Point for eHealth (NCPeH) of the Member States in the field of interoperability of eHealth data, to support the cross border exchange of eHealth data through the eHealth Digital Service Infrastructure. This action will include:

(a) Identification of training needs: areas where training is necessary, on the basis of the situation in different NCPeHs.

(b) Preparation of training programme and modules.

(c) Training of experts from NCPeHs and national competent authorities on elements related to interoperability including for a European electronic health record exchange format (semantics, standards). This action will also support the exchange of best practices among NCPeH and agencies, facilitating the sharing of successful approaches developed by Member States and regions which have established interoperable systems.

(3) Implementation of training to ERN members in the use of the ERN IT Platform (CPMS, ECP and other relevant tools). *(Training)*

(4) Technical assistance supporting the Commission in implementing its obligations, where applicable, as data protection controller.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct service contract and specific contracts under existing FWC (request for services).

Indicative number of contracts envisaged: 4

Indicative timeframe for launching the procurement procedure

Q2-Q3 2019

Implementation

Chafea

8.13. Accessibility of pharmaceutical care and trends in pharmaceutical spending: an analysis of pharmaceutical sales data for 2008-2018

Legal basis

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020) Thematic priorities 3.7. and 4.6 of Annex I to the Programme Regulation

Budget line

17 03 01

Subject matter of the contracts envisaged *(study)*

The analysis of pharmaceutical sales data ("IMS Health data" purchased with IQVIA – formerly IMS) will help address key questions on the accessibility of pharmaceutical care across EU Member States as well as on trends in expenditures of public expenditures on pharmaceuticals, in line with the EU Agenda on health systems (2014 Communication) promoting the cost-effective use of medicines. The action will provide findings from analysing a unique data set on the accessibility of medicinal care as well as the trends in pharmaceutical spending. Both cross-country as well as (10-year) time trend analyses would be applied. This analysis can help overcome current crucial data gaps (notably as regards pharmaceutical spending in hospitals) as well as improve the understanding of pharmaceutical expenditures, notably by drawing on learnings offered by this analysis as regards the comparative accessibility of medicinal care in terms of (timely) availability and cost impacts. Among other, the analysis will allow to map out the volume and type of products sold in EEA markets through parallel imports and indirectly gauge factors that drive variations in the volume of parallel imports (such as price differences, parallel rules in specific Member States restricting parallel exports on public health grounds) Also, patterns in market launches as well as market withdrawals of products in specific Member States will be examined. Further, an analysis of pharma market competition trends and related causal factors will present insights into possible future policy options for ensuring patient access and mitigating possible unfavourable trends in expenditures. Findings from the study will be disseminated through a dedicated event.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

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

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1 2019

Implementation

Commission (DG SANTE)

8.14. Amenable mortality in an International perspective: Feasibility study for Methodological improvements

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(study)*

Amenable mortality is defined as "mortality which could be avoided through optimal quality health care". It is measured as avoidable deaths in a given year, broken down per EU Member State. The indicator is widely used in the European Semester and State of Health in the EU processes. This action concerns statistical research to assess the validity of the amenable mortality indicator as a proxy of comparative health system performance in an international perspective, specifically when taking account of differences in the burden of diseases between countries. Based on the outcome of this research, further avenues for improved performance measurement may be presented. The proposed action will be based on existing data and analyses, no prospective data collection is envisaged. The most immediate purpose of the proposed action is to deliver insights into methodological pitfalls at play and offer avenues for possible future improvements. As such, there is no need for exhaustiveness (e.g. covering all currently listed amenable mortality causes). The action helps improve the understanding of comparative health systems performance with a view to informing the European Semester. In addition, findings may feed into Eurostat's future activities on the collection of morbidity statistics.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

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

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1 2019

Implementation

Chafea

8.15. 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

Budget line

17 03 01

Subject matter of the contracts envisaged *(technical assistance)*

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

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1- Q4 2019

Implementation

Commission (DG SANTE)

8.16. Support to the implementation of HSPA at national level

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(technical assistance)*

The support to the implementation of HSPA (Expert Group on Health Systems Performance Assessment) at national level will comprise: • organisational support to the Expert Group: organisation of four face-to-face meetings per year and other working group meetings; cover costs of travel of Member States participants, costs of meeting rooms and of catering, as well as costs of travel, per-diems and accommodation of up to 4 external experts per meeting. • Supporting tools for dissemination of the findings of the Expert Group, its conclusions and policy recommendations. This may take the form of workshops with stakeholders, seminars, policy focus groups. • channelling expert advice to Member States which request for this capacity building. The advice may be in form of peer reviews and meeting with experts appointed or identified by the Expert Group. Advice can be both of strategic and operational nature: it can be to design policy action and plans, as well as to implement them. This support can be also given in co-operation with the SRSS.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019

Implementation

Commission (DG SANTE)

