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ANNEX 1

Third programme for EU action in the field of health 2020 work programme

ANNEX

to the

COMMISSION IMPLEMENTING DECISION

concerning the 2020 work programme in the framework of the third programme of Union action in the field of health (2014-2020) and the EU's financial contribution to the WHO Framework Convention on Tobacco Control

EN

ANNEX 1

Third programme for EU action in the field of health — 2020 work programme

Introduction

This work programme sets out priorities and actions for 2020, including resource allocation, for the implementation of the third programme of the Union's action in the field of health (2014-2020).

LEGAL BASIS

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

BUDGET LINE

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Article 11 of the Programme Regulation requires the Commission to adopt, by means of implementing acts, annual work programmes setting out actions to be taken and an indicative allocation of financial resources. The actions should fall under the four objectives and 23 thematic priorities identified in Annex I to the Regulation. On the basis of the objectives in the Programme Regulation, this work programme sets out actions to be financed and the budget breakdown for 2020 as follows:

- grants (implemented under direct management): EUR 37 155 000
    - operating grants: EUR 5 000 000
    - action grants: EUR 32 155 000
- prizes (implemented under direct management): EUR 400 000
- procurement (implemented under direct management): EUR 15 565 158
- other actions: EUR 12 241 000

The 2020 work programme is built on the following **objectives** and its **priority areas** and addresses **health inequalities** as a cross-cutting issue:

1. Promote health, prevent diseases and foster supportive environments for healthy lifestyles

1.4 Chronic diseases, including cancer, age-related diseases and neurodegenerative diseases

1.5 Tobacco legislation

1.6 Health information and knowledge system to contribute to evidence-based decision-making

2. Protect Union citizens from serious cross-border health threats

2.2 Capacity-building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries

2.3 Implementation of EU legislation on communicable diseases and other health threats, including those caused by biological and chemical incidents, environment and climate

change

2.4 Health information and knowledge system to contribute to evidence-based decision-making

3. Contribute to innovative, efficient and sustainable health systems

3.1 Health technology assessment (HTA)

3.2 Innovation and e-health

3.3 Health workforce forecasting and planning

3.4 Setting up a mechanism for pooling expertise at EU level

3.6 Implementation of EU legislation in the field of medical devices, medicinal products and cross-border healthcare

3.7 Health information and knowledge system, including support for the scientific committees set up in accordance with Commission Decision 2008/721/EC

4. Facilitate access to better and safer healthcare for Union citizens

4.1 European reference networks (ERNs)

4.2 Rare diseases

4.3 Patient safety and quality of healthcare

4.4 Measures to prevent antimicrobial resistance (AMR) and control healthcare-associated infections

4.5 Implementation of EU legislation in the fields of tissues and cells, blood, organs

4.6 Health information and knowledge system to contribute to evidence-based decision-making

The total available budget for 2020 amounts to EUR 65 361 158.

Geographical coverage of programme

All EU countries plus countries indicated in Article 6 of the Programme Regulation (currently Iceland, Norway, Serbia, Moldova and Bosnia and Herzegovina) can participate, meaning that organisations registered in those countries are eligible to participate in the calls for proposals.

Organisations from other countries are encouraged to get involved, but they are not eligible for funding.

The expected results of the work programme include:

- an improved knowledge base for formulating and implementing reforms on retention policies, medical deserts (i.e. isolated or depopulated areas and urban and rural areas with a low concentration of services) and task-shifting in the health workforce;
- knowledge-sharing and discussion on public procurement in the healthcare sector;
- the exchange and implementation of best practices in different areas of health;
- increased vaccination uptake among disadvantaged groups and migrants;
- an NGO contribution to achieving the health programme's objectives;

- an increased understanding of the properties and regulatory implication of novel tobacco products and e-cigarettes;
- a GDPR-compliant data governance model and code of conduct for health(care)-related data; and

Contents

1. Grants

The overall budget set aside for grants under this work programme is EUR 37 155 000.

Criteria for exceptional utility of grants

Articles 7(2), 7(3) and 8(1) of the Programme Regulation set out criteria for assessing whether applications for projects, operating grants and actions co-financed with Member State authorities are of 'exceptional utility' in achieving the programme's objectives.

Such projects, operating grants and actions may receive co-funding of 80% of the total eligible cost, provided that the proposals meet the relevant eligibility and selection criteria for the type of grant as described under its heading (see below) and the following specific criteria for exceptional utility:

Projects

1. at least 60% of the total budget must be used to fund staff. This is to promote capacity-building to develop and implement effective health policies; and
2. at least 30% of the budget must be allocated to at least five Member States whose gross national income (GNI) per inhabitant is less than 90% of the EU average. This is to encourage the participation of stakeholders from Member States with a low GNI;

Operating grants

1. at least 25% of the members or candidate members of the non-governmental bodies[1] must be from Member States whose GNI per inhabitant is less than 90% of the EU average. This is to encourage the participation of non-governmental bodies from Member States with a low GNI; and
2. reducing health inequalities at EU, national or regional level must be cited as an aim in the applicant's mission statement and annual work programme. This is to ensure that co-funded non-governmental bodies contribute directly to one of the main objectives of the programme, i.e. to help Member States reduce health inequalities (Article 2);

Actions co-financed with Member State authorities

1. at least 30% of the budget must be allocated to Member States whose GNI per inhabitant is less than 90% of the EU average. This is to encourage the participation of Member States with a low GNI; and
2. actions must involve bodies from at least 14 countries participating in the programme, of which at least four must have a GNI per inhabitant less than 90% of the EU average. This is to promote wide geographical coverage and the participation of national authorities of Member States with a low GNI

[1] A 'member of a non-governmental body' is a natural or legal person or an entity which does not have legal personality under the applicable national law, became a member through a procedure laid down in the body's statutes and has membership status under the body's statutes. Only full members or candidates to become full members are considered. National members are counted in the same manner as pan-European/umbrella organisation members. Members of the applicant's members' organisations are not accepted as members of the applicant.

1.1 Operating grants

Operating grants are allocated through calls for proposals under an existing framework partnership. These grants are awarded in accordance with the eligibility criteria established by Article 8(2) of the Programme Regulation.

Eligibility and award criteria

Eligibility and selection criteria

The non-governmental bodies with a framework partnership agreement (FPA) for 2018-2021 were assessed in 2017 against the eligibility and selection criteria. In their application for a specific grant agreement (SGA), they must declare on their honour that there have been no subsequent changes affecting those criteria (or their financial independence).

Award criteria for SGAs

- consistency with 4-year work programme annexed to the FPA (10 points; threshold: 6 points):
    - relevance of annual objectives; and
    - contribution to achieving the multiannual objectives;
- quality of proposed activities in year of funding (10 points, threshold: 6 points):
    - quality of planning of annual work; and
    - quality of implementation of activities and operational management; and
- quality of proposed budget for year of funding (10 points, threshold 6 points):
    - relevance of annual budget to activities in annual work plan.

Ranking of proposals

Having an FPA does not guarantee annual co-funding. SGA applications that pass all thresholds will be ranked according to the number of points received. SGAs will be awarded to those ranked highest, up to the available budget allocated for operating grants.

1.1.1 Operating grants

THEMATIC PRIORITY

All objectives of ANNEX I to the Programme Regulation

TYPES OF APPLICANT

Non-governmental bodies holding an FPA for 2018-2021.

OBJECTIVES

Operating grants may be awarded to non-governmental bodies that aim to achieve one or more of the programme's specific objectives.

EXPECTED RESULTS

The non-governmental bodies are expected to: • assist the Commission by providing the information and advice necessary to develop health policies and implement the health programme's objectives and priorities; • work on increasing health literacy and promoting healthy lifestyles; • organise science policy conferences; and • help optimise healthcare activities and practices by empowering patients to provide feedback on their experiences. The Commission encourages the non-governmental bodies to work with the European Solidarity Corps, where appropriate.

ACTIVITIES TO BE FUNDED UNDER EXISTING FRAMEWORK PARTNERSHIP

In 2017, a call for proposals was organised to agree 4-year FPAs for 2018, 2019, 2020 and 2021. Priority areas include: • disease prevention and health determinants; • chronic diseases; • cancer; • dementia; • rare diseases; • HIV/AIDS, tuberculosis, hepatitis;

- access to healthcare; and
- substances of human origin.

Due to the conclusion of these FPAs, no call for proposals will be organised in 2020.

FPA recipients that are eligible for an SGA (operating grant) will be invited to submit an application for an SGA to cover their operating costs for 2021.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Best practice exchange between Member States.

Supporting networks for knowledge-sharing or peer learning.

1.2 Action grants

1.2.1 Action grants following a call for proposal

Call for projects

Grants for projects are allocated through calls for proposals. They are calculated on the basis of eligible costs incurred. The maximum rate for EU co-financing is 60%, but this may rise to 80% if a proposal meets the criteria for exceptional utility.

Eligibility, selection and award criteria

Eligibility criteria

Applicants must be legally established organisations, public authorities or public sector bodies (in particular, research and health institutions, universities and higher education establishments). Only applications from entities established in one of the following countries are eligible:

- EU Member States;
- Iceland and Norway;
- countries that have a bilateral agreement with the EU in accordance with Article 6 of the Programme Regulation; currently[2]:
    - Serbia;
    - Moldova; and
    - Bosnia and Herzegovina.

Applicants participating in a project proposal must be separate legal entities (i.e. be independent from each other) and from at least three different participating countries[3]. Non-compliant proposals will be rejected.

Selection criteria

Financial capacity: Applicants must have stable and sufficient sources of funding to maintain their activity throughout the activity period and to participate in its co-financing. Where the application concerns an action for an amount above EUR 750 000, they must submit an audit report by an approved external auditor certifying their accounts for the last financial year available[4].

For each action, the applicant must declare:

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[2] See Commission website for an updated list of countries: https://ec.europa.eu/health/funding/programme_en

[3] …In line with the Legislative act of the Health Programme to facilitate cooperation between Member States especially paragraph 1,10,19 and 20.

[4] This condition applies only to a beneficiary's first application to an authorising officer responsible in any one financial year.
The financial capacity of public bodies and international organisations will not be subject to the need for verification.

- all sources and amounts of EU funding applied for or received for that action or part thereof, or for that financial year; and
- any other funding applied for or received for that action.

