



Brussels, 14.1.2022
C(2022) 317 final

ANNEX I

ANNEX I

to the

Commission Implementing Decision

of 14.1.2022

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 2022

Table of Contents

Introduction	4
Legal basis	5
Budget overview for 2022	6
Eligibility, selection and award criteria for action grants	9
Programme performance monitoring and indicators	9
A. GRANTS	10
ACTIONS WITH A COST OF EUR 20 000 000 OR MORE	10
1. CRISIS PREPAREDNESS (CP)	10
2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)	18
3. CANCER (CR)	23
4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)	26
5. DIGITAL (DI)	31
5.1 Establishment of the planned European health data space ('EHDS') – infrastructure and governance: primary use of data (for healthcare)	31
5.2 Establishment of the planned European health data space – infrastructure and governance: secondary use of data (for healthcare)	34
ACTIONS WITH A COST BELOW EUR 20 000 000	36
1. CRISIS PREPAREDNESS (CP)	36
2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)	41
2.1. Health promotion and prevention of NCDs and related risk factors	41
2.2. Addressing mental health challenges	51
3. CANCER (CR)	54
4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)	62
4.1 Enhanced European Reference Networks (ERNs)	62
4.2 Implementation of pharmaceutical legislation and strategy	66
4.3 Strengthening the implementation of the legislation on blood, tissues and cells and organs	70
4.4 Implementation of regulations on medical devices and in vitro diagnostic medical devices	72
4.5 Preparation and implementation of the health technology assessment Regulation ..	79
5. DIGITAL (DI)	81
6. OTHER ACTIVITIES (OA)	83
B. PROCUREMENT	84
ACTIONS WITH A COST OF EUR 20 000 000 OR MORE	84

1.	CRISIS PREPAREDNESS (CP).....	84
	ACTIONS WITH A COST BELOW EUR 20 000 000.....	86
1.	CRISIS PREPAREDNESS (CP).....	86
2.	CANCER (CR).....	87
2.1	Health promotion, cancer prevention and related risk factors	87
2.2	Quality of life of cancer survivors	89
2.3	Evaluating Europe’s beating cancer plan	89
3.	HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS).....	90
4.	DIGITAL (DI).....	94
5.	RECURRENT, HORIZONTAL, IT AND COMMUNICATION ACTIVITIES	98
C.	OTHER ACTIONS AND EXPENDITURE.....	99
D.	ACTIONS IMPLEMENTED IN INDIRECT MANAGEMENT	102
	ACTIONS WITH A COST OF EUR 20 000 000 OR MORE.....	102
	ACTIONS WITH A COST BELOW EUR 20 000 000.....	102

ANNEX I

Draft work programme for 2022 for EU4Health Programme

INTRODUCTION

On 24 March 2021, Regulation (EU) 2021/522 of the European Parliament and of the Council¹ was adopted as part of the Multiannual Financial Framework for the 2021-2027 period. That Regulation established a Programme for the Union's action in the field of health ('the EU4Health Programme').

The COVID-19 pandemic has caused an unprecedented health crisis in the Union and beyond, with severe socio-economic consequences and human suffering. The EU4Health Programme represents an unparalleled Union level financial commitment for health actions in comparison with previous health programmes. The EU4Health Programme is the Union's response to the current public health emergency that will make a significant contribution to the post-COVID-19 recovery aiming to:

- (a) improve public health in the Union through disease prevention and health promotion, as well as international health initiatives and cooperation;
- (b) 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;
- (c) improve access to medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union as well as efficient use of medicinal products;
- (d) 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 Union health legislation and evidence-based decision-making and integrated work among Member States' health systems.

The EU4Health Programme, the main financial instrument to fund the Union health initiatives, is implemented through annual work programmes and on 24 June 2021 the Commission adopted the first one, for 2021.

The EU4Health work programme 2022 will continue 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.

The EU4Health Programme will support the implementation of Union priorities such as the fight against the COVID-19 pandemic, the establishment of European Health Emergency Preparedness and Response Authority ('HERA'), Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe and the implementation of Union health legislation. HERA is set up to strengthen Europe's ability to prevent, detect, and rapidly respond to cross-

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).

border health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures. The EU4Health Programme supports the extended mandate of European Medicines Agency (EMA) and European Centre for Disease Prevention and Control (ECDC) and, once adopted, will support the implementation of the Health Union Package, in subsequent work programmes.

In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, the EU4Health Programme will be implemented in overall consistency, synergy and complementarity with other Union programmes², policies, instruments and actions, *inter alia* Horizon Europe. Through its Mission on Cancer³, Horizon Europe will contribute to the implementation of some of the Europe's Beating Cancer Plan flagships and actions. As part of a joint effort, relevant actions⁴ funded under the 'Cancer' strand of the EU4Health work programme 2022 will be rolled-out in close synergy with the Mission on Cancer.

This work programme sets out priorities and actions, including the resource allocation, for the implementation of the EU4Health Programme in 2022. In pursuing the actions, the needs of vulnerable groups such as people with disabilities as well as a gender sensitive approach will be considered where relevant.

The EU4Health Programme will provide funding to eligible legal entities from Member States, third countries associated to it, or listed in the annual work programme and created under Union law or to international organisations such as health organisations, non-governmental organisations (NGOs), the private sector and other eligible legal entities. Unless otherwise stated, in this work programme, the reference to "Member States' authorities" means "authorities of Member States and of third countries' associated to the EU4Health programme". The funding, in the form of grants and procurement will be provided directly by the Commission or by the Health and Digital Executive Agency ('HaDEA').

LEGAL BASIS

Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, and in particular Article 110 thereof; and

Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 on the establishment of 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, and in particular Article 17(2) thereof.

² For example: Digital Europe Programme, Horizon Europe, the Union Civil Protection Mechanism and in particular its European reserve of additional capacities (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 European Mission – Cancer – Implementation Plan
https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/cancer_implementation_plan_for_publication_final_v2.pdf.

⁴ CR-g-22-08.01, CR-g-22-09.01/02/03, CR-g-22-08.02, CR-g-22-10.01/02/03, CR-p-22-11.01 and CR-p-22-13.01.

BUDGET OVERVIEW FOR 2022

On the basis of the objectives defined in Regulation (EU) 2021/522, this work programme contains the actions to be financed and their total budget (Table 1). The budget breakdown for 2022 is indicated in Table 2.

TABLE 1: BUDGET LINES

BUDGET LINES	2022 (in EUR)
06 06 01 ⁵	835 349 555
TOTAL	835 349 555

Funds committed in the work programme are deployed via grants and procurement, in compliance with the rules set out in the Regulation (EU, Euratom) 2018/1046.

Grants⁶ are financial contributions by way of donation by the Commission in order to finance: (a) an action intended to help achieve a Union policy objective (action grants) or (b) the functioning of a body, which has an objective forming part of, and supporting, a Union policy (operating grants). The award of a grant follows, in general, a call for proposals procedure.

Procurement⁷ is the acquisition of a service by the Commission from an economic operator, which is selected following a call for tenders' procedure.

TABLE 2: OVERVIEW OF FUNDING BY PROCEDURE

FUNDING	2022 Budget (in million EUR)
Direct management	817
of which Grants	513
of which Procurement	300
of which other types of expenditure	4
Indirect management (contribution agreements)	18
TOTAL	835

⁵ Including EFTA contributions of 2.47% of the draft EU4Health budget.

⁶ Article 2(33) and Article 180(2) of Regulation (EU, Euratom) 2018/1046.

⁷ Article 2(49) of Regulation (EU, Euratom) 2018/1046.

The implementation of actions is managed directly by the Directorate-General for Health and Food Safety (DG SANTE) or by Directorate-General European Health Emergency Preparedness and Response Authority (DG HERA) of the Commission unless specified otherwise.

The Commission delegates powers⁸ to implement actions to the Health and Digital Executive Agency ('HaDEA').

The indicative budget allocation per specific objective is presented in Table 3.

TABLE 3: BUDGET BY ACTION AREAS

STRANDS & AREAS OF ACTION	2022 budget (in million EUR)
1. CRISIS PREPAREDNESS (CP)	380.9
01 HERA	274.8
02 TACKLING AMR	50.3
03 SUPPORT TO LARGE-SCALE VACCINATION, INCLUDING AGAINST COVID-19	30.0
04 ONE HEALTH APPROACH FOR CROSS-BORDER PATHOGENS	20.0
05 REINFORCE UNION COOPERATION WITH WHO ON CRISIS PREPAREDNESS	5.8
2. HEALTH PROMOTION & DISEASE PREVENTION (DP)	90.0
06 HEALTH PROMOTION AND PREVENTION OF NON-COMMUNICABLE DISEASES (NCDs) AND RELATED RISK FACTORS	74.0
07 ADDRESSING MENTAL HEALTH CHALLENGES	16.0
3. CANCER (CR)	146.9
08 HEALTH PROMOTION, CANCER PREVENTION AND RELATED RISK FACTORS	105.5
09 INNOVATIVE APPROACHES TO PROSTATE, LUNG AND GASTRIC CANCER SCREENING AT EU LEVEL	31.2
10 REDUCING INEQUALITIES IN CANCER CARE	2.1
11 QUALITY OF LIFE OF CANCER SURVIVORS	2.5
12 TOBACCO CONTROL POLICY	4.1
13 EVALUATION OF EUROPE'S BEATING CANCER PLAN	1.5
4. HEALTH SYSTEMS & HEALTHCARE WORKFORCE (HS)	126.5

⁸ Article 69 of Regulation (EU, Euratom) 2018/1046.

14 REFORMING AND STRENGTHENING HEALTH SYSTEMS	0.7
15 TRAINING FOR HEALTH WORKFORCE, INCLUDING DIGITAL SKILLS	29.0
16 ENHANCED EUROPEAN REFERENCE NETWORKS	52.7
17 IMPLEMENTATION OF THE PHARMACEUTICAL LEGISLATION AND STRATEGY	10.2
18 STRENGTHENING THE IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUES AND CELLS AND ORGANS	6.9
19 IMPLEMENTATION OF REGULATIONS ON MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES	19.8
20 PREPARATION AND IMPLEMENTATION OF THE HEALTH TECHNOLOGY ASSESSMENT (HTA) REGULATION	7.2
5. DIGITAL (DI)	76.6
21 EUROPEAN HEALTH DATA SPACE – INFRASTRUCTURE AND GOVERNANCE; PRIMARY USE OF DATA	41.2
22 EUROPEAN HEALTH DATA SPACE – INFRASTRUCTURE AND GOVERNANCE; SECONDARY USE OF HEALTH DATA	35.4
6. OTHER ACTIONS	14.6
23 OTHER RECURRENT ACTIVITIES, CONFERENCES UNDER COUNCIL PRESIDENCIES, MEMBERSHIPS, IT AND COMMUNICATION SUPPORT TO EVALUATIONS	8.7
24 RECURRENT ACTIVITIES DISEASE PREVENTION	4.3
25 RECURRENT ACTIVITIES HEALTH SYSTEMS	1.2
27 RECURRENT ACTIVITIES HERA	0.4

ELIGIBILITY, SELECTION AND AWARD CRITERIA FOR 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) 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) 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 bodies⁹.

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-financing¹⁰. The maximum possible rate of Union co-financing is up to 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 increased up to 80% of the total eligible costs. In the case of direct grants to European Reference Networks (ERNs) and to the World Health Organization (WHO), the Union contribution may be up to 100% of eligible costs in accordance with Article 8(4) of Regulation (EU) 2021/522.

Ranking of proposals will be done in accordance with the criteria described in the calls for proposals.

PROGRAMME PERFORMANCE MONITORING AND INDICATORS

The EU4Health Programme has in place a sound performance framework, developed by the Commission and stemming out from the list of performance indicators listed in Annex II to Regulation (EU) 2021/522 agreed by the European Parliament and the Council. Those indicators are complemented by a more comprehensive set of indicators as part of the monitoring and evaluation framework of the EU4Health Programme. For each action, meaningful indicators will be included and beneficiaries will collect data for measuring and monitoring progress of implementation and for highlighting the key results achieved. Data needs to be available for these indicators on a regular basis and must be of sufficient quality and reliability; given limited resources, the collection of such data should also be cost-efficient.

⁹ Article 198(5) and (6) of Regulation (EU, Euratom) 2018/1046.

¹⁰ Article 190(1) of Regulation (EU, Euratom) 2018/1046.

A. GRANTS

ACTIONS WITH A COST OF EUR 20 000 000 OR MORE

1. CRISIS PREPAREDNESS (CP)

CP-g-22-01.04 Direct grants to Member States' authorities: enhancing whole genome sequencing (WGS) and/or reverse transcription polymerase chain reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic and future health threats (HERA)

POLICY CONTEXT

As part of the EU Health Union proposals of 11 November 2020, the Commission proposed to set up HERA¹¹ which was established through a Commission Decision on 16 September 2021¹². Overall, HERA will improve the Union's development, manufacturing, procurement and distribution of key medical countermeasures within the Union so to best prepare and respond to serious cross-border threats and emergencies – whether of natural or deliberate origin. In preparation of the formal establishment of HERA, several preparatory actions were launched. On 17 February 2021, the Commission launched 'HERA Incubator', which is a new EU bio-defence preparedness plan against SARS-CoV-2 variants¹³. On 25 February 2021, President Ursula von der Leyen announced that the Union will support the strengthening of the detection and characterisation of variants and the improvement of knowledge on how they are developing and spreading, under the HERA incubator Action Area 1. Building on this, the Commission, together with the ECDC, launched a national infrastructure support programme providing direct grants for strengthening whole genome sequencing ('WGS') and Reverse Transcription Polymerase Chain Reaction ('RT-PCR') in EU/EEA Member States¹⁴. This action will contribute to strengthening health security coordination within the Union during preparedness and crisis response time as outlined in the HERA mission.

In order to ensure the comprehensive and sustainable implementation and integration of this infrastructure initiative, there is a need to continue the support to Member States to consolidate and further expand their capacity to identify and characterise SARS-CoV-2 variants using WGS and RT-PCR by complementing and extending the HERA Incubator national support programme launched in 2021. This action will contribute to a more rapid, comprehensive and effective surveillance of infectious diseases. The capacity building is intended to increase Member States' capacity to respond to the COVID-19 pandemic, but also

¹¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats COM(2020) 724 final

<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0724&from=EN>.

¹² Commission Decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority C(2021) 6712 final

https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/hera_2021_decision_en.pdf.

¹³ Communication from the Commission to the European Parliament, the European Council and the Council Hera Incubator: Anticipating Together the Threat of Covid-19 Variant COM(2021) 78 final

https://ec.europa.eu/info/sites/default/files/communication-hera-incubator-anticipating-threat-covid-19-variants_en.pdf.

¹⁴ For more information: <https://www.ecdc.europa.eu/en/news-events/covid-19-strengthen-member-states-capacities-detect-and-identify-variants>.

to strengthen WGS and RT-PCR capacity in non-crisis time that could be used also for other pathogens. Sustainable use and integration into routine surveillance will be implemented in synergy with international organisations' work in the area, such as WHO.

The setup of national public health WGS and RT-PCR infrastructure for public health microbiology purposes is a national responsibility, and EU/EEA Member States are already at various stages of implementing these technologies for routine testing and characterisation. Therefore, the award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by Member States' public health authorities.

This action supports the policy priority to respond to the COVID-19 crisis and to enhance preparedness for future health emergencies. 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 to cope with serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (a), (b) and (c), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The main focus of this action is to support activities, to enhance and/or improve national public health WGS and/or RT-PCR capacity. The activities may target public health laboratories at national, regional and/or local level, and should facilitate integration of genomics based methods into routine disease surveillance and outbreak preparedness and response.

The direct grant will address specific needs related to WGS and/or RT-PCR infrastructure (e.g. equipment and reagents) and processes that are part of a plan of activities to build on, complement and extend systems and workflows at national and/or regional levels. This can include all relevant phases of the workflow processes with particular attention given to the analytical phase and the data sharing phase.

The activities will be divided to address two sub-topics:

- a) establishment of enhanced WGS and RT-PCR infrastructures and capacities in the Member States that have not already received support for such activities; and
- b) consolidation of WGS and RT-PCR activities in countries that received support in 2021 aiming to ensure the sustainable use and integration of enhanced infrastructure into routine surveillance and outbreak investigation activities, in synergy with relevant on-going work at international level.

EXPECTED RESULTS AND IMPACT

This action will deliver results that are directed, tailored, and contribute towards the following expected outcomes:

- a) in the short-term, contribution to the establishment of a sustainable, efficient and high capacity WGS and/or RT-PCR infrastructure for national public health microbiology;
- b) in the short/medium-term, contribution to early detection and enhanced monitoring of emergent and known SARS-CoV-2 variants at the national and the EU/EEA levels;
- c) in the medium/long-term, contribution to enhanced genomic-based infectious disease outbreak investigation capacities at regional, national and/or EU/EEA levels;

- d) in the medium/long-term, contribution to enhanced routine genomic-based surveillance of infectious diseases at the regional, national and/or EU/EEA levels¹⁵;
- e) in the long-term, contribution to enhanced preparedness to timely and efficiently address cross-border outbreaks of infectious diseases and pandemics in the future.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - CP-g-22-01.04	Q1-Q2/2022	EUR 39 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

¹⁵ In accordance with the 'ECDC strategic framework for the integration of molecular and genomic typing into European surveillance and multi-country outbreak investigations'
<https://www.ecdc.europa.eu/sites/default/files/documents/framework-for-genomic-surveillance.pdf>

CP-g-22-02.01 Direct grants to Member States' authorities: implementation of AMR measures in Member States

POLICY CONTEXT

Antimicrobial resistance ('AMR')¹⁶ 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 Union. It is also estimated that AMR costs in the Union amount to €1.5 billion per year in healthcare and productivity losses.

In June 2017, the 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 Union a best practice region, boosting research development and innovation, and shaping the global agenda.

AMR remains a high priority for the Commission and the aim to build on the 2017 EU AMR Action Plan¹⁷, will further strengthen its implementation by harnessing the new opportunities for action brought by AMR. Member States' authorities should develop and update their national action plans on AMR.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by Member States' authorities as they have the required competence and responsibility to implement the Union policies at national level.

This joint action supports the policy priority to strengthening the responsiveness of health systems and coordination among the Member States in order to cope with serious cross-border threats to health. 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, point (b)) through the specific objectives defined in Article 4, points (a) and (b), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This joint action will aim to provide direct and sizable support to Member States' authorities for their national action against AMR, in particular on the human health side, mainly focusing on antibiotics, and will reinforce AMR in coherence with the Pharmaceutical Strategy for Europe.

This joint action will support Member States in the development and the update of national action plans on AMR (including support for the establishment of national One Health coordinating bodies and supervisory organs) and the wider uptake of state-of-the-art infection prevention and control ('IPC') for both community-acquired and healthcare-associated infections, and antimicrobial stewardship ('AMS') strategies in primary care and hospitals/long-term care facilities.

The joint action will support:

- a) AMS and IPC:

¹⁶ The ability of microorganisms to resist antimicrobial treatments, especially antibiotics.

¹⁷ A European One Health Action Plan against Antimicrobial Resistance (AMR) https://ec.europa.eu/health/sites/default/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf.

