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ANNEX

ANNEX

to the

Commission Implementing Decision

on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2021

Table of Contents

Introduction 4

Legal basis 5

Budget overview for 2021 5

Eligibility, selection and award criteria of action grants 9

A. GRANTS 10

1. CRISIS PREPAREDNESS 10

1.1 Support action to mitigate shortages of medicines and improve the security of supply including on COVID-19 therapeutics 10

1.2 Communicable diseases – surveillance and early detection 15

1.3 Support to the implementation of the 2017 EU one health action plan against antimicrobial resistance 17

2. DISEASE PREVENTION 19

2.1 Prevention of non-communicable diseases and related risk factors 19

2.2 Cancer: **Saving lives through sustainable cancer prevention** 25

2.3 Cancer: **Improving Early Detection** 36

2.4 Cancer: **Ensuring access to high standard cancer care diagnosis and treatment** 39

2.5 Cancer: **Improving the quality of life for cancer patients, survivors and carers including reducing inequalities in cancer care and childhood cancers** 49

2.6 Enhance prevention, testing and linkage to care in communicable diseases 57

3. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE 59

3.1 Reforming and Strengthening of health Systems 59

3.2 A Health Workforce to meet health challenges – forecasting and planning for workforce in the healthcare sector 65

3.3 Strengthening the implementation of the legislation on blood, tissue and cells and organs and cooperation between national authorities and professional sector associations 67

3.4 Implementation of Pharmaceutical Legislation and Pharmaceutical Strategy 73

3.5 Enhanced European Reference Networks (ERNs) 77

3.6 Setting up an EU health system resilience testing and support programme 81

4. DIGITAL 83

4.1 Establishment of European Health Data Space – Infrastructure and governance – Secondary use of health data 83

4.2 **Establishment of European Health Data Space – Infrastructure and governance - Primary use of health data** 85

Direct grant to Member States' authorities: Enlargement of the geographic coverage and scope of MyHealth@EU 85

5. OTHER ACTIVITIES 90
B. Procurement 91
1. Crisis Preparedness 91
Communicable Diseases - surveillance systems requirements, early detection, risk assessment 91
Implementation of the EU AMR One Health Action Plan in Member States 92
EU Immunisation Initiative 92
EU preparedness: Capacity and capability assessment and training programmes for health specialists 93
HERA preparatory actions 93
2. Disease Prevention 95
Prevention of non-communicable diseases and related risk factors 95
Disease knowledge gate 95
Tobacco control policy, implementation and enforcement of tobacco control legislation 96
Cross-cutting Cancer actions: Saving lives through sustainable cancer prevention 96
Cross-cutting Cancer actions: Improving early detection of cancer 96
Cross-cutting Cancer actions: Ensuring access to high standard in cancer diagnosis and treatment 97
Cross-cutting Cancer actions: Improving the quality of life for cancer patients, survivors and carers including reducing inequalities in cancer care and childhood cancers 97
3. Health Systems and Healthcare Workforce 98
Digital collaboration and synergies between EU decentralised agencies and DG SANTE – HPAC (Health Policy Agency Collaboration) 98
Strengthening the implementation of the legislation on blood, tissue and cells and organs and cooperation between national authorities and professional sector associations 98
Implementation of Pharmaceutical legislation and Pharmaceutical strategy 99
Implementation of Medical Device and In-Vitro Diagnosis Regulations 99
Preparation and implementation of HTA Regulation – infrastructure hosted by the European Commission 100
Enhanced European Reference Networks (ERNs) 100
4. Digital 101
European Health Data Space - primary use of health data - infrastructure governance 101
European Health Data Space – secondary use of health data - infrastructure governance 102
Recurrent, horizontal and communication activities 103

C. Prizes 103
1. EU Health Awards 103
D. Other actions and expenditure 104
Membership fees to International Organisations and regulatory bodies 104
Various meeting of standing, ad-hoc meetings, committees and other events 104
Expert Evaluators 105
Contribution agreements with decentralised agencies 105

INTRODUCTION

On 24 March 2021, Regulation (EU) 2021/522[1], (the "EU4Health Regulation") was adopted as part of the EU Multiannual Financial Framework for the 2021-2027 period. The EU4Health Regulation established 'the EU4Health Programme'. This marks an important step towards making available instruments and solutions to support Member States in building stronger, more resilient and accessible health systems.

The COVID-19 pandemic has caused an unprecedented health crisis in Europe, with severe socio-economic consequences and human suffering. The national health systems were severely stretched and the EU mechanisms were urged to bolster solutions, coordination of Member States and provide support. The crisis has revealed fragmentations and vulnerabilities of EU health systems; it is a lesson to learn for handling future crises with care, responsibility and unity; and it is an opportunity to emerge with stronger vision, plan and investment to reinforce EU health policies. The EU traditionally complements national health policies by supporting Member States to achieve common objectives, pool resources and overcome shared challenges. Now, with the COVID-19 global pandemic, health has become an urgency and a priority for the EU.

The EU4Health Programme represents an unprecedented level of financial commitment for the EU in health in comparison with previous health programmes. The Programme is EU's response to the current public health emergency that will make a significant contribution to the post-COVID-19 recovery aiming to:

- improve public health in the Union through disease prevention and health promotion, as well as international health initiatives and cooperation;
- protect people from serious cross-border health threats through prevention, preparedness and response to cross-border health threats; complementing national stockpiling of essential crisis-relevant products; and establishing a reserve of medical, healthcare and support staff;
- improve access to medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union and efficient use of medicinal products;
- strengthen the national health systems through improved health data use and re-use, development of digital tools and services, digital transformation of healthcare; enhancing access to healthcare; developing and implementing EU health legislation and evidence-based decision making; and integrated work among Member States' health systems.

The EU4Health Programme is a success story for the EU health policy. Putting health at its core, the Programme is a tangible evidence of the fact that health is now a high EU priority to ensure that the Union remains the healthiest region in the world. The Programme will be the main financial instrument to fund EU initiatives paving the way to the European Health Union under four overarching "strands": 1) crisis preparedness; 2) disease prevention; 3) health systems and healthcare workforce; and 4) digital. Cancer is a major initiative and a transversal strand. Health challenges are cross-dimensional by nature, henceforth EU4Health is implemented in overall consistency, synergy and complementarity with other Union programmes, policies, instruments and actions.

[1] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p.1).

This work programme sets out the priorities and actions for 2021, including the resource allocation, for the implementation of the EU4Health Programme for the Union's action in the field of health (2021-2027). It will work in synergy with and in a manner that complements other Union policies, programmes and funds[2]. In addition, where relevant, the needs of vulnerable groups such as persons with disabilities as well as a gender sensitive approach will be considered.

The EU4Health Programme will provide funding to eligible legal entities from EU Member States, third countries associated to the Programme, or listed in the annual work programme created under Union law or an international organisation such as health organisations, Non-Governmental Organisations (NGOs), the private sector and other eligible legal entities. The funding will be provided in the forms of grants, prizes and procurement, directly by the Commission and by the Health and Digital Executive Agency (HaDEA).

LEGAL BASIS

Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014.

Article 17 of Regulation (EU) 2021/522 requires the Commission to adopt, by means of implementing acts, annual work programmes setting out actions to be undertaken and an indicative allocation of financial resources. The actions should fall under the four general and ten specific objectives identified in Articles 3 and 4 of the Regulation.

BUDGET OVERVIEW FOR 2021

On the basis of the objectives defined in the Regulation (EU) 2021/522, this work programme contains the actions to be financed and the budget breakdown for 2021 indicated in the table below.

TABLE 1: BUDGET LINES

BUDGET LINES	**2021 (EUR)**
06.06 01	311 684 898
TOTAL	**311 684 898**

Funds committed in the work programme are deployed via grants, procurement and prizes, in compliance with the rules set-out in the Financial Regulation.

Grants[3] are financial contributions by way of donation by the Commission in order to finance: an action intended to help achieve a Union policy objective (action grants); the functioning of a body which has an objective forming part of, and supporting, an EU policy (operating grants). The award of a grant follows, in general, a call for proposals' procedure.

[2] For example: Digital Europe Programme, Horizon Europe, the RescEU reserve, the Emergency Support Instrument, the ESF+, the ERDF, the Recovery and Resilience Facility, and Erasmus +, and the European Solidarity Corps Programme.

[3] Article 2(33) and 180(2) of the Financial Regulation.

Procurement[4] is the acquisition of a service by the Commission from an economic operator, which is selected following a call for tenders' procedure.

Prizes[5] are financial contributions given by the Commission as a reward following a contest. They shall promote the achievement of policy objectives of the Union.

[4] Article 2(49) of the Financial Regulation.

[5] Article 2(48) and 206(1) of the Financial Regulation.

TABLE 2: OVERVIEW OF FUNDING BY PROCEDURE

FUNDING	**2021 Budget (EUR)**
Grants	158 300 000
Procurement	148 418 898
Prizes	400 000
Other	4 566 000
TOTAL	**311 684 898**

The implementation of actions is directly managed by the Directorate-General for Health and Food Safety of the European Commission (DG SANTE) unless specified otherwise. In particular, the implementation of actions xxxx.

The Commission delegates powers[6] to implement actions in the xxxx to HaDEA.

The indicative budget allocation per specific objective is presented in the table below.

TABLE 3: BUDGET BY ACTION AREAS

STRANDS & ACTIONS AREAS	**2021 Budget** (EUR)
1. CRISIS PREPAREDNESS	
Support action to mitigate shortages of medicines and improve security of supply including on COVID-19 therapeutics	**12 000 000**
Communicable Diseases - surveillance and early detection	**8 500 000**
2017 EU AMR[7] One Health Action Plan	**8 500 000**
EU Immunisation initiative	**10 000 000**
EU preparedness: Plan, country-profiles platform, interregional elements and ECDC support, risk assessments	**5 500 000**
HERA preparatory actions	**61 500 000**
2. DISEASE PREVENTION	
Prevention of non-communicable diseases and related risk factors	**10 000 000**
Cancer - Saving lives through sustainable cancer prevention	**20 400 000**
Cancer - Improving early detection of cancer	**15 500 000**

6 Article 69 of the Financial Regulation.

7 Antimicrobial resistance

Cancer - Ensuring access to high standard in cancer Diagnosis and treatment	**26 200 000**
Cancer - Improving the quality of life for cancer patients, survivors and carers	**19 400 000**
Disease knowledge gate – Networking and accessing comparable data for policy, monitoring and research	**3 000 000**
Support tobacco control policy and the implementation and enforcement of tobacco control legislation	**1 850 000**
Enhance prevention, testing and linkage to care in communicable diseases	**5 000 000**
3. HEALTH SYSTEMS & HEALTHCARE WORKFORCE	
Reforming and strengthening health systems	**14 500 000**
A health workforce to meet health challenges – forecasting and planning for workforce in the healthcare sector	**7 000 000**
Digital collaboration and synergies between EU decentralised agencies and DG SANTE – Health Policy Agency collaboration	**8 000 000**
Strengthening the implementation of the legislation on blood, tissue, cells and organs and cooperation between national authorities and professional sector associations	**13 000 000**
Implementation of pharmaceutical legislation and pharmaceutical strategy	**9 790 000**
Implementation of Medical Device and In Vitro Diagnostics Regulations	**5 700 000**
Health Technology Assessment (HTA) preparatory actions	**500 000**
Contribution to the Partnership European Observatory of Health Systems and Policies	**700 000**
Enhanced European Reference Networks	**7 800 000**
Setting up an EU health system resilience testing and support programme	**1 500 000**
4. DIGITAL	
Establishment of European Health Data Space – secondary use of health data	**7 050 000**
Establishment of European Health Data Space – primary use of health data	**25 450 000**
5. OTHER ACTIONS	
Recurrent activities, conferences under Council presidencies, support to evaluations	**3 344 898**

ELIGIBILITY, SELECTION AND AWARD CRITERIA OF ACTION GRANTS

The essential **eligibility** criteria of action grants are specified in the calls for proposals.

Grant applicants and partners must meet the following **selection criteria**:

a) applicants and partners must have stable and sufficient sources of funding to maintain their activity throughout the duration of the grant and to participate in its funding ('financial capacity');

b) applicants and partners must have sufficient operational and professional capacities to implement the activities for which co-funding is requested ('operational capacity').

Organisations participating in several projects shall have sufficient financial and operational capacity to implement multiple projects.

The verification of the financial capacity shall not apply to international organisations and public bodies[8].

Proposals will be assessed based on the following **award criteria**:

a) Relevance to the priorities of the call for proposals;

b) Quality of the proposed action;

c) Impact of the proposed action.

Grants shall involve co-financing[9]. The maximum possible rate of EU co-financing is 60% of the total eligible costs of the action, unless specified otherwise in the specific calls for proposals. In cases of exceptional utility the Union contribution may be up to 80% of total eligible costs.

Ranking of proposals will be done according to the criteria described in the calls for proposals.

[8] Article 198(5)(6) of the Financial Regulation.

[9] Article 190(1) of the Financial Regulation.

A. GRANTS

1. CRISIS PREPAREDNESS

1.1 SUPPORT ACTION TO MITIGATE SHORTAGES OF MEDICINES AND IMPROVE THE SECURITY OF SUPPLY INCLUDING ON COVID-19 THERAPEUTICS

Direct grant to Member States authorities: Availability of medicines, shortages and security of supply

POLICY CONTEXT

The new Pharmaceutical Strategy for Europe[10] highlights medicines shortages amongst long-standing weaknesses in the area of medicines, weaknesses that have been further exacerbated and thrown into sharp focus by the current COVID-19 pandemic. The main challenges concern the affordability, access and shortages of medicines as well as the need to support the EU pharmaceutical industry to innovate, tackle its economic and environmental sustainability challenges and be a world leader.

The COVID-19 pandemic has placed significant pressure on the medicines supply chain and has led (particularly in the early stages of the pandemic) to a significant unexpected increase in the hospital demand for certain medicines used for the treatment of COVID-19 disease. This action is to address medicines shortages in general which will in turn help to address crisis situations such as the COVID-19 pandemic. However, the scope of the action is not limited to emergency situations.

The action supports the policy priority to respond to the COVID-19 crisis and the need to address shortages of medicines by contributing to the affordability and accessibility of medicines. It implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products, medical devices and crisis-relevant products and supporting innovation regarding such products (Article 3(c)) through the specific objectives defined in Article 4(b) and (c).

SCOPE AND ACTIVITIES

The objective of this action is to enhance cooperation between Member States in:

- identifying the root causes of observed shortages,
- monitoring and reporting medicine shortages,
- reducing observed medicine shortages and managing them, and
- reducing the likelihood of shortages via preventative strategies.

The work will be divided in several work packages based on a timetable and concrete deliverables.

This action will complement the proposed enhanced role of the European Medicines Agency (EMA) in monitoring and mitigating shortages by supporting the national authorities in putting in place the structure and resources to monitor and mitigate such shortages.

The action aims to:

- establish a coordinating structure to:
    - steer the coordination of the Joint Action and the cooperation between the authorities/institutions involved

[10] COM(2020) 761 final

- organise the work of the different work packages, coordinate mutual learning and ensure the overall consistency of the project
- design and plan the follow up to the outcome and deliverables produced in the context of the joint action
- ensure the timely preparation of the deliverables of the joint action and the contractual reports including the deliverables;

- structure the collection and consolidate the analysis of relevant data and statistics from Member States and other relevant parties; this should include an analysis of the root causes of shortages as reported to Member States;
- develop IT solutions to monitor and manage shortages in the Member States;
- define preventive strategies of shortages based on observed root causes of shortages and agree on an implementation plan in conjunction with EMA and other relevant stakeholders;
- identify, assess and exchange best practices on systems for monitoring supply and responding to shortages; including on aspects that would require developing cooperation across authorities at national level e.g. on procurement pricing and contracting methods; supply chain and manufacturing monitoring; "greening" manufacturing, etc..

EXPECTED RESULTS AND IMPACT

The expected results are the following:

- better coordination of Member States' joint efforts to prevent, mitigate, monitor, manage and report medicines shortages;
- identification, analysis and definition of modalities of implementation and scaling up for a number of best practices and increased professional capacity to address shortages;
- timely availability of and accessibility to data on shortages;
- improved detection and measurement of the decrease in the number of shortages in the Union overall and in particular on the most affected Member States;
- a better understanding of root causes of shortages and assessment of the success of measures previously taken to address them; and
- a strategy for the prevention of shortages and an implementation plan.

This action will support Member States ensuring appropriate cooperation to tackle causes of shortages; mitigate existing shortages of medicines and improve the security of supply, and overall impact on the reduction of systemic shortages, in line with the objectives set in the Pharmaceutical Strategy for Europe.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grants - 01.1.1	Q3-Q4/2021	10 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**

Direct grant to Member States (Joint Action)	HaDEA	Member States' Authorities

Direct grant to grant to Member States authorities to support coordinated and expedited assessment of clinical trials for COVID-19 therapeutics

POLICY CONTEXT

Therapeutics continue to play a critical role in the response to COVID-19 pandemic, they help to save lives, speed up recovery time, and avoid or reduce periods of hospitalisation. However, joint efforts are still needed to ensure access to safe and effective therapeutics. The EU Strategy on COVID-19 Therapeutics[11] highlighted that robust clinical trials are an essential source of evidence for the authorisation of innovative COVID-19 medicines and there is a need for speeding up and coordinate their authorisation.

This action will implement the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products; (Article 3(c)) through the specific objectives defined in Article 4(b) and (c).

SCOPE AND ACTIVITIES

Clinical trials in the EU need an authorisation by Member States before they can start. In the case of multi-country trials this involves several regulatory bodies (competent authorities and ethics committees) in several Member States, often leading to dis-harmonisation and significant delays. Member States established the voluntary harmonisation process for coordination, which is free of charge to sponsors, however the assessments are often long and burdensome, especially in comparison to fast national authorisation in the case of high priority trials (e.g. COVID-19 trials during the pandemic). Furthermore, once the Clinical Trials Regulation becomes applicable in January 2022, it will require close coordination between Member States, which should not jeopardize the speed and efficiency of the authorisation.

This action will support Member States to ensure expedited and coordinated assessments in a voluntary harmonisation-like procedure at present and later under the Clinical trials Regulation. This will allow for a fast authorisation of harmonised clinical trial protocols for COVID-19 therapeutics in the EU and will make Europe more attractive to run large, multi-country trials using master protocols.

EXPECTED RESULTS AND IMPACT

The action is expected to result in an increase in the number of coordinated assessments of COVID-19 therapeutics' clinical trials and on a reduction of the time needed to authorise such trials.

A favourable regulatory environment for larger trials will reduce fragmentation of trial initiatives and will provide a faster way to generate solid evidence to drive rapid marketing authorisations and public health decisions.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget

[11] COM(2021) 355 final

Direct grants - 01.1.1	Q3-Q4/2021	2 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (Joint Action)	HaDEA	Member States' Authorities

1.2 COMMUNICABLE DISEASES – SURVEILLANCE AND EARLY DETECTION

Direct grant to Member States' authorities: Joint action on EU and /national surveillance systems

POLICY CONTEXT

A rapid response to cross-border health threats requires surveillance and monitoring mechanisms to ensure timely detection and identification of such threats. Early lessons learned from the COVID-19 pandemic have shown that the EU's preparedness and response to cross-border health threats were sub-optimal. Real time surveillance, integrated with other areas, is therefore essential to ensure a timely response to current and future health emergencies. This needs to be based on the capacities and requirements at EU and national level.