8.17. 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

Budget line

17 03 01

Subject matter of the contracts envisaged *(IT)*

Article 81 of the Clinical Trials Regulation (EU) No. 536/2014 provides that EMA is to, in collaboration with the Commission and the Member States, set up an EU portal and database for clinical trials. The objective of this action is to provide IT recommendations to EMA and the Commission for a successful development of the IT portal on clinical trials as well as to test the IT system to confirm that it is user friendly and functional.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019

Implementation

Commission (DG SANTE)

8.18. Data gathering for EMA fee system and evaluation of orphan and paediatric legislation

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(study)*

The actions aim to gather and analyse data and knowledge in support for an impact assessment[8] of different options responding to the findings of the review of EU legislation on EMA fees and support future Commission action in the area of EMA fees charged by EMA, including remuneration paid to National Competent Authorities (NCAs), for activities related to obtaining and maintaining marketing authorisations for medicinal products for human and veterinary use. Following a recent amendment of Regulation (EC) No 726/2004 (the Founding Regulation of the EMA), formally adopted and December 2018 as part of the new veterinary medicines legislation (2014/056(COD), the Commission is obliged to review the legal framework for fees by 2019. Following the relevant evaluation exercise, an impact assessment should be carried out to analyse the policy options in view of supporting a legislative proposal to update the legal framework on EMA fees. In addition, this initiative is essential to ensure the proper financing of new procedures following the changes to the veterinary medicines legislation, which will apply as of January 2022. The intervention logic will build on previous evaluations and link the problem (including subsidiarity issues), its underlying causes, the objectives and range of policy options to tackle the problem. Stakeholder's feedback on the basis of an inception impact assessment will be sought and addressed when comparing policy options on the basis of their economic, social and environmental impacts. The actions will also address questions raised among others by the Member States including in Council conclusions about the functioning of the pharmaceutical system notably on the system of incentives. They will take the form of targeted data gathering and analysis to conclude the evaluation of orphan and paediatric legislation. This evaluation aims to provide an assessment of the strengths and weaknesses of both Paediatric and Orphan Regulations separately and combined. In particular it will assess in what respect have patients' needs been fulfilled and what have been the societal consequences. It will also give an insight on how the various incentives provided by the legislation have been used, and the financial consequences for the different stakeholders (patients, industry, payers etc.). This evaluation will provide for a comprehensive overview together with options to allow the next

[8] Subject to internal political agreement

Commission to take an informed decision on the way forward.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific Service Contract under new Framework Contracts

Indicative number of contracts envisaged: 2

Indicative timeframe for launching the procurement procedure

Q2 2019

Implementation

Commission (DG SANTE)

8.19. Development of the future 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

Budget line

17 03 01

Subject matter of the contracts envisaged *(IT)*

The database is required under Article 33 of the Regulation (2017/745) on medical devices and Article 30 of the Regulation (2017/746) on *in vitro* diagnostic medical devices. The financing through the Health Programme is laid down in the legislative financial statement accompanying the legislative proposal. As laid down in the new legislation a new Eudamed with 6 electronic systems (unique device identification (UDI), registration, certificates, clinical investigation, vigilance, market surveillance) will be set up. Registration in the system for UDI is to be launched and for this, a help-desk, training and quality assurance function is to be established.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1-Q2 2019

Implementation

Commission (DG GROW) or for UDI-related aspects CHAFEA

8.20. IT audit of EUDAMED under article 34 of the Regulation (2017/745) on 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

Budget line

17 03 01

Subject matter of the contracts envisaged *(IT audit)*

The audit is required under Article 34 of the Regulation (2017/745) on medical devices. The financing through the Health Programme is laid down in the legislative financial statement accompanying the legislative proposal.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1-Q2 2019

Implementation

Commission (DG GROW)

8.21. 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

Budget line

17 03 01

Subject matter of the contracts envisaged *(communication services)*

Communication and publication actions to promote understanding and correct implementation of the requirements and risks relating to medical devices under the new Regulation (2017/745) on medical devices and Regulation (2017/746) on in vitro diagnostic medical devices. The financing through the Health Programme is laid down in the legislative financial statement accompanying the legislative proposal.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019

Implementation

Chafea

8.22. 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

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 information on the application of EU Directives on medical devices.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct service contract or specific contract under existing framework contract

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q1-Q2 2019

Implementation

Commission (DG GROW)

8.23. Scientific Committees

Legal basis

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020) Thematic priority 2.4. and 3.7. of Annex I to the Programme Regulation

Budget line

17 03 01

Subject matter of the contracts envisaged *(technical assistance)*

The Scientific Committees provide independent scientific advice and risk assessment to the EU Commission departments in the fields of health, environmental and emerging risks. Sound scientific advice is vital for policy makers to ensure the high level of health and environmental protection that European citizens expect from the European Union institutions. 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, drafting and proofreading. Experts of Scientific Committees may originate from EU or non-EU countries and cover a broad area of disciplines. They are appointed in their personal capacity in the interest of EU citizens. This item will cover the scientific and technical assistance.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 2

Indicative timeframe for launching the procurement procedure

Q1- Q4 2019

Implementation

Commission (DG SANTE)

8.24. European Reference Networks capacity and knowledge sharing through short term mobility and exchanges of healthcare professionals

LEGAL BASIS

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020) Thematic Priorities 4.1. of Annex I to the Programme Regulation

BUDGET LINE

17 03 01

Subject matter of the contracts envisaged *(technical assistance)*

The action aims to strengthen the administrative capacity of ERNs by increasing the capacity and expertise of the ERNs system to better diagnose and treat patients suffering of rare or low prevalence diseases and conditions and contributing to the goals of the ERNs as established in article 12 of the Directive of Patient's Rights to Cross border healthcare and linked to thematic priority 4.1 of the Health Programme.