- i. development of a set of common EU standards and requirements on high-level IPC and AMS in healthcare settings¹⁸ and implement those in several pilots across the Union;
 - ii. mentorship and ‘observership’ programmes for health professionals;
 - iii. development of core competencies for health professionals and training resources.
- b) Capacity building:
- i. strengthening networks and sharing best practices between Member States, at ministries and national agencies level;
 - ii. implementation of evidence-based IPC and AMS programmes and innovative interventions including wider uptake of novel rapid diagnostics and behavioural change among prescribers (e.g. doctors and pharmacists) through different measures (e.g. legal sanctions and/or social incentives) to foster prudent use, in line with the EU guidelines on prudent use of antimicrobials in human health¹⁹;
 - iii. reinforced surveillance through improved laboratory capacities;
 - iv. supporting national reference laboratories on AMR, in foresight of the establishment of an EU Reference Laboratory to promote good practice and alignment by Member States and to coordinate the network of national reference laboratories.
- c) Health literacy on AMR: establishment of a network of AMR ambassadors and awareness-raising activities on AMR, including the organisation of a Union-wide communication campaign with a toolbox of messages to be further tailored to national audiences (including educational resources for the general public and for children).
- d) Launching of the European Antimicrobial Resistance Surveillance Network In Veterinary Medicine (‘EARS-VET’) network (i.e. an EU surveillance network of antibiotic resistance in diseased animals) to implement an operational inter-sectoral strategy to increase interdisciplinary gains:
- i. implementing an integrated epidemiological surveillance system of antimicrobial resistance, antimicrobial use and healthcare-associated infections;
 - ii. increasing literacy regarding infection prevention, antimicrobial resistance and good use of antibiotics;
 - iii. identifying management strategies, through contractual mechanisms, education, or infrastructure, capable of improving the implementation of the existing guidelines in this area.

The joint action will also provide continuity and further uptake of the policy recommendations of the JAMRAI joint action²⁰ (that ended in 2021) and implementation in

¹⁸ Building up on the outputs also on the knowledge gathered as part of the preparatory action CP-g-03.2.1 of the EU4Health 2021 work programme.

¹⁹ Commission Notice EU Guidelines for the prudent use of antimicrobials in human health (2017/C 212/01) (OJ 1.07.2017).

²⁰ JAMRAI Joint Action (761296) on AMR.
https://webgate.ec.europa.eu/chafea_pdb/health/projects/761296/summary.

Member States. In this context, the outputs obtained in the framework of JAMRAI could also support strengthening of laboratory capacity and the production, research, development, and deployment of health products and crisis-relevant niche products within the Union to overcome as well as enhance the availability, accessibility and affordability of medicinal products and medical devices.

EXPECTED RESULTS AND IMPACT

The joint action is expected to result in:

- a) updated national action plans across the Union, with well-defined indicators and targets;
- b) recommendations and specific interventions (e.g. pilots) on common EU standards/requirements for infection prevention and control practices as well as antimicrobial stewardship practices in healthcare settings (in particular hospitals and long-term care facilities but also in primary care) and their implementation ensuring scalability;
- c) novel approaches for fostering antimicrobial stewardship and prudent use including through pilots;
- d) setting up a prototype of the EU Reference laboratory on AMR in human health (i.e. for human pathogens);
- e) materials and strategies for awareness raising and a fully implemented Union-wide awareness-raising campaign, covering conventional and social media, on AMR and the importance of prudent use, including a component for education establishments (e.g. universities).

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - CP-g-22-02.01	Q2-Q3/2022	EUR 50 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

CP-g-22-03.01 Call for proposals to support Member States and other relevant actors to implement relevant results of innovative public health research in relation to vaccination against COVID-19

POLICY CONTEXT

The COVID-19 pandemic created a need for fast vaccination of entire populations in Member States, which was a challenge of historic dimensions for many countries, as it required a multitude of steps to be taken successfully. These range from the design of vaccination plans, to the set-up of appropriate infrastructure and easily accessible, sufficiently resourced vaccination services, to communication and outreach activities to ensure high uptake of the vaccines, including activities to address vaccine hesitancy and disinformation on related risks.

The novelty of the vaccines to be administered and the pandemic context made the task even more demanding. Hence, there is a need to gain efficiency and develop strategies in terms of large-scale vaccination for other diseases as well. Large-scale vaccination could contribute to enhanced catch-up vaccination in the context of routine vaccination programmes rolled out in the Member States that may have been interrupted or delayed during the COVID-19 health crisis.

This action supports the policy priority to respond to the COVID-19 crisis and implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (a) and (b), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The action aims to support Member States and relevant stakeholders to implement the results of recent and relevant research in relation to vaccination against COVID-19 by:

- a) mapping public health evidence and research results on COVID-19 large-scale vaccination that could be relevant for uptake, including findings, from Member States and outside of the Union;
- b) identifying challenges and assess the feasibility to implement solutions in Member States, based on the mapping and taking country-specific factors into account;
- c) developing implementation plans and pilot activities to respond to the current pandemic context or future health crises, or to optimise current routine vaccination practices, including catch-up vaccination;
- d) implementing the pilot activities in volunteering Member States including the activities identified as potentially most effective (e.g. training programmes for health professionals, awareness-raising campaigns to tackle vaccine hesitancy, health preparedness training programmes, infrastructure initiatives, dedicated events for the exchange of good practices, risk communication and community engagement etc.);
- e) identifying successful pilot activities and, based on these, develop a robust sustainability plan for continued implementation and toolkits and recommendations for upscaling in other Member States.

EXPECTED RESULTS AND IMPACT

The action is expected to deliver an inventory of relevant innovative public health research on COVID-19 large-scale vaccination and implement plans in relevant Member States taking into account feasibility and country specific factors. This will result, based on pilot projects implemented in several Member States and, after assessment, in the development of sustainability plans and toolkits and recommendations.

These activities are expected to increase efficiency in terms of large-scale vaccination, making the best possible use of research results to increase uptake of COVID-19 vaccines and/or routine vaccination programmes.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – CP-g-22-03.01	Q2-Q3/2022	EUR 30 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks, private entities, Member States’ authorities, and civil society organisations (associations, foundations, NGOs and similar entities)

2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)

CR-g-22-08.01 Direct grants to Member States' authorities: Cancer and other NCDs prevention – action on health determinants

POLICY CONTEXT

Non-communicable diseases ('NCDs') are responsible for 87% of the disease burden in the Member States and improved health promotion and disease prevention can reduce the prevalence of NCDs by as much as 70% (State of Health in the EU Companion Report 2017²¹). Cancer is a major NCD and about 40% of cancer cases in the Union are preventable. The costs of NCDs and cancer care are very high and they are expected to grow further. In addition, the COVID-19 pandemic has had a negative impact on NCDs prevention and care, including on cancer.

Considering the sharing of common risk factors between cancer and other NCDs, such as tobacco use and harmful alcohol consumption, unhealthy diets, pollution, sedentary lifestyle, physical inactivity, and metabolic disease, strengthened coordination will improve prevention programmes by gaining scale to mobilise actions, avoiding duplication and fragmentation of actions. Finally, by joining efforts, the Member States' authorities will increase the impact of actions on the prevention of cancer and other NCDs, and thus contribute to the implementation of Europe's Beating Cancer Plan. The Steering Group on Health Promotion and Disease Prevention and Management of Non-Communicable Diseases ('SGPP') and its sub-group on Cancer, and the Commission's successful best practice transfer mechanism, as well as the support provided by the Knowledge Centre on Cancer, will help to achieve the objectives of this action. Other synergies will be supported, for instance with the promotion of Health Enhancing Physical Activity (HEPA) through the implementation of the Council Recommendation on promoting health-enhancing physical activity across sectors²².

Under Article 168 TFEU, Member States are responsible for the entire pathway of NCDs and cancer care, including for the planning and implementation of health promotion and prevention programmes. In addition, NGOs, civil society organisations, and professional and patients' groups, are essential to ensure the roll-out of the initiatives as close as possible to the citizens, and convey to health authorities any feedback from the ground, which might be useful to improve and fine-tune national health promotion and prevention programmes.

The Commission supports the Member States' efforts to reduce the burden of NCDs to reach the United Nations Sustainable Development Goals (UN SDGs). In this context, the Commission is working on a new initiative, 'Healthier Together – EU NCD Initiative', which includes five action strands on cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, and a horizontal strand on health determinants. In each of these strands, the reduction of health inequalities will be tackled.

Health promotion and disease prevention can significantly reduce the incidence and prevalence of cancers and other NCDs, potentially reducing the need for long-term care and its resulting individual and public expenditure. Prevention measures targeting common risk factors may have a significant and simultaneous impact on several conditions at the same

²¹ State of Health in the EU Companion Report 2017
https://ec.europa.eu/health/sites/default/files/state/docs/2017_companion_en.pdf.

²² Council Recommendation of 26 November 2013 on promoting health-enhancing physical activity across sectors (OJ C 354, 4.12.2013, p. 1).

time. This rationale supports the choice to have a joint action addressing the prevention of cancer and other NCDs in synergy.

Europe's Beating Cancer Plan outlines actions that support Member States by providing the tools such as the European Code against Cancer and the EU Mobile App for Cancer Prevention²³ to strengthen risk communication and deliver specific activities on cancer primary and secondary prevention. These activities include, *inter alia*, vaccination against human papillomaviruses, detection and treatment of viral hepatitis, early cancer detection and measures to reduce tobacco use and harmful alcohol consumption and to improve health promotion through access to healthy diets and physical activity and the reduction of sedentary behaviour. While policies and actions addressing cancer have already been outlined in the Europe's Beating Cancer Plan, an additional effort to increase support to Member States and stakeholders is necessary to synergise and further coordinate these actions within the area of major NCDs, while using and building upon existing Union systems and information sources, such as the Health Promotion and Disease Prevention Knowledge Gateway.

This approach will allow for Member States' authorities to target their specific needs for either cancer or other NCDs prevention, while contributing to and benefitting from a coordinated and large-scale approach.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can best be carried out by Member States' authorities as they have the required competence and responsibility to implement the Union policies at national level.

The joint action will support the policy objective of reducing the burden of cancer and other NCDs and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives defined in Article 4, points (a) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of the joint action is to reduce the burden of cancer and other NCDs and common risk factors, both at a personal and societal level, and support Member States by taking a holistic approach for the prevention of cancer and other NCDs, through providing a decisive boost for coordinated action.

In the context of the Europe's Beating Cancer Plan and of the need to address NCDs, the joint action will address health determinants common to cancer and other NCDs. It will address jointly their common underlying risk factors, avoiding fragmentation of actions, duplications and overlaps, promoting engagement of Member States, and increasing impact.

Subtopic 1: Among others, the joint action will boost cancer primary and secondary prevention, supporting Member States to design and implement the activities of an 'EU Consortium on Cancer Prevention'. This will identify major gaps in cancer prevention areas and propose options for solutions at national and regional level taking into account the Europe's Beating Cancer Plan and existing experiences and best practices. Actions will support population-based and/or targeted prevention campaigns to support the reduction of harmful alcohol consumption and tobacco use, the reduction of exposure to other risk factors

²³ Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM(2021) 44 final
https://ec.europa.eu/health/sites/default/files/non_communicable_diseases/docs/eu_cancer-plan_en.pdf

and to promote healthy lifestyles and improve health literacy; they will allow for the prevention and early detection of cancer related to risk factors shared with other NCDs. Where major gaps exist, such as in population-based cancer screening, the joint action will provide support to address the related needs. Support to civil society organisations such as NGOs, and professionals' and patients' groups will be provided to facilitate cooperation and help in the roll-out phase of the activities. Specific training to address needs in linking stakeholders on the ground will be supported, as appropriate. Actions will also include piloting and evaluation of novel approaches to prevention, such as on behaviour and the ones related to the potential identification of families at risk of cancer on the base of genetic profiling. An annual high-level event will ensure regular exchanges with all stakeholders.

Subtopic 2: Activities will include the implementation of other non-cancer specific NCD prevention best practices and pilot testing of relevant research results and innovative practices, drafting of public health guidelines and healthcare guidelines, training and twinning, health communication and/or health literacy, interventions to promote healthy settings and improve the choice environment, etc. Among others, the selection of best and innovative practices will also benefit from the Best Practice Portal, from the work of international organisations such as WHO and OECD, and from previous projects and joint actions supported by the Union.

Activities should also include an equity dimension and aim at reducing health inequalities.

EXPECTED RESULTS AND IMPACT

A plan with specific targets, indicators, and actions for the prevention of NCDs will be defined with input of the Member States and stakeholders.

The joint action will support the definition and roll-out of best practices for implementation through population-level disease prevention and health promotion interventions, the definition of public health guidelines, the technical preparation and roll out of new policy approaches, etc. These are expected to reduce the burden of cancer and other NCDs in 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 disease prevention and health promotion, and management policies related to cancer and other NCDs. 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 - CR-g-22-08.01	Q2-Q3/2022	EUR 75 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (one joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

DP-g-22-06.03 Direct grants to Member States’ authorities: prevention of NCDs – cardiovascular diseases and diabetes

POLICY CONTEXT

NCDs are responsible for 87% of the disease burden in the Member States and improved health promotion and disease prevention can reduce the prevalence of NCDs by as much as 70%. The costs of treating NCDs are high and expected to grow further, also considering the Union’s ageing population. Furthermore, the COVID-19 pandemic has posed new health challenges and has shown that NCDs can dramatically increase the negative impact of other diseases. In order for the Union to address these challenges in a sustainable manner, there is a need for enhanced resilience. The Commission’s 2020 Strategic Foresight Report²⁴ puts forward resilience as a new compass for Union policies and proposes to develop resilience dashboards for its monitoring. The childhood obesity rate in the Union has been included in the strategic resilience dashboard and the economic case for prevention has been made by the OECD²⁵. It is also recognised that improved health promotion and disease prevention can reduce the prevalence of NCDs by as much as 70%.

Cardiovascular diseases and diabetes are the leading causes of death globally. Whilst behavioural risk factors are key to preventing these diseases (and are addressed by other actions in this work programme), other complementary, specific and targeted public health measures can prove essential to reduce their associated burden. Among others, voluntary cooperation on hypertension, primary care testing or screening (including the possible use of imaging technologies) may play a role in dealing with these challenges. Therefore, the magnitude of the challenge requires the intervention of Member States’ authorities.

The Commission supports the Member States’ efforts to reduce the burden of NCDs to reach the UN SDGs. In this context, the Commission is working on a new initiative, ‘Healthier Together – EU NCD Initiative’, which includes five action strands on cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, and a horizontal strand on health determinants. In each of these strands, the reduction of health inequalities will be tackled.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action has a Union added value, and can be best carried out by the Member States’ authorities as they have the required legal and technical competences and responsibilities to implement the Union policies at national level.

The joint action(s) will support the policy objective of reducing the burden of NCDs and implements the EU4Health Programme’s general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives defined in Article 4, points (a) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of the joint action(s) is to reduce the burden of NCDs and related risk factors, both at personal and societal level, targeting or addressing the specifics of cardiovascular diseases and diabetes and their health determinants, as necessary.

²⁴ 2020 Strategic Foresight Report. Charting the course towards a more resilient Europe.

²⁵ OECD (2019), The Heavy Burden of Obesity: The Economics of Prevention, OECD Health Policy Studies, OECD Publishing, Paris, <https://doi.org/10.1787/67450d67-en>.

Activities will include the implementation of best practices and pilot testing of innovative practices, including those on early diagnosis, the production of public health guidelines, the technical preparation and roll out of new policy approaches, and support actions such as training and twinning, health communication or health literacy. Activities should also include an equity dimension and aim at reducing health inequalities.

The joint action(s) will create synergies and complementarities with the health determinants action (CR-g-22-08.01) of this work programme.

EXPECTED RESULTS AND IMPACT

The action will implement projects on disease prevention and health promotion, e.g. evidence-based interventions (validated best practices, promising evidence-based practices, research project results), which are expected to reduce the burden of cardiovascular diseases and diabetes in 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 disease prevention and health promotion, and management policies related to cardiovascular diseases and diabetes.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - DP-g-22-06.03	Q2-Q3/2022	EUR 55 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (One or two thematic joint actions) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

3. CANCER (CR)

CR-g-22-09.01/02/03 Call for proposals to monitor and strengthen the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level

POLICY CONTEXT

Cancer prevention and early detection offer the best chance of beating cancer and saving lives. Currently, the 2003 Council Recommendation on Cancer Screening in the Union²⁶ endorses population-based cancer screening for the early detection of breast, cervical and colorectal cancer. As of 2020, 25 Member States had introduced population-based screening in their National Cancer Control Plans programmes for breast cancer, 22 countries for cervical cancer and 20 for colorectal cancer. As announced in the Europe's Beating Cancer Plan, the Commission will make a proposal by 2022 to update that Council Recommendation and ensure the latest available scientific evidence is reflected, including the possible extension of screening to other cancers, for instance prostate, lung, and gastric cancers.

Prostate cancer is the most commonly diagnosed cancer in men with an incidence rate²⁷ of 158.7 per 100 000 in the Member States and a 5-year relative overall survival rate of 83.4% in Europe. Although it is well-known that Prostate Specific Antigen (PSA) tests in population-based screening programmes would contribute to early detection thereby reducing the prostate cancer mortality rate, the discussion on over-diagnosis and over-treatment has pushed for a revision of the screening approaches at Union level.

Lung cancer is the second most diagnosed cancer among males and the third among females in Member States for the year 2020; the estimated incidence²⁸ for the year 2020 is 97.2 per 100 000 in males and 43.9 in females among Member States. Corresponding values for mortality are 15.7 and 7.2, respectively. The National Lung Screening Trial²⁹ showed that individuals randomly assigned to screening with low-dose computed tomography (CT) scans had 20% lower lung cancer mortality than those screened with conventional chest radiography. However, some investigators suggested that the ratio between benefit and harm could be improved through various means, in particular by reducing the impact of over-diagnosis. Furthermore, the exposure of large groups of healthy individuals to ionising radiation as part of population-based lung cancer screening calls for the development of common low-dose CT protocols, quality assurance and patient dose assessment, in line with European legal requirements for radiation protection³⁰.

Gastric cancer is one of the most common cancers in the Union, with an incidence³¹ of 22.4 per 100 000 in males and 10.6 in females, and a 5-year relative survival rate of 23.7% in males and 27.7% in females, with a wide variation among Member States. Early gastric cancer detection could improve the survival rate, although different elements may contribute. *Helicobacter pylori* (*H. pylori*) infection is recognised as an important cause of gastric cancer,

²⁶ Council Recommendation 2003/878/EC of 2 December 2000 on cancer screening (OJ L 327, 16.12.2003, p. 34).

²⁷ Age-adjusted incidence rates in 2020. European Cancer Information System.

²⁸ Age-adjusted incidence rates in 2020. European Cancer Information System.

²⁹ N Engl J Med. 2011 Aug 4;365(5):395-409.

³⁰ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (BSS Directive).

³¹ Age-adjusted incidence rates in 2020. European Cancer Information System.

and its eradication could reduce the incidence and mortality of gastric cancer, although the debate is still open.