A digital platform is needed to enable the automated collection of surveillance and laboratories data. This platform will use electronic health records and the application of artificial intelligence for data validation, analysis and automated reporting and will allow for the computerised handling and exchange of information, data and documents.

The action supports the policy priority to respond to the COVID-19 crisis and prepare for future health threats and implements the EU4Health Programme´s general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States in order to cope with serious cross-border threats to health (Article 3(b)) through the specific objectives defined in Article 4(a) and (b).

SCOPE AND ACTIVITIES

This action aims to support Member States and the EU in the implementation of digitalised, integrated surveillance systems at EU and national level, to ensure better detection of early signals for accurate risk assessment and response.

The activities will be carried out by means of a joint action that will work towards upscaling national surveillance systems. This will facilitate building up the required national capacity for the development of interoperable, reliable and modern national surveillance systems, driven by digital transformation.

The joint action will be focused on capacity building, taking into account the needs analysis and the requirements for the development of national surveillance systems, with the creation of a training package. Three regional trainings of trainers (ToT) will be organised to pilot the integrated, real-time surveillance systems. The regional trainings will be hosted by countries with different needs and will promote exchange of experience. Based on the ToT evaluation, a European training package will be developed.

In order to ensure that the new integrated surveillance systems will be taken-up by all Member States, tailored workshops will be organised, with participation of the European Commission, health authorities (at national and regional level), and stakeholders from different sectors (i.e. managers of data sources which can be integrated in the surveillance systems, such as health systems data, pharmaceutical supplies, trade, transport and economics). As a result of these workshops, recommendations on the development of and implementation of real time national surveillance systems will be elaborated.

EXPECTED RESULTS AND IMPACT

The joint action grant is expected to support capacity building at national and EU level, including an integrated surveillance system training package, exchange of experience and drawing up of recommendations.

Using data analytics and artificial intelligence and electronic health data at EU level, based on the strengthening of capacities and requirements at national level, will allow for real time surveillance. Therefore, this action will support EU and national surveillance systems to ensure they are integrated which is essential to ensure a rapid response to cross border health threats.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grants - 02.1.1	Q2-Q3/2021	5 500 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (Joint Action)	HaDEA	Member States' Authorities

1.3 SUPPORT TO THE IMPLEMENTATION OF THE 2017 EU ONE HEALTH ACTION PLAN AGAINST ANTIMICROBIAL RESISTANCE

Call for proposals: Training activities, implementation, best practices

POLICY CONTEXT

Antimicrobial resistance (AMR) – the ability of microorganisms to resist antimicrobial treatments, especially antibiotics – has a direct impact on human and animal health and carries a heavy economic burden due to higher costs of treatments and reduced productivity caused by sickness. AMR is responsible for an estimated 33,000 deaths per year in the EU. It is also estimated that AMR costs the EU €1.5 billion per year in healthcare costs and productivity losses. The Mission Letter to Commissioner Stella Kyriakides defines the need to tackle the rise or return of highly infectious diseases, highlighting the need to focus on the full implementation of the EU One Health Action Plan against Antimicrobial Resistance to work with international partners to advocate for a global agreement on the use of and access to antimicrobials.

In June 2017, the European Commission adopted the EU One Health Action Plan against AMR. With its holistic view on the issue, recognising the link between human and animal health and the role of the environment, it has three key objectives: making the EU a best practice region, boosting research development and innovation and shaping the global agenda. As part of the first objective, the plan pursues a better prevention and control of AMR, among others, by strengthening infection prevention and control measures. As indicated in the plan, the Commission will help to address patient safety in hospital environments by supporting good practices in infection prevention and control.

The action supports the policy priority to prevent and control the rise or return of highly infectious diseases. It implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States in order to cope with serious cross-border threats to health (Article 3(b)) through the specific objectives defined in Article 4(a), (b) and (i).

SCOPE AND ACTIVITIES

This action aims to support enhanced hospital infection prevention and control practices, and the development of best practices and implementation at all levels. It supports the commitment in the EU One Health Action Plan against AMR for the Commission to help to address patient safety in hospital environments by supporting good practices in infection prevention and control and antimicrobial stewardship.

The activities will focus on capacity building, by providing training and implementation of enhanced infection prevention and control (IPC) practices in hospitals and in long-term care facilities and support for further dissemination.

They shall include training as well as other activities to supporting good practice in IPC including: clinical audit and feedback, incentive schemes, sanction schemes, action by regulators, pilots to showcase state-of-the-art antimicrobial stewardship schemes in hospital settings that can be replicated elsewhere using the Cohesion Policy funds or the Recovery and Resilience Facility in the future (e.g. for investments into healthcare infrastructure).

EXPECTED RESULTS AND IMPACT

The support of capacity building is expected to enhance primary and secondary healthcare services.

An improved effectiveness of healthcare systems to prevent infection is likely to result on reductions in healthcare associated infections and improvements in patient safety in relation to antimicrobial resistance in the participating hospitals and long-term care facilities.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals - 3.2.1	Q3-Q4/2021	7 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (action grant)	HaDEA	Public health Authorities; Academia and education establishments, research institutes, hospitals, expert networks including European Reference Networks (ERNs); and Civil society organisations (associations, foundations, NGOs and similar entities)

2. DISEASE PREVENTION

2.1 PREVENTION OF NON-COMMUNICABLE DISEASES AND RELATED RISK FACTORS

Direct grant to Member States authorities: **Joint Action on implementation of best practices and research results on prevention of non-communicable diseases and risk factors**

POLICY CONTEXT

Non-communicable diseases such as cardiovascular diseases, cancers, chronic respiratory diseases and diabetes, represent the major share of the burden of disease in Europe accounting for 80% of deaths. Non-communicable diseases are the result of a combination of genetic, physiological, environmental and behavioural factors. Beyond environmental issues, a number of modifiable risk factors may have important impacts on people's health and mortality; about 60% of deaths are attributed to modifiable risk factors such as alcohol-related harm, smoking, physical inactivity, unhealthy diet, overweight and obesity. Although these deaths are largely preventable, expenditure on preventive care is only around 3% in the EU.

To support the Member States in reaching the health targets of the 2030 Agenda for Sustainable Development and its goals[12], the Commission has established a Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP) to provide advice and expertise to the Commission and to foster exchanges of relevant experience, policies and practices between the Member States on how to tackle the burden of non-communicable diseases in the EU. Best practices which are developed and implemented successfully in one country are transferred more effectively to other countries by EU level actions with a concrete, direct, positive impact for citizens, health systems and society.

The Commission, via the SGPP, facilitates the transfer of best practices between Member States, allowing them to identify the areas where the interventions are needed. In the prioritisation exercise carried out in 2020, Member States indicated that the areas of need included reducing the use of tobacco products, improving the environmental determinants, reducing overweight and obesity and reducing alcohol-related harm. The Commission launched a best practice call for these risk factors in the Best Practice Portal. The Joint Research Centre will evaluate the submitted best practices and will contribute to identifying those to be proposed for implementation and transfer.

This action supports the policy objective of reducing the burden of non-communicable diseases and implements the EU4Health Programme's general objective of improving and fostering health in the Union' (Article 3(a)) through the specific objectives defined in Article 4(a) and (i).

SCOPE AND ACTIVITIES

The aim of this action is to reduce the burden of non-communicable diseases and related risk factors, both at a personal and societal level.

Activities will include the transfer and implementation of best practices and implementable research results on prevention of diseases and related risk factors that have been identified by the Member States, namely on the following disease risk factors:

[12] https://sdgs.un.org/2030agenda

- reducing the use of tobacco products;
- addressing environmental risk factors which have an impact on non-communicable disease prevention;
- reducing overweight and obesity;
- reducing alcohol-related harm.

EXPECTED RESULTS AND IMPACT

The identification and roll out of best practices for implementation through population-level disease prevention interventions is expected to reduce the burden of non-communicable diseases in the Member States.

The short-term impact would be an increased number of public health interventions being scaled up in all Member States and improvements in prevention and management policies related to non-communicable diseases. Networking between experts will also provide benefits for developing and improving public health policies.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grants – 07.1.1	Q2-Q3/2021	7 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (Joint Action)	HaDEA	Member States' authorities

Direct grant to International Organisations: **Direct grant to OECD for collection and support for implementation of innovative best practices and research results on non-communicable diseases**

POLICY CONTEXT

Non-communicable diseases (NCDs) represent a major cause of disability, ill-health, health-related retirement and premature death in the EU, resulting in considerable social and economic costs. According to the Organisation for Economic Co-operation and Development (OECD), every year in the EU, approximately 550 000 people of working age die prematurely from non-communicable diseases. As the leading cause of mortality in the EU, they account for most healthcare expenses.

Risk factors often contribute to the onset of non-communicable diseases and thus present considerable challenges to patients, health systems and society. Late diagnosis, late intervention and inadequate management are also relevant factors adding to the burden caused by these chronic diseases. Given the long progression of most non-communicable diseases and the consequent burden on individuals and on health systems, it is also essential to identify the most efficient and cost-effective ways of managing these diseases and their effects.

The expertise of the OECD will be mobilised to support Member States with the evaluation, transfer and implementation of best and innovative practices on non-communicable diseases.

This action supports the policy objective of reducing the burden of non-communicable disease in the EU and implements the EU4Health Programme's general objective of improving and fostering health in the Union' (Article 3(a)) through the specific objectives defined in Article 4(a) and (i)).

SCOPE AND ACTIVITIES

To evaluate, identify and promote the exchange of effective, evidence-based and innovative actions which, when applied in a systematic way, could contribute towards reducing the burden of non-communicable diseases and addressing public health challenges across the EU.

Activities will comprise collection and expert support to implementation of innovative or promising practices which could address Member States' challenges as prioritised in the SGPP.

These activities will support Member States' efforts to achieve the Sustainable Development Goal 3.4 in particular by providing an identification of proven or promising innovative practices and research results in the priority areas agreed by the SGPP including gap analysis related to addressing key public health concerns.

EXPECTED RESULTS AND IMPACT

This action is expected to result in:

- Collection of innovative and promising interventions addressing key public health challenges identified under the SGPP.
- Transfer of identified best practices implemented to alleviate the burden from non-communicable diseases to all the Member States.

In the short-term this action will result in an increased number of public health interventions being scaled up in all Member States and improvements in prevention and management policies related to non-communicable diseases. Networking between experts will also provide benefits for developing and improving public health policies.

The action will have an impact on the reduction of premature morbidity from such diseases and conditions in the EU, and will reduce the burden from non-communicable diseases and risk factors, both at personal and societal level.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grants – 07.2.1	Q2-Q3/2021	500 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to International Organisations	HaDEA	International organisation (OECD)

Call for proposals: **Action grant to support implementation of best practices on the ground with direct impact on the effort to tackle mental health challenges during COVID-19**

POLICY CONTEXT

Mental health is an integral and essential component of health. It is critical to individual wellbeing, as well as social and economic participation. The heavy individual, economic and social burdens of mental illness are not inevitable.

Given that in 2018, approximately 13.5% of all hospital beds in the EU were psychiatric care beds, addressing mental health challenges through the identification and transfer of best practices and implementation of relevant research results is a necessary priority. Although many European countries have policies and programmes to address mental illness at different ages, the distribution of these actions is uneven throughout the life course. Fewer countries have programmes targeting the mental health of unemployed people and older people. The total costs of mental health account for more than 4% of GDP across EU countries (Health at a Glance: Europe 2018).

Furthermore, the COVID-19 pandemic has immediate and long-term consequences, including on mental health, which require action. The Commission Communication "Short-term EU health preparedness for COVID-19 outbreaks"[13] calls to support the roll-out of practices that address the mental health impact of COVID-19 and have a potential for improvements and to support health professionals as well as non-governmental organisations focusing on mental health challenges during COVID-19. Best practices which are developed and implemented successfully in one country can be transferred to other countries with a concrete, direct, positive impact for citizens, health systems and society.

This action supports the policy objective of reducing the burden of NCDs and meets the following Programme general objective 'Improve and foster health in the Union (Article 3(a)); including the specific objectives in Article 4(a) and (i).

SCOPE AND ACTIVITIES

The aim of the action is to increase awareness, knowledge sharing and capacity building in the area of mental health.

Activities will include the transfer of practices shared within the Health Policy Platform network on 'COVID-19 mental health support'. The Commission has set up a dedicated space on '*COVID19 mental health support*' within the Health Policy Platform. This allows interested stakeholder organisations to come together to discuss and exchange mental health practices and knowledge. Coordinated by Mental Health Europe, the group includes a focus on the needs of specific and/or vulnerable groups, including children and young people.

In addition to exchanging practices, the network on 'COVID-19 mental health support will increase awareness, knowledge sharing and support for health professionals' training including the development of necessary guidance and/or training material, such as video tutorials, manuals etc.

EXPECTED RESULTS AND IMPACT

It is expected that the implementation of best practices to address mental health challenges during the COVID-19 pandemic, for example targeting mental health in schools, will have a direct impact on the effort to reduce the burden in the Member States and will support health professionals and improve awareness.

[13] COM/2020/318 final

The short-term impact would be achieved through an increased number of public health interventions being scaled up in all Member States and improvements in prevention and management policies to address mental health challenges related to the COVID-19 pandemic, and awareness-building and training capacity for health professionals to strengthen the capacity and capabilities to address the mental health impact of health crises. The long-term impact would be identification of solutions to tackle specific mental health issues, both at personal and societal level. Networking between experts will also provide benefits for developing and improving public health policies.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals – 07.4.1	Q2-Q3/2021	750 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action Grant)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks including ERNs Civil society organisations (associations, foundations, NGOs and similar entities) Public authorities and established networks in the field of public health Established networks in the field of public health

2.2 Cancer: SAVING LIVES THROUGH SUSTAINABLE CANCER PREVENTION

Call for proposals: Action grant to civil society organisations to support actions to improve access to Human Papillomavirus vaccination

POLICY CONTEXT

Cervical cancer is one of the most preventable and treatable forms of cancer. The primary cause of cervical cancer is a persistent infection of the genital tract by a high-risk human papillomavirus (HPV) type. HPV is also associated with other cancers, in both the male and female population.

In May 2018, the World Health Organisation (WHO) called for the elimination of cervical cancer as a public health problem, and set a target of 90% coverage of HPV vaccination in girls by 2030 in the Global Strategy Towards the Elimination of Cervical Cancer as a Public Health Problem drafted in 2019. In the EU, HPV vaccination has been gradually introduced in national immunisation programmes since 2007, but policies and vaccination coverage rates vary across countries.

One of the flagship initiatives of Europe's Beating Cancer Plan is to vaccinate at least 90% of the EU target population of girls and to significantly increase the vaccination of boys by 2030, in order to eliminate cervical cancer and other cancers caused by HPV. To support this initiative, the Commission will propose a Council Recommendation on vaccine-preventable cancers to help address cancer risks associated with HPV infection and other infections.

This action supports the implementation of a Europe's Beating Cancer Plan flagship initiative and meets the following Programme general objective 'Improve and foster health in the Union' (Article 3(a)); including the specific objectives in Article 4(a) and (j).

SCOPE AND ACTIVITIES

The aim of the action is to contribute to the implementation of Europe's Beating Cancer Plan, which aims to support Member States' efforts to extend the roll-out of routine HPV vaccination of girls and boys to eliminate cervical cancer and other cancers caused by HPV in the coming decade.

The action will support civil society organisations, including non-governmental organisations, to complement the Member States' actions according to national and regional needs related to HPV vaccination policies and programmes. Those Member States which need to start large-scale HPV vaccination campaigns will receive support through the provision of expertise, best practices, and guidelines covering the planning and roll-out of vaccination campaigns.

These activities may include training on how to successfully communicate with parents and patients on HPV vaccination, how to ensure the provision of consistent messages to the public, and the provision of concrete examples on how to support vaccination in other Member States. Activities may include recommendations for 'bundling' of all adolescent vaccines, including the HPV vaccine, by establishing a policy to check patients' immunisation status at every visit and to always recommend and administer vaccines to those at need. Actions will be designed on the already available evidence-based understanding of behavioural determinants of vaccination acceptance for HPV vaccination.

EXPECTED RESULTS AND IMPACT

The action will contribute to design, plan and roll-out an HPV vaccination campaign at Member State level.

The action will improve vaccination coverage of the target population, and reduce the incidence and mortality for cervical and other cancers caused by HPV.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals – 08.1.1	Q2-Q3/2021	1 200 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action Grant)	HaDEA	Civil society organisations (associations, foundations, NGOs and similar entities)

Direct grant to Member States' authorities: Support actions to assist Member States to roll out large-scale Human Papillomavirus vaccination campaigns

POLICY CONTEXT

Cervical cancer is one of the most preventable and treatable forms of cancer. Its primary cause is a persistent infection of the genital tract by a high-risk human papillomavirus (HPV) type. HPV is also associated with other cancers, in both the male and female population.

In May 2018, the World Health Organisation (WHO) called for the elimination of cervical cancer as a public health problem, and set a target of 90% coverage of HPV vaccination in girls by 2030 in the Global Strategy Towards the Elimination of Cervical Cancer as a Public Health Problem drafted in 2019. In the EU, HPV vaccination has been gradually introduced in national immunisation programmes since 2007, but policies and vaccination coverage rates vary across countries.

One of the flagship initiatives of Europe's Beating Cancer Plan is to vaccinate at least 90% of the EU target population of girls and to significantly increase the vaccination of boys by 2030, in order to eliminate cervical cancer and other cancers caused by HPV, such as head-and-neck and anal cancers.

This action supports the policy objective of reducing the burden of non-communicable diseases and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives defined in Article 4(a) and (i)).

SCOPE AND ACTIVITIES

The aim of this action is to contribute to the implementation of Europe's Beating Cancer Plan, which aims to support Member States' efforts to extend the roll-out of routine HPV vaccination of girls and boys to eliminate cervical cancer and other cancers caused by HPV in the coming decade.

The action will support the exchange of validated best practices between the Member States to ensure a consistent and efficient roll-out of HPV vaccination.

EXPECTED RESULTS AND IMPACT

The action is expected to result in:

- Identification, sharing, and implementation of validated best practices to support Member States in their national efforts to roll-out HPV vaccination.
- Extending the benefits of these best practices to participating Member States.

The action aims to improve vaccination coverage of the target population, and reduce the incidence and mortality for cervical and other cancers caused by HPV.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants – 08.1.2	Q2-Q3/2021	3 800 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**

Direct Grant to Member States (Joint Action)	HaDEA	Member States' Authorities

Call for proposals: Boosting cancer prevention through the use of European Code against Cancer and other concerted actions

POLICY CONTEXT

About 40% of cancer cases in the EU are preventable. Prevention is also the most cost-efficient long-term cancer control strategy. It is estimated that the cancer burden could be reduced by up to one half if scientific knowledge on causes of cancer could be translated into successful preventive actions, including through improving health literacy with the view to increase access to understandable messages on prevention, including by hard-to-reach and marginalised groups of the population.

One of the policy objectives of Europe's Beating Cancer Plan is to improve health literacy on cancer risks and determinants. Initiatives will be launched to give people the information and tools they need to make healthier choices. The European Code against Cancer (the "Code") has a long tradition as a preventive tool aimed at reducing the cancer burden by informing people on how to avoid or reduce carcinogenic exposures, adopt behaviours to reduce their cancer risk, or to participate in organised intervention programmes. The Code needs to be updated to take into account the latest scientific developments and to include new evidence-based recommendations to improve health literacy and to guide national health policies in cancer prevention.