The short term mobility of key professionals of the ERNs will allow the exchange of technical and organizational highly specialized practices from more to less experienced centres. This "knowledge movement" will facilitate, in a very cost effective way, the spread of innovation and better access of all EU citizens to the higher possible level of healthcare quality.

The objective of the contract is to facilitate and finance short-term professional stays for health professionals working in a healthcare provider, member or affiliated partner, of an ERN, in another provider of the same ERN. The goal of these visits is to share, exchange and acquire clinical and organisation expertise, best practices and knowledge among the ERNs members and to increase and strength the cooperation inside the network.

The motto of ERNs is "knowledge travels, not the patient". The diseases and conditions under the scope of the ERNs are rare by nature and the knowledge scarce and fragmented.

By moving the knowledge instead the patients, Member States with less financial or organizational capacity will strengthen their ability to respond to their patients' needs while at the same time increasing the attractiveness of their healthcare systems to retain specialized healthcare providers avoiding the drain of their best professionals.

It is fundamental for the success of the ERNs and for the benefit of the healthcare systems and patients to maintain and enhance the capacity, knowledge and expertise of all the professionals participating in the system while sharing and transferring best organisation and technical practices and methods between centres across the EU. This is even more relevant now, two years after the launching of the 24 ERNs, with the forthcoming call for new members to join existing networks and the inclusion of affiliated partners. Moreover, in some very rare and complex diseases and procedures, the need of concentration of patients and resources and the high level of expertise needed, makes that only a limited number of professionals are able to train their peers in other member states and to share their knowledge. This action aims at promoting short-term exchanges (1 week to 1 month) of

healthcare professionals. The exchanges will concern different specialities and levels of seniority and will allow knowledge transfer in both directions.

The ERN coordinators will play a fundamental role in identifying the knowledge gaps, areas of expertise and centres and professionals to prioritise in the programme, thus facilitating the exchange of professionals.

The contractor, in accordance with the final approval of DG SANTE, will assist on implementing the modalities of professional exchanges, organising practicalities such as travel and accommodation, preparing and reviewing detailed satisfaction surveys from both, visitors and specialised centres hosting the visits. Moreover, the contractor will be responsible of reporting on the results of the pilot programme, organising review workshops in order to improve the quality of results and of setting conclusions and recommendations for the implementation of a further permanent programme for the exchange of highly specialised professionals of the ERN system. Depending on the results of this pilot project, DG SANTE will analyse the possibility of scaling it up with the support of Erasmus agencies as of 2021.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct contact / service

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q3 –Q4 2019

Implementation

Chafea

8.25. Assessment of healthcare providers wishing to join established ERNs

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(technical assistance)*

In line with Article 9 of the Commission Implementing Decision 2014/287/EU 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 (OJ L 147, 17.5.2014, p. 79) the Commission shall appoint an independent assessment body which shall evaluate the applications for membership to the existing European Reference Networks, including the eligibility checks, and which shall draft evaluation reports on the applications, to be sent to the Commission and healthcare provider concerned, which will then be submitted to the ERN Board of Member States, responsible for the approval of new ERN Members. The service contract will include the necessary technical assistance.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific contract based on an existing FWC

Indicative number of contracts envisaged: 1-2

Indicative timeframe for launching the procurement procedure

Q2 2019

Implementation

Chafea

8.26. Development of an integrated assessment, monitoring, evaluation and quality improvement system (AMEQIS) for the European Reference Networks

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(technical assistance)*

The Contractor will design an integrated approach for the assessment, monitoring, evaluation and quality improvement system (AMEQIS) of the ERNs. This integrated approach will provide the independent assessment body (IAB), the Evaluation Body and the involved actors (Member States, Health Care Providers and ERNs) with clear and robust guidance, criteria and operational tools to ensure a sound and harmonised process in order to (1) assess any new ERN or HCP application, (2) monitor and verify whether the activities carried out and the produced deliverables developed by the approved ERNs and their Members are in accordance and fulfil the requirements set out in the ERN's Delegated and Implementing Decision and the goals and objectives defined in each ERN application, (3) provide input for the improvement of the ERN system based in a Continuous Quality Improvement System approach (Plan -Do-Check-Act) and evaluate the ERNs. The AMEQIS should be based on internationally recognised practices and contain the core principles and methodologies for carrying out assessment, monitoring , evaluation and continuous quality improvement activities by addressing all the steps of the process from the call for Networks and providers to the periodic evaluation of the Networks and their Members. The action will include at least the following blocks or work packages under which the contractor will be required to prepare the deliverables as detailed: 1) The **update and improvement of the assessment methodology, manual and toolkit** based on the lesson learned since their initial application. The update will take particularly in account: a) the opinions and recommendations issued by the IABs in charge of previous assessments of Networks and HCPs, b) the opinion and identified difficulties expressed by the assessed applicant Networks and Members, c) the requests of the Commission, and d) the needed updates of the format, layout or

structure of the Assessment Manual and Technical Toolbox.