The estimation of the direct costs of these three types of cancers shows that they are among the highest when compared to other cancers, with lung and prostate being the two most costly cancers.

This action stems from the Europe's Beating Cancer Plan and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a)), through the specific objectives defined in Article 4, point (a), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is to provide Member States with evidence-based knowledge to be transferred to further design, plan, and implement prostate, lung, and gastric cancer screenings. Methodological approaches will be aligned and coordinated with the European Guidelines and Quality Assurance Schemes for breast cancers.

This action will support the optimisation of knowledge transfer, a better understanding of the needs, and the design, planning and development of possible options for future implementation of targeted screening on prostate, lung, and gastric cancers. In addition, the action will support initiatives to fill the existing gaps in knowledge and to fine-tune and improve the Member States' approaches to the early detection of prostate, lung, and gastric cancer. It will help to align and ensure consistency in addressing a set of basic requirements that are currently being dealt with in a piece-meal manner in Member States.

These activities will develop and roll-out pilot projects through pan-European cooperation, with a special focus on addressing questions that are still open, including on cost-benefit and optimal benefit-harm balance and potential impact on health inequality of prostate, lung and gastric cancer screening programmes including the identification of appropriate financing mechanisms.

EXPECTED RESULTS AND IMPACT

Evidence-based data, including from risk-benefit and cost-effectiveness studies and trials, will provide Member States with essential information for the design, planning and roll-out of potential lung, prostate, and gastric cancer screening, including the best strategies and target groups to take into consideration in function of the available resources.

The initiatives implemented by this action will include a multistep approach to support Member States to organise the evaluation of the practical implementation and the continuous improvement of such screening programmes. The support will include: (1) needs assessment of Member States, taking into account the different epidemiology and populations at risk for lung, prostate and gastric cancers; (2) periodical information on benefit-harm balance and cost-effectiveness of the screenings; (3) regular review of new available approaches; (4) the design, planning and implementation of at least two pilot projects per type of cancer, with the objective of assessing the concrete feasibility of the screenings, fulfilling the requirements of national or regional health authorities; and (5) at least three highly visible conferences targeting all three types of cancers.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for proposals: a) CR-g-22-09.01 Prostate cancer b) CR-g-22-09.02 Lung cancer c) CR-g-22-09.03 Gastric cancer	Q1/2022	a) EUR 10 000 000 b) EUR 10 000 000 c) EUR 10 000 000
Procedure type	Implemented by	Type of applicants targeted
Open calls for proposals (action grants)	HaDEA	Academia and education establishments, research institutes, national and regional health authorities dealing with cancer screening programmes, hospitals, civil society organisations (associations, foundations, NGOs and similar entities), expert networks and established networks in the field of public health

4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)

HS-g-22-15.01 Call for proposals to provide training for health workforce, including digital skills

POLICY CONTEXT

The COVID-19 pandemic showed the enormous scope for mutual learning and the importance of sharing knowledge or updating skills to save lives and achieve better health outcomes. The right skills are also essential to mobilise resources in crisis situations. In addition, the access to continuous professional training is one of the most important motivation factors for the health workforce, and equips them with necessary skills to save lives and improve health outcomes.

The European Health Union package puts particular emphasis on improving the resilience of health systems and staff is at the very core of more resilient health systems. On top of a challenge related to staff shortages, the health systems in the Union should also address skills mismatches. This has already been highlighted in the 2017, 2019 and 2021 State of Health in the EU Companion Reports³², which show that training is key in not only upgrading skills of health workforce, but also in supporting quicker transition to more effective and patient-oriented health models.

This action will address shortages in access to continuous and professional development and training for health professionals (CPD)³³ and it will increase opportunities for training for non-clinical staff working on health planning, procurement and management. This will contribute to the transformation of health systems including digital health solutions.

Improving digital skills is a precondition of a quicker digital transition, one of the priorities for the Commission. Often digital skills are outdated and not adequately considered in professional development, therefore the design of training courses and promoting the results will raise awareness for the need for digital skills, quality of the available training, and the importance of digital skills within the healthcare professions.

Mobilising efforts to address skills mismatches is, among other actions an objective of the EU Pact for Skills³⁴, which calls for efforts in all the sectors, including health, to support skills necessary to recover quicker from the COVID-19 pandemic and to build more resilient societies and economies. A health partnerships under the EU Pact for Skills will promote digital skills, so this action will directly contribute to it.

The training courses will also pay due attention to the digital dimension and will strengthen the digital literacy and use of digital health tools by the health workforce. Investing in digital skills of health workforce enables the safe and effective use of approved latest digital technologies developments, as the recent OECD analysis highlights³⁵.

To address existing skills mismatches, the actions can target upskilling and re-skilling to deal with pressing health challenges such as antimicrobial resistance, emerging infectious diseases,

³² [Companion Report | Public Health \(europa.eu\)](#)

³³ CPD as 'the educative means of updating, developing and enhancing how doctors apply the knowledge, skills and attitudes required in their working lives'.

³⁴ Pact for Skills: <https://ec.europa.eu/social/PactforSkills>.

³⁵ Empowering the health workforce. Strategies to make the most of the digital revolution 2020 <https://www.oecd.org/health/health-systems/Empowering-Health-Workforce-Digital-Revolution.pdf>.

multi-morbidity and chronic diseases and other potential new challenges in the future, depending on the needs of Member States.

This action is closely linked to EU political priorities such as the European Health Union and the EU Pact for Skills. In the implementation, this action will ensure that there is no overlap with projects financed by the NextGenerationEU funds.

This action implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3, point (d)) through the specific objectives defined in Article 4 points (b), (h) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this action is to strengthen the continuous professional development and training through updated or new training courses developed in co-operation with professional associations, education centres and other relevant organisations. This will provide opportunities for up-skilling or re-skilling, taking full advantage of technological developments in line with the EU Pact for Skills (e.g. training will include relevant modules on digital skills).

This action will cover the following activities:

- a) developing and implementing training modules of continuous professional development for medical professions including nurses and other health workforce by addressing their needs;
- b) the training courses will include digital skills and other relevant skills needed for surge capacity in crises and for transformation of health systems into new care models providing more integrated health care;
- c) developing and implementing training modules for non-clinical staff working in health systems to contribute to effective, accessible and resilient health systems with a focus on digital skills for procurement, planning and management;
- d) micro credentials in the training courses (in line with the forthcoming Commission's initiative on micro credentials) could be considered.

This action will complement the activities under the healthcare workforce projects cluster supported under the 3rd Health Programme³⁶ and the joint action ('A health workforce to meet health challenges - forecasting and planning for workforce in the healthcare sector') established under the 2021 EU4Health work programme on building capacity in effective forecasting and planning for health workforce.

EXPECTED RESULTS AND IMPACT

The expected results are the following:

- a) newly designed European training modules for health workforce (physically or online) and their implementation; at least 1 module for general medicine, at least 3 modules for specialists professionals, at least 4 modules for nurses, at least 2 modules for non-clinical staff working in health systems or health authorities;

³⁶ Funding & tender opportunities Single Electronic Data Interchange Area (SEDIA)
<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-search>.

- b) at least seven specific modules to train trainers;
- c) improving the digital skills of health workforce as part of patient care;
- d) developing micro-credentials as appropriate in skills for healthcare;
- e) refining the current educational model to adapt the health workforce skills for surge demand in crisis.

This action will impact on the skills underpinning quicker recovery and transition to more resilient health systems. It will also have an impact on:

- a) organisational change, improvement of workload and team work, especially in surge capacity;
- b) the implementation of the Pact for Skills initiative through provision of training opportunities to upskill and reskill especially in digital skills in healthcare.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – HS-g-22-15.01	Q1/2022	EUR 29 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Academia and educational establishments, european association of healthcare professionals, Trade Unions, civil society organisations (associations, foundations, NGOs and similar entities) and Member States' authorities

HS-g-22-16.01 Direct grants to European Reference Networks (ERNs): support coordinating centres of the 24 ERNs for the coordination, management, and operational activities of the ERNs

POLICY CONTEXT

The ERNs were established in 2017 in accordance with Article 12 of Directive 2011/24/EU of the European Parliament and of the Council³⁷ in the field of rare or low-prevalence complex diseases.

Currently there are 24 ERNs connecting specialised healthcare providers across Europe. The current grants for coordination activities of the 24 ERNs from the 3rd Health Programme will expire on 28 February 2022. New direct grants for ERNs should ensure their business continuity until 2023 when new multiannual grants should be launched that will streamline and simplify the ERN funding structure, and for some of the ERNs will also bring together existing grants for ERN IT and data related activities currently supported from the Connecting Europe Facility fund.

The award of a direct grant as referred to in Article 13(6) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by established ERNs, which solely have the required competence and responsibility to implement the action. In accordance with Article 193(2), point (a), of Regulation (EU, Euratom) 2018/1046 and Article 5 (7) and 14 of Regulation (EU) 2021/522, the starting date of actions may be set, where appropriate, prior to signature of the grant agreement and costs may be eligible before submission of the proposal. Continuous and retroactive funding (as of 1 of March 2022) is essential for ERNs to be fully operational as they play an important role in consolidating knowledge and expertise scattered across the Union on rare or low-prevalence complex diseases.

This action supports the functioning and enhancement of the system of ERNs. It will enable rare disease patients and their health professionals to benefit from pooling of expertise, knowledge and resources at the Union level and to receive the appropriate diagnosis and treatment as well as enhance knowledge generation, training and research in the area of rare diseases. It implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d)) through the specific objectives defined in Article 4, points (f), (g) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The proposed action will support Coordinating Centers of the 24 ERNs for the coordination, management and operational activities of the ERNs (including integration of new members, more than 600 new units, and affiliated partners).

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

- a) coordination, management and operational activities of ERNs (including integration of new members and affiliated partners);
- b) dissemination of generated knowledge on rare or low prevalence diseases to a wider audience;
- c) coordination and promotion of professional training activities;
- d) coordination of and support for virtual discussions of clinical cases through the IT tool and coordination of and support for functioning of ERN registries;

³⁷ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

- e) coordination of development and updating of clinical practice guidelines and other clinical decision support tools;
- f) knowledge generation and exchanges of best practice concerning diagnosis and the delivery of high-quality and cost-effective healthcare for patients with rare or low prevalence diseases.

EXPECTED RESULTS AND IMPACT

This action will support the provision of specialised healthcare for rare diseases and support development of new guidelines, build evidence of best practices, develop educational programmes and training, set the research agenda in collaboration with stakeholders including patients’ representatives, and share knowledge through participation in virtual multidisciplinary teams.

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

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call opening	Budget
Direct (action) grants – HS-g-22-16.01	Q1/2022	EUR 26 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to bodies identified by the basic act in accordance with Article 195, first paragraph, point (d), of Regulation (EU, Euratom) 2018/1046	HaDEA	Coordinating Centre of the 24 established ERNs

5. DIGITAL (DI)

5.1 ESTABLISHMENT OF THE PLANNED EUROPEAN HEALTH DATA SPACE ('EHDS') – INFRASTRUCTURE AND GOVERNANCE: PRIMARY USE OF DATA (FOR HEALTHCARE)

DI-g-22-21.01 Direct grants to Member States' authorities: expansion of MyHealth@EU Digital Service Infrastructure (eHDSI) with new services and to more Member States

POLICY CONTEXT

The recent worldwide COVID-19 pandemic health crisis has reminded that health crises respect no borders and affect all. More than ever before, the access to and sharing of health data are gaining a new sense of urgency and relevance. The successful EU Digital COVID certificate has increased the availability of health data in digital form (including vaccination, test results and medical problems) and further strengthens the relevance of sharing health data.

The eHealth Digital Service Infrastructure (eHDSI) offer health data sharing services to patients (MyHealth@EU) for ensuring the continuity of care for people/individuals while they are travelling abroad in the Union. This gives Member States the possibility to exchange health data in a secure, efficient and interoperable way. Such services enable people/individuals in the Union to benefit from healthcare in their country of travel in the same way that they benefit in their country of residence – via a new digital communication channel.

At present MyHealth@EU with two services operational in the Union – ePrescriptions and Patient Summaries has been progressively rolled-out in 8 Member States and more are in the process of on boarding. Both services aim to convey and translate the respective information into the language relevant in the country of travel. Although progress is being made, a significant share of people/individuals from EU/EEA Member States have no access or only limited access to cross-border health information services.

ePrescriptions and Patient Summaries can be exchanged between participating Member States thanks to the eHDSI/MyHealth@EU infrastructure and patient services and the National Contact Point for e-health (NCPeHs), which securely connects the eHealth national services and facilitates the health data exchange.

There is a need to support the progress in all Member States and offer all relevant patients the same opportunities for cure and to advance in the provision of the current services by improving the information. In addition, it is necessary to enrich MyHealth@EU with new services such as medical images and image reports, laboratory results, hospital discharge letters, as well as original clinical documents or as structured data services. The development and deployment of eHealth solutions in healthcare systems is a national competence, and Member States play a key role for guaranteeing interoperability services for the cross-border exchange of health data and documents.

The NCPeHs aggregate patient information from national electronic health records or other infrastructure and share it across border. For a fully operating system, each participating country has to have in place fully deployed and interoperable services. The handling of sensitive personal health data is a prerogative of designated Member States' authorities. The award of a direct grant as referred to in Article 13(5) of Regulation 2021/522 is duly justified because this action can only be carried out by Member States' authorities as they have the

required competence and responsibility to implement the Union policies at national level and to implement the action. In accordance with Article 193(2), point (a), of Regulation (EU, Euratom) 2018/1046 and Article 5 (7) and 14 of Regulation (EU) 2021/522, the starting date of actions may be set, where appropriate, prior to signature of the grant agreement and costs may be eligible before submission of the proposal. Continuous and retroactive funding (as of 1 of January 2021) is essential for the Member States to continue working on new services that can ensure that patients are able to share their health data cross-border thus ensuring continuity of care.

The action supports the development of the planned EHDS and the use of health data for the provision of healthcare, scaling up the coverage of the cross-border services and making them available to a larger share of the European population. It implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d)) through the specific objectives defined in Article 4, point (f), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to allow patients from more Member States to make full use of the MyHealth@EU services and to progress towards a wider range of services offered.

In consideration of the specific needs and the situation of each country, the action will support:

- a) the setting up of the NCPeH for ensuring the exchange of the ePrescriptions and Patient summaries (including vaccination data etc.), in particular filling the gaps in those countries where the NCPeH have not been fully implemented;
- b) the roll-out of ePrescriptions and Patient summaries in the Member States that have not yet launched these services;
- c) developing and deploying new services (medical images, discharge letters and laboratory results and patients' access to their health data);
- d) maintenance of generic services in MyHealth@EU, for NCPeHs that are already in operation. Setting up of the NCPeH for ensuring the exchange of the ePrescriptions and Patient summaries (including vaccination data, etc.), in particular filling the gaps in those countries where the NCPeH have not been fully implemented;
- e) the roll-out of ePrescriptions and Patient summaries in the Member States that have not yet launched these services;
- f) developing and deploying new services (medical images, discharge letters and laboratory results and patients' access to their health data);
- g) maintenance of generic services in MyHealth@EU, for NCPeHs that are already in operation.

Expected results and impact

This action will contribute to increasing the number of patients and of Member States using MyHealth, ensuring that existing services will gradually be implemented in all participating countries, and that the services are enriched and enhanced.

By facilitating and improving the exchange of health data across borders, this action will facilitate the provision of better cross-border healthcare, continuity of care and ensuring access to safe and high-quality healthcare. This action will also contribute to reinforcing citizens' security and trust.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - DI-g-22-21.01	Q2-Q3/2022	EUR 30 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grants to Member States in accordance with Article 195, first paragraph, point (c), and (f) of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

5.2 ESTABLISHMENT OF THE PLANNED EUROPEAN HEALTH DATA SPACE – INFRASTRUCTURE AND GOVERNANCE: SECONDARY USE OF DATA (FOR HEALTHCARE)

DI-g-22-22.01 Direct grant to Member States: for setting up services by Health Data Access Bodies - Secondary use of health data

POLICY CONTEXT

The Data Governance Act³⁸, under its Article 7, sets out the provision for bodies supporting the re-use of public sector data protected, as it is personal data or commercially sensitive, and the planned EHDS will build upon and extend this function for health. In health area, several Member States have set up health competent data access bodies (such as Findata, French Data Hub, German Research Data Centre, Denmark, Norway health data access bodies etc.) and other Member States aim to set up such structures. They provide core services for a common ICT infrastructure and crosscutting services such as terminology, interoperability etc.

However, there is a need to support and promote the establishment and strengthening of such entities, by expanding core services, nodes and connections between them, and related services for the development of the EHDS for secondary uses of health data ('EHDS2') in all Member States and wider, secure access to data for research, innovation and policy making, including for statistical purposes.

This action supports the establishment and capabilities enlargement of national health data access bodies and related services and infrastructures, taking into account requirements of specific areas of health data and including those linked to quality of health data, as part of the data and infrastructure ecosystem of the planned EHDS for secondary uses of health data, including for statistical purposes.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by the Member States' authorities, competent data access bodies, which solely have the required expertise, competence and responsibility to implement the action. In accordance with Article 193(2), point (a), of Regulation (EU, Euratom) 2018/1046 and Article 5 (7) and 14 of Regulation (EU) 2021/522, the starting date of actions may be set, where appropriate, prior to signature of the grant agreement and costs may be eligible before submission of the proposal. Continuous and retroactive funding (as of 1 of January 2021) is essential for the Member States to continue developing services supporting the re-use of health data for research, innovation and policy making, including for statistical purposes.

This action implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d)) through the specific objectives defined in Article 4, point (f), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action will allow Member States to progress in the setting up of services by health data access bodies by providing support to:

- a) National services and infrastructures: the setting up of national health competent data access bodies, the setting up services and infrastructures to receive, process and reply

³⁸ Proposal for a Regulation of the European Parliament and of the Council on European data governance, COM(2020) 767, 25.11.2020.

to data access requests by national health data access bodies, the setting up services and infrastructures for secure environments to process health data and/or the setting up of metadata catalogues by national health data access bodies;

- b) Cross-border services and infrastructures: the establishment of EHDS2 nodes and its connection to EHDS2 core services by entities eligible to connect to EHDS2 infrastructure;
- c) Data quality: the support to enhance health data quality, to make data available and semantically and technically interoperable for reuse by national health data access bodies or data holders for which data accesses are granted by national health data authorisation bodies.

Member States must include in their applications information on the data access bodies already functioning or in the process of being established. The eligible expenditure can be reimbursed if incurred as of 1 January 2021.

This action will build on the ongoing cooperation in the joint action ‘Towards the European Health Data Space’ (TEHDAS).