Evidence demonstrates that the message of the Code is only partially reaching the general population. Therefore, there is a need to improve its impact across the EU. To achieve this, there is a need for the appropriate tools and instruments to improve communication with the public and to make use of new communication tools, including taking into account a gender-sensitive approach. An 'EU Mobile App for Cancer Prevention' will be developed to extend the coverage of the Code, to help behavioural interventions through commitment devices and reminders, with the aim of empowering people to manage their own health. To ensure that the Code's messages are understood and translated into practice, communication will be adapted according to the literacy level of the target population, as a low health literacy is one of the social determinants of health associated with cancer-related disparities.

This action supports the implementation of a Europe's Beating Cancer Plan flagship initiative and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives defined in Article 4(a) and (j).

SCOPE AND ACTIVITIES

The aim of this action is to improve access to and understanding of risk factors and health determinants to improve health outcomes for cancer.

Action grants will be provided:

a) to civil society organisations to support the Mobile App development, training, piloting, promotions and use. The usability of the Code's recommendations through the 'EU Mobile App for Cancer Prevention' will be supported by activities covering training, piloting and promotion amongst the general population;

b) to civil society organisations and public health authorities to support 'Health Literacy for Cancer Prevention and Care'. The activities will develop and share best practice to strengthen health literacy in cancer prevention and care programmes, with a focus on disadvantaged groups. Literacy on cancer prevention will be assessed and targeted actions will be supported to improve the degree to which individuals have the capacity to obtain, process, and

understand health information to make informed decisions about cancer prevention. Targeted actions will be designed considering health literacy programs developed within healthcare systems and in the community, for instance, to reduce medical jargon and improve education using plain language, easy-to-understand written materials and teach-back, and also designed plain language written materials, including visuals to provide more culturally and linguistically appropriate health education and enhance web-based information.

EXPECTED RESULTS AND IMPACT

The expected results are:

- Increased usability of 'EU Mobile App for Cancer Prevention' amongst the general population through training, piloting and promotion.
- The launch of a project to increase health literacy for cancer prevention and care.

The action aims to reduce individual cancer risks across the EU through the application of the Code's recommendations.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals Sub-topic A 08.2.3 *Support for mobile app training, piloting, promotion, use* Sub-topic B 08.2.4 *Support for health literacy*	Q2-Q3/2021	1 500 000 EUR 1 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action Grant)	HaDEA	Civil society organisations (associations, foundations, NGOs and similar entities) Public authorities and established networks in the field of public health

Direct grant to International Organisations: Direct grant to the International Agency for Research on Cancer (IARC) to update and boost the Code

POLICY CONTEXT

About 40% of cancer cases in the EU are preventable. Prevention is also the most cost-efficient long-term cancer control strategy. It is estimated that the cancer burden could be reduced by up to one half if scientific knowledge on causes of cancer could be translated into successful preventive actions.

One of the policy objectives of Europe's Beating Cancer Plan is to improve health literacy on cancer risks and determinants. Initiatives will be launched to give people the information and tools they need to make healthier choices. The Code has a long tradition as a preventive tool aimed at reducing the cancer burden by informing people how to avoid or reduce carcinogenic exposures, adopt behaviours to reduce their cancer risk, or to participate in organised intervention programmes. The 4th edition of the Code will be updated to take into account the latest scientific developments and include new evidence-based recommendations to improve health literacy. The updated 5th edition of the Code will guide national health policies in cancer prevention.

This action supports the implementation of the Europe's Beating Cancer Plan and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives defined in Article 4(a) and (j).

SCOPE AND ACTIVITIES

The International Agency for Research on Cancer will be mandated to revise the 4th edition of the Code which is a set of recommendations providing advice on the prevention of cancer, taking into account the principles and the three levels of information of the 4th edition.

- Level I: cancer risk-reduction recommendations to the general public;
- Level II: questions and answers to the general public explaining and providing additional information on the recommendations on how to reduce cancer risk, including messages for specific target groups, and information on interventions to reduce exposure and practical preventive actions on how to best follow the recommendations;
- Level III: scientific justification of the recommendations by means of peer-reviewed analysis of available scientific evidence done by experts.

EXPECTED RESULTS AND IMPACT

The expected result is a revised and updated European Code against Cancer 5th Edition.

The action aims to reduce individual cancer risks across the EU through the application of the Code's recommendations.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grant - 08.2.2	Q2-Q3/2021	1 500 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**

Direct Grant to International Organisations	SANTE	International Organisation (International Agency for Research on Cancer)

Call for proposals: Action grant for initiative 'HealthyLifestyle4All': promotion of healthy lifestyles

POLICY CONTEXT

Lifestyle factors, including healthy diet and physical activity, have long been recognised as potentially important determinants of cancer risk and other non-communicable diseases, such as obesity and cardiovascular disease. The 4th edition of the European Code against Cancer recommends that people have a healthy diet to reduce their risk of cancer and are physically active in everyday life and limit the time spent sitting. However, only 3% of national health budgets is currently spent on health promotion and disease prevention. Therefore, there is a need to support Member States' and stakeholders' actions to promote healthy diets, regular physical activity and the creation of environments where the healthy choice is the easy choice.

The action supports the implementation of the Europe's Beating Cancer Plan objective to improve health promotion through access to healthy diets and physical activity, and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objective defined in Article 4(a)).

SCOPE AND ACTIVITIES

The 'HealthyLifestyle4All' is an initiative which will build upon the Tartu Call for a Healthy Lifestyle. The aim of this initiative will be to promote healthy lifestyles in Europe, in particular amongst children, and its scope will be widened to involve various European Commission services, civil society organisations and the Member States.

This specific action will support 'HealthyLifestyle4All' by strengthening the health literacy component for the promotion of healthy lifestyles with a focus on the school setting, ensuring equal access by all socio-economic groups, and thereby reducing health inequalities. The work will be done through a holistic approach of a healthy school initiative, supporting Member States to create a healthy school environment. The action will support public authorities to increase opportunities for regular physical activity, to promote healthy lifestyles by exchanges of best practices on health literacy, including the health aspects of the EU school scheme and promotion of the European Code against Cancer. The project will develop proposals for effective uptake of successful practices on health literacy and healthy lifestyles in schools.

This action will support activities involving key actors, including the Member States, regional and local governments, education establishments and civil society organisations, to help promote healthy choices and to make them easy and affordable choices. An EU approach will be developed and shared to promote investment in active mobility infrastructures, healthy canteens and to develop outreach measures. Targeted activities of the initiative will complement major EU initiatives, including the European Week of Sport, the EU school scheme, and the EU promotion policy for agri-food products, as well as the Action Plan for the Development of Organic Production[14].

EXPECTED RESULTS AND IMPACT

The expected results include the:

- creation of healthy school environments that promote healthy lifestyles with a spill-over effect on the whole community;

[14] COM/(2021/141

- broadening of cross-sectoral cooperation to promote healthy lifestyles across generations;
- investment in a healthy school environment, including healthy canteens.

The action will help to improve healthy lifestyles of children and young people and consequently reduce the incidence of non-communicable diseases and reduce their impacts on the healthcare systems and social care systems, and ensure the growth and competitiveness of the economy by ensuring a healthy workforce.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals – 08.5.1	Q2-Q3/2021	4 400 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action grant)	HaDEA	Civil society organisations (associations, foundations, NGOs and similar entities) Public authorities Established networks in the field of public health

Call for proposals: Action grant to reduce liver and gastric cancers caused by infections

POLICY CONTEXT

Europe's Beating Cancer Plan aims to ensure access to vaccination against Hepatitis B and to treatments to prevent liver and gastric cancers associated with the Hepatitis C virus and *Helicobacter pylori* infections. According to the European Centre for Disease Prevention and Control (ECDC)[15], when compared with 2011, the mortality rate in 2015 for all cases of hepatocellular carcinoma increased by 5.3%, and progress towards the 2030 elimination target of a 65% reduction in mortality from the 2015 baseline is currently sub-optimal. Gastric cancer associated with *Helicobacter pylori* infection show important gaps in incidence across the EU. Therefore, there is an acute need to address the risk of liver cancer associated with these specific viral infections.

The action supports the implementation of the Europe's Beating Cancer Plan objective to prevent cancers caused by infections, and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives defined in Article 4(a) and (j).

SCOPE AND ACTIVITIES

The action aims to reduce the risk of liver cancers associated with infections caused by the Hepatitis B and Hepatitis C viruses, and the risk of gastric cancers caused by *Helicobacter pylori*.

Each of the three types of infectious agents will be addressed by specific approaches targeted to support vaccination in case of Hepatitis B virus, and to treatment in case of Hepatitis C virus and *Helicobacter pylori*. In addition, specific activities will be dedicated to the early detection of infections, the cornerstone strategy to reduce the risk of liver and gastric cancer caused by the three mentioned pathogens.

EXPECTED RESULTS AND IMPACT

Reduction of incidence of Hepatitis B infections and chronic diseases, and reduction of Hepatitis C and *Helicobacter pylori* related liver and gastric cancers, respectively.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – 08.6.1	Q2-Q3/2021	2 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action grant)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks including ERNs Enterprises in the field of public health Public authorities and established networks in the field of public health

[15] Technical Report, Monitoring the responses to Hepatitis B and C epidemics in EU/EEA Member States, 2019

2.3 Cancer: IMPROVING EARLY DETECTION

Call for proposals: Action grant to support accreditation and certification of quality assurance schemes for breast, colorectal and cervical cancer screening programmes.

POLICY CONTEXT

Cancer screening is necessary for disease risk reduction as it allows detection of cancers at an early stage of invasiveness or even before they become invasive. Screening, therefore is an important tool in limiting morbidity and improving survival rates of those who have developed cancer.

In the EU, countries have adopted significant measures to deliver cancer screening services to their populations as recommended in the Council Recommendation (2003). Screening methodologies are subject to ongoing development and therefore, the application of recommended screening approaches and methodologies should be accompanied by simultaneous assessments of the quality, applicability and cost-effectiveness of new methods.

Quality assurance at all levels of population-based screening programmes can only be ensured if good information about benefits and risks, adequate resources, follow-up with complementary diagnostic procedures and, treatment of those with a positive screening test are available.

The report on the implementation of the Council Recommendation on cancer screening (2017) demonstrated barriers to access to screening services by the population and also to deliver quality-assured services. These barriers introduce serious inequities at the European level and the delivery of quality-assured services in a population-based approach still has to be assessed and addressed through pragmatic public health initiatives, in many countries.

This action supports the implementation of a Europe's Beating Cancer Plan flagship initiative and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives defined in Article 4(a) and (j).

SCOPE AND ACTIVITIES

To support the Member States in the implementation of accreditation and certification schemes for cancer screening programmes in agreement with the European guidelines and quality assurance schemes for population based screening programmes. Activities will include the organisation, implementation and running of accreditation and certification activities making use of guidelines for breast, colorectal and cervical cancer screening, diagnosis and care.

EXPECTED RESULTS AND IMPACT

The expected result is the implementation at national and regional level of accreditation and certification of quality assurance schemes for breast, colorectal and cervical cancer screening

This action will improve the quality and performance of population-based breast, cervical and colorectal cancer screenings, and will reduce the disparity among the Member States associated with an unequal access to quality-assured screening programmes.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – 09.1.2	Q2-Q3/2021	2 000 000 EUR

Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (Action Grant)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks including ERNs Public authorities - Cancer Centres

Call for proposals: Data collection tasks in relation to updating the European Cancer Information System to monitor and assess cancer screening programmes

POLICY CONTEXT

The European Cancer Information System (ECIS) managed by the Joint Research Centre, provides the latest information on indicators that quantify cancer burden across Europe. It permits the exploration of geographical patterns and temporal trends of incidence, mortality and survival data across Europe for the major cancer entities. The survival rate for cervical, breast and colorectal cancer is a key indicator of how effective healthcare systems are in cancer care, reflecting both efficiency in early detection and the effectiveness of treatment. There is a need to further develop the ECIS to enable the monitoring and assessment of cancer screening programmes, which will require the collection of the relevant data from those entities in the Member States responsible for cancer screening.

This action supports the implementation of a Europe's Beating Cancer Plan flagship initiative and implements the EU4Health programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives defined in Article 4(a), (f) and (i).

SCOPE AND ACTIVITIES

This action will support linking the data provided by the cancer screening programmes into ECIS with a view to allowing the permanent monitoring of the screening programmes, including the performance indicators.

The action will consist in the collection of data from entities in the Member States that are responsible for collecting data on cancer screening, in order to provide this data to ECIS, and to develop a piloting of the new ECIS functionality as well as a new separate section to ensure a permanent collection and monitoring of the coverage and performance indicators of population-based cancer screening across the EU.

EXPECTED RESULTS AND IMPACT

The expected result is the collection of the relevant cancer screening data from the Member States.

This action will improve the monitoring of the implementation of cancer screening programmes across the EU, and will have an impact on the implementation of such programmes by providing the Member States with evidence-based information to strengthen their programmes.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals – 09.2.2	Q2-Q3/2021	2 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action grant)	HaDEA	Established networks in the field of public health (responsible for cancer screening)

2.4 Cancer: ENSURING ACCESS TO HIGH STANDARD CANCER CARE DIAGNOSIS AND TREATMENT

Call for proposals: Action grant for 'EU Cancer Treatment Capacity and Capability Mapping' project - Network Comprehensive Cancer Centres (NCCC)

POLICY CONTEXT

The European Guide on Quality Improvement in Comprehensive Cancer Control recommends as a priority the establishment of Comprehensive Cancer Care Networks, and likewise the Horizon Europe Cancer Mission Board recommends the establishment of such structures in all Member States and the networking of these centres at EU-level.

One of the flagship initiatives of Europe's Beating Cancer Plan is the establishment by 2025 of an EU Network linking recognised National Comprehensive Cancer Centres in every Member State, to facilitate the uptake of quality-assured diagnosis and treatment, in agreement with the European guidelines and quality assurance schemes for population based screening programmes, including training, research and clinical trials across the EU. The Cancer Plan aims to ensure that 90% of eligible patients have access to such centres by 2030.

This action supports the implementation of a flagship initiative of Europe's Beating Cancer Plan objective to deliver higher-quality care and implements the EU4HealthProgramme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives defined in Article 4(a) and (g).

SCOPE AND ACTIVITIES

The 'EU Cancer Treatment Capacity and Capability Mapping' action aims to map and share the different capabilities and expertise available across the EU. The action will support the identification of the different capabilities and expertise available across the EU, and build the foundation to regularly identify gaps and needs to be addressed at national and regional level across the EU. At the same time, the EU Network of Comprehensive Cancer Centres will be updated on the EU state of the art on innovation in the area of cancer care, including on cancer workforce training.

EXPECTED RESULTS AND IMPACT

The mapping of EU Cancer Treatment Capacity and Capability in the Member States is expected to result in facilitating the delivery of higher-quality care and reduce inequalities across the EU, while enabling patients to benefit from diagnosis and treatment close to home.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – 10.1.1	Q2-Q3/2021	1 200 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action Grant)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks including ERNs Public authorities and established networks in the field of public health Established networks in the field of public health

Direct grant to Member States' authorities: Network of Comprehensive Cancer Centres (NCCC)

POLICY CONTEXT

The European Guide on Quality Improvement in Comprehensive Cancer Control recommends as a priority the establishment of Comprehensive Cancer Care Networks, and likewise the Horizon Europe Cancer Mission Board recommends the establishment of such structures in all Member States and the networking of these centres at EU-level.

One of the flagship initiatives of Europe's Beating Cancer Plan is the establishment by 2025 of an EU Network linking recognised National Comprehensive Cancer Centres in every Member State, to facilitate the uptake of quality-assured diagnosis and treatment, including training, research and clinical trials across the EU. The Cancer Plan aims to ensure that 90% of eligible patients have access to such centres by 2030.

This action supports the implementation of a flagship initiative of Europe's Beating Cancer Plan objective to deliver higher-quality care and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives defined in Article 4(a) and (g).

SCOPE AND ACTIVITIES

a) Preparatory Action on creation of 'National Comprehensive Cancer Centres and EU Networking:

The aim of this action is to establish or upgrade Comprehensive Cancer Centres in Member States, and the creation of an EU network of the already existing, or newly established Comprehensive Cancer Centres.

The EU Network of National Comprehensive Cancer Centres will support the implementation of quality-assured early detection, screening, diagnosis, treatment, support to cancer survivors, and training of the cancer workforce.

b) Preparatory Action to establish EU Network of Expertise on Cancers and Cancer Conditions:

The aim of this action is to establish new EU Network of Expertise on Cancers and Cancer Conditions.

The EU Network will link with the existing four European Reference Networks for Rare Cancers and a group of new (possibly 5) Networks of Expertise to be funded under this action. This action will prepare the establishment of new Networks of Expertise which will be supported to target specific, challenging cancer conditions, benefiting from cross-border cooperation and EU expertise. These conditions include metastatic diseases, co-morbidities in cancer care, complex cancers with poor prognosis and specific conditions related to genomics in cancer care, integrative oncology, palliative care and survivorship.

EXPECTED RESULTS AND IMPACT

The expected results are the following:

a) The establishment of an EU Network of National Comprehensive Cancer Centres. In addition to the benefit of an improvement in early detection of cancers in the general population, cancer patients and survivors will benefit from better access to all steps of cancer care, from diagnosis to treatment, rehabilitation, palliative care, and support to survivorship, and to innovative approaches that will have the potential to be developed in the future. The

establishment of the EU Network will also help with patient mobility to ensure adequate treatment for patients with complex conditions.

b) The EU will benefit from a unique EU Network that will help in the fight against cancer in a more equitable way and following a modern comprehensive approach, including the showcasing of the highest standards of cancer care at an international level. The unique EU Network will ensure shared high-quality cancer care across the EU, and enable patients to benefit from diagnosis, treatment and care of high EU standards as close as possible to home.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grant - 10.1.3 *Preparatory action on creation of National Comprehensive Cancer Centres and EU Networking*	Q2-Q3/2021	3 000 000 EUR
Direct grant 10.1.2 *Establishment of new EU Networks of Expertise on Cancers and Cancer Conditions*		4 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (Joint Action)	HaDEA	Member State's Authorities

Call for proposals: Action grant for inter-speciality cancer training programme

POLICY CONTEXT

An objective of Europe's Beating Cancer Plan is to build a stronger multidisciplinary cancer workforce. High-quality cancer care depends on a high-quality workforce. Patients deserve the best care possible, and health professionals need support to ensure they can receive training and keep updating their skills throughout their professional lives. An 'inter-speciality cancer training programme' will be launched to help deliver a more skilled and mobile cancer workforce through cross-border training and information-sharing.

This action supports the implementation of the Europe's Beating Cancer Plan objective to ensure a high-quality health workforce and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives defined in Article 4(a) and (g).

SCOPE AND ACTIVITIES

The aim of this action is to update the skills of healthcare professionals and foster the development of a high-quality workforce.

This action will develop an inter-speciality cancer training programme focused on clinical oncology, surgery and radiology specialities, including their nursing services, as well as on patients' quality of life and well-being, including mental, psychosocial and nutritional support, along with patient empowerment.

EXPECTED RESULTS AND IMPACT

The establishment of an inter-speciality cancer training programme is expected to result in the upskilling and re-skilling of healthcare professionals in the areas of clinical oncology, surgery and radiology, and related nursing services.