2) The completion and improvement of the Continuous Monitoring and Quality Improvement System of the approved ERNs and their Members that was put in place in 2018 based on the agreement of the ERN Coordinators Group and the ERN Board of Member States.

The proposal for the improved monitoring system must include an analysis of the current ERN monitoring system and data sources, develop the quality check and, through an exhaustive consultation process, produce an improved ERN Continuous Monitoring and Quality Improvement System.

The new system should focus on the Donabedian's structure, process and- in particular- outcome measures which are able to demonstrate that ERNs have improved their quality of diagnosis, care and treatment. The new system should include indicators specific to each ERN related to the conditions that they each address. The Contractor will provide methodological support to the ERNs in the process of election and definition of the Network specific indicators. Individual indicators will need to be discussed internally within each ERN, with patients and with the ERN Coordinators in order to reach agreement on these.

The work to be carried out must address specific indicators on patient reported experiences (PREMs), and patient reported outcomes (PROMs).

The monitoring system shall take in account the previous results and monitor the following areas and the achievement of the following objectives:

- General organisation and coordination: Objective 1: To ensure that ERNs are operational and successfully carry out their organisation activities
- Patient Care: Objective 2: To improve access to clinical advice, diagnosis, treatment and follow-up of patients within the ERNs
- Multidisciplinary approach and sharing of knowledge within the ERN: Objective 3: To optimise patient outcomes by combining skills of healthcare professionals involved and resources used
- Education and Training: Objective 4: To increase capacity of professionals to recognize and manage cases of rare and complex conditions and diseases within the scope of the ERN
- Contribution to research and innovation: Objective 5: To reinforce clinical research in the field rare and complex conditions and diseases by collecting data and carrying out collaborative research activities
- Clinical guidelines: Objective 6: To ensure that all patients referred to ERNs have access to high quality healthcare services
- Communication and dissemination within the scope of the ERN activities -Objective 7: To guarantee that knowledge is spread outside the ERN so that more people can benefit from the ERN activities.

3) The development of the Evaluation Manual and toolkit (i.e. a set of tools designed to be used together by the ERNs, HCP and the Evaluation Body for the particular purpose of the evaluation) for the periodic evaluation of the approved ERNs and their Members.

The Evaluation Manual will take into account: a) the content of the initial Network and HCPs application and their assessment reports and recommendations issued in 2017, b) the goals

and yearly objectives proposed by each ERNs and c) the outputs and outcomes of the Continuous Monitoring and Quality Improvement System.

It will include the description and mapping of the best practices and state of art of the evaluation methodologies (accreditation, certification or licensing) and the methodology and tools allowing for the implementation of a continuous Quality Improvement System. It should include at least:

- Guide and flowchart of the steps and elements of the evaluation process;
- Operational criteria for the evaluation of approved Networks and Members;
- Manual of evaluation and technical toolbox;
- Methodology for integrating the assessment, monitoring, evaluation actions and tools in order to set up a quality improvement system of ERNs
- Technical support to the Commission in the development and follow up of the evaluation Manual and toolbox;
- Instructions on the use of the Manual.

The evaluation should include an exhaustive documentation review and on-site audits of a sample of approved Members.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct contact / service

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q3 –Q4 2019

Implementation

Chafea

8.27. European Reference Networks workshops, seminars, studies

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

Budget line

17 03 01

Subject matter of the contracts envisaged *(technical assistance)*

The ERNs system is assisted in its implementing process by two main bodies, the ERN Board of MS and the ERNs Coordinators Group. Through dedicated working groups, those bodies are addressing in a structured way the main challenges and issues the ERNs system is facing, and the needed governance guidance to effectively tackle these issues. At this stage, a number of working groups are active in several domains (integration of the ERNs into the national healthcare systems, legal and ethical issues, research, knowledge generation and sharing, monitoring and quality improvement, business continuity of the ERNs).

Hospital managers are key players in the success of the ERNs. The hospital environment, how ERN members' work and activities are integrated and working procedures of each hospital, is the backbone of the ERN system. Ad hoc meetings with representatives of the ERNs hospital managers' community are periodically organised with the aim of identifying the operational needs for the effective functioning and integration of the work of the ERNs members in the general hospital system. Sharing best practices and establishing common support actions are addressed in those meetings.