EXPECTED RESULTS

The action is expected to support Member States to progress and align towards:

- a) providing more patients the opportunity to benefit of cross-border health care;
- b) increased capacity, resilience and readiness for Member States to participate in cross-border exchange and reuse of health data for research, innovation, policy-making, statistical purposes and regulatory activities;
- c) scaling-up of national health data access bodies IT infrastructures according to a common set of business capabilities necessary for secondary use of health data;
- d) set the necessary pre-conditions to enable connectivity between national health data access bodies in each Member State.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants – DI-g-22-22.01	Q2-Q3/2022	EUR 30 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grants to Member States in accordance with Article 195, first paragraph, points (c) and (f), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States’ authorities

ACTIONS WITH A COST BELOW EUR 20 000 000

1. CRISIS PREPAREDNESS (CP)

CP-g-22-01.05 Call for proposals to support structured dialogue at national or regional level on public procurement in the health sector - HERA

POLICY CONTEXT

The COVID-19 pandemic has highlighted a need for coordination and cooperation at EU, national, regional and even local level in the health sector. The pandemic has exacerbated the existing weaknesses along the supply chain, including related Member States' public procurement.

New approaches are needed to improve resilience of the healthcare systems in order to increase preparedness for future public health emergencies. They should include concrete actions aiming at making public procurement more efficient and more resilient. Given the different organisations of the healthcare systems and Member States' capacity, drawing up general guidelines does not seem the appropriate approach, relevant national/regional stakeholders are better placed to provide the support needed in assessing the needs and provide recommendations to draw up new strategies. This action will contribute to address vulnerabilities within the Union related to procurement, stockpiling and distribution of medical countermeasures as outlined in the HERA mission.

This action supports the policy priority to respond to the COVID-19 crisis and implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (a) and (b), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The proposed action supports Member States in organising a thorough assessment of public procurement in the health sector at national and/or regional level by way of collective intelligence.

This assessment should be organised by relevant national/regional stakeholders that will involve interested Member States' authorities. The assessment will be organised in working themes that will facilitate exchanges and will collect and analyse the information and data provided. Working sessions and conferences will be organised in Member States that require this support in the preparation of the national or regional procurement strategy.

A European conference will be organised in order to inform Member States on the recommendations provided, including on good practices and will encourage further exchange of experience.

EXPECTED RESULTS AND IMPACT

The action is expected to result in the development of new or improved national and regional strategies on public procurement that will make current practices more resilient and efficient all over the Union. This will increase preparedness for future health crises.

The involvement of Member States at national, regional and/or local level as well as of all relevant stakeholders by using collective intelligence methods will also increase coordination and more and better cooperation for the future.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – CP-g-22-01.05	Q2-Q3/2022	EUR 5 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Public buyers, central purchasing bodies, private entities, Member States' authorities, and civil society organisations (associations, foundations, NGOs and similar entities)

CP-g-22-04.01 Direct grants to Member States' authorities: setting up a coordinated surveillance system under the One Health approach for cross-border pathogens that threaten the Union

POLICY CONTEXT

Many of the important infectious diseases affecting humans that have emerged recently, such as COVID-19, Ebola and the human immunodeficiency virus diseases, are thought to be zoonoses. Scientific literature estimates that approximately 60% of all human pathogens are zoonotic, and that 75% of all recently emerging infectious diseases affecting humans are of animal origin, most frequently wildlife. These diseases pose the greatest public health risk due to their epidemic potential and/or because there are no available known countermeasures, including diagnostic and therapeutic, or non-pharmaceutical interventions or they are insufficient for containing the initial outbreak. The factors that drive the emergence of zoonotic diseases are complex and include ecological, political, economic and social forces. Environmental changes, due to the human and animal expansion in different biotopes, result in loss of wild habitats and biodiversity, due to socio political and economic forces have negative impacts on human, animal and environmental health, because of the increase of inter-species drifting of potential emergent pathogens. Therefore there is a need for more rapid and effective responses to zoonotic diseases resulting in a conceptual shift away from traditionally siloes health approaches, towards practices that are integrated across disciplines, sectors, and agencies that are using a new paradigm called One Health. This is the result of growing recognition of the importance of zoonoses to human health, which emphasizes the critical connections between animal health, human health and the environment.

The surveillance on the animal health side and in the environment needs to be scaled up to set up a One Health surveillance for emerging and re-emerging pathogens. Such surveillance system should be based on a risk assessment³⁹ with an active involvement of the Member States. The joint definition of the surveillance methodologies and priorities is an essential step to duly take best account of the different ecosystems across the Union. The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by Member States' authorities as they have the required competence and responsibility to implement the Union policies at national level.

This action supports the policy priority of strengthening the responsiveness in order to cope with serious cross-border threats to health. 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, point (b)) through the specific objectives defined in Article 4, points (a) and (b), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action will aim to provide support to Member States' authorities to contribute to the setting and scaling up of this animal and environmental surveillance system, including the systematic ongoing collection of data by EFSA.

³⁹ As defined in the proposal for a new Regulation on Serious cross-border threats to health (COM (2020) 727 final); Articles 13 and 20 regulate public health risk assessment, including the role of ECDC, EFSA and EEA. Such risk assessment would consider also the 'global perspective assessment of surveillance and intelligence data for serious cross-border threats to health' as envisaged by the 2021 EU4Health Programme (action CP-p-06.2 - Intelligence gathering), in order to carry out both actions in a synergic manner.

It will build on and be in coordination with the actions carried out on human health surveillance⁴⁰. A coordination mechanism should be established to ensure the regular exchange of knowledge, threats reporting, joint undertaking of risk assessment, between animal and human health surveillance experts at Union and Member State level.

This action will support the capacity building steps and the strengthening of a surveillance system for emerging and re-emerging pathogens in animals and the environment in Member States, taking into consideration neighbouring third countries of concern (e.g. Balkans, Mediterranean, Eastern Partnership) and possibly other third countries. The surveillance system will be designed by EFSA in coordination with ECDC with an active participation of the Member States in synergy with relevant actions carried out at international level. A risk assessment by EFSA (in coordination with ECDC) is a prerequisite for identifying the priorities and methodologies of the surveillance system.

This action will allow Member States to purchase the necessary essential equipment and consumables for diagnostics and sampling.

In addition, this action will develop/improve the conceptual framework of a One Health surveillance system in close collaboration with EFSA and in coordination with ECDC, support pilot Member States to increase capacity⁴¹ through training, awareness campaigns targeted at the most relevant audiences. Subsequently and gradually, Member States will implement the One Health surveillance system by pilot Member States and assess and address residual capacity building needs. Building up on their increased capacity, Member States will implement innovative and reinforced surveillance activities in animals and the environment in synergy with and complementing activities in the human side. The complementarity should be further reassured by close collaboration with ECDC/EFSA in all process/stages. This requires Member States to:

- a) identify the sample collection modalities (using existing sampling schemes or setting up new ones with a novel One Health approach);
- b) carry out the diagnostic procedures (incorporating the equipment acquired as well as improved techniques);
- c) organise the national data collection, collation and national data sharing;
- d) carry out a preliminary national assessment (across animal and public health and the environment in a One Health approach) in order to identify national risks and priorities for the future;
- e) share data with EFSA and actively contribute to the yearly re-prioritisation exercise of EFSA/ECDC aimed at identifying the current and future health risks for the Union. This will contribute to the redesign of the surveillance system for the following year;
- f) address residual capacity building needs not fully addressed in year one including awareness campaigns/events.

To ensure an iterative approach, surveillance must be revised periodically (i.e. yearly) in order to implement the refined surveillance priorities and modalities as identified by the risk assessment by EFSA/ECDC.

⁴⁰ 'Drawing the early lessons from the COVID-19 pandemic', COM(2021) 380 final, and on the joint action CP-g-02.1.1 in the EU4Health work programme 2021.

⁴¹ This capacity building should be based on the identified surveillance priorities and risk factors identified by EFSA and EFSA/ECDC.

EXPECTED RESULTS AND IMPACT

The activities will contribute to the scaling up of existing surveillance and the establishment of a One Health surveillance that will provide the animal health and environmental side to complement in full synergy the ongoing initiatives on the human side for integrated surveillance. This approach will contribute to increase awareness on the fact that human, domestic animal and wildlife health are interconnected within the context of ecosystem/environmental health (environmental reservoirs of infectious diseases) and will provide a useful support for the development of solutions to global health and environmental challenges in the future.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - CP-g-22-04.01	Q2-Q3/2022	EUR 20 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

2. HEALTH PROMOTION AND DISEASE PREVENTION (DP)

2.1. HEALTH PROMOTION AND PREVENTION OF NCDs AND RELATED RISK FACTORS

CR-g-22-08.02 Call for proposals on cancer and other NCDs prevention – action on health determinants

POLICY CONTEXT

In 2020, 2.7 million people in the Union were diagnosed with cancer, and another 1.3 million people lost their lives to it⁴². Unless decisive action is taken, lives lost to cancer in the Union are set to increase by more than 24% by 2035⁴³, making it the leading cause of death. In a holistic approach, the Europe's Beating Cancer Plan and the EU Mission on Cancer address the entire cancer control continuum.

NCDs such as cardiovascular diseases, cancer, chronic respiratory diseases and diabetes, represent the major share of the burden of disease in Europe accounting for 80% of deaths. NCDs 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 tobacco use, physical inactivity, unhealthy diet, overweight and obesity, and alcohol-related harm. Although these deaths are largely preventable, expenditure on preventive care is only around 3% of national health budgets in the Union.

The Europe's Beating Cancer Plan outlines targets related to the reduction of the burden of cancer and specific actions to contribute to their achievement. Among others, these actions will offer tools, such as the European Code against Cancer and the EU Mobile App for Cancer Prevention to strengthen risk communication, and will support the implementation of activities on cancer primary and secondary prevention, such as vaccination against human papillomaviruses, detection and treatment of human hepatitis viruses, early cancer detection and measures to reduce tobacco use and alcohol-related harm, measures to promote healthy eating and physical activity and reduce sedentary behaviour.

The Commission supports the Member States' efforts to reduce the burden of NCDs to reach the UN SDGs. In this context, the Commission is working on a new initiative, 'Healthier Together – EU NCD Initiative', which includes five action strands on cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, and a horizontal strand on health determinants. In each of these strands, the reduction of health inequalities will be tackled.

To promote impact, national authorities will be supported to embed improvements in national policies. NGOs, health professional and patient groups will have the opportunity to engage in the implementation of the actions via various activities reflecting their areas of expertise, that may include public health guidelines, patients' and caregivers' consultations, or other actions that can benefit citizens directly. This also applies to the implementation of the Europe's Beating Cancer Plan in support of national and Union priorities. Stakeholders will also provide input via the Health Policy Platform, namely as regards their role in implementation.

⁴² European Cancer Information System (ECIS); estimate for the EU-27 countries; new diagnoses cover all types of cancer, apart from non-melanoma skin cancer.

⁴³ Cancer Tomorrow <https://gco.iarc.fr/tomorrow/en/>.

This action supports the policy objective of reducing the burden of cancer and other NCDs and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives defined in Article 4, points (a) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is to complement the implementation of the joint action on 'Cancer and other NCDs prevention – action on health determinants' led by the Member States, thus helping to reduce the burden of cancer and other NCDs, and related risk factors, both at a personal and societal level, namely by supporting the Europe's Beating Cancer Plan and policy initiatives on NCDs. It may also support other Union initiatives that aim to improve public health such as the Farm to Fork Strategy and the HealthyLifestyle4All initiative⁴⁴ in so far as it shares the objectives of promoting sustainable food consumption and facilitating the shift to healthy, sustainable diets and promoting a healthy lifestyle.

Activities will run in parallel to the joint action, include implementing targeted projects involving civil society organisations complementing the Member States' efforts in the design, planning and implementation of best practices, the production of public health guidelines, patients' and caregivers' consultations, or other actions that can benefit citizens directly, the preparation and roll out of innovative practices (pilot test), and support actions such as training and twinning, health communication or health literacy. The activities include provision of input via the Health Policy Platform, namely as regards their role in implementation.

Activities should also include an equity dimension and aim at reducing health inequalities.

EXPECTED RESULTS AND IMPACT

The action will implement projects on disease prevention and health promotion, which is expected to reduce the burden of cancer and other NCDs in the Member States.

The expected results will include initiatives to complement the Member States' efforts in the design, planning and implementation of best practices, such as support for the development of public health guidelines and, support for the preparation and roll out of new policy approaches; participation in the pilot testing of innovative practices; development of support actions such as training and twinning, health communication or health literacy; and implementation of best practices in health promotion and disease prevention.

The short-term impact will be an increased number of public health interventions being scaled up in all Member States and improvements in disease prevention and health promotion, and management policies related to cancer and other NCDs.

⁴⁴ The HealthyLifestyle4All Initiative <https://sport.ec.europa.eu/initiatives/healthylifestyle4all>

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals CR-g-22-08.02	Q2-Q3/2022	EUR 11 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Academia and educational institutions, civil society organisations supporting the priority areas (health professional associations, foundations, NGOs and similar entities)

DP-g-22-06.04 and DP-g-22-06.05 Call for proposals on prevention of NCDs - cardiovascular diseases, diabetes and other NCDs

POLICY CONTEXT

NCDs are responsible for 87% of the disease burden in the Member States and improved health promotion and disease prevention can reduce the prevalence of NCDs by as much as 70%. The costs of treating NCDs are high and expected to grow further, also considering the Union's aging population. COVID-19 has shown that NCDs can dramatically increase the negative impact of other diseases; the childhood obesity rate was included in the Commission's strategic resilience dashboard; the economic case for prevention has been made by the OECD.

Cardiovascular diseases and diabetes are leading causes of death globally. While behavioural risk factors are key to preventing these diseases (and are addressed by other actions in this work programme), other complementary, specific and targeted public health measures can prove essential to reduce their associated burden. Among others, voluntary cooperation on hypertension, primary care or testing or screening may play a role in dealing with these challenges.

To support Member States in reaching the health targets of the United Nations 2030 Agenda for Sustainable Development and its goals, the Commission is working on a new initiative, 'Healthier Together – EU NCDs Initiative', which includes five action strands for cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, and a horizontal strand on health determinants. In each of these strands, the reduction of health inequalities will be tackled. In addition, the Commission has established 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 NCDs in the Union. The Commission will work with the Member States to define specific targets and actions for different areas of NCDs, such as cardiovascular diseases and diabetes. Stakeholders will also provide input via the Health Policy Platform, namely as regards their role in implementation.

To promote impact, national authorities will be supported to embed improvements in national policies. In parallel, NGOs as well as professional and patient groups will have the opportunity to engage in the implementation of complementary actions. Such engagement may include the provision of input for the preparation of public health guidelines, awareness actions, training, piloting or other actions that can benefit citizens directly.

This action supports the policy objective of reducing the burden of NCDs and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives defined in Article 4, points (a) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is to reduce the burden of NCDs and related risk factors, targeting:

- a) cardiovascular diseases and diabetes, both at an individual and societal level, namely by supporting the NCDs policies and corresponding actions led by the Member States;
- b) NCDs other than the five action strands of the initiative 'Healthier Together – EU NCD Initiative' and cancer; such as chronic kidney diseases and liver diseases, auto-immune diseases, musculo-skeletal conditions, etc.

This action will complement the Member States' joint action on 'Prevention of NCDs - Cardiovascular diseases and diabetes' (DP-g-22-06.03) that aims to contribute to reducing the burden of NCDs, i.e. cardiovascular diseases and diabetes, and related risk factors, both at a personal and societal level, including the health inequalities dimension.

The civil society organisations will implement targeted projects and activities, complementing the Member States' efforts in the design, planning and implementation of best practices, including support to the definition of public health guidelines, to the preparation and roll out of new policy approaches, to the pilot test of innovative practices, and to support actions such as training and twinning, health communication or health literacy. Activities should also include an equity dimension and aim at reducing health inequalities.

EXPECTED RESULTS AND IMPACT

The action will contribute to the implementation of projects on disease prevention and health promotion, which are expected to reduce the burden of NCDs, namely diabetes and cardiovascular diseases in Member States.

The expected results will include initiatives to complement the Member States' efforts in the design, planning and implementation of best practices, such as support for the development of public health guidelines, support for the preparation and roll out of new policy approaches; participation in the pilot testing of innovative practices; development of support actions such as training and twinning, health communication or health literacy; and implementation of best practices in health promotion and disease prevention. The short-term impact will be an increased number of public health interventions being scaled up in all Member States and improvements in disease prevention and health promotion, and management policies related to NCDs.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
a) Call for Proposals - DP-g-22-06.04	a) Q2-Q3/2022	a) EUR 5 000 000
b) Call for Proposals - DP-g-22-06.05	b) Q1-Q2/2022	b) EUR 5 000 000
Procedure type	Implemented by	Type of applicants targeted
Open calls for proposals (action grants)	HaDEA	(a) Academia and educational institutions, civil society organisations supporting the priority areas (health professional associations, patients' organisations, foundations, NGOs and similar entities) (b) Civil society organisations supporting the priority areas (health professional associations,

		patients' organisations, foundations, NGOs and similar entities)
--	--	--

DP-g-22-26.01 Open call for proposals for operating grants to non-governmental organisations: financial contribution to the functioning of health non-governmental bodies implementing one or more specific objectives of Regulation 2021/522

POLICY CONTEXT

Non-governmental organisations (NGOs) play a major role among others in providing aid at Union, national and local levels. In the field of health, and specially public health, they provide services directly to patients and individuals being in some cases in the first line of action also during emergencies. NGOs are also essential in bridging the gap between institutions and patients and facilitating communication at national and Union level. These organisations are not-for-profit and therefore necessarily rely on funding from different sources, for instance private donations, national or international contributions.

The Commission considers it important that there is continuity in the work carried out by the health NGOs in addressing current health challenges including the COVID-19 pandemic and its consequences, and it intends to award operating grants under this work programme to eligible NGOs.

NGOs' expertise and contribution is expected to be of added value in relation to NCDs, health determinants, ageing society, vulnerable groups and rare diseases. Poor nutrition, physical inactivity, obesity, tobacco use and harmful use of alcohol are risk factors common to other chronic diseases, such as cardiovascular diseases may also require attention.

The demographic changes, in particular the ageing of society, challenge the sustainability of health systems and disorders, such as dementia, and age-related diseases and disabilities may need to be addressed. Patients and health systems need to have access to sustainable, efficient, equitable, and affordable high-quality medicinal products, including in the cross-border context, to fully benefit from those medicinal products on the basis of transparent, consistent, and patient-oriented medical information.

The views of the patients with complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources, need to be heard and their access to diagnosis and high-quality healthcare improved. Furthermore, there is a need to protect people in vulnerable situations, including those suffering from mental illness and those living with or most affected by communicable or non-communicable diseases and chronic diseases, and to promote activities, which address and prevent the collateral impact of health crises on people belonging to such vulnerable groups and actions that improve mental health.

The operating grants linked to a specified time-frame and specific outputs or results are intended to provide support to health NGOs that pursue one or more of the specific objectives of Article 4 points (a) to (j) of Regulation (EU) 2021/522. By analogy to grants without a call for proposals, the award of operating grants with an open call for proposals is subject to compliance with the conditions of Article 13(1)-(4) and (8) of Regulation (EU) 2021/522, and the relevant criteria set in the Financial Regulation, as well as additional criteria set out in the call for proposals.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective is to ensure the participation of health NGOs in activities that are necessary to implement one or more specific objectives of the EU4Health Programme. Hence, operating grants should provide support to the functioning of certain NGOs during 2022 for activities

including awareness raising on various health aspects, communication and dissemination, capacity building and training, expert collaboration and networking.