This action will help the Member States to improve cooperation among their cancer services, by addressing skills gaps and better equipping the health workforce with personnel trained in cancer care.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals 10.2.1	Q2-Q3/2021	5 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action grant)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks including ERNs Public authorities Established networks in the field of public health

Call for proposals: Action grant for project on Quality and Safety of radiation technology in diagnosis and treatment of cancer

POLICY CONTEXT

Europe's Beating Cancer Plan will seek to ensure that people in the EU have the right to access affordable, preventive and curative healthcare of good quality, as called for under the European Pillar of Social Rights. High-quality cancer care depends on a number of factors including access to essential medicines and innovation.

The large majority of current radiation technology for medical applications address cancer diagnosis and treatment, and quality and safety of applications need to be harmonised across the EU as inequality in standards are evident. In addition, the supply of radioisotopes used for cancer diagnosis and treatment is still not constant and subject to interruptions, therefore measures should be developed to ensure their sustainable supply, in particular at long-term.

This action supports the Europe's Beating Cancer Plan objective to ensure high standards in cancer care and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives defined in Article 4(a) and (g).

SCOPE AND ACTIVITIES

The aim of the action is to enhance the quality and safety and optimise radiation technology in medicine.

This action will be implemented in close cooperation with the Strategic Agenda for Medical Ionising Radiation Applications of nuclear and radiation technology (SAMIRA) and the activities will be grouped as follows:

a) Quality and Safety of medical radiation applications

The action will include accompanying activities to build co-operations, support and monitor medical radiations applications, develop evidence-based guidance and practical tools for quality and safety of medical ionising radiation applications, EU dose registry for patients undergoing radiological and nuclear medicine imaging, support to align Euratom / EU action on medical radiological diagnostic and therapeutic equipment, including acceptance and performance testing, technical standards and harmonized reporting of adverse events, align Euratom / EU action on radiopharmaceuticals, and support actions for clinical audit of radiology, nuclear medicine and radiotherapy practices.

b) Workforce education and training

The action will include activities for the EU-wide monitoring of workforce availability, education and training; capacity building in modern radionuclide cancer diagnosis, therapy and 'theragnostics'; and to establish EU curricula and certification schemes in the quality and safety of radiology, nuclear medicine and radiotherapy.

c) Equal access to modern medical radiation technology and interventions

The action will include monitoring of the EU imaging and radiotherapy equipment base and the availability of modern quality and safety features; develop quality and safety criteria and optimised imaging protocols for advanced medical imaging; cover medical radiation technology, including diagnostic and therapeutic application, in national cancer plans; improve evidence for clinical efficacy of novel cancer interventions involving ionising radiation.

EXPECTED RESULTS AND IMPACT

The action will contribute to improve the quality and safety of medical radiation applications, the standards of the workforce in the radionuclear medical sector through education and training, and it will facilitate a more equal access to modern medical radiation technology and interventions.

In addition, the action will help to better align Euratom and EU health actions on important issues such as safety and quality in medical and radiation application and in radiopharmaceuticals. It will contribute to a reduction in discrepancies through a shared and harmonised approach to current radiation technology for medical applications to address cancer diagnosis and treatment.

This action will ultimately benefit cancer patients and the general population in accessing radiology and nuclear medicine services in the Member States.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals – 10.3.1 **Sub-topic A** *Access to quality and safety of medical radiation applications* **Sub-topic B** *Workforce, education and training* **Sub-topic C** *Access to modern medical radiation technology and interventions*	Q2-Q3/2021	3 500 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action grant)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks including ERNs Enterprises in the field of public health Public authorities Established networks in the field of public health

Call for proposals: Action grant for Computer-aided Drug Repurposing for Cancer Therapy Project

POLICY CONTEXT

Despite huge improvements, current anticancer pharmacological therapies are effective in a limited number of cancer cases. Tumours with a high mortality rate, a target not reachable by chemotherapy, and chemotherapy resistance, represent the current challenges of cancer treatments. As the pharmaceutical productivity and drug efficacy in oncology seem to have reached a plateau, 'drug repurposing' – meaning the use of old drugs, already in clinical use, for a different therapeutic indication, is a promising and viable strategy to improve cancer therapy. Opportunities for drug repurposing are often based on occasional observations or on time-consuming pre-clinical drug screenings that are often not hypothesis-driven.

This action supports the implementation of Europe's Beating Cancer Plan objective to ensure high standards in cancer care and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3.a) through the specific objectives defined in Article 4(a) and (g).

SCOPE AND ACTIVITIES

The aim of the action is to identify potential viable effective anti-cancer drugs by making use and piloting 'in-silico drug repurposing' including by using the new big-data technology and high-performance computing while reducing timeframes, and development costs.

The action will launch an EU platform based on 'computational drug networks' to predict, in-silico, the efficacy of approved drugs against relevant cancer targets, as well as to select better responder patients or disease' biomarkers. This will be implemented following a time and cost-effective approach, also building on experiences with repurposing of medicines to treat COVID-19, where High-Performance Computing will be used to rapidly test existing molecules and new drug combinations.

The action will also devise and test models for closer collaboration among stakeholders.

EXPECTED RESULTS AND IMPACT

The launch of an EU platform based on improved 'computational drug networks' is expected to result in a better prediction of the efficacy of approved drugs against relevant cancer targets, as well as to select better responder patients or disease' biomarkers, and to link Member States' structures responsible for cancer treatment and care.

Starting with cancers with poor prognosis and rare cancers, and High-Performance Computing, this work will help to improve the arsenal of anticancer drugs and overcome certain limitations of modern cancer therapies against old and new therapeutic targets in oncology.

The action is likely to increase available anticancer drugs and overcome limitations of current cancer therapies against old and new therapeutic targets in oncology, to the final benefit of patients with poor prognosis and rare cancers.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – 10.4.1	Q2-Q3/2021	3 000 000 EUR

Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (Action grant)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks including ERNs Private entities Public authorities Established networks in the field of public health

Call for proposals: Action grants for 'Cancer Diagnostic and Treatment for All' including 'Genomic for Public Health'

POLICY CONTEXT

Cancer is strongly driven by genomic modifications, and new technological approaches are now available for diagnostic, therapeutic and personalised risk-assessment for prevention. These new approaches have a relevant positive impact on the outcome of cancer care. Therefore there is a need to support the access to such measures while guaranteeing a viable and a high standard of performance of these new techniques.

This action supports the implementation of Europe's Beating Cancer Plan objective to ensure high standards in cancer care and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)); through the specific objectives defined in Article 4(a) and (g).

SCOPE AND ACTIVITIES

The new 'Cancer Diagnostic and Treatment for All' initiative, and the 'Genomic for Public Health' project will help Member States to improve access of individuals and cancer patients and survivors to prevention, diagnosis and treatment of cancer through personalised medicine.

Sub-topic a) - 'Cancer Diagnostic and Treatment for All' initiative: It will use the 'next generation sequencing' technology for a quick and efficient application of personalised cancer diagnosis and treatments. The action will scale up the already available results in genetic profiling of patients and tumour cells allowing Cancer Centres to share such cancer profiles with the view to apply the same or similar diagnostic and therapeutic approaches, to patients with comparable cancer profiles across the EU.

Sub-topic b) - 'Genomic for Public Health' project: which is expected, to scale up the '1+ Million Genome Initiative' results, to translate them in implementable public health measures to address cancer prevention on the base of specific individual genetic profiles, which indicates the susceptibility of individuals to developing certain type of cancers. Therefore the project will open new perspectives to personalised risk-assessment and targeted cancer prevention.

EXPECTED RESULTS AND IMPACT

The 'Cancer Diagnostic and Treatment for All' and the 'Genomic for Public Health' actions will help Member States to develop guidelines and recommendations to better determine who and what to test, organise health services to implement genetic testing, and provide specific education and training for health workers to advance our understanding of cancer control. Ultimately, individuals and cancer patients will benefit on a large-scale of high quality and viable way to prevent cancer, and to diagnosis and treatment.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals **Sub-topic 10.5.1** *Cancer Diagnostic and Treatment for All*	Q2-Q3/2021	3 000 000 EUR
Sub-topic 10.5.2 *Genomics for Public Health project*		3 000 000 EUR

Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (Action grant)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks including ERNs Private entities Established networks in the field of public health

2.5 Cancer: IMPROVING THE QUALITY OF LIFE FOR CANCER PATIENTS, SURVIVORS AND CARERS INCLUDING REDUCING INEQUALITIES IN CANCER CARE AND CHILDHOOD CANCERS

Call for proposals: Action grant to create a 'Cancer Survivor Smart Card'

POLICY CONTEXT

Evidence shows that cancer survivors often report difficulties with communication with oncologists, general practitioners, and nurses, and to establish a link with social services, which can be of relevant importance to reduce the risk of negative quality-of-life outcomes, therefore it is imperative to develop interventions to improve communication between survivors, health and social care providers. The action will be implemented taking into account the assumption that communication between patients and clinicians embraces three core attributes of 'patient-centered' care: (1) consideration of patients' needs, perspectives, and individual experiences; (2) provision of opportunities to patients to participate in their care ('self-management'); and (3) enhancement of the patient-clinician-nursing relationship.

This action supports the implementation of Europe's Beating Cancer Plan objective to improve the quality of life for cancer patients, survivors and carers and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)); through the specific objectives defined in Article 4(a), (f) and (g).

SCOPE AND ACTIVITIES

The aim of the action is to improve the quality of life and health status of cancer survivors, and to address the potential needs of cancer survivors through the development and support for the wide use of new approaches to communication.

A 'Cancer Survivor Smart Card' will link with a 'resource' function to give access to best practices, guidelines, and recommendations specifically targeted to cancer survivors, with a view to helping them to address, or to connect with professionals in different areas, to deal with the most common issues that survivors face, such as insufficient management of late and long-term effects of treatment, unmet psychosocial needs, self-management, pain management, and issues related to rehabilitation, emotional distress, tumour recurrence, and metastatic disease.

The action will support the development, deliver, and usability of a personalised 'Cancer Survivor Smart Card' by 2022. The Smart Card, in the form of an interoperable portable eCard or app, will store certain information related to the monitoring and follow-up of the survivor, including the survivor's clinical history and follow-up. The Smart Card will allow connection with the health professionals responsible for the individual's follow-up, including survivor's general practitioner, to improve healthcare provider and survivor communication on the survivor's worries, questions, and other matters of relevance to improve the survivor's quality of life. The action will involve patients' groups and health and social care providers, in order to apply a participatory and co-creative approach to help with the development of the tool, and to coach a group of 'card-users' to pilot the Smart Card's usage once it has been developed, in preparation for the wider production phase.

EXPECTED RESULTS AND IMPACT

The co-creation, piloting, promotion, and use of the 'Cancer Survivor Smart Card' is expected to improve patient-centred communication between cancer survivors and health care providers, through the wide use of communication tools and the application of new approaches to communication to improve quality of life, promote healing and reducing suffering.

This is likely to improve the quality of life of cancer patients, including of children and young cancer survivors, through dissemination of best practices on issues such as psychological support, self-management, pain management, and professional re-integration. The action will also facilitate the portability and the sharing of data from medical records.

The action will ensure a shared and equal access to high quality information, data, and best practices for cancer survivors across the EU. No country can reach the same results alone, in particular considering that survivorship is still an area that requires additional evidence-based information, and that a sharing approach will ensure the improvement of the quality of life of cancer survivors.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals – 11.1.1	Q2-Q3/2021	1 800 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action grant)	HaDEA	Civil society organisations: associations, foundations, NGOs and similar entities Enterprises in the field of public health Social Media, Press and journalist association IT developer supported by Expert Networks and Civil Society Organisations

Direct grant to International Organisations: Establishment of a Cancer Inequalities Register to map disparities and inequalities between Member States and regions

POLICY CONTEXT

Currently no systematic surveillance and reporting mechanism exists to track the cancer situation in the EU. Building on (mostly) existing data and indicators collected for instance through the augmented European Cancer Information System, and the European Statistical System (Eurostat), the registry, is expected to make available comparable up to date quantitative cancer indicators in a systematic and easily accessible way to the general public and policy-makers.

A number of indicators show major differences in cancer prevention and care between and within Member States. These disparities and inequalities can be seen in access to prevention programmes, in rates of early cancer detection, diagnosis, treatment, survival and measures to improve quality of life of cancer patients and survivors. These inequalities are unacceptable in a European Health Union that seeks to protect everyone.

This action supports the implementation of Europe's Beating Cancer Plan flagship initiative to establish a Cancer Inequalities Registry to reduce cancer inequalities across the EU, and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)) through the specific objectives in Article 4(a) and (i).

SCOPE AND ACTIVITIES

The aim of this action is to make available quantitative data and contextual qualitative analysis of the cancer situation in EU Member States in an easily accessible and digestible form.

To monitor the cancer situation and trends in the EU and Member States, including at sub-national level and for specific socioeconomic groups and to identify areas of potential action and to guide investment decisions on EU and national level.

These activities will provide systematic and comparable information and analysis on the cancer situation in Member States and at EU level, including on inequalities between and within Member States to inform EU investment decisions in cancer control.

The quantitative indicators will be complemented by the regular publication of analytical reports contextualizing the quantitative data, and complemented with qualitative information in relation to EU and national cancer control policies identifying trends, gaps and inequalities, with a view to informing and steering future investment decisions at EU and national level.

EXPECTED RESULTS AND IMPACT

The establishment of a Cancer Inequalities Registry to map key cancer data is expected to result in the identification of inequalities between Member States and regions.

Reduction of measurable disparities in cancer prevention and care across the EU. Quantitative indicators will be complemented by the regular publication of analytical reports contextualizing the quantitative data in relation to EU and national cancer control policies identifying trends, gaps and inequalities as well future investment needs.

A consolidated view of inequality landscape across the EU will assist in targeting investments and interventions at EU, national and regional level to address trends, disparities and inequalities between Member States and regions.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grant – 11.2.2	Q2-Q3/2021	1 500 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to International Organisations	HaDEA	International organisation (OECD)

Direct grant to Member States' authorities: Strengthening e-health, integrating telemedicine and remote monitoring in health and care systems for cancer prevention and care

POLICY CONTEXT

Disparities in cancer prevention and care are also linked to geographical context, such as in rural and difficult to reach areas of countries, which are disadvantaged in comparison with other territorial settings. The COVID-19 pandemic has even further hit the most disadvantaged groups in our society, including cancer patients. Isolation and containment measures due to the pandemic have affected their follow-up care and quality of life. The EU is working to ensure continued and equitable access to care, including in crisis situations, and the activities under this action are a key part of these efforts.

Telemedicine has also been acknowledged in responding and coordination of actions in epidemic situations, including in COVID-19 response that is severely impacting cancer care, through online consultations and real-time clinical data exchange, and providing technical support to the emerging need for big-data analysis and digitalisation.

This action supports the implementation of Europe's Beating Cancer Plan objective to reduce cancer inequalities across the EU, and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)); through the specific objectives defined in Article 4(a) and (b).

SCOPE AND ACTIVITIES

The objective of this action is to strengthen and integrate telemedicine and remote monitoring in health and care systems and to promote the virtual consultation model of the ERNs.

Activities in this area will include strengthening and integrating telemedicine and remote monitoring in health and care systems building on innovative approaches and by deployment actions with EU funds.

Telemedicine services will help individuals and providers to meet the needs of rural and remote residents, by enabling remote consultations, in-home monitoring, outsourced diagnostic analysis, remote specialist consultations, and direct-to-consumer telemedicine, for instance through virtual consultations for urgent care needs. Furthermore telemedicine activities will help in improving the response to rapid spread of epidemics, and their impact on cancer care, through the ability of delivering clinical care in a timely manner and through a more efficient coordination amongst health authorities, hospitals, and patients.

Additionally, the already established virtual consultation model of the ERNs will be upgraded using the mechanisms and instrument which will be developed to improve the knowledge-sharing among healthcare professionals.

EXPECTED RESULTS AND IMPACT

It is expected that the exchange of best practices on using digital tools will provide assistance to individuals and patients during serious cross-border emergencies and health crisis in particular those in remote and rural areas.

Such improvement of cancer care in remote areas will (i) allow for a better response in case of a rapid spread of an epidemic and in crisis situations, where isolation of patients will be an urgent requirement to respond to events; (ii) increase capability and capacity to communicate between cancer services during an emergency situation and health crisis; (iii) improve knowledge of cancer care workforce in the virtual consultation of patients and survivors resident in areas that are difficult to be reached, as well as improving preparedness to respond

to emergency and crisis situations; (iv) increase efficiency of the virtual consultation model of the ERNs, and promotion; and (v) increase communication to support knowledge-sharing among healthcare professionals.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grant – 11.3.1	Q2-Q3/2021	4 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (Joint Action)	HaDEA	Member States' Authorities

Call for proposals: Action grant for EU Network of Youth Cancer Survivors

POLICY CONTEXT

In 2020, over 15,500 children and adolescents were diagnosed with cancer, with over 2,000 young patients losing their lives to it. In fact, cancer is the principal cause of death by disease in children beyond the age of one. Up to 30% of children affected by cancer suffer severe long-term consequences. The number of childhood cancer survivors continues to grow and comprehensive care, treatment and follow-up are essential to help young patients make a good recovery and enjoy an optimal quality of life. There is a need of multidisciplinary and proactive approaches to healthy cancer survivorship, as well as improved social networking and establishment of communication and information sharing platforms tailored specifically to young adult cancer survivors, which are well demonstrated instruments to improve the quality of life of children and young adult cancer survivors.

This action supports the implementation of Europe's Beating Cancer Plan objective to put childhood cancer under the spotlight and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3(a)); through the specific objectives in Article 4(a), (c), (g) and (j).

SCOPE AND ACTIVITIES

The action will improve the quality of life of children and young adult cancer survivors through improved social networking and the use of a platform to improve the links amongst individuals, patients, cancer survivors, and social and health professionals active in cancer prevention and care across the EU.

Building on the experiences gained by several organisations, non-governmental organisations and cancer care institutions active in childhood, adolescent, and young adult cancers, the action has the ambition of establishing the new 'EU Network of Youth Cancer Survivors' through federating the mentioned bodies to create an EU-wide platform to support the promotion of targeted actions and initiatives, covering the main areas which are of demonstrated benefit to improve the quality of life of young cancer survivors. The activities will be designed taking into account those key factors that may influence childhood cancer survivors' participation in social networking and programmes tailored to their needs, such as the resources accessed by individuals through a broad range of social connections ('social capitals of individuals'), social support, family interaction, self-efficacy, and self-reported quality of life.

Children, adolescents and young adult survivors will be at the core of the actions and will be the main actors in linking with their countries and/or organisation. A conference will give the possibility to show and share the results of the activities implemented and on-going across the EU, and to discuss as widely as possible the needs and challenges. The Network will be also open to establish international links through direct contacts with partners outside the EU or through links with international organisation. Particular attention will be given to actions limiting the disruptive impact of cancer on the education of children and young people affected by cancer. This will happen with the involvement of patients and of formal and informal carer, on a voluntary base.

EXPECTED RESULTS AND IMPACT

The action is expected to result in an expansion of the current support to improve quality of life of young cancer survivors through networking, targeted actions implementation, linking with existing organisations at EU and international level, and through highly visible periodical events to showcase the impact of the work done, and the future challenges.