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

Award criteria

Grants are awarded on the basis of a points system; the criteria and sub-criteria are as follows:

- policy and contextual relevance (10 points; threshold: 7 points):
  - relevance of the project to the objectives and priorities of the annual work programme under which the call for proposals is published, in particular:
    - EU added value in the area of public health;
    - appropriate geographical coverage of the proposal; and
    - consideration of the social, cultural and political context;
- technical quality (10 points; threshold: 6 points):
  - quality of evidence base;
  - quality of content;
  - innovative nature, technical complementarity and avoidance of duplication with other EU-level actions;
  - quality of evaluation strategy; and
  - quality of dissemination strategy and action plan;
- management quality (10 points; threshold: 6 points):
  - quality of planning and appropriate task distribution to implement project;
  - relevance of organisational arrangements, including financial management; and
  - quality and complementarity of the partnership; and
- comprehensive and detailed budget (10 points; threshold: 6 points):
  - realistic estimate of person-days per deliverable and per work package; and
  - appropriate budget allocation for evaluation and dissemination activities.

Ranking of proposals

Applications passing all thresholds will be ranked according to the number of points received. The grant agreement(s) will be awarded to those ranked highest, up to the available budget for project grants.

1.2.1.1 Support for health workforce reforms

THEMATIC PRIORITY

3.3 of ANNEX I to the Programme Regulation

TYPES OF APPLICANT

Legally established organisations, public authorities, public sector bodies (in particular, research and health institutions, universities and higher education establishments in Member States and other participating countries).

OBJECTIVE

To support health system reforms focusing on workforce policies, access to care in disadvantaged areas and reorganisation of care delivery.

EXPECTED RESULTS

An improved knowledge base for formulating and implementing such reforms.

ACTIVITIES TO BE FUNDED

The action will finance initiatives on:

1. policies focusing on health workforce retention – initiatives by public authorities responsible for providing healthcare and ensuring an adequate workforce in terms of numbers and skills. This will entail the analytical work and research necessary for national or regional public authorities to develop retention policies;
2. policies addressing access to healthcare in medical deserts; and
3. reorganisation of care delivery (task-shifting and inter-professional coordination) between hospitals and other community and primary healthcare providers. This will entail the analytical work necessary for them to formulate, implement and assess policy projects and provide support.

Activities may focus on:

- monitoring the implementation of selected initiatives;
- creating a community among all participants;
- identifying emerging good practices and facilitating their exchange among participants;
- organising workshops and seminars to ensure joint reflection by participants and

experts, and (where relevant) the cross-fertilisation of ideas across reform areas;

- identifying lessons learned from the initiatives and developing guidelines for public authorities and healthcare providers involved in health workforce reforms; and
- organising events to present lessons learned and guidelines to the relevant public authorities and healthcare providers.

Six to nine initiatives involving interested parties from various Member States will be developed and financed over 2-3 years.

IMPLEMENTATION

Consumers, Health, Agriculture and Food Executive Agency (Chafea)

EU ADDED VALUE

Best practice exchange between Member States.

1.2.1.2 Healthcare public procurement in the EU[5]

THEMATIC PRIORITY

3.2 & 3.4 of ANNEX I to the Programme Regulation

TYPES OF APPLICANT

Legally established organisations, public authorities, public sector bodies (in particular, research and health institutions, universities and higher education establishments in Member States and other participating countries).

OBJECTIVES

To map initiatives, procedures and the organisation of public procurement in the health sector, including the procurement of medicinal products, medical devices and services. To analyse available data in existing formats (e.g. Tenders Electronic Daily data as available through the EU open data repository). To identify and analyse possible further EU actions in public procurement in healthcare, building on the mapping and data analysis work foreseen under the project. To provide opportunities for discussion and knowledge-sharing between actors in the area of public procurement in the healthcare sector in the Member States.

EXPECTED RESULTS

An overview of public procurement in the EU healthcare sector, consolidating existing knowledge to provide a basis for subsequent actions. The project should also analyse what further non-legal EU action (e.g. projects, research, actions) can be taken to facilitate public procurement in the healthcare sector.

ACTIVITIES TO BE FUNDED

The action will provide actors in the area of public procurement in the health care sector in the Member States with an opportunity to come together and reflect on how public procurement practices in the health sector can be optimised against the backdrop of applicable regulatory frameworks (notably EU directive 2014/24/EU on public procurement)): how it can be carried out to maximize

[5] This item has been developed in collaboration on DG Grow and their directive on public procurement.

possible efficiency gains and potential health benefits. To this purpose close involvement of relevant services at the European Commission (notably those dealing with public procurement) will be ensured. The action will organize meetings to provide opportunities for discussion and research on public procurement in the healthcare sector.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Best practice exchange between Member States.

Supporting networks for knowledge-sharing or peer learning.

1.2.1.3 Support for health investment

THEMATIC PRIORITY

3.2 & 3.4 of ANNEX I to the Programme Regulation

TYPES OF APPLICANT

Legally established organisations, public authorities, public sector bodies (in particular, research and health institutions, universities and higher education establishments in Member States and other participating countries).

OBJECTIVES

To identify health-related investments planned under the European Structural and Investment Funds (ESIFs) in 2021-2027.

To develop a methodology and a toolkit to map health needs and health system assets in EU countries. Member States can then use these to prepare health investment strategies, also linked to the use of cohesion policy funds. In order to meet the targets for the strategies and individual Member States.

To organise workshops and events by theme and region to:

- disseminate the methodology, toolkit and educational material;
- promote cooperation and peer learning between Member States; and
- provide training tailored to national contexts and processes.

EXPECTED RESULTS

To raise awareness, develop educational material, provide training (‘train the trainers’) and, ultimately, improve health stakeholders’ capacity to use financial instruments, consolidate multi-source financing and prepare investment plans.

ACTIVITIES TO BE FUNDED

This action will:

- provide an overview of envisaged investments in health-related areas planned for implementation in the 2021-2027 programming period with ESIF support;
- help Member States to identify health needs and map available health system assets; this can then form the basis for strategic investment planning; and

- raise health stakeholders'[6] awareness of, and capacity for accessing, financing, using and combining financial instruments, and preparing investment plans and projects.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Best practice exchange between Member States.

Supporting networks for knowledge-sharing or peer learning.

[6] National/regional authorities, health service providers, healthcare payers, investors and other stakeholders involved in the design, organisation and delivery of health services.

1.2.1.4 Support for the implementation of best practices in the area of mental health

THEMATIC PRIORITY

3.4 of ANNEX I to the Programme Regulation

TYPES OF APPLICANT

Legally established organisations, public authorities, public sector bodies (in particular, research and health institutions, universities and higher education establishments in Member States and other participating countries.

OBJECTIVE

To allow stakeholders other than Member State authorities to support the roll-out of best practices in mental health that have a proven impact and can directly benefit people and health systems in participating countries. To complement action 1.3.2.2 (Support for Member States' implementation of best practices in the area of mental health).

EXPECTED RESULTS

Support from participating organisations for the implementation of best practices in their constituencies. This may involve a pilot project, regional roll-out or even national implementation. Measurable results in terms of mental health outcomes for the target populations.

ACTIVITIES TO BE FUNDED

This action will help stakeholders, in particular non-governmental bodies, support the wider roll-out of validated best practices[7]. These have been discussed with national authorities, who expressed their commitment to introducing those on the shortlist. The action will support the transfer of best practices agreed for inter-country transfer by the Steering Group on Promotion and Prevention (SGPP).

IMPLEMENTATION

[7] These are listed on DG SANTE's best practice portal and are based on DG RTD's selection of implementable projects and previous Commission initiatives.

Chafea

EU ADDED VALUE

Best practice exchange between Member States. Supporting networks for knowledge-sharing or peer learning. Unlocking the potential of innovation in health.

1.2.1.5 Increased access to vaccination for disadvantaged groups, difficult-to-reach groups and migrants

THEMATIC PRIORITY

2.2 of ANNEX I to the Programme Regulation

TYPES OF APPLICANT

Legally established organisations, public authorities, public sector bodies (in particular, research and health institutions, universities and higher education establishments in Member States and other participating countries).

OBJECTIVES

The Council Recommendation on strengthened cooperation against vaccine-preventable diseases[8] welcomes the Commission's decision to identify barriers to access to vaccines and support interventions that increase access for disadvantaged and socially excluded groups, including by promoting health mediators and grassroots community networks, in line with national recommendations.

The objectives of the action are to:

- support Member States to reduce the transmission and outbreaks of vaccine preventable disease by increasing vaccination uptake among disadvantaged groups and migrants;andclose vaccination coverage gaps

EXPECTED RESULTS

Reduced transmission of vaccine-preventable diseases through an increased vaccination uptake among disadvantaged groups and migrants.

ACTIVITIES TO BE FUNDED

The action will support disadvantaged sub-populations, newly arrived migrants and difficult to reach groups to increase their access to vaccination, thereby improving the uptake of both childhood and life-course vaccines in individuals in these sub-populations.

[8] Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases 2018/C 466/01 (OJ C 466, 28.12.2018, p. 1.).

The action will result in two individual projects with different geographical coverage, for which separate calls will be launched. The projects will develop, disseminate and implement, as widely as possible in their geographical area, guidance on increasing access to vaccination for disadvantaged and socially excluded groups.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Addressing cross-border threats to reduce risks and mitigate their consequences.

1.2.1.6 Stakeholder activities to support strengthened cooperation against vaccine-preventable diseases

THEMATIC PRIORITY

2.2 of ANNEX I to the Programme Regulation

TYPES OF APPLICANT

Legally established organisations, public authorities, public sector bodies (in particular, research and health institutions, universities and higher education establishments in Member States and other participating countries).

OBJECTIVES

To implement the commitments made by the member associations of the Coalition for Vaccination, established in March 2019, in areas covered by the Council Recommendation. The Coalition declaration commits members to:

- delivering accurate and transparent information to patients and the general public;
- joining efforts to increase confidence in vaccines and improve vaccination uptake;
- leading by example (i.e. getting vaccinated themselves) to prevent infectious diseases being spread to patients and publicly show confidence in vaccination;
- combating myths and fake information relating to vaccines, including by working with the media;
- exchanging good practices among countries, regions, settings and professions; and
- investing in education and communication and collaborating with peer organisations.

EXPECTED RESULTS

Training (and training of trainers) programmes for health professionals and/or students to improve their communication skills to better address concerns about the safety and benefits of vaccines.

Workshops and regional meetings to present project results.

Awareness-raising campaigns, social media and traditional media activities.

Guidelines, information materials and other tools to help stakeholders achieve their objectives.