The working methodology of the working groups is based on virtual meetings and exchange of documents and online surveys. Physical meetings of some of the above-mentioned groups are needed in order to reach final agreements and to enhance the working capacity and the sense of community and team spirit of those working groups.

ERN workshops and seminars:

a) 4th ERN Hospital managers workshop. This 4th meeting will continue with the consolidation of good practices and strategies to support the healthcare providers members of ERNs. This will also be the opportunity for the analysis and evaluation of the actions already developed to support the ERNs by the Hospital Managers' community.
b) 2nd seminar on ERN research capabilities. Further to the results of the study on ERN research capabilities of 2018 and the 1st seminar on this field, this second edition will be the opportunity to present the results of the work of the ERN Research Working Group and to interact with representatives of research infrastructures (ECRIN, ELIXIR etc. – already identified, supported by DG Research), to enable them to work more closely and thus enhance synergies in the field of health research for the diseases

and conditions covered by the 24 ERNs. The meeting aims, with the cooperation of a professional facilitator, to reach common views on the most difficult approaches to research activities in the frame of the ERN system.

c) Workshop on integration of ERN in the national Health systems, with the participation of Coordinators and representatives of Member States; Integration of ERNs into the healthcare system of the Member States is a key and challenging area. In order to finalise the work developed so far by mean of periodical virtual meetings a face-to-face meeting will be organised to agree on the Statement on Integration of the ERN Board for its later approval by the ERN Board of Member States. The meeting aims to prepare and finalise for adoption such a document.
d) Workshop on the ERN strategy on Knowledge Generation: The workshop will support the work developed by the working group on Knowledge Generation and gather ERNs and Member States representatives members and other key actors, to exchange best practices on eTraining and eLearning activities and follow up the implementation of the ERNs training and Education strategy.
e) Workshop on ERNs on legal and ethical issues. This workshop will support the work carried out by the ERN Working Group on Legal and Ethical issues and relations with Stakeholders, to discuss and explore with industry and patients' organisations the possible cooperation areas and mechanisms for private support to ERNs, additional and compatible to EU and national public funding.
f) Organisation of an ERN specific training-seminar on managerial skills and technics for coordinators. ERNs will be growing as a result of the endorsement of affiliated partners and the invitation to new healthcare providers to join the existing networks. This situation will represent a challenge for the coordinators of the ERNs in terms of organisation and management or the network. This seminar looks at providing coordinators with a common culture and skills in order to manage this growing highly specialised community.

Studies and literature reviews: In order to support the implementation process of the ERNs the Commission advised by the ERN working groups and governance bodies may need to carry out ad hoc studies or analysis of the state of play of different topics.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct contact / specific contract under existing FWC

Indicative number of contracts envisaged: 4

Indicative timeframe for launching the procurement procedure

Q3 –Q4 2019

Implementation

Chafea

8.28. Patient Safety: 10 years following the Council Recommendation on Patient Safety, taking stock and moving forward

Legal basis

Regulation (EU) No 282/2014 — Third Programme for the Union's action in the field of health (2014-2020) (Thematic priority 4.3. of the Programme Regulation)

Budget line

17 03 01

Subject matter of the contracts envisaged *(communication services)*

This contract will support the organisation of a conference on patient safety for experts from Member States, policy makers, patient associations and other stakeholders. Background: In June 2009, the Council adopted a Recommendation on patient safety, including the prevention and control of healthcare-associated infections (2009/C 151/01). Since then much progress has been made. Most EU Member States have developed specific policies on patient safety and/or embedded them as priorities in their health policies. The conference will show good practices in the field including by the Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections, and other activities contributing towards improving patient safety. It will reflect on progress and include discussion on the remaining challenges ahead.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Service contract under framework contract Chafea/2018/Health/03

Indicative number of contracts envisaged: 1

Indicative timeframe for launching the procurement procedure

Q3 2019

Implementation

Commission (DG SANTE)

8.29. Communication (cross-cutting activities)

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 cross-cutting communication activities (graphic designers, web, support to events) will support the specific objectives and thematic priorities of the Health Programme and will include services supporting Commission departments in their outreach actions. The actions will strengthen the visibility and optimising the impact of actions financed by the Health Programme.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct Service Contracts or Specific Service Contracts under *existing* Framework Contracts managed by DG COMM

Indicative number of contracts envisaged: 10/12

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019

Implementation

Commission (DG SANTE)

8.30. Communication activities in support of health policy priorities

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 communication activities in support of Health policy priorities will notably focus on major deliverables in the areas of: AMR, the State of Health in the EU and related initiatives on health systems, crisis preparedness and response, vaccination, HTA, ERNs, and eHealth. The activities will contribute to the specific objectives and thematic priorities of the Health Programme.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct Service Contracts or Specific Service Contracts under *existing* Framework Contracts managed by DG COMM Co delegation to SCIC

Indicative number of contracts envisaged: 8/10

Indicative timeframe for launching the procurement procedure

Q1 – Q4 2019

Implementation

Commission (DG SANTE)