The action will improve the communication between children and adolescents cancer survivors, formal and informal carers, and civil society; strengthen the knowledge on how to better recognise the risk of getting cancer, and how to make a difference in the lives of young people with cancer and survivors; and allow them to learn how to become an advocate to bring to civil society key messages and knowledge on cancer survivorship.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals – 11.4.1	Q2-Q3/2021	5 000 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action grant)	HaDEA	Civil society organisations (associations, foundations, NGOs and similar entities) Private entities Public authorities Established networks in the field of public health

2.6 ENHANCE PREVENTION, TESTING AND LINKAGE TO CARE IN COMMUNICABLE DISEASES

Action grants to support the implementation of best practices in community-based services for the Human immunodeficiency virus infection and acquired immunodeficiency syndrome (HIV)/AIDS, tuberculosis, viral hepatitis and sexually-transmitted infections

POLICY CONTEXT

Communicable diseases such as tuberculosis, HIV/AIDS, viral hepatitis and sexually-transmitted infections are examples of epidemics that continue to beset our societies, posing a public health burden. In addition, major communicable diseases can be serious cross-border health threats, with the potential to rapidly escalate, if left unchecked. HIV, tuberculosis and viral hepatitis, in particular, remain a challenge to Member States' health systems. Moreover, the EU is not yet on track to reach the Sustainable Development Goals, including ending HIV and tuberculosis, and combatting viral hepatitis by 2030. In 2016, the Commission committed to support EU Member States in reaching these targets[16].

There is wide recognition (including by ECDC, UNAIDS and WHO) that community responses must play an increasing role in addressing the epidemics and many EU Member States include community-based services in their response. Further support is needed to broaden the reach of services, supporting retention in care, increasing demand, monitoring quality, advancing human rights and combatting stigma and discrimination.

This action supports prevention and monitoring of communicable diseases and implements the EU4Health Programme's general objective of 'Improve and foster health in the Union' (Article 3(a)); through the specific objectives in Article 4(a), (b) and (j).

SCOPE AND ACTIVITIES

To strengthen and support community-based service organisations in the Member States and neighbouring countries in the implementation of people-centre effective and integrated interventions, as well as linkage to care amongst groups at high risk of contracting HIV/AIDS, tuberculosis, viral hepatitis and sexually-transmitted infections. It will also directly contribute to national programmes and public health measures. Thus, supporting the implementation of internationally agreed goals

The action will build on the results of the 3rd Health Programme, which, among others, served to foster the development of integrated community-based services, the setting-up of EU-wide networks and the design of tools/guides for community-based services.

This action will support the implementation and practical operationalisation of the generated knowledge, as well as piloted good practices. Activities will support:

- strengthening and expansion of outreach voluntary testing, early diagnosis and linkage to care of HIV/AIDS, tuberculosis, viral hepatitis and STIs as well as counselling approaches. They will also pursue harm-reduction, peer support, prison-in-reach and through-care services approaches in hard-to-reach vulnerable groups;
- practical application, operationalization and scaling up of tools developed under previous actions and other practical approaches to support community-based activities and outreach including the implementation and quality assurance of a brief set of

[16] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Next steps for a sustainable European future: European action for sustainability, COM(2016) 739 final, 22.11.2016

Europe-wide standardised indicators on testing and linkage to care and treatment among key risk groups;

- consolidation of the existing network(s) of community-based services in Europe in order to forge closer interaction, facilitate the exchange of best practice and promote innovative approaches fostering the increase of early HIV/STI, tuberculosis and hepatitis diagnosis and linkage to care in Europe among the most affected groups.

EXPECTED RESULTS AND IMPACT

The expected results are:

- Integrated community-based health services, including prevention, counselling, peer-support, harm-reduction, prison-in-reach and through-care services, as well as testing and linkage to care;
- capacity and network building in the areas of HIV/AIDS, hepatitis and tuberculosis, including training, promotion and use of relevant IT tools towards hard-to-reach populations.
- managerial tasks including organisation of meetings and exchange of information facilitating the participation of relevant civil society organizations and networks.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals – 27.1	Q3-Q4/2021	5.000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action Grant)	HaDEA	Civil society organisations (associations, foundations, NGOs and similar entities)

3. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE

3.1 REFORMING AND STRENGTHENING OF HEALTH SYSTEMS

Direct grant to International Organisations: Supporting Member States in improving access to healthcare and effectiveness of health coverage, taking into account vulnerabilities of specific groups and targeted intervention

POLICY CONTEXT

As part of the commitments of the Commission expressed in the Action Plan on the Implementation of the European Pillar of Social Rights (announced by the Commission on 4 March 2021), measures need to be proposed to improve accessibility metrics with a view of reducing persisting inequalities in access to healthcare (Principle 16 Access to healthcare of the Pillar).

The action supports the policy priority to respond to health inequalities and to improve the access to healthcare and it implements the EU4Health Programme´s general objective of 'strengthening health systems' (Article 3(d)) through the specific objectives defined in Article 4 (g), (i) and (j).

SCOPE AND ACTIVITIES

The action will help Member States in designing and implementing more tailored policies and measures to address persisting gaps in access to healthcare. The action will also look at health systems accessibility, a challenge that has been exacerbated due to the COVID-19 pandemic.

This action will also consider and put into practice tools and solutions, including tools proposed in the Report of the Expert Group on Health Systems Performance Assessment (HSPA) "Improving access to healthcare through more powerful measurement tools", affordability metrics developed by the WHO Regional Office for Europe and new tools to monitor how different health systems' financing affects equitable access.

The action will support Member States in improving access to healthcare and effectiveness of health coverage, taking into account vulnerabilities of specific groups and targeted interventions.

The activities include development and delivery of:

- Recommendations on more effective policies to close gaps in access to healthcare, taking into particular account specific groups of the population with biggest access inequality.
- Recommendations for different health systems on more equitable financing solutions of healthcare, addressing also long-term challenges related to shrinking resources due to ageing (with the breakdown by type of healthcare service and goods).
- Policy assistance to Member States who are interested on a voluntary basis in implementing the recommendations.

EXPECTED RESULTS AND IMPACT

The expected results are the following:

- report/ reports with recommendations per Member State on the use of metrics to better capture challenges in access to healthcare, especially for vulnerable groups, clearly identifying these groups, problems they face and proposing solutions to reduce hurdles they experience. The analysis will build on the available WHO Regional Office for Europe series on affordability and the HSPA report as referred above;

- report/ reports on more equitable financing solutions of healthcare, addressing long-term challenges related to shrinking resources due to ageing (with the breakdown by type of healthcare service and goods);
- thematic policy dialogues with Member States on a voluntary basis on: 1) instruments of financial protection, 2) more equitable financing solutions of healthcare.

The action will increase the capacity of national, regional and local authorities to design, finance and implement innovative approaches to improve accessibility of health systems, in particular with reference to groups of the population with biggest access inequity.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grant - 14.1.1	Q2-Q3/2021	1 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to International Organisations	HaDEA	International Organisation (WHO Regional Office for Europe)

Direct grant to International Organisations: State of Health in the EU (4th cycle): 'Health at a Glance: Europe 2022', Country Health Profiles 2023 and strengthened Voluntary Exchanges

POLICY CONTEXT

With the COVID-19 pandemic, the pressing need to develop better health data, analyses and technical exchanges has come to the fore, together with the need to strengthen health systems resilience. In this context, the deliverables from the State of Health in the EU cycle and their focus on the dimensions of accessibility, effectiveness and resilience proved a useful starting point to identify weaknesses in the early phase of the pandemic, when information on resilience was scant.

In light of the success of its first iterations and the renewed focus on its objectives brought to the fore by the COVID-19 pandemic, the State of Health in the EU is fully in line with Commissioner Stella Kyriakides' mission letter to find ways to improve information, expertise and the exchange of best practices in the field of health systems.

Following three successful cycles of State of Health in the EU, the fourth cycle will be strengthened, with additional and more impactful knowledge-brokering products and services offered to Countries. It implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3(d)) through the specific objectives defined in Article 4 (a) and (i).

SCOPE AND ACTIVITIES

The scope of this action is to revamp the 'classic' structure of the previous State of Health in the EU cycles by strengthening the set of deliverables and services developed in the next cycle (2022-2024).

The activities that are to be carried out are the following:

- expanding the *Country Health Profiles* and breaking them into two sections – a general one (which would always be based on the 'triad' of effectiveness, access and resilience) and a thematic one, which would provide a detailed analysis focused on a specific health policy topic of high interest to EU countries;
- stepping up the *Voluntary Exchanges* (VEx). These would in practice become 'mini-technical assistance projects', with 2-3 day-long technical meetings per country organised across the 2-year project cycle. This would guarantee continued support and follow-up on the practical impact of the technical exchanges on policymaking at the national level. Voluntary Exchanges should be organised whenever an opportunity/need arises at the national level. This revised calendar for the delivery of the Voluntary Exchanges would also provide a convenient platform to support the dissemination of best practices in specific technical areas of health policy;
- digitalisation of the project deliverables to increase users' engagement with the deliverables from the project by creating a reference website that presents their analysis and findings using dynamic data visualisation tools and some possibilities for user interaction.

EXPECTED RESULTS AND IMPACT

The proposed changes/additions to the classic structure of the project are expected to enable its output to 1) reach a wider audience, 2) provide more detailed country-specific insights on selected topics, 3) provide more impactful technical exchanges and 4) continued support to policymakers at the national level on their health investment and reform efforts.

In the short-term, the *State of Health in the EU* cycle will support Member States by strengthening the analytical base on the performance of their health systems. The deliverables and related support services provided will contextualise country-specific data in a comparative, analytical perspective, and provide national authorities with a library of high-quality resources that will support their development of more effective health system investments, policies and reforms.

In the medium term, the revamped project will increase the capacity of national, regional and local authorities to design, finance and implement innovative approaches and reforms for more effective, accessible and resilient health systems.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grant - 14.2.1	Q2-Q3/2021	3 500 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to International Organisations	HaDEA	International Organisations (OECD and European Observatory on Health Systems and Policies)

Direct grant to Member States' authorities: Transfer of best practices in primary care

POLICY CONTEXT

The topic of primary care is chosen in relation to the European Semester and the COVID-19 crisis. Strong primary care is a key element in achieving the Country-Specific Recommendations (CSR) provided to all Member States in 2020, in order to strengthen the resilience of their health systems, as well as to improve their accessibility in many cases. In addition, the COVID-19 crisis highlighted that where primary care services were effective, there was less pressure on hospitals.

Primary care is also in the focus of the Cohesion Policy 2021-2027, closely linked with the CSRs implementation, where support to primary care is explicitly mentioned as one of the objectives of the European Regional Development Fund's investments.

This action implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3(d)) through the specific objectives defined in Article 4 (g) and (i).

SCOPE AND ACTIVITIES

The proposed action (joint action) will transfer a number of best practices in primary care (the number will be decided by Member States before the joint action will start) and will support Member States to raise their capacity in implementing innovative care models in their health systems.

Member States that 'own' the selected best practices will help the Member States that are 'interested to adopt' them. Activities will entail knowledge-transfer and "twinning" actions between the 'owners' of best practices and the 'new adopters' (e.g. policy dialogues, workshops, staff visits and secondments, short courses, expert advice, mutual and peer learning programmes, etc.). There will also be pilots for the actual 'replication' of the best practices, as well as activities to monitor and assess the pilot implementation in the 'interested' Member States.

EXPECTED RESULTS AND IMPACT

The expected results are the following:

- transfer and pilot implementation of good practices in primary care into new locations in a number of Member States;
- reports with lessons from the transfer process and recommendations how to do this successfully;
- reinforced capacity of health authorities in Member States to address important aspects of health system transformation in primary care.

The action will increase the capacity of national, regional and local authorities to design and implement innovative approaches and reforms for strengthening their health systems, improving health outcomes and increasing safety of patients.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grant – 14.3.1	Q2-Q3/2021	10 000 000 EUR

Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (Joint Action)	HaDEA	Member States' Authorities

3.2 A HEALTH WORKFORCE TO MEET HEALTH CHALLENGES – FORECASTING AND PLANNING FOR WORKFORCE IN THE HEALTHCARE SECTOR

Direct grant to Member States' authorities: A health workforce to meet health challenges – forecasting and planning for workforce in the healthcare sector

POLICY CONTEXT

Even before COVID -19 pandemic many Member States were confronted with critical health workforce problems such as structural shortages, recruitment, retention and lack of "self-replenishment". Various factors can influence the numbers and availability of health workforce and the adequate skill-mix of the health workforce to ensure for the better access to quality care and patient safety.

The COVID-19 crisis has also highlighted the need of a structural and functional healthcare staff "*capacity-buffer*" for better preparedness and reactiveness to surges in healthcare demand. The pandemic uncovered a relatively low level of investments in healthcare workforce and emphasised the health workforce's critical role in the resilience of the healthcare systems. It has also revealed that difficult working conditions can have direct consequences on the health workers' well-being and mental health, influencing health service delivery and patient safety.

Asymmetries still exist in the ability of Member States to collect and analyse complex datasets on existing and future structural shortages of healthcare workers and to develop/make use of a detailed planning model for healthcare workforce.

The action supports the policy priority to respond to the COVID-19 crisis by improving the health system resilience and reinforcing the healthcare workforce. It implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3(d)); through the specific objective defined in Article 4 (i).

SCOPE AND ACTIVITIES

To support Member States' administrative capacity building and develop knowledge on datasets needed for a more future–proof comprehensive workforce planning and build capacity in effective planning and forecasting of the health workforce.

The proposed joint action's activities will continue the existing EU-level support for a cross-country collaborative model of work (including technical work of an established informal network of experts). Activities should help to close the divide between Member States on expertise in health workforce planning. It should also support Member States' authorities and the professional organisations to address common challenges and to e use improved tools and methodologies to achieve a higher effectiveness in health workforce planning processes and policy (in both numbers and skills of staff needed).
Activities will include twinning, mentoring or "clustering", joint workshops, technical assistance work and specific blended learning or training courses.

EXPECTED RESULTS AND IMPACT

The expected results are:

- A refined model for the "Minimum Data Set" needed for the optimal health workforce planning and forecasting activity at Member State level.
- An improved tool/methodology for the health workforce planning and forecasting, which will take into account the identified key drivers likely to impact on skills and competences for the health workforce.

The action will increase the administrative capacity of Member States in planning and forecasting health workforce and to understand principles for using extended datasets and tools for workforce planning and forecasting.

In the medium term, Member States participating in this joint action will gather experience to look into their own national planning system through:

- better use of tools for health workforce planning and its integration into financing models and organization of services taking into account lesson learnt from COVID-19 pandemic;
- multi-stakeholders' cooperation mechanisms to analyse and adapt health workforce specific education and training requirements to the skills and competences needed for future care delivery models.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grant - 15.1.1	Q3-Q4 /2021	7 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (Joint Action)	HaDEA	Member States' Authorities

3.3 STRENGTHENING THE IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUE AND CELLS AND ORGANS AND COOPERATION BETWEEN NATIONAL AUTHORITIES AND PROFESSIONAL SECTOR ASSOCIATIONS

Direct grant to International Organisations: Improving the quality & safety of SoHO, disseminating best practices, implementing EU and CoE Standards and tackling new challenges

POLICY CONTEXT

While the EU legislation defines safety and quality rules, the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM) works with professional experts and authorities to develop and disseminate technical guidelines to ensure a standardised effective approach to the application of the rules. It also supports implementation by providing quality management training for professionals, a donor testing proficiency scheme, vigilance data analysis and guidance on topics not currently addressed in EU legislation such as emergency planning. The collaboration with EDQM has proven to be an essential element in the effective implementation of the EU rules and a key to promoting networking for best practice among Substances of Human Origin (SoHO) professionals.

The action supports the policy priority to respond to effective implementation of the EU safety and quality rules for substances of human origin and addresses also the consequences of the COVID-19 crisis. It implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products (Article 3(c)) through the specific objectives defined in Article 4 (b), (c), and (h).

SCOPE AND ACTIVITIES

This action will build on the programmes established in the previous grant agreements and will introduce new actions to improve the safety, quality and availability of substances of human origin. The new actions will include reviewing national responses during the COVID-19 crisis to identify those practices that successfully mitigated the impact of the pandemic and allowed donations and transplants to proceed safely.

The following activities will be conducted by EDQM:

- Support the exchange and implementation of good practices and the development of an action plan for achieving and maintaining sustainable supplies of SoHO particularly in the context of:
  - the severe pandemic impact on organ transplantation and the need to rebuild these programmes and
  - the increasing reliance on third countries for plasma (to manufacture plasma derived medicinal products);
- Maintain/update (following the current 2-3 year cycle) each of the blood, tissue and cell and organs sector-specific technical guidance documents to support effective implementation of EU safety and quality requirements for all SoHO sub-sectors;
- Continue to aggregate and analyse vigilance data collected annually by the Commission from the 27 Member States for blood and for tissues and cells and draft annual vigilance reports for each of those sub-sectors for validation by national competent authorities and publication by the Commission.
- Provide training to authorities on effective vigilance and participation in EU level reporting of serious adverse reactions and events;
- Maintain and organise further quality management courses and audits for blood and tissue establishments/banks in the context of the established programmes;

- Maintain an established scheme of proficiency testing (external quality control) for blood establishment laboratories that test donors for communicable diseases.

EXPECTED RESULTS AND IMPACT

The expected results are:

- Developing a model for an action plan and recommendations for Member States organisations, and involved SoHO establishments, for monitoring, maintaining and/or increasing the supply of critical SoHO, particularly at times of crisis, including building effective preparedness and crisis management plans.
- Recommendations on building effective preparedness and crisis management plans addressing risks to SoHO at establishment and authority levels.
- Supporting the Commission in the assessment of the level of compliance with EU legislation on SoHO of EU candidate countries, potential candidates and neighbourhood countries by organisation.

Other deliverables of this action are the following:

- development and updating of guidelines for the implementation of safety and quality rules for blood, for tissues & cells and for organs;
- training courses for vigilance officers and analysis of annual EU vigilance data for publication by the Commission;
- training courses and audits of SoHO establishments to support improvements in quality management and a programme to monitor and improve proficiency of donor testing;
- Three assessment missions and associated reports on the organisation of national transplant/blood services and national oversight applicant/candidate/neighbourhood country, compared to expectation in EU law.

This action will support professionals in SoHO establishments and authorities in Member States to implement EU safety and quality requirements more effectively. It will also help them mitigate/address the impact of COVID-19 on the supply of SoHO. It will strengthen oversight by national competent authorities, in particular through improved vigilance of serious adverse events and reactions.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grant - 17.1.1	Q2-Q3/2021	3 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to International Organisations	HaDEA	International Organisation (Council of Europe/EDQM)

Call for proposals: Action grant on substances of human origin - increase resilience, ensure continuity of supply and access to safe therapies of high quality therapies, in particular in times of crisis

POLICY CONTEXT

The COVID-19 crisis has significantly tested the resilience of blood and transplant systems and has strongly reduced supply, availability, use and access to these therapies.

There is a need to improve resilience, ensure continuity of supply, increase access, safety and quality of therapies, in particular in times of infectious disease outbreaks.

The action supports the policy priority to respond to COVID-19 crisis and implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products (Article 3(c)) through the specific objectives defined in Article 4 (c), (g) and (h).

SCOPE AND ACTIVITIES

This action aims to enable the medical/professional organisations in SoHO subsectors to develop and exchange good practices for professionals to optimize supply and increase access to quality and safe use of critical therapies based on substances of human origin donated by fellow citizens.

The work will aim to identify, share, assess and refine measures and actions taken and foreseen to mitigate the impact of COVID-19 pandemic on safety, quality and accessibility of these therapies.