ACTIVITIES TO BE FUNDED

Activities to increase access to accurate information about vaccination, confidence in vaccines and vaccination uptake.

Activities enabling Coalition member associations to fulfil their commitments in any of the areas covered by the Council Recommendation.

The action should support projects involving member organisations and partners in individual Member States and other participating countries that aim to develop and implement:

- training (and training of trainers) programmes for health professionals and/or students, to improve their communication skills to better address concerns about the safety and benefits of vaccines;
- workshops and regional meetings to present project results;
- awareness-raising campaigns, social media and traditional media activities; and/or
- guidelines, information materials and other tools to help stakeholders achieve their objectives.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Addressing cross-border threats to reduce risks and mitigate their consequences.

Supporting networks for knowledge-sharing or peer learning.

1.2.2 Action grants directly awarded

Direct grants with international organisations

These grants are to be awarded without a call for proposals.

Award criteria

- technical quality of proposal (10 points; threshold 6 points):
    - quality of content (clear objectives, appropriate methodology, well-defined deliverables, pertinent outcomes); and
    - quality of evaluation strategy (logical framework method and process, well-defined and pertinent output and outcome/impact indicators); and
- quality of planned dissemination actions – management quality (10 points; threshold 6 points):
    - quality of planning and implementation (logical timetable with milestones set, and adequate risk analysis and contingency planning);
    - clearly described management structure and staff competences; and
    - appropriate, well-defined technical and financial reporting procedures and quality controls.

1.2.2.1 Council of Europe — contribution to work of European Pharmacopoeia

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

TYPE OF APPLICANT[9]

Council of Europe

OBJECTIVE

Support for the European Directorate for the Quality of Medicine and Healthcare (EDQM) and the European Pharmacopoeia.

EXPECTED RESULTS

Continued coordination of the network of national control laboratories (OMCL), which verifies the composition of medicinal products as required by EU legislation and develops common terminology for medicines. Development of monographs (i.e. technical specifications for obligatory standards for medicinal products) and analytical testing methods to ensure a high quality of medicines in the EU to protect public health and animal welfare. Harmonisation of quality standards set out in EU pharmaceutical legislation. Facilitation of the placing on the market of medicines in all Member States Greater availability of safe medicines for the whole EU population.

ACTIVITIES TO BE FUNDED

The grant will contribute to the work of the European Pharmacopoeia (part of EDQM). The EU is a party to the Council of Europe's Convention on the European Pharmacopoeia.

IMPLEMENTATION

Chafea

EU ADDED VALUE

[9] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

Addressing issues related to the internal market.

1.2.2.2 OECD – health information support for prioritisation of best practice implementation

THEMATIC PRIORITY[10]

3.7 of ANNEX I to the Programme Regulation

TYPE OF APPLICANT

OECD

OBJECTIVES

To provide the Steering Group for Promotion and Prevention, SGPP, with relevant health information to support decision-making in the context of its prioritised activities. To provide technical expertise to support the development, implementation and monitoring of best practice indicators. To provide technical analysis to help identify research gaps in public health.

EXPECTED RESULTS

Closer alignment of EU funding instruments with identified EU health challenges and the roll-out of targeted best practices by Member States.

ACTIVITIES TO BE FUNDED

The action will provide technical and analytical expertise, mainly in the form of health data analytics and reports to the Expert Group on Health Information and the SGPP, with a view to setting priorities as to best practices to implement, and linking policy priorities with EU-level investment.

IMPLEMENTATION

Chafea

EU ADDED VALUE

[10] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

Best practice exchange between Member States. Supporting networks for knowledge-sharing or peer learning. Unlocking the potential of innovation in health.

1.2.2.3 OECD – support for development and implementation of patient-reported measures

THEMATIC PRIORITY

1.6 of ANNEX I to the Programme Regulation

TYPE OF APPLICANT[11]

OECD

OBJECTIVES

To develop and carry out the patient-reported indicators survey by:

- building on existing national instruments – OECD will identify cross-country measurement efforts and data collection guidelines to generate comparable data for specific conditions, procedures or outcome dimensions (e.g. knee and hip replacement, mental health, pain and fatigue, patient safety); and
- developing an international survey for patients with chronic conditions who are managed in primary care settings, so that their input can enable system-level assessments in outcomes of care and experiences of care.

EXPECTED RESULTS

An increase in the number of countries participating in data collection efforts.

Greater comparability of data through ongoing research and development.

Further expansion of the measurement scope beyond the existing focus areas (including hip and knee replacement, breast cancer and mental health) and support for individual Member States to build the necessary capacity to implement patient-reported outcome measures (PROMs) and participate in international data collection efforts.

The main survey, data collection and an international database with outcome and experience indicators to build on and finalise the OECD's work in this area under the 2019 work programme.

ACTIVITIES TO BE FUNDED

[11] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

Extending and expanding the existing base of international PROM and patient-reported experience measures (PREM) data collections by working with selected Member States to build capacity for measuring existing PROMs. Work will primarily be with patients, clinicians, measurement experts and country representatives, who will provide input for guidelines on international data collection of measures in one or two additional areas, such as cardiovascular and nephrological conditions. This work will contribute to the expanded reporting of measures in the OECD's *Health at a glance 2023* report and on the OECD.stat website.

The action will focus on phase 3 of the international survey work. Building on the field trial carried out under the 2019 work programme, the main survey will be conducted in all participating countries between September 2021 and the end of 2023. Data will be collected in as many European countries as possible. Anonymised datasets will be fed into an international database, allowing comparative analysis at international level[12].

IMPLEMENTATION

Chafea

EU ADDED VALUE

Best practice exchange between Member States.

Supporting networks for knowledge-sharing or peer learning.

Benchmarking to allow informed decision-making at European level.

[12] Current standard health system performance metrics, such as life expectancy and mortality, are not specific enough to allow Member States to take concrete actions. Furthermore, they do not account for large variations in patients' health service experiences and health outcomes.

1.2.2.4 OECD – pharmaceutical innovation and access to medicines

THEMATIC PRIORITY[13]

3.7 of ANNEX I to the Programme Regulation

TYPE OF APPLICANT

OECD Health Division

OBJECTIVES

To allow Member State governments to identify efficiency gains in pharmaceutical spending. To improve Member States' negotiation and monitoring capacities, including for performance-based managed entry agreements. To provide Member States with new information on the feasibility and potential of using financing tools and to help them allocate resources to the right innovation. To help the Commission and Member States create the right conditions for increasing the availability and affordability of medicines, while incentivising innovation and preserving health system sustainability.

EXPECTED RESULTS

Reports and guidance documents that can inform policies at national and European level. Capacity-building workshops and seminars where Member States can share experiences and best practices in pharmaceutical policy performance. Member States are better able to assess their health systems and thus to improve their financial sustainability and address the challenges of scientific breakthroughs.

ACTIVITIES TO BE FUNDED

The action will explore how the current framework can keep pace with scientific developments. By analysing practices around the world, it will look at feasibility and convergence across policies for medicines and other technologies, and address new business models for integrating successful treatments into care. The work will also contribute to mapping the mix of available instruments to promote

[13] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

cooperation between Member States. It will involve stakeholders in order to help build consensus and ensure coordination between EU and national actions.

It will continue to address the access to medicines challenge and will help develop useful policy documents and analysis for Member States, so that they can reflect on how to improve pharmaceutical policies in their health systems.

It will also support the new Commission's work on pharmaceuticals policy and ensure that all EU patients have access to the best available treatment.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Addressing issues related to the internal market.

Joint actions

These grants are to be awarded without calls for proposals[14].

The Joint Actions have to take into account the outcomes of past actions funded by the Health Programme on similar topics. Joint Actions shall take account of the outcomes of ongoing negotiations of a legislative nature.

Eligibility and award criteria

Eligibility criteria

Under Article 195c of the Financial Regulation, grants may be awarded without a call for proposals to:

- bodies identified by a basic act as beneficiaries of a grant; and
- bodies designated by a Member State as being under its responsibility, where a basic act identifies that Member State as a beneficiary.

Under Article 7(2)(a) of the Programme Regulation, grants may be awarded for actions with clear EU added value that are co-financed by:

- authorities responsible for health in the Member States or other participating countries; or
- public sector bodies and non-governmental bodies, as referred to in Article 8(1) of the Programme Regulation[15], acting individually or as a network, mandated by those competent authorities.

Member States' and other participating countries' authorities will be invited to nominate one competent authority[16] responsible for implementing the action on their behalf. The nomination should confirm that:

- the nominated entity is a competent authority; and
- the nominated entity and its affiliated entities[17] are eligible to participate in the action on behalf of the country concerned and under its responsibility.

[14] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

[15] Under Article 8(1), grants for actions referred to in Article 7(2)(a) may be awarded to legally established organisations, public authorities, public sector bodies (in particular, research and health institutions, universities and higher education establishments).

16 A 'competent authority' is a Member State's or participating country's authority responsible for health or a specific health topic, or any other authority on which that competence has been conferred.

[17] 'Affiliated entities' are entities that satisfy the eligibility criteria, do not fall within one of the situations referred to in Articles 136(1) and 141(1) and have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

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

Selection criteria

- financial capacity – applicants must have stable and sufficient sources of funding to maintain their activity throughout the activity period and to participate in its co-financing[18]; and
- operational capacity – applicants must have the professional resources, competences and qualifications required to complete the proposed action.

Award criteria

- contribution to public health in Europe (10 points, threshold: 7 points):
  - quality of joint action's contribution to public health in Europe; and
  - consideration of social, cultural and political context;
- technical quality (10 points, threshold: 6 points):
  - quality of evidence base;
  - quality of content;
  - innovative nature;
  - technical complementarity and avoidance of duplication with other EU-level actions;
  - quality and relevance with regard to promoting dialogue with NGOs in the field;
  - quality of evaluation strategy and plan; and
  - quality of dissemination strategy and plan;
- management quality (10 points, threshold: 6 points):
  - quality of planning and appropriate task distribution;
  - relevance of organisational capacity, including financial management; and
  - quality of partnership; and
- comprehensive and detailed budget (10 points, threshold: 6 points):
  - budget's relevance to activities;
  - consistency of estimated cost per applicant and corresponding activities;
  - realistic estimate of person-days per deliverable and per work package; and
  - appropriate budget allocated for evaluation and dissemination activities.

[18] The financial capacity of public bodies and international organisations will not be subject to the need for verification.