EXPECTED RESULTS AND IMPACT

Through their core operational activities they will deliver on increased health literacy and health promotion, capacity building and networking contributing to the optimisation of healthcare activities and practices, by providing feedback from and facilitating communication with patients.

The beneficiaries are expected to further demonstrate in their proposals the Union added value of their activities and commit to deliver concrete results such as: online materials, webpages, manuals and tools on case studies promoting health in schools, factsheets and relevant literature, materials for teachers on health literacy, and assistance and promotion of twinning with other European schools; capacity-building and training activities to reduce the impact of risk factors for non-communicable diseases; new approaches to promote healthy and sustainable diets; expert guidance and peer-to-peer connections; and collaborate in shared areas of activity.

Some of the beneficiaries' activities are expected to contribute to the implementation of non-legislative policy initiatives and/or the implementation of relevant Union health legislation.

The beneficiaries will facilitate the exchange of knowledge, capacity building related to their expertise and should cooperate with other civil society organisations and international organisations (e.g. WHO and other organisations).

ELIGIBILITY AND AWARD CRITERIA

Applicants are required to comply with the criteria set out in Article 13(1)-(4) and (8) of Regulation (EU) 2021/522, including the specific criteria detailed below, as well as possible additional specific criteria set out in the text of the call for proposals and relevant criteria set in the Financial Regulation.

ELIGIBILITY CRITERIA

Criterion	Sub-criterion	Conditions to fulfil	Proof
Non-for-profit	n/a	The applicant must be organised and operated for collective, public or social benefit; any revenues that exceed expenses must be committed to the organisation's purpose, not taken by private parties.	<ul style="list-style-type: none"> – Statutes – Annual financial reports of the last three years
Independence of industry, commercial and business	Financial independence	<p>The applicant must, at submission stage, demonstrate that it is financially independent by:</p> <ul style="list-style-type: none"> a) submitting proof that not 	<ul style="list-style-type: none"> a) Annual financial reports of the last three years b) Supporting documents such as minutes and attendee lists of recurrent meetings, brochures and other

		more than 30% of the core funding ⁴⁵ of the applicant organisation is received from private sector donors. b) Or, if the above core funding threshold is exceeded, but is below 50%, demonstrate that private sector donors do not exercise influence on the decision and regular activities of the applicant organisation.	communication (including exchanges with the Commission) , annual activity reports and a mandatory declaration on honour; internal procedures/policies/ mitigating measures to safeguard independence
	Legal independence	The applicant must provide proof of the absence of direct or indirect holding of decision-making powers, de facto or in law, by another legal entity or natural person	<ul style="list-style-type: none"> – Statutes – Extract from the register of associations – Minutes of the last 3 general assemblies
	Absence of conflict of interest	The applicant must prove the absence of conflict of interest of board of management or similar governing body	– Declaration on honour (free format)
Active in the public health area	n/a	The applicant must demonstrate being active in the public health area	<ul style="list-style-type: none"> – Statutes – Extract from the register of associations – Annual activity report
Pursue at least one of the specific objectives of Regulation (EU) 2021/522	n/a	The applicant must demonstrate pursuing at least one of the specific objectives laid down in Article 4 of Regulation (EU) 2021/522	<ul style="list-style-type: none"> – Statutes – Extract from the register of associations – Annual activity report from the last 2 years – Supporting documents such as minutes and attendee lists of recurrent meetings, brochures and other communication (including exchanges with the Commission)
Being active at Union level and in at least half of the Member States with a balanced geographical coverage of the Union.	n/a	The applicant must provide proof of being active at Union level and, through its statutory member organisations, in at least half of the Member States, geographically balanced	<ul style="list-style-type: none"> – Statutes – List of statutory member organisations – Annual activity report
Play an effective role at Union level	n/a	The applicant must provide proof of effectiveness at Union level	– Self-assessment of the effectiveness of previous actions (free format)

AWARD CRITERIA

Criterion	Sub-	Conditions to fulfil	Proof
------------------	-------------	-----------------------------	--------------

⁴⁵ Core funding means financing required for the basic structure of an organisation, including salaries of full-time staff, facilities, equipment, communications and direct expenses of its day-to-day work.

	critterion		
Financial support necessary for the implementation of one or more of the specific objectives of Regulation (EU) 2021/522	n/a	The applicant must justify why the financial support of the Union is needed for the achievement of one or several of the specific objectives of Regulation (EU) 2021/522.	– Justification provided by the applicant organisation (free format)

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Operating grants – DP-g-22-26.01	Q1/2022	EUR 9 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals	HaDEA	Non-governmental organisations active in the public health area, that fulfil the criteria set out in the Financial Regulation, Article 13(1)-(4) and (8) of Regulation 2021/522, including those detailed in this work programme and the call for proposals.

2.2. ADDRESSING MENTAL HEALTH CHALLENGES

DP-g-22-07.01/03/04 Call for proposals on promoting mental health

POLICY CONTEXT

Mental health is an integral and essential component of health. It is critical to individual well-being, as well as to social and economic participation. Prior to the COVID-19 pandemic, the total costs arising from mental health problems accounted for more than 4% of GDP across the Member States (Health at a Glance: Europe 2018). The heavy individual, economic and social burdens of mental illness are not inevitable.

Although many Member States have policies and programmes to address mental illness at different ages, the distribution of these actions is uneven throughout the human life course. Furthermore, the COVID-19 pandemic has immediate and long-term consequences, including on mental health, which require action that focuses on vulnerable groups, including children and refugees and migrant populations. Hence, there is an acute need to increase awareness, knowledge sharing and capacity building in the area of mental health.

The Commission supports Member States to reduce the burden of non-communicable diseases in order to reach the UN SDGs. The Commission is working on a new Initiative, ‘Healthier Together – EU NCD Initiative’, which includes five strands: cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, and a horizontal strand on health determinants. In each of these strands, the reduction of health inequalities will be tackled.

In addition, the Commission has established the SGPP to support Member States in reaching the health targets of the UN SDGs. The expert group provides advice and expertise to the Commission to foster exchanges of relevant experience, policies and practices between Member States on how to tackle the burden of NCDs in the Union. Therefore, addressing mental health challenges through the identification and transfer of best practices, which are developed and implemented successfully in one country, can have a concrete, direct, positive impact for citizens, health systems and society.

This action will provide support to stakeholders in implementing best practices promoting children and adolescent mental health and well-being, with a focus on vulnerable groups, such as children living in deprived areas. It will contribute to giving young people more and better opportunities for the future, in line with the activities of the 2022 European Year of Youth as declared by the Commission⁴⁶. Moreover, the action will support initiatives that will promote mental health of vulnerable groups, such as migrants and refugees.

This action supports the policy objective of reducing the burden of NCDs and meets the following EU4Health Programme general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives in Article 4, points (a) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of the action is to increase awareness, knowledge generation and sharing, and capacity building in the area of mental health. Activities will include the transfer of best

⁴⁶ Press release: European Year of Youth 2022: Commission kick-starts work
https://ec.europa.eu/commission/presscorner/detail/en/ip_21_5226

practices, as indicated by the SGPP, on children's and adolescents' mental health and well-being.

Specifically, the actions will support interested stakeholder organisations, to come together to discuss and exchange mental health practices and knowledge, to implement validated best practices and evidence-based projects. The activities should focus on the needs of specific and/or vulnerable groups, such as children and adolescents, or migrant and refugee populations.

The actions developed by civil society and health professionals' organisations to improve mental health, namely by exchanging and implementing best practices, and implementing activities that will increase awareness, knowledge sharing and support for health professionals' training, include the development of necessary guidance and/or training material, such as video tutorials, manuals, etc.

Subtopic 1: implementing the best practice (Icehearts⁴⁷) to improve life skills and social, psychological and emotional resources among socially vulnerable children and adolescents.

Subtopic 2: implementing the best practice (Let's Talk about Children⁴⁸) to support mental health and wellbeing of young people and their families in vulnerable groups.

Subtopic 3: implementing promising best practice(s) to improve mental health and psychosocial wellbeing in migrant and refugee populations.

EXPECTED RESULTS AND IMPACT

The action will implement two best practices (Icehearts and Let's Talk about Children) to address the mental health and well-being of children and adolescents (e.g. in schools, and through sport programmes).

The action will also support activities that address the mental health challenges and psychosocial needs of migrant and refugee populations, with a direct impact on the effort to reduce the burden in the Member States and will support health professionals and improve awareness.

The short-term impact would be achieved through an increased number of interventions being scaled up in Member States providing long-term professional support for vulnerable young people and migrant and refugee populations, to prevent social exclusion, promote psychosocial well-being and enhance social skills. The long-term impact would be to identify solutions to tackle specific mental health issues, both at personal and societal level. Networking between experts and additional cross-learning other than via practice transfer *per se*, will also provide benefits for developing and improving public health and social inclusion policies.

⁴⁷ Icehearts – sport-based, long term positive Youth Development programme
https://ec.europa.eu/health/sites/default/files/non_communicable_diseases/docs/ev_20210630_co09_en.pdf

⁴⁸ Let's talk about children, Mental Health Finland
https://ec.europa.eu/health/sites/default/files/non_communicable_diseases/docs/ev_20210630_co10_en.pdf

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
a) Call for Proposals - DP-g-22-07.01 b) Call for Proposals - DP-g-22-07.03 c) Call for Proposals - DP-g-22-07.04	a) Q1/2022 b) Q1/2022 c) Q2-Q3/2022	a) EUR 4 000 000 b) EUR 4 000 000 c) EUR 7 000 000
Procedure type	Implemented by	Type of applicants targeted
Open calls for proposals (action grants)	HaDEA	Academia and educational institutions, civil society organisations supporting the priority areas (health and social professional associations, schools, foundations, NGOs and similar entities)

3. CANCER (CR)

CR-g-22-10.01/03 Direct grant to international organisation (European Observatory on Health Systems and Policies) and Member States' authorities: contribution to the Cancer Inequalities Registry to monitor national cancer control policies

CR-g-22-10.02 Direct grant to international organisation (International Agency for Research on Cancer , IARC): contribution to the Cancer Inequalities Registry to map disparities and inequalities between Member States and regions, with a focus on socio-economic inequalities

POLICY CONTEXT

There are 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 future European Health Union that seeks to protect everyone.

Currently no systematic surveillance and reporting mechanism exists to track the cancer situation across the Union. The establishment of a Cancer Inequalities Registry is a flagship initiative of the Europe's Beating Cancer Plan and will identify trends, disparities and inequalities between Member States and regions. The Registry will provide a regular reporting mechanism based on cancer indicators covering the whole cancer control continuum complemented by analytical reports providing contextual information and qualitative assessments.

The Registry will make available comparable up-to-date cancer indicators in a systematic and easily accessible way to the general public and policy-makers by building on (mostly) existing quantitative data and indicators collected for instance through the augmented European Cancer Information System, the European Statistical System (Eurostat) and from other data sources. OECD has been tasked with developing and reporting on the core indicator set for the Registry. For the assessment of socio-economic inequalities, which is one important aspect to be monitored by the Registry, IARC holds critical expertise that should be integrated in this work.

To complement the quantitative data collection, qualitative data and contextual information could be derived from surveys and reporting mechanisms, such as the monitoring reports on the implementation of the Council Cancer Screening Recommendations, the Commission Initiatives on Breast, Colorectal and Cervical Cancers, surveys on National Cancer Control Programmes and policies as previously undertaken by the iPACC joint action.

In addition, the national cancer control situation and policy actions in all Member States will be monitored, including at sub-national level and for specific socioeconomic groups, to identify areas of potential action and to guide investment decisions on Union and national level.

These activities will provide systematic, comparable and frequently updated information and analysis on the cancer control situation in Member States including the state of play of implementation of the Europe's Beating Cancer Plan at national level to inform contextual analytical reporting carried out as part of the Cancer Inequalities Registry.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified. For the qualitative data collection this action can best be performed by a joint action

complemented by a collaboration with and support from the European Observatory on Health Systems, which has the required and unique expertise and capacity in health systems' performance assessment, in networking and as a knowledge broker, to support the Member States in implementing this action.

For the contribution to the quantitative data collection with specific data and indicators, this action can best be carried out by IARC, as it is the global reference for cancer surveillance data and indicators to the international cancer community, and has the required, unique expertise on the economic and societal impacts of cancer to contribute to this action, complementing the ongoing work of OECD.

This action supports the Europe's Beating Cancer Plan flagship initiative to establish a Cancer Inequalities Registry to reduce cancer inequalities across the Union and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives in Article 4, points (a) and (i) of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is:

Subtopic 1: to make available a mainly qualitative analysis of the national cancer control situation in the Member States, including the state of play of implementation of the Europe's Beating Cancer Plan at national level in a comparable and frequently updated form.

Subtopic 2: to make available data and insights on socio-economic inequalities to complement and enhance the analysis for the Cancer Inequalities Registry.

EXPECTED RESULTS AND IMPACT

Through the Cancer Inequalities Registry, a consolidated view of the national cancer control landscape across the Union and resulting inequalities will assist in targeting investments and interventions at Union, national and regional level to address trends, disparities and inequalities between Member States and regions. The expected impact will be a reduction in measurable disparities in cancer prevention and care across the Union.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants Subtopic 1 CR-g-22-10.03 and CR-g-22-10.01	Q3/2022	Subtopic 1 EUR 1 000 000 (Member States' authorities) and EUR 500 000 (European Observatory on Health Systems and Policies)
Subtopic 2 CR-g-22-10.02		Subtopic 2 EUR 600 000 (IARC)

Procedure type	Implemented by	Type of applicants targeted
<p>Subtopic 1</p> <p>CR-g-22-10.03 and CR-g-22-10.01</p> <p>Direct grant to Member States in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046</p> <p>and</p> <p>Direct grant to international organisations in accordance with Article 195, first paragraph, point (f), of Regulation (EU, Euratom) 2018/1046</p> <p>Subtopic 2</p> <p>CR-g-22-10.02</p> <p>Direct grant to international organisations in accordance with Article 195, first paragraph, point (f), of Regulation (EU, Euratom) 2018/1046</p>	<p>HaDEA</p>	<p>Member States' authorities / International organisation (European Observatory on Health Systems and Policies)</p> <p>International organisation (IARC)</p>

CR-g-22-09.04 Direct grant to international organisation (IARC): to update the European guidelines for quality assurance in cervical cancer screening

POLICY CONTEXT

Cervical cancer is one of the most preventable and treatable forms of cancer. In the Member States (EU-27) in 2020, estimates for cervical cancer accounted for 2.5% of all new cancer cases (excluding non-melanoma skin cancers) diagnosed in women and for 2.4% of all deaths in women due to cancer. Cervical cancer ranks 11th among the most frequently occurring cancers in women and 12th among the most frequent causes of cancer death.

In addition, estimated cervical cancer incidence rates varies five-fold and mortality rates eight-fold in 2020 across Member States (EU-27); this clearly points to unacceptable inequalities across the Union. This wide variation can be explained by differences in human papillomavirus (HPV) prevalence and vaccination, and cervical cancer screening policies among Member States.

Two flagships of the Europe's Beating Cancer Plan support actions to improve access to the prevention, early identification and diagnosis of cervical cancer. These actions, including a Union-supported Cancer Screening Scheme, will help Member States ensure that 90% of the Union population who qualify for breast, cervical and colorectal cancer screenings are offered screening by 2025. The scheme will focus on making improvements in three key areas: access, quality and diagnostics. In addition, the Europe's Beating Cancer Plan states that dedicated Union funds will support Member States' efforts to extend routine vaccination against HPV of girls and boys, in order to eliminate cervical cancer and other cancers caused HPV, with an objective to vaccinate at least 90% of the EU target population of girls by 2030. These objectives are also supported by the World Health Organisation that calls for the elimination of cervical cancer as a public health problem by 2030.

The current supplements to the second edition of the European guidelines for quality assurance in cervical cancer screening⁴⁹ have been developed in a time of transition when primary testing for oncogenic HPV types and vaccination against infection with the HPV types that cause most cases of cervical cancer have become complementary approaches to cervical cancer prevention in Europe. However, such supplements have been published in 2015, and they need to be updated in the light of recent scientific developments and the new national and regional health systems' strategical and methodological approaches following, in particular the evidence of the role of HPV vaccination in the prevention of cervical cancer.

The award of a direct grant to an international organisation (IARC) as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified. This action can best be carried out by IARC as it has the required, unique expertise and capacity to inform and guide the development of public health policies for the implementation of cervical cancer screening programmes.

This action supports the implementation of a Europe's Beating Cancer Plan flagship initiative and meets the following EU4Health Programme general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives in Article 4, points (a) and (j) of Regulation (EU) 2021/522.

⁴⁹ European guidelines for quality assurance in cervical cancer screening
<https://op.europa.eu/en/publication-detail/-/publication/f6d9b1fb-6404-49f2-a4ae-8763ee8b0c52/language-en/format-PDF/source-31407900>.

OBJECTIVES, SCOPE AND ACTIVITIES

This action will support the knowledge transfer and a better understanding of the needs for cervical cancer screening, and the design, planning and development of possible options for future implementation of cervical cancer screening in the Union.

This action will include the following activities:

- i) establishment of the Cervical Cancer Executive (expert panel);
- ii) development of the cervical cancer guidelines and recommendations for prevention (e.g. vaccination), screening and diagnosis as well as all elements that will constitute the quality assurance scheme covering the entire care pathway from screening until end-of life care;
- iii) development of quality assurance manuals and tools, including the requirements testing in real settings.

EXPECTED RESULTS AND IMPACT

This action will provide new user-friendly technical guidelines, recommendations, best practices, requirements, indicators packed as a ready-to-use quality assurance scheme for real settings to be made publicly accessible via the Joint Research Centre web hub for guidelines and requirements⁵⁰. The approach will follow the methodology adopted under the EU Initiative on Breast Cancer that is currently applied also for the development of the colorectal cancer screening.

The guidelines and resulting quality assurance scheme shall be usable by: i) the target population of cervical cancer screening and patients; ii) health professionals; and iii) policy makers. The guidelines will be complemented by the quality assurance manuals and tools to help the implementation and monitoring of their use in the Member States.

This action will result in an updated package of ‘European Guidelines for Quality Assurance in Cervical Cancer Screening’ to support Member States to further design, plan, and implement population-based and targeted cervical cancer screenings and diagnosis.

⁵⁰ European Commission Initiative on Breast Cancer
<https://healthcare-quality.jrc.ec.europa.eu/>

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants CR-g-22-09.04	Q2-Q3/2022	EUR 1 200 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to international organisations in accordance with Article 195, first paragraph, point (f), of Regulation (EU, Euratom) 2018/1046	HaDEA	International organisation (IARC)

CR-g-22-08.06 Call for proposals to support the roll-out of the second cohort of the inter-speciality cancer training programme

POLICY CONTEXT

An objective of the 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.

The inter-speciality cancer training programme will help to deliver a more skilled and mobile cancer workforce through cross-border training and information sharing. As high-quality cancer patient's care depends on a continuous and sustainable training and education of a high-quality workforce, an extended number of cancer care infrastructures across the Union, as well as of trainers and trainees will be supported by this action.