The specific sub-sectors that will be supported include in particular:

- blood and blood components (red blood cells, plasma);
- organs (like kidneys, liver, heart);
- haematopoietic stem cells (bone marrow, cord blood);
- gametes and embryos (for reproductive medicine);
- tissues (corneas, heart valves).

Proposed measures and actions can be targeted at local/hospital level, regional/national level and supra-national/EU level. The measures and actions developed can then be implemented by professionals in collaboration with their national Authorities, as appropriate, across the EU.

EXPECTED RESULTS AND IMPACT

The expected results of this action are the following:

- development and dissemination of good practices and guidance by medical/professional associations in SoHO subsectors to strengthen and make more resilient transplant, transfusion and medically assisted reproduction systems, in particular in case of crises;
- contribution to a more sustainable supply and increased access to essential SoHO therapies without disruptions (comparison with the annual volumes monitored for several SoHO subsectors).

These activities will enable professional associations in the sector to ensure a more resilient supply systems for sustainable access to safe SoHO. Ultimately, this action will contribute to strengthening the safety and protection of patients receiving SoHO therapies.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals - 17.2.1	Q3-Q4/2021	3 500 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action grant)	HaDEA	Professional medical societies exchanging and developing know-how on the collection, preparation and application of one or more Substances of Human Origin. Societies should have professional members from hospitals, transplant centres and blood/tissue establishments across the EU

Call for proposals: Organise and collect data to understand safety, quality and efficacy of therapies (1) applied in the field of assisted reproduction and (2) based on haematopoietic stem cells

POLICY CONTEXT

Hematopoietic stem cells (HSCs) play a significant role in the area of cancer immunotherapy, in particular for liquid blood cancers like leukaemia and lymphoma.

Medically assisted reproduction (MAR) is a field of major and increasing importance, where shortcomings have been identified related to the protection of donors and offspring. In addition, MAR can also play a direct role in cancer care by sustaining fertility of young patients by preserving their reproductive cells for use in MAR after cancer treatment that would have rendered them infertile.

The action supports the policy priority to respond to COVID-19 crisis and implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products as defined in (Article 3 (c)) through the specific objectives defined in Article 4 (g) and (h).

SCOPE AND ACTIVITIES

This action will support the professional sector associations to collect and organise in registries data on the safety, quality and efficacy of therapies applied in the field of medically assisted reproduction (MAR) and haematopoietic stem cell transplantation.

This action will support EU data collection, aggregation and analyses on the use and outcome of therapies in the fields of:

a) assisted reproduction,

b) haematopoietic stem cells.

For both a) and b) it will facilitate the design, development and management of dedicated IT solutions with and for medical/healthcare professionals.

EXPECTED RESULTS AND IMPACT

The expected results are new or substantially upgraded digital registries with more high quality data entries from medical professional across the EU. This will provide good quality data collection on therapies in the field of MAR and based on HSCs and facilitate sharing of data for open science and for EU legal requirements on oversight purposes for monitoring safety and outcome and also the protection of donors and offspring.

Proposed solutions should ensure the Findability, Accessibility, Interoperability, and Reuse of digital assets (FAIR principles), use or interoperate with main European and Global data standards, and other initiatives (i.e. European Health Data Space, EOSC Life).

Qualitative data will be available for professionals as well as authorities and other stakeholders in the sector and facilitate their respective tasks in the sector (such as clinical protocols, authorizations, market feedback, value based reimbursement).

This will allow improving and promoting medical excellence, as well as increasing efficiency of healthcare systems and transparency for patients.

The action will have an impact on the digital transformation and uptake of digital solutions in the EU sector of medically assisted reproduction and hematopoietic stem cells, in order to facilitate the monitoring of activities and outcomes.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for Proposals - 17.3.1	Q2-Q3/2021	a) 2 000 000 EUR b) 2 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action grant)	HaDEA	Civil society organisations (associations, foundations, NGOs and similar entities)

3.4 IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION AND PHARMACEUTICAL STRATEGY

Direct grant to Member States' authorities: to promote quality of medicines and to increase cooperation between Member States and between the EU and third countries through trainings, joint audits, reassessments and inspections on good manufacturing and good distribution practices. Implementation of international mutual recognition agreements on pharmaceutical good manufacturing practices (GMP) with United States, Switzerland, Australia, Japan, New Zealand, Canada, Israel, UK, and cooperation with third countries such as China and India

POLICY CONTEXT

The implementation of Directive 2001/83/EC (Article 111), the Pharmaceutical Strategy for Europe[17], the international mutual agreements, and the cooperation with third countries require concerted and continuous efforts and cooperation between national Competent Authorities, Compliance Group of the GMP/GDP Inspectors Working Group (GMDP IWG) and the Commission.

The Joint Audit Programme for Good Manufacturing Practices (GMP) inspectorates is an important tool for continuous improvement, ensures consistency of GMP standards and a harmonised approach within EU/EEA in line with the Compilation of Union Procedures on Inspections and supports confidence building within the EU/EEA and with other authorities.

There is a need for activities targeting all Member States and EEA competent authorities, to join efforts in inspection and audit trainings including capacity building, and to carry-out joint audits. These activities will further strengthen the EU medicines regulatory network, will ensure the oversight of the quality of medicinal products and enhance the Member States' capacity to participate in international inspections and audit programmes. Moreover the improvement of the Member States' capacity will enhance compliance with the Union legislation and guidelines and the implementation of Pharmaceutical Strategy for Europe. This will facilitate patients' access to high quality medicines and building a robust supply chain.

Furthermore, in the framework of preparations for future cooperation with international partners, there is a need to engage more to ensure the quality of the active pharmaceutical ingredients (API) imported from non-EU countries that are used to produce medicinal products. To this end, Member States will lead and organise fact-findings missions. The quality of API is a key factor in a robust supply chain guaranteeing high quality medicines for EU patients (nitrosamine case).

The action supports the policy priority to implement the Pharmaceutical Strategy for Europe as it concerns the enhancement of compliance with good manufacturing and distribution practices. It implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products (Article 3(c)) through the specific objectives defined in Article 4 (c), (h) and (j).

[17] COM(2020) 761 final

SCOPE AND ACTIVITIES

The scope of this action is to support the cooperation between competent authorities by organising trainings, joint audits, reassessments and inspections on good manufacturing practices and good distribution practices in the EU and third countries.

Preparatory work of a joint audit programme training, planning of joint audits, conducting of joint audits and reassessment planning in the EU and third countries including for implementation of the mutual recognition agreements with the United States, Switzerland, Japan, New Zealand and Canada, Australia, Israel, UK in consultation with the Compliance Group of the GMDP Inspection working Group will be supported.

Once the joint audits will be carried out, in the framework of preparation for future cooperation on the quality of active substances with third countries this action will also cover the preparation of fact finding missions in Third Countries with inspectors from the Member States.

EXPECTED RESULTS AND IMPACT

This action will:

- Improve compliance with the EU pharma acquis and alignment with the Pharmaceutical Strategy for Europe thus contributing to the highest quality of pharmaceutical products through all the proposed activities.
- Enhance oversight and strengthen capacity of EU and EEA GMDP inspectors and auditors/National Competent Authorities to ensure compliance with good manufacturing and distribution practices in inspections and audits.
- Contribute to the development of a crisis proof GMP medicines regulatory system based on a network of EU agencies operating to best practice standards.
- Assure the quality of the active pharmaceutical ingredients (API) imported from non-EU countries, as they are a critical element of a reliable global supply chain that secures high quality medicines in the EU.

This action will be a continued implementation of international agreements with United States, Canada, Switzerland, Australia, Japan, New Zealand, Israel, and UK, as these agreements are extended in scope or either require continuous maintenance. It will also enable future cooperation with strategic third countries.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grant - 18.2.1	Q2-Q3/2021	2 150 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (Joint Action)	HaDEA	Member States' Authorities

Direct grant to Member States' authorities: Safety assessment cooperation and facilitated conduct of clinical trials

POLICY CONTEXT

There is a need to build up and harmonise the necessary expertise of Member States National Competent Authorities and the relevant ethics committees in some Member States on the safety assessment of information on active substances in clinical trials. This will be achieved through expert exchange and assessor "twinning" programmes as well as to set-up a secretariat to provide administrative support to the coordinated safety assessment. The secretariat would identify the Member State responsible for assessing the safety of each active substance used in the context of clinical trials. Based on data in the EudraCT database (European Union Drug Regulating Authorities Clinical Trials Database[18]), it can be seen that the number of active substances continued to increase in the past years and in 2019 reached about 3500 active substances used in about 6600 active clinical trials authorised in the EU.

The majority of these trials will be transitioned from the current Clinical Trials Directive to be regulated under the Clinical Trials Regulation in the coming years in addition to new trial application submitted already under the Clinical Trials Regulation, which will become applicable on 30 January 2022.

The action supports the policy priority to implement the Union legislation for clinical trials and the Pharmaceutical Strategy for Europe as it concerns the safety assessment cooperation for clinical trials. It implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products (Article 3(c)) through the specific objectives defined in Article 4 (g), (h) and (i).

SCOPE AND ACTIVITIES

The aim of this action is to set up of the framework for cooperation between Member States authorities (including a secretariat) on the assessment of participants' safety in clinical trials.

The main task of the secretariat will be to support the coordination of different safety assessment activities. Safety assessors will carry out safety assessments and will participate in mentoring and twinning programmes to help other Member States to build the necessary expertise to be able to carry out safety assessments and acting as safety assessing Member States.

These activities will facilitate Member States coordination under the Clinical Trials Regulation (CTR) and the successful implementation of the Pharmaceutical Strategy for Europe by supporting patient oriented trials also those with innovative trial designs.

EXPECTED RESULTS AND IMPACT

The expected results are the following:

- build up and harmonise the necessary resources and expertise of Member States National Competent Authorities and relevant ethics committees in some Member States on the safety assessment of information on active substances in clinical trials through expert exchange and assessor "twinning" programmes;
- Effective and timely implementation of coordinated safety assessment between Member States National Competent Authorities for a qualitative and quantitative improvement of safety assessment in EU/EEA.

[18] The European database for all interventional clinical trials on medicinal products authorized in the European Union (EEA) and outside the EU/EEA if they are part of a Paediatric Investigation Plan (PIP)

The effective and timely implementation of coordinated safety assessment will contribute to higher safety standards and improved participants' safety in clinical trials and for the future patients. It will also contribute to higher quality safety profile of medicines for marketing authorisations.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grant - 18.3.1	Q4/2021	4 500 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States (Joint Action)	HaDEA	Member States' Authorities

3.5 ENHANCED EUROPEAN REFERENCE NETWORKS (ERNS)

Direct operating grant: ERN eUROGEN

POLICY CONTEXT

The European Reference Networks (ERNs) were established in 2017 in accordance with Article 12 of the 2011 Directive on Patients' Rights in Cross-border Healthcare in the field of rare or low-prevalence complex diseases. There are 24 virtual networks involving healthcare providers across Europe. ERN eUROGEN is dealing with rare and complex urogenital diseases and conditions.

ERN eUROGEN has not applied for a multiannual grant in 2017 as majority of the existing ERNs but only in 2018. The current grant for coordination activities for ERN eUROGEN will end in May 2021. This new direct grant to ERN eUROGEN should be provided to ensure their business continuity until the end of February 2022, when the launch of the new the multiannual grants for all 24 existing networks shall take place. In the future, the timing of the multiannual grants for all ERNs will be aligned.

This action supports the coordination, management and non-clinical activities of the ERN eUROGEN. It implements the EU4Health Programme's general objective of strengthening health systems (Article 3(d)) through the specific objectives defined in Article 4(f), (g) and (i).

SCOPE AND ACTIVITIES

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

The action aims to fulfil the goals of the network including inter alia, through:

- networking and coordination activities;
- virtual expert consultations on diagnosis and treatment;
- development of knowledge generation tools (e.g. development of clinical practice guidelines, development of training programmes);
- enhancing research.

EXPECTED RESULTS AND IMPACT

This action will support the provision of specialised healthcare for rare urogenital conditions and support development of new guidelines, build evidence of best practice, develop education programmes and training, set the research agenda in collaboration with patient representatives, and share knowledge through participation in virtual multidisciplinary teams.

This action will help in pooling knowledge, expertise and resources for the benefit of European patients suffering from rare urogenital diseases and their health professionals.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call opening	Budget
Direct grant – 22.2.1	Q2 2021	200 000 EUR

Procedure type	Implemented by	Type of applicants targeted

Direct grant to ERNs (operating grant)	HaDEA	Coordinating Centre of ERN eUROGEN

Direct grant on the basis of Article 195(c) of the Financial Regulation (de facto monopoly): technical assistance and support for disease codification through a direct grant with Orphanet

POLICY CONTEXT

Orphanet was established in 1997 to gather scarce knowledge on rare diseases so as to improve the diagnosis, care and treatment of patients with rare diseases. It is a multi-stakeholder, global network of 41 countries, coordinated by the Orphanet Coordinating team at the French National Institute of Health and Medical Research (INSERM) in Paris. Orphanet produces massive, computable, re-usable scientific data that can be used to identify rare disease patients and help expand knowledge about such diseases. Orphanet produces the only nomenclature specific for rare diseases, with the aim to provide stakeholders with a common, controlled language to improve interoperability between health information systems and databases and registries. As such Orphanet constitutes a *de facto* monopoly.

An essential part of the ERN project is the possibility of integration of clinical cases in medical registries. This is only possible if a coherent and uniform coding system is widely used which, in the domain of rare diseases, is the orphacode system.

This action supports the establishment of a harmonised coding system for rare diseases. It implements the EU4Health Programme's general objective of strengthening health systems (Article 3(d)) through the specific objectives defined in Article 4 (f), (g) and (i).

SCOPE AND ACTIVITIES

The proposed action will include the integration of orphacodes as the main codification system for rare diseases in the new IT system of the ERNs and the continuous scientific update and analysis of the rare diseases coverage and state of the art of knowledge in this domain.

The action aims to fulfil the goals of Orphanet including inter alia, through:

- continuous scientific update and analysis of the rare disease coverage with orphacodes and state of the art of knowledge in this domain;
- extending integration of orphacodes as the main codification system for rare diseases in the new IT system of the ERNs.

EXPECTED RESULTS AND IMPACT

This action will contribute to the harmonisation of the coding systems and thus enable to populate medical registries with data coming from the ERN clinical discussion system. Quantity and quality of research activities on rare diseases are expected to improve substantially.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call opening	Budget
Direct grant – 22.4.1	Q2 2021	1 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**

Direct grant (Article 195(c) of the Financial Regulation)	HaDEA	Orphanet Coordinating team

3.6 SETTING UP AN EU HEALTH SYSTEM RESILIENCE TESTING AND SUPPORT PROGRAMME

Direct grant to International Organisations: EU HEALTH SYSTEM RESILIENCE TESTING AND SUPPORT PROGRAMME

POLICY CONTEXT

Developing a resilience testing methodology will facilitate better data, information and enable cross-country learning. This action will assist in contributing to the European Semester which addresses the effectiveness, accessibility and resilience of health systems.

The encompassing resilience assessment framework ("the testing framework") will serve to detect critical health system weaknesses against specific shocks as well as long-term structural challenges. This will help develop recommendations for remedial action.

The testing framework will build on the work carried out by the 'Expert Panel on effective ways of investing in health' in its "opinion on the organisation of resilient health and social care following the COVID-19 pandemic", adopted on 25 November 2020 as well as the December 2020 report by the EU Expert Group on Health Systems Performance Assessment (HSPA) titled "Assessing the resilience of health systems in Europe: an overview of the theory, current practice and strategies for improvement". This work presents relevant conceptual sub-dimensions related to health system resilience as well as real-life measurement strategies and "toolkit materials". The testing framework will be developed using focus groups, pilots and structured dialogues with Member States.

The action supports the policy priority to respond to COVID-19 crisis and it prepares the grounds for the rollout of resilience testing. It implements the EU4Health Programme's general objective of strengthening of health systems (Article 3(d)) through the specific objectives defined in Article 4(b) and (i).

SCOPE AND ACTIVITIES

The objective is to establish a solid operational methodology for carrying out health system resilience tests and, when applicable, help develop remedial action. The methodology will be accompanied by a manual. Trainings for Member State authorities on the methodology can be provided upon request

A framework for possible remedial action will be developed to follow up on the resilience tests. This framework will be designed in collaboration with national/regional health authorities and with the European Centre for Disease Prevention and Control to prepare support programmes to Member States. It will include an implementation plan to assist Member States to enhance crisis preparedness and to strengthen health system resilience against specific shocks.

EXPECTED RESULTS AND IMPACT

By establishing a resilience testing methodology and technical support, Member States will be able to regularly review health crisis preparedness and check their health systems' resilience against specific high-pressure scenarios and long-term structural challenges.

This action will generate insight and evidence through resilience tests and will reinforce the ability of Member States and regions to become more resilient.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget

Direct grant – 23.1.1/23.1.2	Q2-Q3/2021	1 500 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to International Organisations	HaDEA	International Organisation (OECD and European Observatory on Health Systems and Policies)

4. DIGITAL

4.1 ESTABLISHMENT OF EUROPEAN HEALTH DATA SPACE – INFRASTRUCTURE AND GOVERNANCE – SECONDARY USE OF HEALTH DATA

Call for proposal: Action grant for developing a pilot programme for an EU infrastructure ecosystem for the secondary use of health data for research, policy-making and regulatory purposes

POLICY CONTEXT

The cross-border access to health data is fragmented, and makes it particularly difficult to re-use health data collected during healthcare provision. There is a need to initiate and fund a pilot project on health data exchange in collaboration with national authorities in order to facilitate access to European health data repositories through common rules, instruments and procedures. The use cases of this pilot use cases would demonstrate cross-country re-use of health data for research, policy-making and regulatory activities by connecting the health data permit authorities and highlight the potential benefits and added value of a large-scale infrastructure for the reuse of health data.

An improved coordination of national efforts and harmonisation of digital infrastructure and data quality would promote the collaboration of several stakeholders relevant in the health data processing towards the delivery of better healthcare to citizens. It would contribute to the creation of an ecosystem of infrastructures relying on common standards and policies to enable integration of currently fragmented national system while at the same time provide space for diversity and specificity for each research, policy-making or regulatory needs. The action supports the development of a European health data space and the re-use of health data for the research, policy-making and regulatory activities. It implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3(d)) through the specific objectives defined in Article 4(f).

SCOPE AND ACTIVITIES

This pilot will design, develop, deploy and run a network of nodes (representing different data brokers, holders and data consumers) federated by central services.

This pilot will demonstrate and prove the value of an infrastructure ecosystem for the secondary use of health data, as well as to assess the ability to scale towards an EU-wide infrastructure.

In particular, it will require to:

- Define and select key use cases that build on health data made available by the pilot partners to demonstrate added value of cross-country re-use of health data for policy-making, regulatory and research activities including, for example, the verification of the safety and efficacy of therapeutics;
- Elicit requirements (business, functional and non-functional) for an IT infrastructure to enable EU-wide re-use of health data;
- Design the specifications for the building blocks necessary for an IT infrastructure to enable EU-wide re-use of health data;
- Develop, customise or integrate technology to fulfil the agreed requirements.
- Deploy, in conformity with the design specifications, at partner level (nodes) and at central level (federation services), the components necessary for an IT infrastructure to enable EU-wide re-use of health data;
- Run the selected use cases over the implemented IT infrastructure;

- Assess the performance of the technological building blocks used and their ability to scale towards an EU-wide infrastructure.