1.2.2.5 Strengthening cooperation on tobacco control between interested Member States and Commission

THEMATIC PRIORITY

1.5 of ANNEX I to the Programme Regulation

TYPE OF APPLICANT[19]

Countries participating in the health programme (competent authorities).

OBJECTIVES

To facilitate the exchange of good practices between Member States in order to improve implementation of the Tobacco Products Directive[20] (TPD) and related implementing and delegated acts in a number of areas of tobacco product and e-cigarette regulation, including laboratory capacity, analysis and assessment. To ensure greater consistency in the application of the TPD to ensure a fair internal market for tobacco and related products. Promote activities consistent with the objectives of the WHO Framework Convention on Tobacco Control.

EXPECTED RESULTS

Identification of best practices for assessing product data and collaborating on data analysis. A better understanding of the properties and regulatory implications of novel tobacco products and e-cigarettes. Increased technical/laboratory capacities and cooperation.

ACTIVITIES TO BE FUNDED

Building on/complementing the ongoing joint action on tobacco control. Identification and dissemination of best practices to develop an effective and comprehensive tobacco control policy.

[19] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

[20] 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 and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1).

Improvement in participating Member States' capacities to assess, report and regulate ingredients of tobacco and related products. Strengthening cooperation between Member States and the Commission in the area of tobacco control.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Best practice exchange between Member States.

1.2.2.6 Support for Member States' implementation of best practices in the area of mental health

THEMATIC PRIORITY

3.4 of ANNEX I to the Programme Regulation

TYPE OF APPLICANT[21]

Countries participating in the health programme (competent authorities).

OBJECTIVES

The roll out by participating Member States of best practices on mental health from our Best Practice Portal which were selected by the Members of the SGPP.

EXPECTED RESULTS

Extending the benefits of these best practices to participating Member States.

ACTIVITIES TO BE FUNDED

Support for participating countries that have expressed their commitment to widespread roll-out of the best practices.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Best practice exchange between Member States. Supporting networks for knowledge-sharing or peer learning. Unlocking the potential of innovation in health.

[21] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

1.2.2.7 Increasing the capacity of national focal points (NFPs) to provide guidance, information and assistance to national applicants on the implementation of the ESF+ health strand and possible support for health-related actions under other EU funding instruments

THEMATIC PRIORITY

All priorities of ANNEX I to the Programme Regulation

TYPE OF APPLICANT[22]

Countries participating in the health programme (competent authorities).

OBJECTIVES

To have well-trained national focal points (NFPs) who understand the health objectives, priorities, procedures and rules, and can interact with other NFPs, EU programmes, stakeholders, etc.

The specific aims are to:

- improve understanding of the possibilities offered by different programmes;
- develop cooperation with NFPs for other EU funding programmes (e.g. Horizon Europe, the Employment and Social Innovation (EaSI) programme, etc.) and cohesion funds managing authorities in order to spread information about EU health funding and its impact;
- organise national knowledge-sharing activities on the results of co-funded actions to raise awareness and take-up of evidence-based practices and increase their impact; and
- help Member States build their capacity to design sustainable implementation actions, irrespective of the source of funding – European Social Fund Plus (ESF+) health strand or other EU funding instruments.

EXPECTED RESULTS

NFPs, Member State authorities and other stakeholders are better able to identify funding instruments. They are also more aware of how best to implement the key recommendations of a given action and how to bridge any gaps.

Improved priority-setting under, and use of, other EU funding mechanisms for health purposes, e.g. Horizon Europe, the EaSI health strand, the cohesion fund, Structural Reform

[22] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

Support Service technical assistance projects, etc.

ACTIVITIES TO BE FUNDED

Support for the health programme NFPs' capacity-building activities, to ensure they are ready to implement the ESF+ health strand, in cooperation with the NFPs for other EU funds.

Identification of mechanisms that will support better coordination between national competent authorities, EU funds (e.g. for research), the EaSI NFP network(s) and the Commission. This could entail joint planning, implementation, monitoring and evaluation at national level.

The activities will focus on:

- information/promotion of EU funding;
- disseminating the results of co-funded actions; and
- feedback to the Commission on the evaluation of the programme, the use of results and the assessment of impact.

The health programme NFPs will complement the SGPP. Their role is defined in Article 15, which provides a legal framework for this action.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning.

1.2.2.8 Ironing out differences in national General Data Protection Regulation (GDPR) implementation in the health sector — development of a code of conduct for data processing (Article 40 GDPR)

THEMATIC PRIORITY

3.2 of ANNEX I to the Programme Regulation

TYPE OF APPLICANT[23]

Countries participating in the health programme (competent authorities).

OBJECTIVES

To examine national implementation of the General Data Protection Regulation (GDPR)[24] in the health sector and ensure that possible differences do not hamper the free flow of health and genetic data across borders. Building on the outcomes of the 2020 preparatory workshops with the Member States' and other experts (in particular the final report on Member States' rules on processing of health data). To provide technical support for the development of guidelines on effective methods for enabling the use of medical information for public health and research to be endorsed by the eHealth Network.To support the e-health network in drawing up guidelines on effective methods for enabling the use of medical information for public health and research. To develop a governance model for data-sharing.

EXPECTED RESULTS

A data governance model. A code of conduct.

ACTIVITIES TO BE FUNDED

[23] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

[24] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

The joint action will examine how Member States have applied the GDPR rules on processing health data and will contribute to ensuring the protection and free flow of data in the health sector.[25]

It will build on the outcomes of the 2020 preparatory workshops with Member States' and other experts (in particular the final report on Member States' rules on processing of health data) and on other existing national and EU initiatives (e.g. BBMRI-ERIC, European research infrastructure for biobanking, eHAction) and it will encourage and support production of a code of conduct for health data processing.

Special attention should be given to the secondary use of health data in Europe, including the application of big data and artificial intelligence in health and long-term care.

The action will provide technical support for the development of guidelines on effective ways of enabling the use of medical information for public health and research, in accordance with Article 14.2(b)(ii) of the Cross-Border (Healthcare) Directive (CBD)24 to be endorsed by the eHealth Network.[26].

It will also propose a governance model for data-sharing at EU level, for primary and secondary use.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning.

[25] With possible participation of health and other public authorities of the Member States.

[26] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

1.2.2.9 EU Health Technology Assessment (HTA) cooperation, with a focus on joint clinical assessments

THEMATIC PRIORITY

3.1 of ANNEX I to the Programme Regulation

TYPES OF APPLICANT[27]

Countries participating in the health programme (competent authorities).

OBJECTIVES

The main overall objective of this action is to ensure that joint clinical assessments continue to be produced until planned legislation on HTA comes into effect.

The action has the following two **specific objectives**:

- overall coordination of HTA cooperation, supporting the work of the relevant EU body to prepare for implementation of the planned HTA legislation – a smooth transition from the current project-based cooperation to the new legal framework is essential to the work of the national HTA authorities/Member State representatives, who will be involved in the relevant EU bodies; and
- ensuring that joint clinical assessments continue to be produced before the legal framework is applicable – continuity of production is important to maintain the momentum and the expertise built up by Member State authorities and relevant stakeholders. The aim is to produce six assessments per year for pharmaceutical products and one for medical technologies. This is broadly in line with the assessments currently produced under the EUnetHTA III joint action. Each assessment must start promptly in parallel with the regulatory procedure and may take up to 18 months. Therefore, bridging the gap may initially involve completing the assessments initiated but not finished under EUnetHTA III.

Technical feasibility: These activities are currently being carried out under EUnetHTA III and a similar working method would be expected once the legislation is in force (see https://eunethta.eu/). However, the action is expected to include a transition to improved working methods and requirements, as set out in future legislation.

EXPECTED RESULTS

[27] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

Overall coordination of HTA, supporting the work of the relevant EU body to prepare for implementation of the planned HTA legislation.

Input to the relevant EU bodies, so that the legal framework is fully operational from the date of application. This will involve preparing reports and working papers, and organising regular and *ad hoc* meetings.

Continued production of joint clinical assessments until the new legal framework is adopted.

ACTIVITIES TO BE FUNDED

Overall coordination of HTA, supporting the work of the relevant EU body to prepare for implementation of the planned HTA legislation.

Ensuring the continued production of joint clinical assessments until the legal framework is applicable.

Six joint clinical assessments per year for pharmaceutical products and one for medical technologies. This may involve finalising any joint clinical assessments already initiated under EUnetHTA III (see above). The secretariat should have the capacity to support the development of additional joint assessments.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning.

Best practice exchange between Member States.

Unlocking the potential of innovation in health.

Other action grants directly awarded

These grants are to be awarded without calls for proposals.

1.2.2.10 Direct grant to presidency holders for two conferences

THEMATIC PRIORITY

Depending on the topics of the conferences, may relate to various thematic priorities of Annex I to the Programme Regulation

TYPE OF APPLICANT[28]

Countries holding the EU presidency in the second half of 2020 (Germany) and the first half of 2021 (Portugal).

OBJECTIVE

Germany and Portugal will each organise a conference on a particular topic in line with the objectives of the health programme.

EXPECTED RESULTS

Greater awareness of the results of projects co-funded by the health programme on topics to be chosen by the two Member States concerned.

ACTIVITIES TO BE FUNDED

Presidency conferences are highly political and gather national and European representatives of the highest level. They are organised exclusively by the Member State holding the EU presidency (Germany in the second half of 2020; Portugal in the first half of 2021). Given the presidency's unique role in EU activities, the Member State responsible for organising the event is considered to have a legal monopoly.

IMPLEMENTATION

Chafea

EU ADDED VALUE

[28] Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

Best practice exchange between Member States. Supporting networks for knowledge-sharing or peer learning.

2. Prizes

An overall budget of EUR 400 000 is reserved for prizes under this work programme.

2.1 EU Health Award for NGOs, cities and schools

THEMATIC PRIORITY

1&2 of ANNEX I to the Programme Regulation

OBJECTIVES

To collect good practices on the selected topic. These may be fed into a database of good practices in various health fields. Selected good practices could serve as models for future action by other stakeholders, national authorities and/or international organisations on priority health issues. To stimulate dialogue among EU NGOs, schools and cities on EU health priorities. To raise the profile of small-scale health stakeholders in the Member States.

EXPECTED RESULTS

Identification of good practices and stimulation of dialogue with stakeholders on key issues at EU and Member State level. Commission interaction with stakeholder organisations to provide health policy support and improve the transparency of, and democratic input into, the policy cycle.