8.31. 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 increase the visibility of the results obtained by actions funded under the Third Health Programme in support of those carried out by each of the co-funded actions themselves and thus demonstrate the impact of European investment in the field of public health, as recommended final evaluation of the Second Health Programme and the mid-term evaluation of the Third Health Programme. By highlighting and promoting concrete results/outputs and good practices delivered under previous annual work programmes, the present action aims to scaling up and transfer validated good practices across the EU.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 10

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019

Implementation

Chafea

8.32. Management of 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 *(communication services, technical assistance)*

The scope of the FWC is the support of the Steering Group and its sub-groups, but also other expert groups of the DG Health and Food Safety, mentioned in the terms of reference of the FWC e.g. the Health Security Committee. The FWC holder will be providing organisational, administrative and communication/dissemination services. The FWC holder will be providing services to permanent groups such as the Steering Group on Health Promotion, Prevention and Management of Non-communicable Diseases as well as sub groups, which are called to life to accomplish one specific task. The services will include the organisational running of the expert groups via a "promoter" who will ensure that the mandate is respected, draft documents, collect comments, follow-up documents etc., the organization of meetings including travel, accommodation, catering, minutes taking etc., and dissemination and communication activities concerning the results of the group e.g. writing a flash report after a meeting, translation and dissemination of a consensus document, annual reports on the group's activities etc. The contract holder will organise the group's discussion via the Health Policy Platform. It is expected that in 2019 the framework contract holder would provide support to four expert group meetings and organise two time-bound expert sub-groups.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific contracts based on framework contract to be established after call for tender Chafea/2018/Health/03

Indicative number of contracts envisaged: 1-4

Indicative timeframe for launching the procurement procedure

Q1-Q4 2019

Implementation

Chafea

8.33. Health Policy Platform

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 *(IT and communication services)*

The Platform provides a framework and IT-infrastructure for an improved, more interactive and more outcome-oriented communication between the Commission and its stakeholders and between the stakeholders themselves. It is open to all health stakeholders across the EU that comply with the established working methods of the Platform. Secondly, the IT-infrastructure of the Platform is also used as exchange and repository space improving the work of the Commission expert and stakeholder groups. The EU Health Policy Platform consists of the online Platform, regular meetings with stakeholders and the EU Health Award.

Type of contract *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Specific service contract under existing framework contract or direct service contract

Indicative number of contracts envisaged: 2

Indicative timeframe for launching the procurement procedure

Q1- Q4 2019

Implementation

Commission (DG SANTE)

8.34. Information technologies in support of public health policies

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 *(IT)*

This action concerns the setting up, support to and maintenance of relevant IT applications, in support EU public health policy/activities as set out in Article 168 TFEU and in support of public health policies relevant to the Third Health Programme. The provisional list of applications to be covered by this action is as follows: Alcohol and nutrition Platforms; Platform on Workforce, European Reference Networks, eHDSI, 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), Ras-Bichat, 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 *(new FWC / direct contract / specific contract based on an existing FWC / contract renewal)* and type of procurement *(service/supply/works)*

Direct service contract or specific contract based on existing framework contract

Indicative number of contracts envisaged: 10

Indicative timeframe for launching the procurement procedure

First half of 2019

Implementation

Commission (DG SANTE)

9. OTHER ACTIONS OR EXPENDITURES

The overall budgetary allocation reserved for other actions or expenditures in 2019 amounts to EUR 7 893 000.

9.1. 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 priority 1.1, 1.4 and 4.2. of Annex I to the Programme Regulation

Budget line

17 03 01

Amount

EUR 4 570 000

Description and objective of the implementing measure

Administrative Agreement with JRC

Thematic area 1: Healthcare quality – Underlying objective: improve the quality of breast and colorectal cancer care.

The JRC will have completed the guidelines and quality assurance scheme for Breast Cancer care and will perform a feasibility study on impact.

For the colorectal cancer initiative (ECICC), the JRC will: i) initialise a new approach to develop the guidelines in tandem with the quality assurance scheme; ii) organise meetings of the expert working group and with buy-in from National Contacts for the implementation of recommendations; iii) organise on-line surveys and searches to ensure ECICC implement-ability across Europe.

Thematic area 2: Cancer information – Underlying objective: provide on a regular and permanent way data and indicators related to cancer epidemiology and care at European level by operating and improving the European Cancer Information System.

Actions JRC will be implementing:

1. Improvement of the European cancer registry data collection and related data management and processing; 2. Inclusion of the geographical reference for the cancer cases and data linkages to other geo-referenced datasets; 3. Enhancement of dissemination tools and activities; 4. Coordination and promotion of a unique European dataset of cancer cases; 5. Development of a methodology to extrapolate from regional to national indicators for countries not fully covered by cancer registration; 6. Definition of the workflow for yearly computation of predictions for cancer incidence and mortality.