EXPECTED RESULTS AND IMPACT

The expected results of this action are the following:

- Candidate requirements and specifications for the technological building blocks for an IT infrastructure to enable EU-wide re-use of health data;
- Deployment of an IT infrastructure consisting of, at least, 6 nodes and central federation services enabling EU-wide re-use of health data;
- Assessment of the proposed technological building blocks impacting the potential to scale for an EU-wide solution.

This pilot aims at reducing risks and unknowns regarding an EU-wide large scale deployment of an infrastructure for re-use of health data. It would demonstrate the feasibility and added value of a cross-border infrastructure for secondary use of health data. The experience gained in such project would also provide a better understanding of the limitations and potentials of a common EHDS.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Call for proposals - 24.1.1	Q3/2021	5 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Open call for proposals (Action grant)	HaDEA	Member States' Authorities and health institutions and similar entities

4.2 ESTABLISHMENT OF EUROPEAN HEALTH DATA SPACE – INFRASTRUCTURE AND GOVERNANCE - PRIMARY USE OF HEALTH DATA

Direct grant to Member States' authorities: Enlargement of the geographic coverage and scope of MyHealth@EU

POLICY CONTEXT

There is a need to set up National Contact Points for eHealth in Romania, Denmark, Norway, Germany and Austria. It will broaden the scope and the number of Member States included in the MyHealth@EU (eHDSI) network.

The action supports the development of a European health data space and the use of health data for the provision of healthcare. It implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3(d)) through the specific objectives defined in Article 4(f).

SCOPE AND ACTIVITIES

This action will allow, from newly participating Member States, to aggregate the patient information from national electronic health records or other infrastructure and share it cross-border. It will also broaden the coverage of ePrescriptions and Patient summaries in Member States that have not currently this system in place.

This action will allow Member States to apply for:

- Setting up the NCPeH and start exchanging the ePrescription (eP) and/or Patient Summary (PS)
- Adding new available services to existing NCPeH
- Deploying new structured services (medical images and image reports, laboratory results, hospital discharge letters)
- Deploying new service Original Clinical Documents

EXPECTED RESULTS AND IMPACT

This action will make MyHealth@EU available in more countries and for more citizens in Europe.

The new service will increase the type of Health data being exchange across borders and add value to the continuity of care. It will facilitate cross-border healthcare and contribute to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants – 25.3.1	Q4 2021	11 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**

Direct grant to Member States	HaDEA	Member States' Authorities

Direct grant to Member States' authorities: Enabling patient access to MyHealth@EU (eHDSI)

POLICY CONTEXT

Current services enabled by the MyHealth@EU eHealth Digital Service Infrastructure (eHDSI) provide health professionals with access to patient data. However, the infrastructure does not include services aimed at providing patients directly with their own data. Additionally, the services are lacking a mobile element which could work for example on a citizen's smartphone.

Thus there is a need for National Contact Points for eHealth to develop new elements and services in order to explore possible way to provide services directly to citizens. In addition, the action supports the targets expressed in the Commission's Communication "2030 Digital Compass: the European way for the Digital Decade", calling for enabling access to medical records (e-records) for 100% of European citizens.

The action supports the development of a European health data space, the use of health data for the provision of healthcare and the target calling for enabling access to medical records (e-records) for 100% of European citizens. It implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3.d) through the specific objectives defined in Article 4(f) and (g).

SCOPE AND ACTIVITIES

This action will enable a few first pioneers Member States to design and implement this service. It would enable direct access for patient to their health data and translate it into a target language used in a country of treatment. It will allow the opportunity at the same time to explore challenges for implementing this new service.

This action will:

- design and develop the proposed new service;
- test the developed service;
- deploy the new service by the first pioneer Member States.

EXPECTED RESULTS AND IMPACT

Patients will be able to get access to their health data for example using their smartphone. The data will be translated to the language understood by the health professional in another Member State or even outside the European Union. Member States will launch national projects developing or improving patient access to health data.

The availability of a new mobile service offered directly to patients will create a new platform that can be dynamically expanded to support EU citizens in cases of new health threats by providing them with relevant health data and related digital tools at the point of care.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grant – 25.4.1	Q4 2021	2 000 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**

Direct grant to Member States	HaDEA	Member States' Authorities

Direct grant to Member States' authorities: Increase health semantics interoperability and for capacity building related to digitalisation

POLICY CONTEXT

There is currently a fragmentation of standards used to express clinical concepts. It hamper the semantic interoperability of health data. Thus, there is a need to provide a standard terminology to express clinical meanings captured by the clinicians and harmonise the way health professional express themselves.

The action supports the development of a European health data space and the use of health data for the provision of healthcare. It implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3(d)) through the specific objectives defined in Article 4(f).

SCOPE AND ACTIVITIES

The objective is to facilitate the use of a standardised terminology to express clinical meanings.

This action will propose to provide access to Member States to SNOMED CT which supports the development of comprehensive high-quality clinical content in electronic health records. SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms) is a standardized, multilingual vocabulary of clinical terminology that is used by physicians and other health care providers for the electronic exchange of clinical health information.

EXPECTED RESULTS AND IMPACT

This action will incentive Member States to use a common terminology.
It would increase the semantic interoperability of health data and thus facilitating cross-border exchange and re-use of health data.
It could facilitate patient access and translation of their health data.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grant – 25.5.1	Q4 2021	3 600 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States	HaDEA	Member States' Authorities

5. OTHER ACTIVITIES

Direct grants to Member States' authorities: Events organised by the Presidency of the Council of the EU

The programme will support the multiple objectives of the EU4Health Programme during the rotating Presidencies of the Council of the EU with two conferences to be organised in 2021 and early 2020.

SCOPE AND ACTIVITIES

These conferences are an opportunity for a discussion among Member States on how to work better together at EU level on one or more health-related topics and improve implementation on a Member State-level.

Conferences to provide a platform for Member States and relevant stakeholders to exchange information and good practice, in particular on promoting the implementation of innovative solutions for resilient health systems in the EU and other relevant topics in the field of public health.

EXPECTED RESULTS AND IMPACT (INCLUDING OUTPUTS)

The Member States holding the rotating Council Presidency are the beneficiaries of the grants to be awarded without a call for proposals on the basis of Article 195(c) of Financial Regulation. The form, topic and expected results are established by the Presidency in agreement with the Commission. These events which are highly political in nature and which need representation at the highest level both from national authorities and European representatives, are to be organised exclusively by the Member State holding the Presidency. Given the unique role of the Presidency in the framework of EU activities, the Member State responsible for the organisation of the event is considered as a de jure monopoly.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grant – 26.1.1 & 26.2.1	Q2/2021-Q1/2022	200 000 EUR
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States	HaDEA	Member States' Authorities

B. PROCUREMENT

The overall allocation reserved for procurement contracts and administrative arrangements in 2021 amounts to EUR 00 000 000, distributed amongst the different strands of action as follows:

Crisis Preparedness:	EUR 81 500 000
Disease Prevention:	EUR 30 450 000
Health Systems and Healthcare Workforce:	EUR 24 904 000
Digital:	EUR 10 150 000
Recurrent, horizontal and communication activities:	EUR 1 414 898

1. CRISIS PREPAREDNESS

In 2021, the Commission intends to undertake actions through contracts following public procurement (call for tenders and use of existing framework contracts) or administrative arrangements (including service level agreements, co-delegations and memoranda of understanding) with other Commission services to support priorities in the following thematic areas:

Communicable Diseases - surveillance systems requirements, early detection, risk assessment

The actions under this thematic section have as objectives:

- to support a real-time integrated surveillance system at EU level, assist and support Member States in the development of interoperable of reliable and modern national surveillance systems, driven by digital transformation;
- to conduct a data protection impact assessment of the Early Warning and Response System (EWSR) digital platforms;
- to perform an analysis of the contact tracing management in EWRS taking into account the impact of COVID-19 on contact tracing practice;
- to support the technical finalisation of the European digital platform for traveller contact tracing (Healthy Gateways), a digital single entry point and database for passenger locator form.

The expected results are a gap analysis feeding into the development of requirements for future-oriented integrated, artificial intelligence and electronic data based, real-time surveillance systems and subsequently an adequate deployment of digital platforms and applications supporting epidemiological surveillance that comply with the data protection requirements. Furthermore, the results include the sustainable establishment of the digital platform for traveller contact tracing.

Within this thematic area, the Commission plans to launch open procedures for

- Feasibility study on whether the contact tracing tools and application used at national and EU level could be integrated and interoperable within Early Warning and Response System (EWRS), selective exchange module

Type of contracts: service

Indicative budget for this thematic area: EUR 3 000 000

Implementation: by DG SANTE and HaDEA

Implementation of the EU AMR One Health Action Plan in Member States

The actions under this thematic section have as objectives to strongly contribute to the goal of the European Action Plan on AMR for the EU to become a 'best practice region" and to support the coordination of measures to combat serious cross-border threats to health as well as to raise awareness on the citizens' use of antibiotics.

The expected results include an inventory of existing barriers to the development and implementation of national action plans on AMR, and of infection prevention and control and antimicrobial stewardship measures, at both the policy and clinical levels in Member States as well as the identification on feasible measures to overcome these obstacles. Furthermore, activities will lead to insights into reported public use of and knowledge about antimicrobials in the general public. The results will contribute to the ongoing review of the Commission on the AMR situation in Member States and to the identification of options for provision of additional EU support.

Within this thematic area, the Commission plans to launch open procedures for

- A service contract covering in particular an interview survey of key informants from the policy, clinical and managerial levels; in-depth field investigation and reports for several EU Member States selected on the basis of the first survey as having the greatest need for assistance in overcoming barriers; results of literature reviews of methods for overcoming barriers identified; a series of workshops.

Type of contracts: service

Indicative budget for this thematic area: EUR 1 500 000

Implementation: by HaDEA

EU Immunisation Initiative

The actions under this thematic section have as objectives:

- To identify obstacles to vaccination of physical, practical or administrative nature, assess to what extent such obstacles have a negative impact on vaccination coverage rates, to identify best practices to overcome them and develop recommendations;
- To support EU Member States in defining and delivering national vaccination programmes and services, based on the monitoring of performance, including at subnational level and among specific population groups;
- To support EU Member States in their decision-making on national vaccination plans, by strengthening the assessment and sharing of scientific evidence related to vaccines of interest, including COVID-19 vaccines and any adaptations of those vaccines due to the emergence of SARS-CoV-2 variants. This action will be carried out in close collaboration with relevant bodies such as ECDC or the EU/EEA National Immunisation Technical Advisory Groups (NITAG);
- to have a dynamic and up to date communication system to respond to the latest misinformation myths or trends on vaccination, to measure the confidence on vaccines and to train the professionals in contact with children and parents - and the children themselves – to understand and to be proactive in promoting vaccination.

The expected results are an inside on barriers and risks in achieving a high uptake of vaccines in the Member States, leading towards recommendations, mitigating measures and initiatives to overcome these obstacles. Furthermore, increased knowledge and data sharing on scientific evidence related to vaccines of interest including capacity building activities. Finally, to set up a powerful vaccine misinformation counter initiative.

Within this thematic area, the Commission plans to launch open procedures for

- a service contract for a study to identify obstacles to vaccination of physical, practical or administrative nature
- a service contract for a study on guidance on methodologies to assess the performance of vaccination programmes
- a service contract to support systematic reviews of scientific evidence on vaccines, and capacity building activities.

Type of contracts: service

Indicative budget for this thematic area: EUR 10 000 000

Implementation: by HaDEA

EU preparedness: Capacity and capability assessment and training programmes for health specialists

The actions under this thematic section have as objectives to support the enhancement of existing pandemic preparedness capacities and capabilities such as national plans, coupled with a comprehensive and transparent framework for reporting and assessment.

The expected results are a series of benchmarks and indicators for the assessment of preparedness of EU Member States as well as increased capacity and knowledge of public health specialists through trainings.

Within this thematic area, the Commission plans to launch open procedures for

- a service contract for a study to outline the indicators for which Member States should report their capacity and capability
- a service contract for an analysis of capacity gaps and training needs, development of adequate trainings at national and EU level and the roll out of pilot training courses

Type of contracts: service

Indicative budget for this thematic area: EUR 5 500 000

Implementation: by HaDEA

HERA preparatory actions

The actions under this thematic section have as objectives:

- to support bringing AMR medical countermeasures to market, prudent use of antimicrobials, as well as stockpiling feasibility;
- to develop a common methodology and protocol for intelligence gathering and analysis for serious cross-border threats to health and relevant medical countermeasures, which could ultimately be employed by the European Health Emergency Preparedness and Response Authority (HERA), once operational. The action aims at developing a prototype IT platform, accompanied by modelling tools where relevant, that integrates the methodology and protocols, as well as a proposal for its operationalisation going forward. The work will be supported by a multi-disciplinary team of experts per subject area to develop the methodologies and protocols for intelligence gathering and analysis, as well as the prototype IT platform and modelling tools;
- to support global surveillance by analysing the global nature of disease transmission including but not limited to the identification of key hotspot countries for zoonotic infections, engagement with relevant competent authorities to establish reliable global surveillance network for collecting information, and support to partner countries' capacity for efficient identification, reporting and outbreak management under a One Health

approach (this will include gap analysis, cooperation and coordination with EU agencies, International Organisations and EU funded projects);
- to support flexible manufacturing and access for COVID-19 therapeutics under the EU FAB[19] project;
- to support the mapping of COVID-19 therapeutics, including ICU medicines, heparin, dexamethasone and availability of in vitro diagnostics devices including companion diagnostics, and antibiotics.

The expected results are:

- a technological review of the latest AMR medical countermeasures, gap analysis and needs assessment in the EU Member States;
- a stockpiling feasibility study;
- a model agreement for procurement and stewardship for critically important antimicrobials in the EU to use between the producers of a novel class of antimicrobials and EU Member States to pursue an EU-wide common approach, possibly also in cooperation with other countries;
- Methodologies for anticipatory threat assessment, medical counter-measures requirements and consequence management;
- the establishment of a multidisciplinary team per subject area to develop methodologies and protocols, serving intelligence gathering and analysis and the creation of modelling tools, and a real-time prototype IT platform, integrating the methodology and protocols;
- a proposal for the long-term operationalisation of the real-time prototype IT platform, modelling tools where relevant, and methodologies and protocols for intelligence gathering and analysis (anticipatory threat assessment; medical countermeasure requirements and consequence management);
- a global perspective assessment of surveillance for serious cross-border threats to health and integration into EU surveillance and intelligence gathering and analysis tools, serving to optimise their use and increase accuracy of threat prioritisation and prediction; a study assessing scientific, engineering, legal and economic considerations of flexible EU manufacturing and innovation capacities and EU reservations for access to COVID-19 therapeutics and/or medical products;
- key details of technical specifications, volumes and types of product in order to enable COVID-19 manufacturing capacities and improve access to such capacities at EU level;
- the mapping identifying in detail the current developments and future production of COVID-9 therapeutics and availability of in-vitro diagnostics, as well as an analysis of the supply chains and any possible bottlenecks. This includes the development of an interactive mapping platform.

Within this thematic area, the Commission plans to launch open procedures for

- a service contract for needs assessment and technology review reports (to feed into future work to bring AMR medical countermeasure s to market);
- a service contract for stockpiling feasibility study;
- a service contract for development of common model agreements for procurement and stewardship for critically important antimicrobials in the EU;
- a service contract for horizontal Intelligence Gathering and Analysis for Emergency Preparedness and Response, a prototype for the Health Emergency Response Authority (HERA);
- a service contract for global Surveillance: disease mapping, transmission and identification of emerging threats;

[19] COM(2021) 355 final

- a service contract for a study assessing scientific, engineering, legal and economic considerations of flexible EU manufacturing and innovation capacity;
- a service contract for EU manufacturing capacities, mainly focused on COVID-19 therapeutics;
- a service contract for mapping of COVID-19 therapeutics, including ICU medicines, heparin, dexamethasone and availability of in vitro diagnostics devices including companion diagnostics and antibiotics.

Type of contracts: service

Indicative budget for this thematic area: EUR 61 500 000

Implementation: by DG SANTE/HaDEA

2. DISEASE PREVENTION

In 2021, the Commission intends to undertake actions through contracts following public procurement (call for tenders and use of existing framework contracts) or administrative arrangements (including service level agreements, co-delegations and memoranda of understanding) with other Commission services to support priorities in the following thematic areas:

Prevention of non-communicable diseases and related risk factors

The actions under this thematic section have as objectives the implementation, in the field of disease prevention, of best practices and the monitoring of policy developments to foster public health investments at EU level.

The expected results focus on the identification of concrete challenges in the prevention of non-communicable diseases and policy solutions in the form of best practices and innovative solutions for collective action between the Member States and the Commission, to tackle the main public health challenges.

Type of contracts: service

Indicative budget for this thematic area: EUR 1 750 000

Implementation: by DG SANTE

Disease knowledge gate

The actions under this thematic section have as objectives:

- to increase the availability and coordinated access to basic data on non-communicable diseases, supporting evidence-based national and EU policy-making, monitoring and research;
- to link and provide access to data on the prevalence of various diseases such as the number of Europeans with i) diabetes, cardiovascular or COPD; ii) (long) COVID; iii) certain types of cancer or, iv) certain types of rare diseases.

The expected results are the design of the use cases and architecture of the access platform/portal, the definition of the approach for achieving buy-in for the use cases for monitoring, research and policy use, and the design of the incentive scheme for Member States including how to effectively promote that the data is produced and curated in the correct formats.

Type of contracts: administrative arrangement

Indicative budget for this thematic area: EUR 3 000 000

Implementation: by DG SANTE

Tobacco control policy, implementation and enforcement of tobacco control legislation

The actions under this thematic section have as objectives to support the implementation of Tobacco Products Directive (2014/40/EU) and related tobacco control legislation by means of:

- practical sensory and chemical assessments of tobacco products;
- improving the use and interpretation of tobacco product related data, through the procurement of technical expertise and laboratory capacity, including access to reliable and up-to-date market data; and
- evaluating legislation in the field of tobacco control for possible revisions.

The expected results are clear indicators for prohibiting the placing on the market of non-compliant tobacco products, better use and interpretation of tobacco control related data, and studies supporting first steps in the adaptation of the legal framework in this field towards the ambitious goal of the Europe's Beating Cancer Plan to significantly reduce the tobacco use rates in the EU.

Type of contracts: service, administrative agreements

Indicative budget for this thematic area: EUR 1 600 000

Implementation: by DG SANTE and by HaDEA

Cross-cutting Cancer actions: Saving lives through sustainable cancer prevention

The actions under this thematic section have as objectives:

- to give citizens the information and tools they need to make healthier choices including recommendations and questions and answers to the general public, and messages to specific target groups;
- to update the European Code against Cancer ("the Code") according to new scientific developments in the area of cancer prevention;
- to contribute to the delivery of an 'EU Mobile App for Cancer Prevention' to support the usability of the Code's messages by the general population; and
- to gain a better understanding of the health literacy level of the target populations and to support the improvement of health literacy on cancer prevention.

The expected results are the development of the 5th edition of the European Code against Cancer, leading to an increased coverage of the Code across the EU. Moreover, the actions will contribute to the development of an 'EU Mobile App for Cancer Prevention' and to the increase of health literacy on cancer prevention within the EU.