DESCRIPTION

The Health Award aims to reward outstanding initiatives by NGOs, cities and schools that have helped to improve public health in Europe. For 2020, the awards will be as follows: • award on **vaccination** (open to schools and NGOs); and • award on **healthy lifestyles** (open to schools and cities).

AMOUNT OF PRIZE(S)

EUR 100 000 for the winner in each category.

TYPE OF PARTICIPANTS TARGETED BY THE CONTEST

NGOs, schools and cities.

IMPLEMENTATION

Commission (DG SANTE)

EU ADDED VALUE

Best practice exchange between Member States. Supporting networks for knowledge-sharing and peer learning.

3. Procurement

An overall budget of EUR15 565 158 is reserved for procurement under this work programme.

3.1 Enhancing implementation of the cross-border healthcare Directive to ensure patients' rights in the EU

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

OBJECTIVES

To help Member States exchange good practices to improve aspects of the implementation of the Cross-Border Healthcare Directive (CBD), e.g. reimbursement systems, prior authorisation and the use of prior notification. To ensure greater consistency and transparency in the application of the CBD, *inter alia* through legal expertise and analytical support. To improve the Commission's annual collection of Member State data on cross-border patient mobility in healthcare.

EXPECTED RESULTS

Commission guidelines for Member States. Measures to reduce administrative obstacles, improve information for patients and prevent waste in healthcare. Improvement in the Commission's annual collection of Member State data on cross-border patient mobility in healthcare (more user-friendly, complete and informative).

ENVISAGED CONTRACTS

Procurement, under an existing framework contract, of three analytical reports and organisation of three workshops on CBD implementation. The purpose is to gather information and analysis for the Commission's 3-yearly report on CBD implementation, which is due by October 2021.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Best practice exchange between Member States. Supporting networks for knowledge-sharing or peer learning.

3.2 Future-proofing pharmaceutical legislation — study on medicine shortages

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

OBJECTIVES

To provide data on the causes of medicine shortages — by Member State and EU-wide.

To assess whether current legal obligations on marketing authorisation holders, manufacturers and distributors are fit for the intended purpose, including mitigating risks of shortages.

To identify and benchmark possible future actions that could address risks of shortages. These could include:

- greater oversight of the supply chain;
- EU action to restrict parallel export of medicines at risk of shortage;
- reinforcing public service obligations to ensure continuous supply;
- introducing earlier notification of supply interruptions; and
- adding a requirement in the good manufacturing practice (GMP) guidelines for manufacturers to introduce shortage contingency measures (back-up site, second active substance manufacturer, etc.).

To assess potential tools whereby the pharmaceutical industry, Member States, pharmacists and others involved in the supply chain can exchange information.

EXPECTED RESULTS

A data summary on the number of shortages in the EU and their causes.

An assessment of current legal provisions according to the criteria.

An assessment of potential tools for exchanging information.

An outline of the pros and cons of the possible future actions.

ENVISAGED CONTRACTS

Procurement of a study under an existing framework contract.

EU pharmaceutical legislation requires manufacturers to ensure a continuous supply of products placed on the EU market. To help Member States mitigate shortages, it includes a

public service obligation for wholesalers and a requirement to notify any supply interruptions. The action should examine whether this part of the legislation is fit for this purpose and up to date with scientific developments, and ensures public health protection and the proper functioning of the internal market.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Addressing issues related to the internal market.

3.3 Health Policy Platform operation

THEMATIC PRIORITY

3.4 of ANNEX I to the Programme Regulation

OBJECTIVES

To operate an online platform that:

- raises awareness of a wide range of key health policy topics;
- informs and consults stakeholders; and
- encourages them to interact with each other and the Commission.

To organise and promote online webinars on key health topics.

To promote the call to participate in the Health Award.

EXPECTED RESULTS

Greater interaction between health stakeholders and between them and the Commission.

Significant reduction of face-to-face meetings, but more overall interaction.

The platform participants prepare three to four joint statements per year through thematic networks. The stakeholder community then endorses these joint statements.

ENVISAGED CONTRACTS

Procurement, under an existing framework contract, of the services of an external project manager and a content manager.

IMPLEMENTATION

Commission (SANTE C2)

EU ADDED VALUE

Facilitate best practice exchange between Member States.

Supporting networks for knowledge-sharing or peer learning.

3.4 Scientific committees — Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)

THEMATIC PRIORITY

3.7 & 2.2 of ANNEX I to the Programme Regulation

OBJECTIVES

To provide scientific and technical assistance for the functioning of the scientific committees, including literature searches and the organisation of hearings and workshops. To disseminate information about the work of the scientific committees via their website, science factsheets, web summaries, articles in scientific journals, a *Health-EU* newsletter edition fully dedicated to their activities, infographics, annual compilation of opinions and press releases.

EXPECTED RESULTS

SCHEER's activities mainly impact the regulatory work of DG SANTE and DG ENV. However, its opinions are also used as a reference by other EU bodies, Member States, risk-assessment bodies in non-EU countries and international organisations (for policymaking). They also have a big impact on the scientific community (peers) and on risk communication with the general public on sensitive issues such as medical devices and the environment.

ENVISAGED CONTRACTS

Procurement of expert advice under an existing framework contract.

IMPLEMENTATION

Commission (DG SANTE)

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning. Benchmarking to allow informed decision-making at European level.

3.5 Feasibility study – 'monograph' system and other potential alternatives for the environmental risk assessment of veterinary medicinal products

THEMATIC PRIORITY

2.3 of ANNEX I to the Programme Regulation

OBJECTIVES

To study antimicrobial resistance (AMR) and the links between AMR in human and animal health.

The action will examine:

- the feasibility of using the active substance based review ('monograph') system and other potential alternatives for the environmental risk assessment of veterinary medicinal products;
- the possibility of developing a system for sharing comprehensive active-substance-based environmental risk assessment data at EU level;
- how the monograph system would best contribute to protecting public health from the risks posed by the presence of pharmaceuticals (and residues thereof) in the environment; and
- how to improve public access to the main environmental risk assessment results and the exchange of information between Member States, the European Medicines Agency (EMA) and marketing authorisation applicants, in order to make better-informed decisions about protecting human health.

EXPECTED RESULTS

The results of the feasibility study will inform the Commission report under Article 156 of the Regulation on veterinary medicinal products[29].

ENVISAGED CONTRACTS

Procurement of a feasibility study under an existing framework contract.

IMPLEMENTATION

[29] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

Commission (DG SANTE)

EU ADDED VALUE

Addressing cross-border threats to reduce risks and mitigate their consequences.

3.6 Dissemination of the results of the health programme

THEMATIC PRIORITY

All objectives of ANNEX I to the Programme Regulation

OBJECTIVES

To increase the visibility of the results of actions co-funded under the health programme.

To demonstrate the impact of EU investment in public health, in line with the recommendations of the final evaluation of the second programme and the mid-term evaluation of the third programme.

The activities will also take account of the transition between the current programme and the new multiannual financial framework, which includes it in the ESF+ programme.

Activities to be funded include:

- preparing and disseminating material and publications (in electronic form and on paper);
- updating the Chafea website (including editing);
- audio-visual productions on health policy priorities and related action results;
- support for conferences and other stakeholder-related events; and
- other web 2.0 activities.

EXPECTED RESULTS

By highlighting and promoting concrete results/outputs and good practices under previous work programmes, the action will help scale up and cross-fertilise validated good practices across the EU.

In 2020, the selected dissemination activities will put Chafea's strategy into effect, as provided for in the 2018 dissemination plan, with a focus on the priority health areas identified by DG SANTE, e.g.:

- implementing the International Health Regulations and activities in the areas of preparedness, vaccination and AMR;
- public health promotion and prevention of chronic disease, in line with the sustainable development goals; and
- implementation of the Cross-Border (Healthcare) Directive, including HTA, ERNs and health in the digital single market.

ENVISAGED CONTRACTS

Procurement, under direct contracts or using a specific contract under an existing framework, contract of activities that help Chafea disseminate the results of the programme.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning.

3.7 Remuneration of expert evaluators and reviewers

THEMATIC PRIORITY

All priorities of ANNEX I to the Programme Regulation

OBJECTIVES

This action concerns proposals, submitted under different calls, that are evaluated by external experts (peer review) and peer reviews for other financing instruments (quality assurance workshop for actions co-funded with the competent authorities of Member States/other participating countries — joint actions). To ensure the well-founded and transparent selection of proposals to be funded,the experts participate in: • the evaluation of actions under the work programme; and • the technical review of selected running projects under previous work programmes.

EXPECTED RESULTS

Expert evaluations.

ENVISAGED CONTRACTS

Procurement of external reviews through a direct contract or through specific contracts under an existing framework contract. The experts receive EUR 450/day of work. Their travel costs and subsistence allowances (if applicable) are reimbursed according to the Commission’s standard rules.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning.

3.8 Horizontal and policy-related communication activities

THEMATIC PRIORITY

All priorities of ANNEX I to the Programme Regulation

OBJECTIVES

To support policy implementation by highlighting the added value of the Commission's work on health and to raise the profile of the Commission's actions in the area of health.

Communication measures are key to explaining the Commission's health policy objectives and deliverables to key stakeholders, multipliers (media and others) and target sections of the public.

Policy-related communication in 2020 will help achieve the Commission's health policy objectives in line with the Health Commissioner's mission letter, in areas such as pharmaceuticals, health systems, AMR and major chronic diseases such as cancer. They will also contribute to the Commission's corporate agenda on 'a Europe that protects, empowers and defends'.

EXPECTED RESULTS

Communication services and products, such as:

- simplification and regular updating of the health website;
- information material, e.g. factsheets and infographics;
- promotional material for conferences, meetings and stakeholder events, e.g. animations, videos and social media trailers; and
- targeted communication campaigns on specific topics.

ENVISAGED CONTRACTS

Procurement of communication activities under existing framework contracts and through sub-delegation and or co-delegation of some activities to DG DIGIT and DG AGRI.

This action also involves:

- graphic designers producing quality visual communication products (mainly for the website and social media) to make complex topics accessible and messages compelling;
- website management and maintenance – the Commission-wide digital transformation programme will continue throughout 2020. The migration of DG SANTE's public

health website to the Drupal web content management system is coordinated by DG COMM (project owner). DG DIGIT, with which DG SANTE has a memorandum of understanding, is the service provider;

- management, maintenance and update of the public health pages on ec.europa.eu – a permanent web team is needed to carry out editorial and technical tasks; and
- technical support for web development to ensure that DG SANTE has the technical know-how to put in place effective back-office solutions.