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, point (a)) through the specific objectives defined in Article 4, points (a) and (g), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The aim of this action is to extend the implementation coverage of the first cohort of the inter-speciality cancer training programme through enrolling new cancer centres, as well as additional trainees and trainers.

The action will roll-out the second cohort of trainees, and, in addition, will organise a dissemination event to present the outcomes of the training. The action is expected to be complemented by the organisation of events to share the experiences developed during the training, which will also strengthen the networking of the trainees and trainers across the Union.

Specific activities will include a selection process for the trainees, trainers, and cancer centres which will participate in the inter-speciality cancer training programme. The programme is expected to train medical doctors and nurses and other specialised staff (such as those involved in medical imaging and radiation oncology including radiation technologists, medical physicists, radiobiologists, etc.) working in cancer centres in the three specialties of clinical oncology, surgery, radiology and radiation oncology with the aim of optimising the inter-speciality approach and cooperation. The training will be based on curricula previously developed *ad hoc* for the action and will include technology-based learning, simulations, and on-the-job training. The training programme will follow a coaching and mentoring approach with regular reporting and assessment of skills and tasks developed; case studies will be part of the training programme.

EXPECTED RESULTS AND IMPACT

The action will increase the coverage of the inter-speciality cancer training programme across the Union, and will result in the upskilling and re-skilling of healthcare professionals in the areas of clinical oncology, surgery, radiology and radiation technology, and nursing and other specialised services, with an increase in the number of training centres engaged in the initiative, as well as trainees and trainers. This action will help Member States to improve cooperation among their cancer services, by addressing skill 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 CR-g-22-08.06	Q3/2022	EUR 7 000 000
Procedure type	Implemented by	Type of applicants targeted
Open calls for proposals (action grants)	HaDEA	Academia and education establishments, research institutes, hospitals, expert networks, Member States' authorities and established networks in the field of public health

4. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)

4.1 ENHANCED EUROPEAN REFERENCE NETWORKS (ERNS)

HS-g-22-16.02 Direct grants to Member States' authorities: support ERNs integration to the national healthcare systems of Member States

POLICY CONTEXT

The ERNs were established in 2017 in accordance with Article 12 of Directive 2011/24/EU of the European Parliament and of the Council⁵¹ in the field of rare or low-prevalence complex diseases. There are 24 virtual networks involving healthcare providers across the Union.

This action supports the integration of the ERNs into the national healthcare systems that will ensure long term sustainability of the ERN system, enable the Member States to strengthen the resilience of their national health system and improve accessibility of the ERN system to rare diseases patients and their health professionals at national, regional, and local level with the aim to enable access to timely diagnosis and appropriate treatment.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by Member States' authorities as they have the required competence and responsibility to implement the Union policies at national level.

This joint action supports the enhancement of ERNs by contributing to the effective integration of ERNs in the national health systems. It implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d)) through the specific objectives defined in Article 4, points (f), (g) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The joint action will support ERN integration to the national healthcare systems. Activities will include exchanges of best practice and concrete proposals and guidelines for better integration of ERNs in the national healthcare systems, including well-defined patient pathways, referral procedures, development of national networks on rare disease (including support for capacity building in the Member States, for national rare disease plans, setting up of the national networks and their integration with the ERNs) and guidelines for development of national teleconsultation tools interoperable with the ERN Clinical Patient Management System ('CPMS'), taking into account the preparatory work of the planned EHDS. In particular:

- (a) development of proposals for national governance models and practices for rare and complex disease centres and care pathways that are fully interoperable with ERNs and recommendations to ensure interoperability between national and local data structures and ERN data structures (including ERN registries and CPMS), taking fully into account the ongoing work on the European Health Data Space and the joint action 'Towards the European Health Data Space' (TEHDAS);
- (b) development of a proposal for national quality assurance models for rare and complex diseases and recommendations for the organisation of national care pathways for rare

⁵¹ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

- and complex diseases that interface with ERNs, including processes to recognise at the national level evidence-based resources such as ERN Clinical Practice Guidelines;
- (c) development of a proposal for the referral systems to the ERNs, including guidelines for incorporation of CPMS advice into patients' care and recommendations on CPMS reimbursement models;
 - (d) preparation of a blueprint for a national dissemination and communication strategy on the ERNs and patient empowerment targeted at multi-stakeholder communities at national level;
 - (e) preparation of an overview of good practices of mechanisms to provide support to the healthcare providers that participate in the ERNs at the national level and develop a set of specific recommendations on how the Member States should support their healthcare providers participating in the ERN system;
 - (f) support for capacity building in the Member States, for national rare disease plans and setting up of the national networks on rare disease and their integration with the ERNs.

EXPECTED RESULTS AND IMPACT

The expected results are exchange of best practice and concrete proposals, guidelines, models and recommendations for better integration of ERNs in the national healthcare systems, including well-defined patient pathways, referral procedures, development of national networks on rare disease and guidelines for development of national teleconsultation tools interoperable with the ERN CPMS. For each of the above-mentioned tools developed by the joint action, the joint action should also develop a mechanism for monitoring the progress and implementation of these proposals, guidelines, models and recommendations.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - HS-g-22-16.02	Q2-Q3/2022	EUR 11 200 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

HS-g-22-16.03 Direct grant on the basis of Article 195, first paragraph, point (f), of Regulation (EU, Euratom) 2018/1046 (*de facto* monopoly): technical assistance and support for disease codification knowledge and information sharing 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, databases and registries. As such, Orphanet constitutes a *de facto* monopoly.

An essential part of the ERN initiative is the possibility to integrate clinical cases in medical registries. This is only possible if a coherent and uniform coding system is widely used by all health care providers which, in the domain of rare diseases, is the existing orphacode system. Since Orphanet and the 24 ERNs are involved in the large research consortium ‘European Joint Programme on Rare Diseases’ as a co-fund with Member States, and also in the ‘Coordination and Support Action’ under Horizon 2020 meant to coordinate clinical research activities of the 24 ERNs, this action will also contribute to streamlining research and healthcare coding efforts.

The award of a direct grant as referred to in Article 195, first paragraph, point (f), of Regulation (EU, Euratom) 2018/1046 is duly justified since the designated beneficiary, due its high degree of specialisation and specific technical competence, is the sole entity capable of carrying out this action.

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, point (d)) through the specific objectives defined in Article 4, points (f), (g) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The proposed action will include the integration of Orphanet nomenclature and orphacodes as the main codification system for rare diseases in the IT systems of the ERNs and healthcare providers, and the continuous maintenance, update and improvement of the system based on scientific analysis of the state-of-the-art knowledge in the area of rare diseases. In addition, it will assure the harmonisation with other codification systems (e.g. SNOMED).

The action aims to support achievement of the abovementioned objectives inter alia, through:

- a) continuous scientific update and analysis of the rare disease coverage with orphacodes and state of the art knowledge in this domain;
- b) extending integration of Orphanet nomenclature and orphacodes as the main codification system for rare diseases in the IT system of the ERNs and healthcare providers at the national level.

EXPECTED RESULTS AND IMPACT

This action will contribute to the harmonisation of the codification systems and thus enable to fill medical registries with data coming from the ERN clinical discussion system and potentially also from national systems. Quantity and quality of healthcare and 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 grants - HS-g-22-16.03	Q2/2022	EUR 3 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant in accordance with Article 195, first paragraph, point (f), of Regulation (EU, Euratom) 2018/1046	HaDEA	Orphanet coordinating team

4.2 IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION AND STRATEGY

HS-g-22-17.01 Call for proposals to develop early warning features and guidance in the area of pricing through the EURIPID database, based on competition cases

POLICY CONTEXT

The Pharmaceutical Strategy for Europe⁵² mentions that the Commission will engage with Member States to foster transparency of price information to help them take better pricing and reimbursement decisions. Prices and pricing decisions influence access to cost-effective and affordable medicines. The 2019 report on the Competition enforcement in the pharmaceutical sector (2009-2017) revealed that the distortion of the price competition in the Union can affect the functioning of internal market⁵³. Voluntary collaborations on pricing, like the EURIPID database⁵⁴, can support early identification and warning for such practices through exchanges of relevant information at Union level.

This action will contribute to the policy priority to implement the Pharmaceutical Strategy for Europe as it concerns the support Member States in national pricing and reimbursement policies. 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 of supporting innovation regarding such products (Article 3, point (c)) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The scope of this action is to develop early warning mechanism and guidance in the area of pricing through the EURIPID database, based on lessons from competition cases, in particular on excessive pricing.

This action will create common approaches to verify claims on price information and to provide appropriate guidance to adjust pricing methodologies.

The activities will include the monitoring of strategic sequencing of price increases, of threats to de-list reimbursable medicines or withdraw of medicines. These activities may prevent price increases based on unfounded claims to recover investments and increased costs.

EXPECTED RESULTS AND IMPACT

This action will:

- a) strengthen the cooperation between national authorities to address the challenges due to certain commercial practices;
- b) extend the EURIPID database to develop warning features;
- c) develop relevant and related technical guidance;
- d) provide updated guidance document on External Reference Pricing.

⁵² [COM \(2020\) 761 final](#) .

⁵³ <https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html>

⁵⁴ European Integrated Price Information Database (EURIPID).

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – HS-g-22-17.01	Q2-Q3/2022	EUR 300 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Member States' authorities

HS-g-22-17.02 Direct grants to Member States' authorities: increasing capacity building of the EU medicines regulatory network

POLICY CONTEXT

Medicines regulators, in particular assessors, are increasingly challenged on one side by the significant increase of workload caused by the COVID-19 pandemic, while in parallel there is a rapid evolution of science for which sufficient expertise is not currently available in the network of EU medicines regulatory agencies.

It is crucial that regulators, scientific assessors and inspectors are up to date with scientific developments across a wide range of areas of regulatory science, receive appropriate training on the latest scientific developments in the field of drug development, new technologies in the field of pharmaceutical developing and manufacturing, e.g. the integration of innovative science and technology in medicines development, the development of innovative methodologies and new analytical approaches, the use of artificial intelligence.

Therefore, it is necessary to provide training for medicinal products assessors, scientific experts supporting the regulatory network and, when appropriate, inspectors, initiating work sharing for example in decentralised procedures ('DCPs') for marketing authorisation, applications or variations, and increasing cooperation in multi-national assessment. The challenge is not only to maintain and further develop the necessary capacity but also to develop the additional capacity available to the regulatory network (e.g. through collaboration with academia).

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by national competent authorities that are members of the EU medicines regulatory network, as they are solely responsible for the authorisation of medicinal products in Member States and implement the pharmaceutical legislation at national level.

This action 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 encouraging innovation regarding such products (Article 3, point (c)) through the specific objectives defined in Article 4, point (h), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective is to increase the necessary regulatory expertise and competences in the European medicines regulatory network and to develop additional capacities to face the challenges represented by upcoming scientific developments. For example, by contributing to the network's transition to digital transformation, modernization, and operational excellence.

As part of the joint action, Member States' authorities will explore through the network of national medicines agencies and scientific experts supporting the regulatory network, the most pressing and specific needs in relation to the available and required competences of the network and propose themes of action.

The activities delivered by the joint action would consist of the identification and exchange of knowledge capacity to support a better collaboration between the members of the EU regulatory network, training actions (training courses and symposia), best practice sharing (e.g. through mentorship/assessment of high risk/complex reports/dossiers), exchange programmes among partners of the EU regulatory network through short secondments and on-the-job-coaching and training, also in close collaboration with EMA. Contributors from

outside of the network as well as of EMA staff (pro-bono) could be considered based on their knowledge and proven expertise in the development and delivery of training.

EXPECTED RESULTS AND IMPACT

This joint action is expected to result in:

- a) developing skills to maintain and improve regulatory experience in handling marketing authorisation procedures including on applications involving upcoming scientific developments; this will also contribute to the development of clusters of excellence in identified areas of interest for the regulatory network;
- b) fostering the exchange of experts and expertise among Member States authorities and providing education and training through courses and on-the-job coaching to regulatory national experts (mainly assessors of the marketing authorisation procedure), creating long lasting cooperation opportunities between national medicines agencies;
- c) fostering work sharing in DCPs and increasing cooperation in Multinational Assessment Teams.

The expected impact is to complement existing similar actions organised by the network and by EMA such as the EU Network Training Centre, actions derived from the European Medicines Authorities Network Strategy and EMA's Regulatory Science Strategy, joint HMA/EMA Big Data Steering Group and the planned European Health Data Space initiative.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - HS-g-22-17.02	Q4/2022	EUR 8 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

4.3 STRENGTHENING THE IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUES AND CELLS AND ORGANS

HS-g-22-18.01 Direct grants to Member States' authorities: piloting a new model approach for assessing and authorising novel Blood, Tissues and Cells (BTC) preparation processes

POLICY CONTEXT

The joint action 'facilitating the authorisation of preparation process for blood, tissues and cells'⁵⁵ (GAPP) founded under the 3rd EU Health programme was aiming at facilitating the development of a common and optimal approach to assess and authorize preparation processes in blood and tissues establishments. The GAPP joint action developed a harmonised and tailored methodology to authorize novel BTC preparation process. It also assessed and prepared a risk assessment tool and delivered protocols of working methods for authorities when being presented with a request to authorize a new BTC preparation process. The GAPP joint action concludes in January 2022.

This follow-up joint action will need to pilot this GAPP approach, collect experience in practice from and professional societies to improve the methodology, tools and protocols to make it broadly useable across the Union.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by Member States' authorities as they have the required competence on the assessment and the authorisation of preparation processes in blood and tissues and cells and have expertise on the work conducted under the previous joint action.

This action 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, point (c)) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This joint action will test the GAPP methodology on new developments in different BTC sub-sectors (blood and plasma for transfusion, tissues for transplantation, cells for transplantation and gametes for reproductive medicine).

It will test assessment and authorisation of BTC with different levels of risk and will try-out cross Member State collaboration, both for professionals preparing a new BTC and for authorities assessing it.

The learnings from these experiences will further improve the GAPP methodology and facilitate its broader use across the Union.

This action excludes any activities on advanced therapy medicinal products as well as the development of any information and communication technologies (ICT).

This joint action is a follow up of 'facilitating the authorisation of preparation process for blood, tissues and cells' and build on that outcome.

⁵⁵ HP-JA-05-2016- facilitating the authorisation of preparation process for blood and tissues and cells (GAPP).

EXPECTED RESULTS AND IMPACT

The expected results are pilot cases providing guidance on how to assess and authorize changes in different steps of BTC preparation process, from donation to clinical application, following the GAPP methodology. The pilots will apply the key steps in the proposed GAPP methodology from initial risk-assessment, over gathering of proportionate data collection from the clinic to eventual assessment and authorisation.

Specifically, the pilots should also investigate the cross-border dimension on how to allow establishments from multiple countries to apply for an authorisation and authorities from multiple countries to jointly assess BTC preparation processes before authorisation. The pilots should cover cases with various risk levels from low-risk cases, requiring limited clinical evidence, to high-risk cases, with possible need for clinical trials.

As a result of every pilot, documented experiences and learnings will be collected. The learnings will be compiled in a common set of recommendations that allow to improve the GAPP methodology and to facilitate its broader implementation across the EU.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - HS-g-22-18.01	Q4/2022	EUR 1 500 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

4.4 IMPLEMENTATION OF REGULATIONS ON MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

HS-g-22-19.01 Direct grants to Member States' authorities: reinforced market surveillance of medical devices and *in vitro* medical devices

POLICY CONTEXT

Reinforced market surveillance is a key feature of the new regulatory framework for medical devices and *in vitro* diagnostic medical devices. Regulation (EU) 2017/745 on medical devices⁵⁶ (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices⁵⁷ (IVDR) requires Member States' competent authorities to coordinate their market surveillance activities, cooperate with each other and share information with each other and with the Commission to provide for a harmonised and high level of market surveillance in all Member States. In addition, the new framework calls on the Commission to provide the necessary support to Member States' authorities to coordinate and ensure that the new regulatory system is uniformly implemented at Union level.

Considering the highly decentralised market access path for medical devices and *in vitro* diagnostic medical devices, and the reinforced obligations of the national competent authorities on market surveillance, there is a need to support Member States' authorities in strengthening coordination. This is key for achieving a better market surveillance of devices on the Union market and therefore further strengthening patient safety across the Union.

The EPSCO Council Conclusions in June 2021⁵⁸ welcomed strengthening joint efforts to secure effective implementation of the new regulatory framework for medical devices and *in vitro* medical devices. In addition, Member States have called for increased coordination and cooperation on market surveillance activities under the MDR and the IVDR. This joint action responds to the Member States' call and will build on the previous joint action on market surveillance financed under the 3rd Health Programme⁵⁹. Furthermore, it will expand its scope and ambition to support Member States in their efforts to secure the implementation of the MDR and IVDR Regulations.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by Member States' authorities as they have the required competence and responsibility to implement the Union policies at national level.

The action 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, point (c)) through the specific objectives defined in Article 4, points (c), (h) and (i), of Regulation (EU) 2021/522.

⁵⁶ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117/1, 5.5.2017 p. 1–175).

⁵⁷ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, (OJ L 117, 5.5.2017, p. 176–332).

⁵⁸ Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU: <https://data.consilium.europa.eu/doc/document/ST-9750-2021-INIT/en/pdf>.

⁵⁹ https://webgate.ec.europa.eu/chafea_pdb/health/projects/723964/.

OBJECTIVES, SCOPE AND ACTIVITIES

The joint action will:

- a) support regular exchange of market surveillance information between Member States' competent authorities, and collaboration on enforcement activities including capacity building activities, e.g. on assessment and case-handling of devices presenting an unacceptable risk or other non-compliances, and cooperation with relevant activities (e.g. vigilance);
- b) support the cooperation of inspectors from national competent authorities responsible for market surveillance of medical devices, in particular by:
 - i. facilitating the sharing of expertise and best practices, and the exchange of information and knowledge between inspectors regarding their inspection of economic operators/medical devices;
 - ii. establishing and implementing a common framework for joint inspections to facilitate the harmonisation of approaches at national level throughout the Union;
 - iii. identification of available inspectors' expertise, developing a unified network of expertise and performing capacity building activities across the network;
 - iv. assessment of needs and, if appropriate, development of a secure IT infrastructure to share and exchange information on joint inspections;
- c) support joint inspections of manufacturers of medical devices, and other economic operators as appropriate, to be performed by a team of inspectors from different Member States with the required expertise with a view to harmonisation of inspections at Union level:
 - i. contributing to a harmonised approach to inspections at Union level;
 - ii. combining efforts when inspecting economic operator activities that are relevant in more than one Member State (e.g. manufacturer, subcontractor or supplier are registered in different Member States);
 - iii. making an efficient use of resources through sharing of expertise (e.g. very specific experts to be used for inspections where this expertise is needed regardless of the Member State authority they work for);
 - iv. providing on-the-job training to less experienced inspectors and/or retraining.

The action builds on the outcome of the JAMS joint action that aimed to reinforce market surveillance between Member States by sharing best practice, training, knowledge, and resource to increase public health protection in the medical devices sector.