Thematic area 3: EU Platform on Rare Disease Registration (EU RD Platform) – Underlying objective: provide, in a regular and permanent way, data and information related to rare diseases, prepare linking rare diseases data with biobanks and, 'omics' information and monitor rare congenital anomalies and cerebral palsies.

Actions JRC will be implementing:

1. Further expand European Rare disease Registry Infrastructure towards interoperable rare disease registries and making patient data searchable and findable; 2. Establish seamless cooperation with European Reference Networks' rare disease registries; 3. Prepare linking with biobanks and 'omics' data; and 4. Coordination of the networks and data analysis on congenital anomalies and cerebral palsy.

Thematic area 4: Prevention of non-communicable diseases – Underlying objective: supporting the work of the Steering Group on Promotion and Prevention (SGPP) on non-communicable diseases through best practice pre-selection and evaluation, and taking into account outcomes of relevant scientific projects funded by EU research programmes, such as H2020.

Actions JRC will be implementing:

1. Supporting best practice pre-selection and evaluation, facilitate knowledge transfer before and after selection for EU funding and other support to the Steering Group on Health Promotion and Prevention. 2. Direct support on scientific aspects related to disease prevention and promotion activities.

Thematic area 5: European Reference Networks (ERNs) (time of implementation 3 years) – Underlying objective: to support the policy and technical work of the 24 approved ERNs in the area of registries, to consolidate their development in the Research area.

Actions JRC will be implementing:

(1) Support DG SANTE in the development of its strategy for the development of registries for ERNs; (2) Direct support to the ERNs in the development of registries, in compliance with JRC tools and standards; (3) training by JRC to ERN Coordinators and members notably on the tools developed by the JRC in registries.

Thematic area 6: Behavioural study on vaccination

The Council Recommendation on strengthened cooperation against vaccine preventable diseases indicates the need to invest in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers.

Underlying objective: identify determinants of vaccine hesitancy across different subgroups of the population and health workers.

Actions JRC will be implementing:

1. Behavioural study on the differences, explanations and countermeasures to improve confidence in vaccines.

2. identify barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups,

The activities will be coordinated with ECDC and the WHO as appropriate.

9.2. Joint Research Centre – 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

Budget line

17 03 01

Amount

EUR 100 000

Description and objective of the implementing measure

The Joint Research Centre supports the work of the Commission, by measuring and analysing tobacco products and e-cigarettes, providing technical support and advice on the work of the Independent Advisory Panel on characterising flavours in tobacco products and the technical group of sensory and chemical assessors established via Commission Implementing Decision 2016/786. Furthermore, the JRC provides an analysis and assessment of individual security features technologies, particularly those that are newly introduced to the market, and their compliance with the legal requirements.

9.3. Support for methodological work and statistical analysis on the health-related information collected in various EU surveys and modules / Support for development of diagnosis-based 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 and 3.7. of Annex I to the Programme Regulation

Budget line

17 03 01

Amount

EUR 450 000

Description and objective of the implementing measure

Sub-delegation to Eurostat

Support for methodological work and statistical analysis on the health-related information collected in various EU surveys and modules

The European Health Interview Survey (EHIS) is a key data source on self-reported health status, health care consumption and health determinants. It produces survey data for numerous statistical indicators, including the European Core Health Indicators (ECHI), used in various Commission analytical tools such as the State of Health in the EU cycle, or JAF health contributing to benchmarking and policy evaluation. It is the only EU-level data set that allows crossing and breaking down information by individual (e.g. sex, age) and socio-economic characteristics (e.g. income, education). Additional areas, which are currently not yet covered, can be included in future surveys in new dedicated modules.

The aim is to provide support to Eurostat for the analysis of the health survey data and metadata from EHIS wave 3 and the EU Statistics on Income and Living Conditions (EU-SILC) 2017 module on health and children health with a view to checking the coherence of the results from both sources and proposing improvements for future rounds of both data sources, including development of further modules.

Support for development of diagnosis-based morbidity statistics

Eurostat has foreseen to have a pilot data collection on diagnosis-based morbidity through a coordinated approach across Member States. The aim of the action is to provide support to Eurostat in relation to methodological questions, data validation and preliminary analysis.

The legal basis for Eurostat´s Public Health Statistics is the Framework Regulation (EC) 1338/2008 establishing a framework for Community statistics on public health and health and safety at work. One of the five domains for its implementation is "health status and health

determinants", which covers statistics from surveys and "other statistics compiled from administrative sources such as those on morbidity" (Regulation 1338/2008 Annex I).

9.4. Expert Panel on 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

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 advice is provided by the Expert Panel on effective ways of investing in Health in line with Commission Decision 2012/C 198/06. This action contains special indemnities paid to experts for their work on opinions and reports.

9.5. Active pharmaceutical ingredients – system inspections in third 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

Budget line

17 03 01

Amount

EUR 30 000

Description and objective of the implementing measure

For an effective assessment of medicinal products to ensure public health protection, the EU has strengthened the rules to import active substances from the non-EU countries since 2011. This action contributes to the implementation of EU health legislation in the field of Pharmaceuticals. 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 allow verifying whether the regulatory framework for the manufacture of active pharmaceutical ingredients, including inspection and enforcement systems, are equivalent to that of the EU. 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 under Article 111(b) of Directive 2001/83/EC. This action covers the reimbursement of expenses of Member States' 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.