IMPLEMENTATION

Commission (DG SANTE).

EU ADDED VALUE

Addressing issues related to the internal market.

Addressing cross-border threats to reduce risks and mitigate their consequences.

Supporting networks for knowledge-sharing or peer learning

3.9 Follow-up to evaluation of orphan and paediatric legislation

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

OBJECTIVES

To assess the strengths and weaknesses of the Paediatric Regulation[30] and the Orphan Regulation[31], both separately and how they interact. To ensure a well-functioning internal market for medicines; To ensure that the legislation caters for innovation in the health sector; and To allow informed decision-making at European level.

EXPECTED RESULTS

An evaluation and (possibly) an impact assessment of the options for follow-up actions.

ENVISAGED CONTRACTS

Procurement of studies through an existing framework contract. These will entail targeted data-gathering and analysis to follow up on the results of the evaluation of the Paediatric and Orphan Regulations. They may also be used for possible impact assessments. A stakeholder event and consultations may be organised to gather data.

IMPLEMENTATION

Commission (DG SANTE)

EU ADDED VALUE

Unlocking the potential of innovation in health. Addressing issues related to the internal market. Benchmarking to allow informed decision-making at European level.

[30] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

[31] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

3.10 Ex post evaluation of third health programme

THEMATIC PRIORITY

All priorities of ANNEX I to the Programme Regulation

OBJECTIVES

To procure an independent study to inform the Commission's final evaluation of the third health programme (Article 21 of the Programme Regulation).

- The study should cover the main outcomes and results over the period, a review of the programme indicators, the main problems encountered in taking up the results of the last mid-term evaluation and the solutions found. The evaluation should include lessons learned facilitating both closure of the current programme and feeding into the implementation and evaluation of future programmesaligning implementation with the objectives in the legal basis, including the thematic priorities in Annex I to the Programme Regulation;
- assessing the programme's impact in supporting Member States, with an emphasis on joint actions;
- assessing the programme's dissemination practices; and
- assessing management tools, including the financing mechanisms for carrying out the programme, and making recommendations for increasing their effectiveness.
- a thorough review of the indicators for monitoring and evaluating;
- identification and assessment of the data sources needed to compile each indicator; and
- an assessment of the technical and statistical features of the indicators.

EXPECTED RESULTS

Evaluation of the third health programme. A baseline for evaluation

ENVISAGED CONTRACTS

Procurement, under an existing framework programme, of an independent study to inform the Commission's final evaluation of the third health programme (2014-2020).

IMPLEMENTATION

Commission (DG SANTE)

EU ADDED VALUE

This action constitutes an obligation for the Commission, which is responsible for producing an evaluation that cover the programme actions in all participating countries.

3.11 Maintenance of the current European medical devices database (Eudamed 2)

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

OBJECTIVE

To ensure the continued maintenance needed of the current Eudamed 2 system before the phasing out once the new European medical device database,Eudamed, (action 3.12).[32] under Regulations (EU) 2017/745 on medical devices[33] and (EU) 2017/746 on in-vitro diagnostic medical devices[34] becomes fully functional and operational.

EXPECTED RESULTS

Ensuring the continued operation of the existing Eudamed 2.

ENVISAGED CONTRACTS

Procurement, under existing framework contracts or direct service contract of the needed maintenance of the current Eudamed 2

IMPLEMENTATION

Commission (DG GROW/DG SANTE)

EU ADDED VALUE

Addressing cross-border threats to reduce risks and mitigate their consequences. Addressing issues related to the internal market.

[32] Eudamed is an information system that the Commission and EU national competent authorities use to exchange information relating to the operation of the current the EU medical devices directives.

[33] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

34 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in-vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

3.12 Development of the future European medical devices database (Eudamed) for the new regulations on medical devices and in vitro diagnostic medical devices

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

OBJECTIVES

The Regulations (EU) 2017/745 on medical devices and (EU) 2017/746 on in-vitro diagnostic medical devices both require that economic operators, notified bodies, sponsors and Member States use a common information system (Eudamed) to exchange information on medical devices and submit certain data. The purpose of the action is to manage two websites to facilitate this: a public one on Europa and another with restricted use.

This database will eventually replace Eudamed 2 (action 3.11)

The objectives of the database are to:

- enhance overall transparency;
- avoid multiple reporting requirements;
- enhance coordination between Member States; and
- streamline and facilitate the flow of information.

EXPECTED RESULTS

The roll-out of the new Eudamed, featuring six electronic systems:

- unique device identification (UDI);
- actor registration;
- certificates;
- clinical investigation/performance study;
- vigilance/post-market surveillance; and
- market surveillance.

ENVISAGED CONTRACTS

Procurement of services under an existing framework contract or direct service contract.

The main activities will include gathering of the required new content and the resulting technical developments of the database.

IMPLEMENTATION

Commission (DG GROW/DG SANTE)

EU ADDED VALUE

Addressing issues related to the internal market. Improving economies of scale (e.g. joint procurement).

3.14 IT audits of European medical devices database (Eudamed)

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

OBJECTIVES

To provide IT audits on Eudamed in accordance with Article 34 of Regulation (EU) 2017/745.

EXPECTED RESULTS

Audit reports on Eudamed.

ENVISAGED CONTRACTS

Procurement under an existing framework contract or via a direct contract.

IMPLEMENTATION

Commission (DG GROW/DG SANTE)

EU ADDED VALUE

Addressing issues related to the internal market. Unlocking the potential of innovation in health.

3.15 Support for expert groups in the field of (public) health

THEMATIC PRIORITY

3.7, 1.6, 2.4 of ANNEX I to the Programme Regulation

OBJECTIVE

To support SGPP expert groups and subgroups. The groups will have time-limited mandates, agreed by the SGPP, to work on questions of immediate interest to the health ministries in the Member States. The action allows technical work to be done without the need to establish a permanent group.

EXPECTED RESULTS

Well-managed expert groups that provide high-quality and punctual support for DG SANTE's work.

ENVISAGED CONTRACTS

Procurement of services under an existing framework contract. In 2020, we expect the following subgroups to use the contract: • SGPP proton therapy subgroup; • a subgroup on patient safety; and • a subgroup on data protection.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Best practice exchange between Member States. Supporting networks for knowledge-sharing or peer learning. Benchmarking to allow informed decision-making at European level.

3.16 IT systems and services in support of public health policies

THEMATIC PRIORITY

All priorities of ANNEX I to the Programme Regulation

OBJECTIVE

To support, facilitate and accelerate the implementation of health policies and activities.

EXPECTED RESULTS

High-quality IT systems, services and collaborative tools that comply with the various stakeholders' requirements and the Commission's digital strategy.

ENVISAGED CONTRACTS

The action concerns:

- the development, support, maintenance and continuous improvement of relevant IT applications; and
- the provision of IT services and administrative collaboration systems/platforms.

It supports EU public health policy/activities, as set out in Article 168 TFEU, and the public health policies relevant to the third health programme.

It covers security, knowledge management, licences and maintenance for central applications and common systems technical support.

The required services and products will be obtained via different types of procurement, including procurement under an existing framework contract.

IMPLEMENTATION

Commission (DG SANTE)

EU ADDED VALUE

Best practice exchange between Member States.

Supporting networks for knowledge-sharing or peer learning.

Addressing cross-border threats to reduce risks and mitigate their consequences.

Addressing issues related to the internal market.

Unlocking the potential of innovation in health.

Benchmarking to allow informed decision-making at European level. Improving economies of scale.

3.17 Call for a framework contract with reopening of competition with independent assessment and evaluation bodies (IAEBs)

THEMATIC PRIORITY

4.1 & 4.2 of ANNEX I to the Programme Regulation

OBJECTIVE

To conclude multiple framework contracts with reopening of competition with independent assessment and evaluation bodies (IAEBs) capable of technically assessing and evaluating ERNs and healthcare providers (Article 12 of the Cross-Border (Healthcare) Directive).

EXPECTED RESULTS

Selecting and awarding (a) contract(s) to one or more IAEBs.

ENVISAGED CONTRACTS

Call for tenders for multiple framework contracts with reopening of competition with IAEBs to assess and evaluate ERNs and healthcare providers.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Unlocking the potential of innovation in health. Supporting networks for knowledge-sharing or peer learning.

3.18 Expert panel on effective ways of investing in health — technical assistance

THEMATIC PRIORITY

3.7 of ANNEX I to the Programme Regulation

OBJECTIVES

To improve cooperation and information exchange among groups and individuals involved in health services on effective ways of investing in health. To promote greater transparency on effective ways of investing in health.

EXPECTED RESULTS

Improved cooperation and information exchange among groups and individuals involved in health services that can lead to more efficient health and care systems, and conditions that are conducive to their long-term sustainability. The expert panel publishes opinions and provides independent, non-binding advice to help achieve sustainable health systems. This advice can inform Member States' and the Commission's policies in this area.

ENVISAGED CONTRACTS

Procurement, under an existing framework contract, of scientific and technical assistance for the expert panel on effective ways of investing in health. The work will include organising hearings with stakeholders, working group meetings and thematic workshops, and direct support for drafting documents, e.g. expertise-gathering, literature searches, editing, translating texts for publications targeting the general public and disseminating the publications.

IMPLEMENTATION

Commission (DG SANTE)

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning. Benchmarking to allow informed decision-making at European level.

3.19 Support for the implementation of health systems performance assessment (HSPA) at national level

THEMATIC PRIORITY

3.2 of ANNEX I to the Programme Regulation

OBJECTIVES

To support the expert group on health systems performance assessment (HSPA) with organisational back-up, additional expertise and help with drafting and disseminating reports. Helping Member States make HSPA part of their health system reform agendas.

EXPECTED RESULTS

Organisation of four face-to-face meetings per year and other working group meetings. Workshops with stakeholders, seminars and policy focus groups for disseminating the group's findings, conclusions and policy recommendations. Advice to Member States that ask for capacity-building support on peer reviews and meetings with experts appointed or identified by the group. The advice could be both strategic and operational (on designing policy action and plans, and on implementing them).

ENVISAGED CONTRACTS

Procurement, under an existing framework contract, of support services for an expert group.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Supporting networks for knowledge sharing or peer learning. Benchmarking to allow informed decision-making at European level.