EXPECTED RESULTS AND IMPACT

The expected results include securing a smooth and timely implementation of the new regulatory framework, in particular through more effective market surveillance activities, increasing coordination and work-sharing including cooperation with vigilance activities, in particular by harnessing the use of vigilance data. Moreover, it will result in capacity sharing and building up of expertise on market surveillance. The joint action will contribute to the increased safety of medical devices by ensuring that non-compliant devices are kept off the Union market.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - HS-g-22-19.01	Q2-Q3/2022	EUR 4 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member State' authorities (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

HS-g-22-19.02 Direct grants to Member States' authorities: supporting the maintenance of the European Medical Device Nomenclature

POLICY CONTEXT

The European Medical Device Nomenclature ('EMDN') is intended to be utilised by manufacturers for the registration of medical devices in the European database on medical devices ('EUDAMED'), where it will be associated to each Unique Device Identifier - Device Identifier. The EMDN also plays a key role in MDR and IVDR device documentation and technical documentation, sampling of technical documentation conducted by notified bodies, post-market surveillance, vigilance, and post-market data analysis, etc. It will support all actors in their activities under the MDR and IVDR and provide key device descriptions to patients as regards their own devices and all other devices available on the market and registered in EUDAMED.

The new Regulations establish the need for the Commission to make available free of charge to manufacturers and other natural or legal persons, and where reasonably possible to other stakeholders, an internationally recognised medical devices nomenclature. In accordance with criteria and requirements set out by the Commission and the Union regulators in the Medical Device Coordination Group (MDCG) and based on orientations provided by the MDCG, the EMDN was founded following a Commission notice indicating the utilisation of the Italian Health Ministry's 'Classificazione Nazionale Dispositivi Medici' ('CND') as the basis for the future EMDN⁶⁰. A first version of the EMDN was released on 4 May 2021.

In order for the Commission to fulfil its legal obligation, it is essential that the Italian Health Ministry continues to provide its support and competences, ensuring adequate maintenance of the EMDN. The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified, since this activity can only be carried out with the support of the unique expertise of the Italian Health Ministry gained by developing the CND.

The action 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 encouraging innovation regarding such products (Article 3, point (c)) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The action will support the maintenance and update of the EMDN including:

- a) communication with Member States' authorities and stakeholders to respond to requests for information and clarifications linked to the nomenclature;
- b) regular revision of codes and descriptors including granting of new codes and descriptors for devices not yet included in the nomenclature according to the state of the art as requested by the MDCG sub-group on nomenclature and provided through the public platform;
- c) update CND definitions to reflect new EMDN codes;
- d) contribute to the mapping of the EMDN to the Global Medical Device Nomenclature (GMDN);
- e) support the Commission in its collaboration with WHO in relation to a future international medical device nomenclature.

⁶⁰ https://ec.europa.eu/health/sites/default/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf

EXPECTED RESULTS AND IMPACT

The expected results are the provision of a high quality, clear and accurate EMDN for the relevant stakeholders free of charge that is regularly maintained.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - HS-g-22-19.02	Q1-Q2/2022	EUR 1 800 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States' authorities in accordance with Article 195, first paragraph, point (d), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

HS-g-22-19.03 Call for proposals to support increased capacity of notified bodies for medical devices

POLICY CONTEXT

The MDR and IVDR greatly rely on the capacity of notified bodies to certify such products, ensuring the placing on the market of devices compliant with the high level of safety and performance standard set out in the legislation. If notified bodies' capacity falls short, the key objective of the legislation to secure access and availability of safe and performant devices to the health sector and ultimately to patients in the Union is jeopardised. There is therefore a need to increase capacity of notified bodies to secure a proper and smooth application of the legislation especially in IVDs, which is largely composed by SMEs and where the new Regulation identifies many new essential tasks to be performed by notified bodies with specialised expertise.

The limited capacity of notified bodies currently represents a bottleneck for those market operators that are ready to implement the Regulations but unable to find notified bodies available to certify their devices. On the other hand, several market operators have shown poor preparedness and incur delays to adapt to the high-level standards set up by the Regulations which has increased the expected time spent by notified bodies to certify such medical devices. In summary, the current situation raises serious concerns about potential risk of shortages and disruption of supply of devices, especially critical IVDs.

This action supports the policy priority to respond to support the implementation of the legislation and implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d)) through the specific objectives defined in Article 4, points (h) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action will contribute to addressing serious concerns about the lack of availability of vital devices in the medium to long term by increasing capacity of notified bodies and preparedness of market operators, in particular SMEs, with a particular focus on IVDs. In particular by:

- a) supporting training, coaching and internship activities addressed to medical devices' notified bodies as well as third-party entities (conformity assessment bodies) on the process to become a notified body for medical devices;
- b) capacity building activities such as webinars, workshops, targeted feedback and informative sessions addressed to market operators;
- c) appraisal of the certification demand, with the objective to identify the types of devices for which availability of notified bodies is particularly low or lacking;
- d) proposing solutions to facilitate matching the demand of market operators with the availability of notified bodies, in particular in the area of IVDs where SMEs are prominent.

EXPECTED RESULTS AND IMPACT

The action is expected to increase the capacity of notified bodies, increase preparedness of market operators in particular in the area of IVDs (including SMEs) and facilitating the match of demand from the market with the availability of capacity in notified bodies. This ultimately will contribute to secure availability of safe and performant devices in the best interest public health and patients' safety in Union, thus safeguarding essential objectives of the new regulatory framework.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals – HS-g-22-19.03	Q1-Q2/2022	EUR 4 000 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (action grants)	HaDEA	Member States' competent authorities; academia and education establishments, research institutes, hospitals; international organisations and civil society organisations (associations, foundations, NGOs and similar entities) and private entities (including conformity assessment bodies and notified bodies)

4.5 PREPARATION AND IMPLEMENTATION OF THE HEALTH TECHNOLOGY ASSESSMENT REGULATION

HS-g-22-20.01/20.02 Call for proposals to support the implementation of the Regulation on health technology assessment – training of patient and clinical experts contributing to joint health technology assessment activities

POLICY CONTEXT

As envisaged by the Regulation on health technology assessment ('the HTA Regulation')⁶¹, patient and clinical experts will play an important role in implementing the new framework. In order to ensure that joint work is of the highest scientific quality and reflects the state of the art, the HTA Regulation establishes that external experts with relevant in-depth specialised expertise should provide input on joint clinical assessments and joint scientific consultations. Such experts should include clinical experts in the therapeutic area concerned, patients affected by the disease, and other relevant experts on, for example, the type of technology concerned or issues related to the relevant clinical study design. In addition, patient organisations and learned societies will have the opportunity to provide input through the Stakeholder Network.

The EUnetHTA joint actions took the first steps to engage external experts in their activities, however currently there is still further need to engage patients and clinical experts as experts contributing to joint scientific consultations and joint clinical assessments. There is therefore a need to put in place appropriate training programmes for both patient and clinical experts. Such training should be based on the work carried out by EUnetHTA joint actions and the subsequent adaptation to fulfil the needs set out in the HTA Regulation. This action should ensure the appropriate and timely contribution to the joint activities that should start at the implementation date. Transparency on funding as well as representativeness and independence of the experts and organisations involved are key in the appropriate implementation of the action.

This action supports the implementation of the HTA Regulation and implements the EU4Health Programme's general objective of strengthening health systems (Article 3, point (d)) through the specific objectives defined in Article 4, points (h) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The action will support a timely implementation of the new legislation through capacity building activities, aiming at:

- a) increasing the capacity of patient organisations and learned societies to provide robust and meaningful input to HTA activities carried out by the Coordination Group and its sub-groups, including dissemination of the output produced;
- b) increasing the knowledge of patients and clinical experts on the new Union HTA legal framework, clarifying their role when invited to contribute to joint HTA activities for their subject matter expertise and acting in individual capacity (rather than representing any particular organisation, institution, or Member State);
- c) ensuring the appropriate implementation of the rules to ensure the independence and impartiality of patients and clinical experts involved in joint HTA work.

⁶¹ Regulation EU (2021)/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L458, 22.12.2021, p.1-32).

EXPECTED RESULTS AND IMPACT

The action is expected to:

- a) develop training programmes for patients and clinical experts participating in their individual capacity to joint scientific consultations and joint clinical assessments;
- b) contribute to the appropriate implementation of the rules to ensure the independence and impartiality of patients and clinical experts involved in joint HTA work;
- c) raise awareness among patient and clinical experts on the new Union legal framework on HTA and stimulate their engagement with HTA bodies at national and Union level, including dissemination of produced output.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Call for Proposals Subtopic a) HS-g-22-20.01 Subtopic b) HS-g-22-20.02	Q2/2022	Subtopic a) EUR 500 000 Subtopic b) EUR 500 000
Procedure type	Implemented by	Type of applicants targeted
Open call for proposals (one or two thematic action grants)	HaDEA	Civil society organisations (associations, foundations, NGOs and similar entities), professional medical societies; competent health authorities; academia and education establishments, research organisations

5. DIGITAL (DI)

DI-g-22-22.06 Direct grants to Member States' authorities: preparatory actions for a European Health Data Space; primary use of data (for healthcare) and reuse of data

POLICY CONTEXT

The Commission intends to put forward a proposal for a Union legislation on a European Health Data Space ('EHDS'), covering use of primary data for healthcare and re-use of data for policy making, regulatory purposes and research. Cooperation has been going on in several areas, including the eHealth Network joint action⁶², towards the development of an EHDS.

The planned EHDS is one of the priorities of the Commission 2019-2025. Setting up a health data space will be part of building a European Health Union, a process launched by the Commission on 11 November 2020 with a first set of proposals to reinforce preparedness and response during health crises. It is also a follow-up of the European data strategy adopted in February 2020, in which the Commission had stressed the importance of creating European data spaces, including on health.

This joint action supports the Commission's policy priority for 'A Europe fit for the digital age'. The joint action will contribute to promote better exchange and access to different types of health data, by preparing the ground for the implementation of new services in MyHealth@EU, interoperability of electronic health records, telehealth, mobile health and relevant health software and electronic identification (eID), evaluation of the quality of mobile wellness applications and guidelines on ways to satisfy the data requirements set out in the proposed artificial intelligence regulation.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can only be carried out by Member States authorities as they have the required competence and responsibility to implement the Union policies at national level.

The action implements the EU4Health Programme's general objective of 'strengthening health systems' (Article 3, point (d)) through the specific objectives defined in Article 4, point (f), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objective of this joint action is to enhance cooperation among Member States regarding primary and secondary data by:

- a) preparing guidelines and technical specifications on interoperability of medical images, laboratory results and discharge letters towards the European electronic health record exchange format (EEHRxF);
- b) preparing guidelines and technical specifications on interoperability of telehealth, mobile health and other health software;
- c) preparing guidelines and technical specifications on the use of electronic identification in health, for health professionals and patients taking into account the developments of the European Digital Identity Framework;

⁶² Health Programme DataBase - European Commission (europa.eu) Health Programme DataBase - European Commission (europa.eu)

- d) preparing guidelines and technical specifications on cross-border telehealth, including telemonitoring;
- e) preparing an assessment framework and technical specifications for the evaluation of the quality of mobile wellness applications;
- f) preparing an assessment framework and technical specifications for the evaluation of the interoperability of electronic health records, personal health data spaces and other software in health;
- g) preparing guidelines and technical specifications on the quality of mobile wellness applications.

EXPECTED RESULTS AND IMPACT

The expected results are the following:

- a) groundwork for the expansion of MyHealth@EU with new services (e.g. medical images, laboratory results and discharge letters) and support for Member States' national interoperability;
- b) groundwork for the implementation of different interoperable software in health, including electronic health records, telehealth, mobile health and other health software;
- c) better coordination of Member States' joint efforts towards the use of electronic identification in health, for health professionals and patients;
- d) groundwork for the evaluation of the quality of mobile wellness applications;
- e) groundwork for the implementation of cross-border telehealth services, including telemonitoring.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants – DI-g-22-22.06	Q2-Q3/2022	EUR 4 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant (joint action) to Member States' authorities in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

6. OTHER ACTIVITIES (OA)

OA-g-22-23.01 Direct grants to Member States' authorities: events organised by the Presidency of the Council of the European Union

The work programme will support the multiple objectives of the Regulation 2021/522 during the rotating Presidency of the Council with two conferences to be organised in 2022 and early 2023.

OBJECTIVES, SCOPE AND ACTIVITIES

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

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

EXPECTED RESULTS AND IMPACT (INCLUDING OUTPUTS)

The Member States holding the rotating Presidency of the Council are the beneficiaries of the grants to be awarded without a call for proposals based on Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046. 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 the Union, are to be organised exclusively by the Member State holding the Presidency. Given the unique role of the Presidency among Union 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 grants – OA-g-22-23.01	Q2/2022-Q1/2023	EUR 200 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States' authorities in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

B. PROCUREMENT

The overall allocation reserved for procurement contracts and administrative arrangements in 2022 amounts to EUR 300 480 960.

IT development and procurement choices will be taken in line with the guidelines proposed by the Commission Information Technology and Cybersecurity Board.

ACTIONS WITH A COST OF EUR 20 000 000 OR MORE

In 2022, 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 (e.g. JRC, DIGIT, ESTAT, COMM) or European bodies (e.g. European Environmental Agency) to support priorities in the following thematic areas.

1. CRISIS PREPAREDNESS (CP)

CP-p-22-01.01 Ever-warm facilities (EU FAB) for vaccines and therapeutics production - European Health Emergency Preparedness and Response Authority (HERA)

Although the Union has substantially scaled up by now the manufacturing capacities for COVID-19 vaccines, it remains crucial that, after the current pandemic, sufficient and agile manufacturing capacities will be maintained for possible future health threats, even when there is no more demand on the market. EU FAB will make available a network of 'ever-warm' production capacities for vaccine and medicine manufacturing at Union level, including qualified staff, clear operational processes, quality controls and regular investments in infrastructure, thus allowing the Union to be better prepared and respond to future health threats.

As announced by the Commission Communication on HERA⁶³, this action will support the large-scale production of vaccines and therapeutics, to maintain and quickly guarantee access to sufficient production capacity under the EU FAB project. The facilities have to be operational during non-crisis times, during which they can be used for their regular activities. In case of activation, they must be capable to produce and supply the quantities of vaccines and therapeutics to be agreed, upon request and within the requested timeframe.

The expected result of this action is to guarantee quicker access to sufficient manufacturing capacities for vaccines and therapeutics at Union level in case of a future public health emergency and also to respond to global obligations. It will ensure heightened supply in case of a surge in demand due to public health emergencies, by reducing the time needed between development and industrial scale-up and provide for solid supply chains thereto.

Within this thematic area, the Commission plans to launch open procedures or competitive procedures with negotiation or competitive dialogue procedure for either framework contracts

⁶³ Commission Decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority C (2021) 6712 final.

and/or service contracts for the provision of production capacity and for the production and supply of vaccines (such as mRNA-, vector-, protein- and inactivated virus-based vaccines, etc.) and therapeutics.

Type of contracts: service/supply

Indicative budget for this thematic area: EUR 160 000 000

Implementation by: HaDEA

CP-p-22-01.02 Procurement of vaccines against infectious disease threats such as pandemic influenza (HERA)

Vaccination is the most effective medical countermeasure for mitigating the impact of epidemics and pandemic influenza. For instance, pandemic influenza vaccines need to be specifically developed against the strain of virus causing a pandemic. Because the strain of flu virus causing a pandemic is not known before a pandemic is imminent, pandemic influenza vaccines can only be prepared once a pandemic has emerged and the exact strain of flu virus responsible can be identified.

The action aims to procure and supply essential crisis-relevant products in a manner that complements Member States' reservation and stockpiling actions. In particular, it will reserve capacities for the production of vaccines against infectious disease agents such as pandemic influenza vaccines and will primarily focus on products with a Union-wide marketing authorisation but also on products under development. The action aims to reserve manufacturing capacity and assign these capacities for orders placed by the Union contracting authorities and/or the Commission. HERA will manage the reservation through negotiated procedures and invitations to tender. This action will provide a continuation to the joint procurement procedure and framework contracts signed by the Commission and Member States in 2019.

The expected result of this action is ensuring access to vaccines against infectious diseases with a pandemic potential increasing pandemic preparedness at Union level.

Within this thematic area, the Commission plans to launch open procedures for framework contracts and/or competitive dialogue for the procurement and reservation contracts for the production and supply of vaccines against infectious disease threats such as pandemic influenza vaccines to improve preparedness for pandemics.

Type of contracts: service/supply

Indicative budget for this thematic area: EUR 46 000 000

Implementation by: HaDEA

CP-p-22-01.03 IT development for early warning, modelling, simulation, and forecasting (HERA)

This action follows from the 'preparatory action; Horizontal – Intelligence gathering, Threat Assessment & Global Surveillance' under the EU4Health Programme 2021⁶⁴.

⁶⁴ CP-p-06.2 - Intelligence gathering - Preparation of HERA.

The expected results are comprehensive IT tools that host, publish and analyse (including modelling, simulating and forecasting) the data in order to support the intelligence gathering and analysis function of HERA, to guide and underpin its work. These IT tools will incorporate the following elements: threat assessments, medical countermeasure requirements, consequence management, as well as local, regional and international data on serious cross border threats to health. Bringing this data and tools together will allow for a bespoke and tailored IT platform for HERA, which will help to underpin the decision making of HERA as well as early warning functionalities, in terms of medical countermeasures required in preparedness and response of chemical, biological, radiological, and nuclear public health threats of natural, accidental or intentional origin.

To enable this, the IT tools of HERA must also allow machine-to-machine exchange with existing IT platforms, such as those of the Union Civil Protection Mechanism, the Emergency Response and Coordination Center, ECDC and EMA, and smoothen sharing of pertinent data. In a first stage, the design of the specifications of this new IT platform will therefore carefully review the landscape of existing EU systems for early warning (e.g. EWRS), public health surveillance (e.g. TESSy, EPIS) and medical countermeasures (e.g. EUDAMED, clinical trials portal) to ensure complementarity and avoid any duplication. Specifications will also cover strict security requirements to facilitate the exchange of information with other secured platforms while preserving the integrity of the whole IT architecture. At the same time, it must also have the capacity to be interoperable with national IT platforms and other data sources without burden of use. The IT tools must also ensure a high level of security, including robustness to cyber threats and the protection of commercial data, as well as offering secure servers for the safeguarding of past and present data.

Within this thematic area, the Commission plans to launch open procedures for service contracts for the development and maintenance of HERA's comprehensive data collection IT platform based on the IT prototype developed under the 2021 EU4Health Work Programme expected by mid-2022.

Type of contracts: service/supply

Indicative budget for this thematic area: EUR 24 500 000

Implementation by: DG HERA / DG SANTE / HaDEA

ACTIONS WITH A COST BELOW EUR 20 000 000

In 2022, 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 (e.g. JRC, DIGIT, ESTAT, COMM) or European bodies (e.g. European Environmental Agency) to support priorities in the following thematic areas.

1. CRISIS PREPAREDNESS (CP)

CP-P-22-01.08 Study on market research and mapping of innovative diagnostic testing solutions (HERA)

The action under this section has as the objective to support the gathering of information and mapping of innovative diagnostic solutions that could be used for preparedness and response to cross-border health threats.