Within this thematic area, the Commission plans to launch open procedures for

- a service contract for the development of an 'EU mobile app for cancer prevention'

Type of contracts: service, administrative arrangements

Indicative budget for this thematic area: EUR 5 000 000

Implementation: by DG SANTE and by HaDEA

Cross-cutting Cancer actions: Improving early detection of cancer

The actions under this thematic section have as objectives:

- to ensure that Guidelines and Quality Assurance schemes for cancer screening programmes reflect the latest available scientific evidence and to assess the possibility to expand to other cancers;
- to update the European Cancer Information System to monitor and assess cancer screening programmes, and to support the development and roll out of protocols for future data collections from cancer registries.

The expected results are an update of guidelines on breast, colorectal and cervical cancer screening, diagnosis, and care, including recommendations on early screening of high-risk individuals and implementation at national and regional level, assessment of extending population screening to other cancers, and an update to the European Cancer Information System to ensure it will provide the latest information on incidence, mortality, and survival across Europe for the major cancer entities.

Indicative budget for this thematic area: EUR 11 500 000

Type of contracts: service, administrative arrangements

Implementation: by DG SANTE

Cross-cutting Cancer actions: Ensuring access to high standard in cancer diagnosis and treatment

The actions under this thematic section have as objectives to enhance the quality and safety of radiation technology and optimise its use in medicine.

The expected results aim at improving the quality and safety of medical radiation applications, the standards of the workforce in the radio-nuclear medical sector through education and training, and the facilitation of a more equal access to modern medical radiation technology and interventions.

Within this thematic area, the Commission plans to launch open procedures for

- a service contract for an analysis in the area of access to quality and safety in the use of medical radiation applications

Type of contracts: service

Indicative budget for this thematic area: EUR 500 000

Implementation: by HaDEA

Cross-cutting Cancer actions: Improving the quality of life for cancer patients, survivors and carers including reducing inequalities in cancer care and childhood cancers

The actions under this thematic section have as objectives, at one hand, to contribute to the creation of a 'Cancer Survivor Smart Card which will link with a 'resource' function to give access to best practices, guidelines, and recommendations specifically targeted to cancer survivors and, on the other hand, to provide easily accessible quantitative data and a contextual qualitative analysis of the cancer situation in the Member States through establishing a Cancer Inequalities Registry.

The expected results are enabling access to comparable up-to-date quantitative cancer indicators in a systematic and easily accessible way to the general public and policy-makers, as well as to improve patient-centred communication between cancer survivors and health care providers. Moreover, the results aim at providing a tool to monitor the cancer situation and trends in the EU and the Member States, including at sub-national level and for specific socio-economic groups, and to identify areas of potential action and to guide investment decisions at EU and national level.

Within this thematic area, the Commission plans to launch open procedures for

- a service contract for supply of the software to develop the IT tool for a 'Cancer Survivor Smart Card'.

Type of contracts: service, administrative arrangements.

Indicative budget for this thematic area: 7.100 000.

Implementation: by DG SANTE and by HaDEA.

3. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE

In 2021, the Commission intends to undertake actions through contracts following public procurement (call for tenders and use of existing framework contracts) or administrative arrangements (including service level agreements, co-delegations and memoranda of understanding) with other Commission services to support priorities in the following thematic areas:

Digital collaboration and synergies between EU decentralised agencies and DG SANTE – HPAC (Health Policy Agency Collaboration)

The actions under this thematic section have as objectives:

- to create a series of domain specific data lakes to nurture data ecosystems for HPAC members enabling the sharing of structured and unstructured data and providing the groundwork to launch more modern tools and techniques, such as using artificial intelligence to gain insights from data or employing process automation techniques to bring further efficiencies;
- to provide for a single digital customer relationship management (CRM) solution to capture the interactions with various stakeholders and hold a common repository to manage these stakeholders;
- to evaluate and assess the current digital landscape with the goal to find common business needs for common solutions and to propose rationalisation and strategic actions for evolution.

The expected results aim at having common data in electronic platforms which will provide valuable knowledge and information that can be used in policy analysis and decision processes. Being able to have statistics, simulations, visualisations and navigation across this huge knowledge base will provide answers to questions about value of legislation implementation, degree of adherence to legislation, benchmarking and cross checking available data.

Within this thematic area, the Commission plans to launch open procedures for

- a framework contract for services related to 'Health Policy digital domain solutions and services'.

Type of contracts: service

Indicative budget for this thematic area: EUR 8 000 000

Implementation: by DG SANTE, co-delegation to DIGIT

Strengthening the implementation of the legislation on blood, tissue and cells and organs and cooperation between national authorities and professional sector associations

The actions under this thematic section have as objectives

- to organise training and networking activities for Competent Authorities' staff, in particular inspectors and preparation process assessors, for strengthening the implementation of oversight in the field of SoHO;
- the provision of immediate laboratory capacity to optimize utilisation of COVID-19 convalescent plasma (CCP) in view of the emergence and spread of SARS-CoV-2 variants.

The expected results aim at:

- increasing and standardising the competence of inspectors and assessors in this sector across the EU as well as building a network of senior inspectors/ experts, facilitating

possible joint inspections and peer audits among Member States, and reinforcing trust between them to facilitate the exchange of SoHO;

- Building capacity for the assessment of the neutralising capacity of convalescent plasma samples, assessing the effect of different spike mutations on neutralisation, supporting the sequencing of recipient viruses and enabling the monitoring of the virus evolution among donors.

Type of contracts: service

Indicative budget for this thematic area: EUR 2 500 000

Implementation: by DG SANTE

Implementation of Pharmaceutical legislation and Pharmaceutical strategy

The actions under this thematic section have as objectives:

- the in-depth analysis of the legislative framework for medicines in the format of evaluations and impact assessment;
- the training scheme activities supporting the Member States to increase their capacity building and address the knowledge gaps related to the environmental risk assessment aspects that would support the pharmaceuticals strategy and reply to the environmental challenges identified therein; and
- Supporting cooperation between the national authorities to improve the affordability and cost-effectiveness of medicines and health system's sustainability, including on cancer treatment.

The expected results are preparatory works in accordance with the better regulation provisions in view of the revision of Directive 2001/83/EC and Regulation (EC) 726/2004; capacity building and training scheme related to the environmental risk assessment to strengthen the framework of pharmaceuticals; increase co-operation with and among Member States on improving the affordability and cost-effectiveness of medicines.

Within this thematic area, the Commission plans to launch open procedures for

- a service contract for a training scheme and training-related activities for Member States, to increase their capacity building and fill in the training needs related to the environmental risk assessment, on pharmaceuticals in the environment and the environmental challenges under the Pharmaceutical Strategy.

Type of contracts: service

Indicative budget for this thematic area: EUR 1 850 000

Implementation: by DG SANTE

Implementation of Medical Device and In-Vitro Diagnosis Regulations

The actions under this thematic section have as overall objective to reinforce the safety requirements for all operators for the placing of their products on the EU market among others by:

- facilitating of the adoption of science-based regulatory measures on specific health-related aspects (e.g. surface characterisation of breast implants);
- supporting the development of the EUDAMED database that will allow centralisation and efficient management of data on medical devices and in-vitro devices in a single database accessible to all actors placing medical devices on the EU market, their notified bodies and the national competent authorities and the public;
- supporting the establishment of a network EU reference laboratories, introduced by the IVDR to perform, among others, additional assessment of high risk IVDs, who

will verify, by laboratory testing, that these IVDs perform as stated by the manufacturers;

- medical proof reading and quality control of the European nomenclature for medical devices (ENMD) to be made available by the Commission under the Medical Device Regulation (MDR) 2017/745.

The expected results are reinforced safety requirements for medical devices on the Union's market, including an improved data management for all involved actors, a European nomenclature for medical devices in all EU languages and the establishment of EU reference laboratories for IVDs.

Type of contracts: service, administrative arrangements

Indicative budget for this thematic area: EUR 5 450 000

Implementation: by DG SANTE

Preparation and implementation of HTA Regulation – infrastructure hosted by the European Commission

The actions under this thematic section have as overall objective to ensure that the future EU framework on HTA has the necessary IT infrastructure (e.g. website, intranet, secure system for exchanging information) to produce joint work, joint clinical assessments; joint scientific consultations carried out each year, reports on the identification of emerging health technologies, as well as results of other joint voluntary activities agreed by the Member States.

The expected results are a one-stop-shop for HTA national experts when preparing and endorsing high quality and timely joint HTA reports relevant for decision-making, and for industry when submitting commercially confidential data required for joint clinical assessments (restricted access module), also ensuring access to joint HTA summary reports and activities for patients, healthcare professionals and industry (public module), with potential contribution to the EHDS.)

Type of contracts: service

Indicative budget for this thematic area: EUR 500 000

Implementation: by DG SANTE

Enhanced European Reference Networks (ERNs)

The actions under this thematic section have as objectives

- to provide support for the functioning and enhancement of the system of the European Reference Networks (ERNs) for rare, low prevalence and complex diseases (as established under Article 12 of Directive 2011/24) and for activities addressing the specific unmet needs in this area. This will enable rare disease patients to benefit from pooling of expertise, knowledge and resources at the EU level and to receive the appropriate diagnosis and treatment as well as enhance knowledge generation, training and research in the area of rare diseases;
- the coordination, management and operational activities of the ERNs (including integration of new members and affiliated partners);
- dissemination of generated knowledge on rare diseases to a wider audience and promoting online professional training; ensuring proper rare disease codification and evolution of the IT tool for virtual consultations of clinical cases;
- an analysis of options reducing the administrative burden for the coordination teams of ERNs through the use of simplified cost options.

The expected results are

- an optimisation of the administrative framework for the ERN System and a centralised IT platform serving the training needs of all 24 ERNs regarding content hosting and management of training activities. This will include support to the production of specialised medical content by the networks and other content producers and the possibility to host content produced by other eHealth initiatives such as the EHDS and MyHealth@EU ("Virtual ERN and EHDS Academy");
- an upgrade of the current Clinical Patient Management System (CPMS) to a new enhanced modular version, addressing the growing needs of the networks and incorporating the latest trends in user-centric design. The maintenance of the current CPMS until the new one becomes available, the addition of updated orphacodes in the codification system of CPMS and the maintenance of other ERN-related IT tools.
- a set of recommendations envisaging administrative simplifications for ERN coordination teams to allow for an even greater focus on the outputs and results achieved.

Within this thematic area, the Commission plans to launch open procedures for

- a service contract for logistic, administrative and secretarial support related to the tasks of the functioning of the governing bodies of the ERN system and eHealth Network.

Type of contracts: service, administrative arrangements

Indicative budget for this thematic area: EUR 6 600 000

Implementation: by DG SANTE and by HaDEA

4. DIGITAL

In 2021, the Commission intends to undertake actions through contracts following public procurement (call for tenders and use of existing framework contracts) or administrative arrangements (including service level agreements, co-delegations and memoranda of understanding) with other Commission services to support priorities in the following thematic areas:

European Health Data Space - primary use of health data - infrastructure governance

The actions under this thematic section have as objectives

- the management and governance support to eHealth DSI Member States Expert Group (eHMSEG) and the eHealth Operational Management Board (eHOMB) and management of eHDSI Solution Provider team;
- the design and continuous improvement of MyHealth@EU requirements and specifications as well as the operation and continuous improvement of MyHealth@EU core Configuration and Terminology services;
- the continuous improvement and support to the NCPeH Reference implementation used by most of the National Contact Points for eHealth to enable cross-border health care information services and the continuous improvement and operationalization of the Test and Audit (compliance Check) frameworks;
- the orchestration of MyHealth@EU communities of practice;
- proving NCPeH compliance with the eHDSI requirements to conclude on potential risks to the confidentiality, integrity and availability of health data;

- by using a twinning approach, to support Member States in the development and/or improvement of their own digital health strategies at national level. Support exchange of best practices;
- support for the managed operations, maintenance of software and onboarding support for Member States in the context of the European Federation Gateway Service for contact tracing and warning apps.

The expected results are increased safety and quality of care throughout the Union and an enlargement of the geographical coverage of MyHealth@EU (eHDSI) in order that all Member States can start cross border exchanges of health data. In addition it will result in an increased Member States' capacity to develop national digital health strategies and as a follow up to implement and increase the capacity to perform digital transformation of national health services.

Within this thematic area, the Commission plans to launch open procedures for

- A service contract for supporting Member States to improve their capacities in the field of digital health

Type of contracts: service, administrative arrangements

Indicative budget for this thematic area: EUR 8 850 000

Implementation: by DG SANTE and by HaDEA, co-delegation to COMM, DIGIT

European Health Data Space – secondary use of health data - infrastructure governance

The actions under this thematic section have as objectives to provide support for the development of a governance model and rules on access to health data for secondary use and for the development, deployment and operation of infrastructures and IT systems that will enable access to health data for secondary use, i.e. for research and development, policy-making and regulatory activities. The EHDS supports research and development on new preventive strategies, treatments, medicines, medical devices and better outcomes, and it should support policy-makers and regulators to make evidence-based decisions, ensuring in full the preservation of the privacy and the personal data of citizens. Furthermore, and embracing the 'One Health' approach, the set-up of the European Climate and Health Observatory aims at supporting adaptation plans and measures in Member States related to climate change and health.

The expected results are the setting of the foundations of a common European Health Data Space (EHDS), both at national and European level with due respect to all aspects related to the processing of data. The expected results of the European Climate and Health Observatory are the establishment of a knowledge base for better-informed EU policy-making on climate change-related health effects.

Within this thematic area, the Commission plans to launch open procedures for

- A service contract for support services in the field of development, deployment and operation of infrastructures and IT systems enabling access to health data for secondary use

Type of contracts: service, administrative arrangements, co-delegation to DIGIT

Indicative budget for this thematic area: EUR 1 300 000

Implementation: by DG SANTE and by HaDEA

RECURRENT, HORIZONTAL AND COMMUNICATION ACTIVITIES

In 2021, the Commission intends to undertake actions through contracts following public procurement (call for tenders and use of existing framework contracts), special indemnities or administrative arrangements (including service level agreements and memoranda of

understanding) with other Commission services to support activities with a horizontal and/or recurrent character.

The actions have as objectives the organisation of events in the field of health, the support of expert groups and scientific committees (e.g. Scientific Committee on Consumer Safety, Scientific Committee on Health, Environmental and Emerging risks, etc.) in the field of risk assessment and research, the enhancement of the Health Policy Platform, the support in studies, analysis and evaluations of health-related legislation and of the activities of the "Expert Panel on effective ways of investing in health". Furthermore, the objectives are the support of traditional and on-line communication and dissemination activities on the EU4Health Programme and the results of actions supported by the programme as well as the support of various policy-related communication and dissemination activities in the field of health as well as horizontal activities such as graphic design or website management and maintenance.

The expected results are improved capacities to carry out evaluations of existing legislation and/or legislative proposals, an enhanced Health Policy Platform and improved communication with the with range of stakeholders in the field of public health. Moreover, the expected results will ensure a broad coverage for EU health policy activities, and in so doing gain support for them.

Within this thematic area, the Commission plans to launch open procedures for

- A framework contract for evaluation and impact assessment-related services

Type of contracts: service, administrative arrangements

Indicative budget for this thematic area: EUR 1 214 898

Implementation: by DG SANTE and by HaDEA

C. PRIZES

In 2021, the Commission intends to launch contests for the following awards:

1. EU HEALTH AWARDS

The EU Health Awards focus on practices and interventions which support the implementation of the Sustainable Development Goals in priority health topics such as in the fields of cancer and mental health. The awards create an incentive for European health stakeholders to share their evaluated good practices/interventions and get involved in EU health policy. The awards will be an opportunity to reward stakeholders that have been proactive or reactive in helping to prevent, address and/or mitigate the mental health impact of the pandemic. In this sense, it aims to acknowledge and highlight the work of stakeholders that developed and initiated dedicated activities to support individuals whose mental health was most affected or at risk of being affected. Furthermore, the awards will acknowledge and highlight recognised innovative and excellent actions by cities, NGOs/other civil society organisations, schools, etc., which contribute to promoting and improving cancer prevention through the strengthening of communication, including health literacy, promoting healthy lifestyles for children, adolescents and young people (from 6 to 25 years old).

Participants targeted for the contest: NGOs from both health and the wider civil society, cities or schools in different areas and at any level (European, national, regional or local) and any similar entities.

D. OTHER ACTIONS AND EXPENDITURE

In 2021, the Commission intends to launch the following other actions which contribute to one or several strands:

MEMBERSHIP FEES TO INTERNATIONAL ORGANISATIONS AND REGULATORY BODIES

Assessed Contribution to the World Health Organization Framework Convention on Tobacco Control

This action covers the Union contribution to the World Health Organisation Framework Convention on Tobacco Control (FCTC), which the Community ratified and to which the Union is a party.

Annual Membership fee to the International Council for harmonisation of Technical requirements for Pharmaceuticals for human use – ICH

This action covers the contribution to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) of which the Commission is a founding member.

Annual Contribution to the International Pharmaceutical Regulators Programme - IPRP

This action covers the contribution to the International Pharmaceutical Regulators Programme of which the Commission is a member.

Annual Contribution to the Partnership European Observatory of Health Systems and Policies

This action covers the contribution to the Partnership European Observatory of Health Systems and Policies to which the Commission is a participating member.

Implementation: by DG SANTE

VARIOUS MEETING OF STANDING, AD-HOC MEETINGS, COMMITTEES AND OTHER EVENTS

This action intends to support events and meetings organised by the DG, including special indemnities, in particular in relation to participation in steering groups and expert panels and their cost incurred[20] the participation of experts in joint assessments of notified bodies and related training and audits in the fields of medical devices, active pharmaceutical ingredients and clinical trials; the expert exchange program to support the safety assessment for active substances used in clinical trials, good manufacturing practices and good distribution practices in the EU and third Countries for the quality of medicines, support international harmonisation of requirements for pharmaceuticals and regulatory convergence; activities related international activities with the regulators of the Union's main trading partners; activities related international activities with the regulators of the Union's main trading partners as well as the VICH[21] committee and expert group and the participation in the VICH outreach forum.

[20] Where applicable, the reimbursement of daily subsistence and accommodation allowances will be aligned with the scales of the amounts for staff missions to Member States as provided for in Article 13, paragraph 2 of the Annex VII of the Staff Regulations of officials and other servants of the EU as amended by the Commission Delegated Regulation (EU) 2016/1611 of 7 July 2016 on reviewing the scale for missions by officials and other servants of the European Union in the Member States and as further detailed in Commission's Missions Guide [C(2017) 5323 Annex 1].

[21] VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration.

Within this thematic area, the Commission plans to launch open procedures for

- A framework contract for services related to the organisation of meetings and events as well as related activities.

Implementation: by DG SANTE, by HaDEA and by sub-delegation to PMO

EXPERT EVALUATORS

DG SANTE and HaDEA publish an increasing number of calls for proposals in highly technical fields requiring expert knowledge in the respective areas. This action covers the assistance to evaluation committees for calls for proposals by assessors with a specific technical expertise in the field of public health.

Implementation: by HaDEA

CONTRIBUTION AGREEMENTS WITH DECENTRALISED AGENCIES

This activity covers contribution agreements with decentralised agencies, which have as an objective the setting-up and follow-up pilot of ePI (electronic product information) including tools needed for generation of ePI, guidance and reference implementation for EMA and National Competent Authorities. Furthermore, the activity targets the reinforcement of the Vaccination Information Portal.

Implementation: by ECDC, EMA