3.20 Support for Tobacco Products Directive.(TPD) implementation — Eurobarometer

THEMATIC PRIORITY

1.5 of ANNEX I to the Programme Regulation

OBJECTIVES

To support the application and monitoring of the TPD[35] by collecting data on public attitudes to tobacco and related products. To assess the prevalence and pattern of tobacco and e-cigarette use and exposure to smoke in public places. To explore the motivations for smoking and help identify measures to reduce the number of smokers in the EU.

EXPECTED RESULTS

The 2020 Eurobarometer survey will provide essential quantitative input for a report on the application of the TPD, which must be submitted to the European Parliament and the Council by 20 May 2021 (Article 28 TPD). The TPD mentions the Tobacco Eurobarometer as a reference for defining the 'substantial change of circumstances' (point 28 of Article 2 TPD) that can give rise to exemptions, more stringent rules or reviews of specific elements of the Directive (e.g. on products such as pipe tobacco and cigars). The survey would also help monitor whether a 2% drop in consumption has been achieved, as estimated in the impact assessment report, and trends in the uptake and pattern of use of e-cigarettes and other emerging products.

ENVISAGED CONTRACTS

Procurement of the Eurobarometer under an existing framework contract with DG COMM.

IMPLEMENTATION

Commission (DG SANTE)

[35] 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 and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1).

EU ADDED VALUE

Benchmarking to allow for informed decision-making at European and national levels. Addressing issues related to the internal market.

3.21 Support for Tobacco Products Directive.(TPD) implementation — operation of technical group

THEMATIC PRIORITY

1.5 of ANNEX I to the Programme Regulation

OBJECTIVES

To support the TPD's application and monitoring through the smooth operation of technical features that enable the assessment of sensory and, where appropriate, chemical properties of tobacco products that may impart 'characterising flavours' (Article 7 TPD).

EXPECTED RESULTS

Under the prescribed procedure[36], a technical group will provide the Commission and the independent advisory panel with assessments of the sensory and, where appropriate, chemical properties of products to help determine whether they may impart a 'characterising flavour'.

GENERAL DESCRIPTION OF THE CONTRACTS ENVISAGED

Procurement of technical assistance under an existing framework contract or open call for tender.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning. Benchmarking to allow for informed decision-making at both European and national levels. Addressing cross-border threats to reduce risks and mitigate their consequences. Addressing issues related to the internal market.

[36] Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour (OJ L 131, 20.5.2016, p. 48).

3.22 Support for Tobacco Products Directive.(TPD) implementation — better use of IT data

THEMATIC PRIORITY

1.5 of ANNEX I to the Programme Regulation

OBJECTIVE

To support TPD application and monitoring by improving the use and interpretation of tobacco product-related data, as collected through IT systems established by the TPD, in particular the common entry gate (EU-CEG), which allows manufacturers and importers of tobacco products to submit data to the Commission on tobacco and related products placed on the EU market.

EXPECTED RESULTS

The efficient analysis and interpretation of the data will improve understanding of novel products placed on the market, and further encourage the enforcement of the TPD.

ENVISAGED CONTRACTS

Procurement, under an existing framework contract or through an open call for tenders, of support services to assess product-related data collected through IT systems set up under the TPD.

IMPLEMENTATION

Commission (DG SANTE)

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning. Benchmarking to allow for informed decision-making at both European and national levels. Addressing issues related to the internal market.

3.23 Clinical patient management system (CPMS) – licensing and storage costs

THEMATIC PRIORITY

4.1 & 4.2 of ANNEX I to the Programme Regulation

OBJECTIVES

To cover the licensing and storage costs of using the clinical patient management system (CPMS), the software used by ERNs to discuss the diagnosis and therapy of patients with rare and low-prevalence complex diseases in a secure, data-protection-compliant manner. To accommodate the expected increase in the number of CPMS users due to the integration of affiliated partners in existing ERNs.

EXPECTED RESULTS

Coverage of the usage fees for 100 CPMS users per ERN for all 24 ERNs in 2020. Coverage of the storage costs for 325 terabytes of CPMS data.

ENVISAGED CONTRACTS

The procurement, under an existing framework contract, of a service covering the CPMS licensing and storage costs.

IMPLEMENTATION

Commission (DG SANTE)

EU ADDED VALUE

Unlocking the potential of innovation in health. Supporting networks for knowledge-sharing or peer learning.

3.24 Requests for services from independent assessment and evaluation bodies (IAEBs) of European reference network (ERN) members

THEMATIC PRIORITY

4.1 & 4.2 of ANNEX I to the Programme Regulation

OBJECTIVES

Article 9 of Commission Implementing Decision 2014/287/EU[37] sets out criteria for establishing and evaluating ERNs and their members, and for facilitating their exchange of information and expertise. The Commission will appoint an independent assessment body to evaluate applications for membership of existing ERNs. The work will include carrying out eligibility checks and drafting evaluation reports on applications submitted to the ERN Board of Member States (the body responsible for approving new ERN members).

EXPECTED RESULTS

Assessment reports, produced by the independent assessment body, on each application from eligible healthcare providers participating in the 2019 call.

ENVISAGED CONTRACTS

Procurement, under existing multiple framework contracts with reopening of competition with independent assessment body(ies), of services (assessments and necessary technical assistance).

IMPLEMENTATION

Commission (DG SANTE)

EU ADDED VALUE

Unlocking the potential of innovation in health. Supporting networks for knowledge-sharing or peer learning.

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

3.25 Study to support follow-up actions to address shortcomings identified in the evaluation of the EU legislation on blood, tissues and cells (BTC)

THEMATIC PRIORITY

4.5 of ANNEX I to the Programme Regulation

OBJECTIVES

To evaluate five areas of the EU legislation on blood, tissues and cells (BTC) where shortcomings should be mitigated. The study will assess whether:

- the technical provisions are out of date in a rapidly changing sector;
- the oversight provisions are adequate for today's BTC landscape;
- certain groups (donors, children born from in-vitro fertilisation) are inadequately protected;
- innovation is optimally facilitated; and
- sufficiency is optimally addressed.

The study will assess the potential of different options to remedy these issues.

EXPECTED RESULTS

An impact assessment of options for remedying the shortcomings identified in the evaluation of the EU legislation on BTC.

ENVISAGED CONTRACTS

Procurement, under an existing framework contract, of an impact assessment study to support legal follow-up actions to address shortcomings identified in the evaluation of the EU legislation on BTC.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning.

Benchmarking to allow informed decision-making at European level.

Addressing issues related to the internal market.

3.26 Pharmaceutical framework – studies, conferences and working groups

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

OBJECTIVES

To provide data to support a holistic pharmaceutical policy that is conducive to improving the availability and affordability of healthcare and the sustainability of health systems. To produce an adaptable framework that can keep pace with scientific developments and ensure the sustainability of health systems and the functioning of the internal market, while continuing to provide a high level of public health. To improve convergence across policies (on medicines, medical devices, substances of human origin, IP protection, competition, health systems, research and the environment).

EXPECTED RESULTS

Studies, conferences and working groups to complement other data-gathering activities to support pharmaceutical policy development and related initiatives. These will focus on: • the performance of EU law on pharmaceuticals (future-proof regulatory framework and consistency with related policy areas); and • data-gathering on emerging pharmaceutical topics, e.g. AMR, pharmaceuticals in the environment, repurposing of existing medicinal products and information for patients.

ENVISAGED CONTRACTS

Procurement of studies and support services under existing framework contracts or an open call for tender.

IMPLEMENTATION

Chafea

EU ADDED VALUE

Addressing issues related to the internal market.
Unlocking the potential of innovation in health.
Benchmarking to allow informed decision-making at European level.

3.27 Development of the clinical patient management system (CMPS)

THEMATIC PRIORITY

4.1 & 4.2 of ANNEX I to the Programme Regulation

OBJECTIVES

To prepare for, and accommodate the development and future use of, a clinical patient management system (CPMS), a collaboration software used by ERNs in their diagnosis and treatment of rare and low-prevalence complex diseases or conditions across national borders.

EXPECTED RESULTS

Conclusion of a new framework contract.

ENVISAGED CONTRACTS

Launch of a call for tenders for a new framework contract.

IMPLEMENTATION

Commission (DG SANTE)

EU ADDED VALUE

Unlocking the potential of innovation in health. Supporting networks for knowledge-sharing or peer learning.

4. Other actions and/or expenditure

4.1 Administrative agreement with the Joint Research Centre (JRC) to support work on tobacco ingredients, e-cigarettes and security features

THEMATIC PRIORITY

1.5 of ANNEX I to the Programme Regulation

AMOUNT

EUR 100 000

DESCRIPTION

The Commission's Joint Research Centre (JRC) has the necessary expertise and laboratory capacity to support the technical provisions of the TPD, in particular to analyse the ingredients of tobacco products and e-cigarettes. The research requirements for these products include determining their composition and nicotine content, and assessing whether they contain particular ingredients such as flavouring substances. The JRC may also support the monitoring of security features, as required under Article 16 TPD, in light of rapid technological developments in this area.

EU ADDED VALUE

Benchmarking to allow informed decision-making at European level.

4.2 Audits of national contact points for eHealth wishing to join the cross-border exchange of health data

THEMATIC PRIORITY

3.2 of ANNEX I to the Programme Regulation

AMOUNT

EUR 30 000

DESCRIPTION

Reimbursing the expenses of the national experts tasked with helping the Commission to carry out audits of national contact points for eHealth of those Member States wishing to join the cross-border exchange of health data (e-prescriptions; patient summaries) within the eHealth digital service infrastructure (eHDSI).

EU ADDED VALUE

Best practice exchange between Member States. Addressing issues related to the internal market.

4.3 Coordination of rare disease registers for the European reference networks (ERNs)

THEMATIC PRIORITY

4.1 & 4.2 of ANNEX I to the Programme Regulation

AMOUNT

EUR 500 000

DESCRIPTION

In the Council Recommendation of 8 June 2009 on an action in the field of rare diseases, Member States committed to consider supporting at all appropriate levels, including the EU level, for epidemiological purposes, registries and databases, while being aware of independent governance. The JRC has set up a European platform for rare disease registration, which provides operational concepts, metadata repositories and data handling support. As the registries can help the ERNs reach their full capacity, it is necessary to continue to enable each ERN to set up a register in its specific area. It is also necessary to strengthen the coordination of the work of the existing ERNs and their registers to ensure that resources are used in a synchronised way, scaling up the action, achieving mutual benefits and avoiding duplication of similar actions.

EU ADDED VALUE

Improving economies of scale. Supporting networks for knowledge sharing or mutual learning.