9.6. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and International Pharmaceutical Regulators Programme (IPRP)

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

Budget line

17 03 01

Amount

EUR 600 000

Description and objective of the implementing measure

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and International Pharmaceutical Regulators Programme (IPRP) are the leading international organisations and global platforms for harmonisation and regulatory cooperation between all regions in the field of medicinal products. This item covers the ICH annual membership fee and reimbursement of the Member States experts participating in the ICH working group, as well as annual contribution fee of IPRP.

9.7. 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

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 (HMA) is a programme that monitors the equivalence of Member State good manufacturing practices (GMP) inspectorates. The programme consists of audits carried out by Member States authorities (the auditors) to a given Member State GMP system (the auditee). The JAP programme is however under-resourced as travel and accommodation are, in the absence of Commission funding, paid by Member State authorities budgets. The objective of this action will be to fund the JAP audits based on objective criteria based on specific requirements vested in EU legislation.

9.8. Annual Commission Membership fee to the European Observatory on Health Systems and Policies[9]

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

Budget line

17 03 01

Amount

EUR 500 000

Description and objective of the implementing measure

The objective of the Commission's participation in the European Observatory on Health Systems and Policies is to generate and disseminate quality information and actionable evidence on EU health systems whereby supporting Member States reforms of national health systems. The three main working areas of the Observatory are: 1. Country monitoring and information 2. Comparative health systems studies 3. Dissemination and knowledge brokering.

[9] Commission Decision of 12.12.2018 on its prolongation as Participating Organisation of the "European Observatory on Health Systems and Policies" project (C(2018)8402 final).

9.9. Scientific Committees and Rapid Risk Assessment

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. and 2.4. of Annex I to the Programme Regulation

Budget line

17 03 01

Amount

EUR 420 000

Description and objective of the implementing measure

The Scientific Committees provide independent scientific advice and risk assessment to the EU Commission departments in the fields of health, environmental and emerging risks. Sound scientific advice is vital for policy makers to ensure the high level of health and environmental protection that European citizens expect from the European Union institutions. Experts of Scientific Committees may originate from EU or non-EU countries and cover a broad area of disciplines. They are appointed in their personal capacity in the interest of EU citizens. This action comprises travel and accommodation expenses, daily allowances and special indemnities for the experts for their work on scientific opinions and rapid risk assessment.

9.10. 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

Budget line

17 03 01

Amount

EUR 30 000

Description and objective of the implementing measure

VICH is an action launched to bring together the drug regulatory authorities of EU, Japan and the United States along with experts from the pharmaceutical industry in the three regions to develop harmonised guidelines for product registration.

The VICH Steering Committee has the decision-making role and is the driver of the harmonisation process. The Steering Committee is composed of two delegates of the regulatory authorities and two delegates of representative industry associations from the three regions (EU, US and Japan). Australia/New Zealand, Canada and South Africa have observer status with one delegate representing government authorities and one delegate representing industry associations. OIE, the associate member, has one delegate.

The Steering Committee is the body within VICH that is empowered to take decisions such as selecting topics, releasing draft guidelines for consultation, and adopting final guidelines for implementation in the three regions. The VICH Steering Committee currently meets approximately every nine months. The location of meetings, which normally last two days, alternates between Japan, the EU and the US.

VICH Outreach Forum (VOF) is a VICH initiative in conjunction with World Organisation for Animal Health (OIE) and the meetings are held in between VICH Steering Committee meetings.

This action covers the expert mission costs related to these the meetings.

9.11. Medical devices: reimbursement of experts' expenses for joint assessments

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

Budget line

17 03 01

Amount

EUR 213 000

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.

9.12. Organisation and management of the meetings of the Medical Device Coordination Group (MDCG)

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

Budget line

17 03 01

Amount

EUR 300 000

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.

9.13. Health Award and Health Policy Platform meetings – payment and reimbursements of the participants and jury and materials

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 120 000

Description and objective of the implementing measure

The budget is used for the organization of the EU Health Award and also reimbursement of participants as well as the work of the Jury and the Health Policy Platform meetings, communication materials and award materials.

9.14. 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 150 000

Description and objective of the implementing measure

This action has two objectives:

1. Remunerate the experts participating in the evaluation of actions under the annual work programme to ensure a qualified and transparent selection of proposals to be funded

   The proposals submitted under different calls for proposals are evaluated by external experts (peer-review). Peer-review is also provided for other financing instruments, e.g. during the quality assurance workshop for the actions co-funded with the competent authorities of Member States/other countries participating in the Programme (Joint Actions).

2. Remunerate the experts participating in the technical review of selected running projects funded under previous AWPs to ensure a qualified opinion on action outputs and optimize impact of co-funded actions.