4.4 Development of a strategy on e-training, e-learning and education actions for European reference networks (ERNs)

THEMATIC PRIORITY

4.1 of ANNEX I to the Programme Regulation

AMOUNT

EUR 3 200 000

DESCRIPTION

ERNs are being set up to obtain and improve knowledge and the capacity to deal with rare or low prevalence and complex diseases and conditions. The knowledge generated by the ERNs should be made available in a virtual and accessible environment using the most advanced e-training and e-learning methods and solutions. The ERN coordinators and the members of the ERN Board of Member States are currently developing a common strategy on e-training, e-learning and education. This will provide the ERN members with technical support and system for developing their e-training and e-learning strategy. The system should enable users to develop and put into practice training material and to share it with patients, patients' representatives and the extended healthcare providers' community dealing with rare or low prevalence and complex diseases and conditions and others involved in the ERN system.

EU ADDED VALUE

Best practice exchange between Member States. Supporting networks for knowledge sharing or mutual learning.

4.5 Clinical trial EU portal and database

THEMATIC PRIORITY

4.6 of ANNEX I to the Programme Regulation

AMOUNT

EUR 150 000

DESCRIPTION

This action involves IT expertise to:

- allow the European Medicines Agency (the EMA) to monitor the development of an EU portal and database on clinical trials;
- facilitate the dialogue with Member States to develop this tool; and
- enable the Commission to chair a coordination group and a monitoring group composed of EMA representatives and Member States to monitor IT development and ensure the quality of the tool.

EU ADDED VALUE

Best practice exchange between Member States.

Supporting networks for knowledge sharing or mutual learning.

Addressing issues related to the internal market.

4.6 Administrative agreement with the Joint Research Centre (JRC) – healthcare quality, cancer, rare-disease registration, health promotion and prevention of non-communicable diseases

THEMATIC PRIORITY

1 of ANNEX I to the Programme Regulation

AMOUNT

EUR 2 500 000

DESCRIPTION

Thematic area 1: Healthcare quality — improve the quality of breast and colorectal cancer care; Thematic area 2: Cancer information — provide data and indicators on cancer epidemiology at European level by operating and improving the European Cancer Information System; Thematic area 3: EU platform on rare-disease registration — provide data and information on rare diseases, making rare-disease registry data searchable/findable at EU level; link rare-diseases data with other health-related data and maintain/improve the European network of population-based registries for the epidemiological surveillance of congenital anomalies (EUROCAT), and The Surveillance of Cerebral Palsy in Europe (SCPE) registries and surveillance networks; Thematic area 4: Health promotion and prevention of non-communicable diseases — support the work of the SGPP, e.g. evaluating best practices, and the health promotion and disease prevention knowledge gateway.

EU ADDED VALUE

Best practice exchange between countries. Supporting networks for knowledge-sharing or peer learning. Addressing issues related to the internal market. Unlocking the potential of innovation in health. Improving economies of scale.

4.7 Contribution to survey on gender-based violence, its impact on health and the provision of services

THEMATIC PRIORITY

1.1, 1.6 & 4.6 of ANNEX I to the Programme Regulation

AMOUNT

EUR 100 000

DESCRIPTION

To help DG ESTAT conduct an EU-wide survey on gender-based violence in order to provide the EU and Member States with robust and comparable data to help develop and monitor policies in this area. The survey will collect data on the prevalence of violence its specific characteristics and its consequences for victims and society. The financial contribution of the Health Programme will facilitate gathering data on the health consequences of gender-based violence, which includes data on physical injuries, mental health, and usage of the health services after experienced violence. The survey will allow assessing the degree of preparation of the health services to act relevantly to support victims of violence. In a broader context, this Survey will allow for the monitoring the prevalence of gender-based violence based the Istanbul Convention, which recommends providing information on characteristics of victims, including disability. Furthermore, the contribution of the Health Programme to this survey is part of its aim to encourage a 'health in all policies' approach.

EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning. Benchmarking to allow informed decision-making at European level.

4.8 Technical, scientific and related logistical support for medical devices (JRC)

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

AMOUNT

EUR 3 420 000

DESCRIPTION

The JRC will provide technical, scientific and related logistical support for implementing and managing the new legislative framework for medical devices (Regulation (EU) 2017/745) and in-vitro diagnostics (Regulation (EU) 2017/746).

EU ADDED VALUE

Addressing issues related to the internal market.

4.9 Special indemnities for the expert panel on effective ways of investing in health

THEMATIC PRIORITY

3.7 of ANNEX I to the Programme Regulation

AMOUNT

EUR 300 000

DESCRIPTION

This action will cover special indemnities for the work of the expert panel on effective ways of investing in health, an interdisciplinary and independent group set up by the Commission to provide non-binding advice on achieving effective, accessible and resilient health systems. The panel was created following the June 2011 Council Conclusions on health systems, which invited the Commission and EU countries to put in place a system to identify effective ways of investing in health and provide independent advice on health-related questions.

EU ADDED VALUE

Benchmarking to allow informed decision-making at European level.

4.10 Medicinal products for human use, clinical trials for human medicines, substances of human origin — reimbursement of experts' expenses

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

AMOUNT

EUR 102 000

DESCRIPTION

This action will cover the expenses of Member State experts participating with Commission officials in on-the-spot appraisals (audits, fact-finding missions and associated activities) of EU and non-EU countries' official controls systems. The checks concern medicinal products for human use (in particular, active pharmaceutical ingredients), clinical trials for human medicines and substances of human origin.

EU ADDED VALUE

Addressing issues related to the internal market. Supporting networks for knowledge-sharing and peer learning.

4.11 International Council for Harmonisation (ICH) of technical requirements for pharmaceuticals for human use and the International Pharmaceutical Regulators Programme (IRPP)

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

AMOUNT

EUR 600 000

DESCRIPTION

This action is to cover:

- the annual membership fee and reimbursement of Member State experts participating on the Commission's behalf in the working group of the International Council for Harmonisation of technical requirements for pharmaceuticals for human use (ICH)[38]; and
- the annual contribution fee to the International Pharmaceutical Regulators Programme (IRPP)[39].

EU ADDED VALUE

Addressing issues related to the internal market.

[38] The ICH is the international harmonisation forum dealing with standard-setting in the field of medicinal products for human use.

[39] The IRPP is a new initiative that will enable regulatory cooperation between countries and regions in the field of medicinal products (both innovator products and generics).

4.12 EU Health Award and Health Policy Platform – meetings, expenses and materials

THEMATIC PRIORITY

All priorities of ANNEX I to the Programme Regulation

AMOUNT

EUR 200 000

DESCRIPTION

This action is to cover the costs of organising Health Policy Platform meetings and the EU Health Award, including the reimbursement of participants' and jury members' expenses, and the production of communication materials and award materials.

EU ADDED VALUE

Best practice exchange between Member States. Supporting networks for knowledge-sharing or peer learning.

4.13 International cooperation on harmonisation of technical requirements for registration of veterinary medicinal products (VICH) and VICH outreach forum (VOF)

THEMATIC PRIORITY

2.3 & 3.6 of ANNEX I to the Programme Regulation

AMOUNT

EUR 26 000

DESCRIPTION

This action is to cover the costs, each year, of:

- organising one face-to-face meeting of the VICH expert group; and
- ensuring proper participation in the VICH steering committee, once a year; and
- participation in meetings of the concurrent VICH Outreach Forum (VOF).

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is the leading international body and framework for harmonisation and regulatory cooperation in the field of veterinary medicinal products. The EU is a full member of the steering committee.

The VICH Outreach Forum (VOF) is a VICH initiative in conjunction with World Organisation for Animal Health (OIE) to encourage the regulatory bodies of its member countries to take into consideration the VICH Guidelines.

EU ADDED VALUE

Addressing issues related to the internal market.

4.14 Assessment of notified bodies in medical devices field – reimbursement of experts' expenses and associated expenses

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

AMOUNT

EUR 213 000

DESCRIPTION

The action will cover the expenses of Member State experts participating with Commission experts in the joint assessment of notified bodies in the field of medical devices, and associated activities, in particular the training of national experts. These activities are carried out under:

- Article 3 of Commission Implementing Regulation (EU) No 920/2013[40];
- Articles 39-40 and 48 of Regulation (EU) 2017/745 on medical devices; and
- Articles 35-36 and 44 of Regulation (EU) 2017/746 on in-vitro diagnostic medical devices.

EU ADDED VALUE

Addressing issues related to the internal market.

[40] Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8).

4.15 Organisation and management of the Medical Device Coordination Group (MDCG) meetings (DG GROW)

THEMATIC PRIORITY

3.6 of ANNEX I to the Programme Regulation

AMOUNT

EUR 260 000

DESCRIPTION

This action is to organise, and reimburse expenses for, meetings of the Medical Device Coordination Group (MDCG) and its subgroups. The MDCG's tasks are laid down in Regulations (EU) 2017/745 and (EU) 2017/746.

EU ADDED VALUE

Best practice exchange between Member States.
Supporting networks for knowledge-sharing or peer learning.
Addressing cross-border threats to reduce risks and mitigate their consequences.
Addressing issues related to the internal market.
Unlocking the potential of innovation in health.
Benchmarking to allow informed decision-making at European level.
Improving economies of scale.

4.16 Annual membership of the European Observatory on Health Systems

THEMATIC PRIORITY

3.7 of ANNEX I to the Programme Regulation

AMOUNT

EUR 500 000

DESCRIPTION

The European Observatory on Health Systems is a repository of technical expertise and independent analysis and advice. Its analyses contribute to the strengthening of health systems in Member States and support evidence-based policymaking.

EU ADDED VALUE

Best practice exchange between Member States. Supporting networks for knowledge-sharing or peer learning. Benchmarking to allow informed decision-making at European level.

4.17 Joint audit programme (JAP) on good manufacturing practice (GMP) inspections for the Mutual Recognition Agreement on GMP inspection between the EU and the US and other strategic partners

THEMATIC PRIORITY

2.3, 3.6 and 4.5of ANNEX I to the Programme Regulation

AMOUNT

EUR 40 000

DESCRIPTION

This is to cover the costs of:

- inspections on vaccines (human) and plasma-derived products under the EU-US joint audit programme (JAP) for the mutual recognition agreement (MRA) between the EU and the United States and other strategic partners on GMP inspection; and
- some veterinary audits that prepare the US authorities' final assessment of the evaluation of Member State GMP inspectorates.

EU ADDED VALUE

Addressing issues related to the internal market.