The expected results are the identification of the current developments and the future production of *in-vitro* diagnostics for the early and reliable identification of relevant cross-border health threats, as well as an analysis of the supply chains and any possible bottlenecks.

Within this thematic area, the Commission plans to launch an open procedure for a service contract for a study on market research and mapping of innovative diagnostic testing solutions.

Type of contracts: service

Indicative budget for this thematic area: EUR 200 000

Implementation: by HaDEA

CP-p-22-02.02 Study on tackling AMR

The actions under this thematic section have as objectives to allow for the continuous monitoring of the progress towards the objectives of strengthening the EU One Health Action plan against AMR, as well as the monitoring of the outcomes of the actions and towards potential targets. Ultimately, this strongly contributes to ensure the effectiveness of the actions and their relevance for the fight against AMR.

The expected result of the study is the design of a cost-effective monitoring and evaluation framework to follow and assess the progress towards the objectives of the strengthened EU One Health Action Plan against AMR. This includes the identification of existing indicators and data sources, the development of new indicators and the design of new data collection activities when needed. Furthermore, the activities will lead to the identification of gaps in AMR surveillance-related data.

Indicative budget for this thematic area: EUR 250 000.

Implementation by: DG SANTE / HaDEA

2. CANCER (CR)

2.1 HEALTH PROMOTION, CANCER PREVENTION AND RELATED RISK FACTORS

CR-p-22-12.01 and 12.02 Tobacco control policy, implementation and modernisation of tobacco control legislation

The actions under this thematic section have as objectives to support the implementation of the EU tobacco control framework and its adaptation to new developments and market trends with an ultimate goal of creation of a Tobacco-Free Generation by 2040, as announced in the Europe's Beating Cancer Plan.

The implementation of Directive 2014/40/EU of the European Parliament and of the Council⁶⁵ would entail in particular:

- a) practical sensory and chemical assessments of tobacco products;
- b) improving the use and the interpretation of data on tobacco and related products, through the procurement of technical expertise and laboratory capacity, including access to reliable and up-to-date market data;
- c) legal assistance in processing the notifications of storage contracts for primary repositories from the manufacturers and importers of other tobacco products than cigarettes and roll-your-own tobacco;
- d) audits related to the operation of the track & trace system;
- e) IT services for the operation and monitoring of the EU Common Entry Gate (EU-CEG) and the tobacco track and trace system.

Furthermore, the work will continue on the evaluation of the current tobacco control legislative framework including preparatory work on scientific and technical elements in view of its future revision.

The expected results will improve the application of existing legislation in the context of the Member States' overall tobacco control strategies, enabling among others better implementation of the Framework Convention on Tobacco Control. Moreover, the envisaged actions will provide for an information and knowledge base for the comprehensive review of the tobacco control legislation.

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

- a) a framework contract to provide services to support the assessment of characterising flavours in tobacco products;
- b) a service contract in support of specific technical services which cannot be carried out under the existing framework contracts;
- c) a service contract in support of IT aspects of data analysis.

Type of contracts: service, administrative agreements

Indicative budget for this thematic area: EUR 4 130 000

Implementation by: DG SANTE / HaDEA

CR-p-22-08.05 Study on the effectiveness of health information on alcoholic beverages

The action under this thematic section has an overall objective to support the implementation of the Europe's Beating Cancer Plan, in particular the policy objective of proposing health information on labels of alcoholic beverages before the end of 2023.

In this context, the Commission plans to launch open procedures for a service contract for a study to map existing health information on alcoholic beverage labels and to assess the effectiveness of different types of health information on the labels of alcoholic beverages.

Indicative budget for this thematic area: EUR 1 000 000

Type of contracts: service

Implementation by: DG SANTE / HaDEA

⁶⁵ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p.1).

CR-p-22-08.04 Study on the evaluation of the EU Action Plan on Childhood Obesity

The actions under this thematic section have as an overall objective to support the implementation of the Europe's Beating Cancer Plan, in particular the evaluation of the EU Action Plan on Childhood Obesity 2014-2020 and to propose follow-up actions before the end of 2023.

In this context the Commission plans to launch open procedures for a service contract for a study to evaluate the progress in the different areas for action in the Action Plan. In addition, the contractor will propose possible next steps that could be taken to effectively reduce the rates of childhood obesity, especially among children in disadvantaged situations, and identify and collect validated best practices on how to best tackle childhood obesity.

Indicative budget for this thematic area: EUR 1 500 000

Type of contracts: service

Implementation by: DG SANTE / HaDEA

2.2 QUALITY OF LIFE OF CANCER SURVIVORS

CR-p-22-11.01 Study on obstacles for cancer survivors to return to work

In 2022, the Commission plans to launch open procedures for a service contract for a study related to the return to work of cancer survivors, mapping national employment and social protection policies and identifying obstacles and remaining challenges.

Indicative budget for this thematic area: EUR 500 000

Type of contracts: service

Implementation by: DG SANTE / HaDEA

CR-p-22-11.02 Call for tender on the development of a code of conduct on fair access of cancer survivors to financial services

Many cancer survivors in long-term remission often experience an unfair treatment in accessing to financial services. Through the Europe's Beating Cancer Plan, the Commission will closely examine practices in financial services (including insurance) from the point of view of fairness towards cancer survivors in long term remission.

The Commission will launch a service contract for a study on the legal situation concerning fair access to financial services in Member States. Furthermore, activities will include engaging with relevant stakeholders to identify obstacles and challenges for cancer survivors to access financial services and work with business; to develop a draft code of conduct to ensure that developments in cancer treatments and their improved effectiveness are reflected in the business practices of financial service providers; to ensure that only necessary and proportionate information is used when assessing the eligibility of applicants for financial products, notably credit and insurance linked to credit or loan agreements. This work will also include recommendations for potential regulatory action at Union level.

Indicative budget for this thematic area: EUR 2 000 000

Type of contracts: service

Implementation by: DG SANTE / HaDEA

2.3 EVALUATING EUROPE’S BEATING CANCER PLAN

CR-p-22-13.01 Mapping and evaluating the implementation of the Europe’s Beating Cancer Plan

Europe’s Beating Cancer Plan will be reviewed by the end of 2024. The review will assess whether the action taken is sufficient to achieve the objectives, or whether additional measures are necessary. In this context, the Commission plans to launch open procedures for a service contract for a study to map and evaluate the implementation of the Europe’s Beating Cancer Plan at Union and national level including relevant actions of the Horizon Europe Mission on Cancer to ascertain whether its objectives are on track to being achieved.

Indicative budget for this thematic area: EUR 1 500 000

Type of contracts: service

Implementation by: DG SANTE / HaDEA

3. HEALTH SYSTEMS AND HEALTHCARE WORKFORCE (HS)

HS-p-22-14.02 Guidelines on access to healthcare for people with disabilities

The actions under this thematic section have as objectives:

- a) to map and analyse the main bottlenecks in accessing healthcare for people with disabilities;
- b) to provide guidelines on how to increase access and overcome barriers in access to healthcare (e.g. medical setting, digital health services and others) for people with disabilities;
- c) to shed light on the situation of the people with disabilities in terms of access to cancer diagnosis and care, including barriers they encounter and differences in quality of care they receive.

The expected results are:

- a) mapping the barriers and challenges in access to healthcare for people with disabilities;
- b) guidelines on how to improve access to healthcare for people with disabilities, as committed in the European Strategy for the Rights of Persons with Disabilities;
- c) quantitative and qualitative data on the situation of people with disabilities in view of receiving cancer care in all Member States.

Type of contracts: service

Indicative budget for this thematic area: EUR 700 000

Implementation by: DG SANTE / HaDEA

HS-p-22-16.04-16.06 Enhanced European Reference Networks (ERNs)

The actions under this thematic section have as objectives:

- a) evaluation of 24 ERNs and their members by an Independent Assessment and Evaluation Body;
- b) maintenance of the non-clinical and clinical (Clinical Patient Management System – ‘CPMS’) IT tools of the ERNs and evolution of the new IT tool for virtual discussions of clinical cases of rare diseases patients (new CPMS);

The expected results are:

- a) evaluation of all Networks and their Members in accordance with Article 14 of Commission Implementing Decision 2014/287/EU⁶⁶;
- b) business continuity of the non-clinical IT tools of the ERNs and of the CPMS as well as preparation to migrate to a more user-friendly and cost-efficient system.

Type of contracts: service, administrative arrangements

Indicative budget for this thematic area: EUR 12 500 000

Implementation by: DG SANTE / HaDEA

HS-p-22-17.03, 17.04, 17.05, 17.06 and 17.07 Implementation of pharmaceutical legislation and pharmaceutical strategy

The actions under this thematic section are part of the package that will help the implementation of the initiatives described in the Pharmaceutical Strategy for Europe (ensuring affordability of medicines for patients and health systems' financial and fiscal sustainability) and will promote further cooperation between national authorities to address the challenges due to certain commercial practices and they have the following objectives:

- a) to support the cooperation between national authorities to address affordability challenges, as provided for in the Pharmaceutical Strategy for Europe, including through the mechanisms under Council Directive 89/105/EEC⁶⁷;
- b) to improve transparency on costs of medicines by filling the knowledge gaps on principles and costing methods for verifying the cost claims of medicines (Pharmaceutical Strategy for Europe's flagship initiative);
- c) to support the group of National Competent Authorities on Pricing and Reimbursement and public payers (NCAPR) on identifying needs for evidence generation from the lifecycle of medicines and improving transparency of data (Pharmaceutical Strategy for Europe's flagship initiative). It covers information exchange on affordability on a voluntary basis;
- d) administrative agreement on support for pharmaceuticals and substances of human origin ('SoHO') data analytics;
- e) IT support to the European Medicinal Products database ('EMP').

The expected results are:

- a) report on the possible uses of Directive 89/105/EEC to achieve the affordability objectives of the Pharmaceutical Strategy for Europe;
- b) analysis on ways to make costing methods and principles more transparent and explore the feasibility for future guidance;
- c) support for the implementation of the NCAPR 2021-2023 work plan (which also includes exchanges between current regional initiatives) via dedicated workshops and support to collaborations on pricing by facilitating meetings, gathering data and knowledge, developing dashboards, producing technical reports and others;
- d) data analytics of the relevant datasets provided by DG SANTE to support data-driven policy making; including project management services and facilitation of the innovation process;

⁶⁶ Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79).

⁶⁷ Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).

- e) continuing support of the maintenance and the update of the EMP.

Within this thematic area, the Commission plans to launch open procedures to support the objectives described in the Pharmaceutical Strategy for Europe, the current mechanisms and tools (like the ones under Directive 89/105/EEC) and the support to payers in developing minimal data sets and registries for therapies (especially from pharmaceuticals and SoHO).

Type of contracts: service, administrative arrangements, co-delegations

Indicative budget for this thematic area: EUR 1 150 000

Implementation by: DG SANTE / HaDEA

HS-p-22-18.02, 18.03 and 18.04 Supporting the cooperation between the national authorities and professional sector associations in the blood, tissue and cells and organs sectors

The actions under this thematic section have as objectives:

- a) to update and develop ICT modules to support network of national SoHO authorities (NCAs) overseeing safety, quality and efficacy of blood and transplant therapies, including the use of reproductive and non-reproductive cells;
- b) to facilitate exchanges between key associations of hospital blood banks and associations of medical professionals which are regular therapies users in hospitals, to develop an extended role for hospital blood banks to support the supply and use of these other SoHO therapies in hospitals;
- c) IT support for SoHO sector.

The expected results are:

- a) development of concrete ICT modules to be used as support to the needs and urgency of Member States competent authorities, blood, tissue and cells establishments and their professional associations;
- b) definition and extension of the role of hospitals' blood banks for new activities related to the supply and the use of SoHO, and providing the required organisational and administrative support in order to provide administrative practices;
- c) continuing the IT support in the SoHO sector.

Within this thematic area, the Commission plans to launch open procedures to support the network of NCAs overseeing safety, quality and efficacy of blood and transplant therapies and to facilitate exchanges between key associations of hospital blood banks and associations of medical professionals.

Type of contracts: service, administrative arrangements, co-delegations.

Indicative budget for this thematic area: EUR 5 390 000

Implementation by: DG SANTE / HaDEA

HS-p-22-19.04, 06, 07, 08, 09, 10 and 11 Supporting the implementation of Regulations on medical devices and in vitro diagnostic medical devices

The actions under this thematic section have as overall objective to support the implementation of MDR and the IVDR. These actions will reinforce the safety requirements for all operators for the placing of their products on the Union market among other things by:

- a) facilitating the adoption of science-based regulatory measures on specific health-related aspects (e.g. surface characterisation of breast implants);

- b) providing technical and administrative support to manufacturers and other economic operators both on the use of the unique device identification (UDI) database and on new UDI obligations;
- c) raising awareness about the MDR and IVDR including the production of materials, organisation of webinars and intensification of outreach activities for stakeholders;
- d) supporting the development of the EUDAMED database (including the audit on the 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 Union market, their notified bodies and the national competent authorities and the public;
- e) supporting the current regulatory governance for medical devices to improve working methods and ensure regulatory governance is fit to manage requirements and ensure adequate coordination. This will be done by gathering feedback from Member States' authorities and other relevant stakeholders to assess the current regulatory governance, including lessons learnt, and making recommendations;
- f) supporting the International Medical Device Regulators Forum presidency, including the organisation of meetings and communication activities;
- g) survey key actors operating on the market, namely notified bodies and manufactures (also authorised representatives if appropriate) to get information on devices and certificates.

The expected results are: reinforced safety requirements for medical devices on the Union market, including an improved data management for all involved actors; securing the relevant resources and secretariat support for the functioning of expert panels; continue activities of the UDI helpdesk; and communication activities and surveys to support adequate and timely implementation of regulations. In addition, these actions will provide an insight into the most appropriate governance structure with efficient working methods and procedures that could be implemented to ensure an effective implementation of the regulatory framework.

Within this thematic area, the Commission plans to launch open procedures for a framework contract or a service contract for the UDI helpdesk, a framework contract or a service contract for communication activities related to the MDR and IVDR, an assessment and foresight proposals related to the governance structure and its methods.

Type of contracts: service, administrative arrangements

Indicative budget for this thematic area: EUR 9 968 000

Implementation by: DG SANTE / HaDEA

HS-p-22-20.03-20.04 Preparation and implementation of HTA Regulation

The actions under this thematic section have as overall objective to ensure the setting up and running of the Commission secretariat supporting the new HTA framework (both at administrative and technical level) and upgrading and ensuring maintenance of the IT platform supporting the HTA Regulation.

The expected results are:

- a) securing an operational secretariat that can facilitate ensuring the timely and high-quality production of joint work to meet the legal obligations set out in the newly adopted Regulation. The secretariat will facilitate and enable timely discussions and interactions between members of the Coordination Group, its subgroups and collaboration with EMA, for joint work (e.g. joint clinical assessment and parallel joint scientific consultations) allowing input from all relevant stakeholders and

building synergies with other Union initiatives. This will result in the development of the necessary methodologies to carry out joint HTA work, preparation for adequate running of joint parallel scientific consultations and joint clinical assessments and the implementation of the conflict of interest and transparency policy defined in the HTA Regulation;

- b) delivering a secure IT platform to ensure an effective exchange of information with health technology developers, internal communication and drafting of HTA reports by the Member States experts and exchange of information with stakeholders.

Type of contracts: service, administrative agreement, use of existing framework contract.

Indicative budget for this thematic area: EUR 6 200 000

Implementation by: DG SANTE / HaDEA

4. DIGITAL (DI)

DI-p-22-21.02 Expansion of core services to support access of patients to their health data - primary use of health data

The action will support the development of patient access to translated health data, offered through mobile apps or patient portals published by Member States. A pilot supporting first pioneer Member States to develop this new service as part of MyHealth@EU is planned to be launched in 2022. The pilot will need the support from MyHealth@EU central services. The following actions will be required to ensure the full process by supporting:

- a) analysis of the necessary changes to MyHealth@EU in order to enable access of patients to their translated health data;
- b) support for the development and integration of the changes in the Member States' systems;
- c) implementation of the changes to core services in order to enable new functionalities;
- d) scaling up of lessons learned;
- e) coordination with other initiatives (e.g. eID wallet);
- f) benchmarking, such as through the expansion of MyHealth@EU KPIs (Key Performance Indicators).

The expected results are:

- a) technical specifications, business requirements and software support at the level of core services in order to enable access of patients to their translated health data;
- b) coordinated uptake by the Member States of the new functionality resulting from the pilot project⁶⁸.

This action will contribute to enable citizens to securely access and share their health data across borders, improving the quality and continuity of care offered to citizens.

Type of contracts: service, administrative arrangements, co-delegations

Indicative budget for this thematic area: EUR 700 000

Implementation by: DG SANTE / HaDEA

⁶⁸ DI-g-24.1.1 Call for proposal: action grants for developing a pilot project for an EU infrastructure ecosystem for the secondary use of health data for research, policymaking and regulatory purposes (EU4Health work programme 2021)

DI-p-22-22.03 Developing and deploying the basic EHDS2 core services - secondary use of health data

The action supports the development and deployment of the planned European Health Data Space for secondary use of health data (EHDS2) core services, including the setup of a European health data catalogue to facilitate health data discoverability for secondary purposes (i.e. policy making and regulatory activities, research, statistics and innovation). This action will require to:

- a) elicit the functional and non-functional requirements for the basic EHDS2 core services for large-scale deployment and routine operations (e.g. a European health metadata catalogue to facilitate health data discoverability for secondary purposes, building on the outcomes from the EHDS2 pilot project);
- b) design, specify and develop and implement the necessary core services and software basic building blocks for EHDS2;
- c) analyse the necessary IT infrastructure and software basic building blocks and test potential candidates;
- d) design the business and operational procedures necessary for the core services of the EHDS2 infrastructure;
- e) support and consolidate the work of the pilot project infrastructure for secondary uses of health data towards a large-scale deployment of the EHDS2 infrastructure;
- f) prepare handover for routine operations and prepare for deployment and operation of basic building blocks.

The expected results are:

- a) requirements and specifications for IT and data infrastructure technological building blocks to enable Union-wide reuse of health data;
- b) development and deployment of core services to support the IT infrastructure enabling Union-wide reuse of health data;
- c) operational procedures for the deployment of the IT infrastructure enabling Union-wide reuse of health data.

This action aims at deploying a Union-wide large-scale infrastructure for reuse of health data. It will contribute to enhance the EU added value of a cross-border infrastructure for secondary use of health data.

Type of contracts: service, administrative arrangements, co-delegations

Indicative budget for this thematic area: EUR 4 000 000

Implementation by: DG SANTE / HaDEA

DI-p-22-21.03, 21.04 and 21.05 Operations of MyHealth@EU core services, ensuring compliance with the requirements of the planned European Health Data Space and supporting data controllers - primary use of health data and support for capacity building

This action supports the core services and sharing of best practices, allowing the functioning of eHDSI/MyHealth@EU and exchange of data between Member States. This action will support:

- a) the management and governance of the eHealth DSI Member States Expert Group and the eHealth Operational Management Board and the management of eHDSI Solution Provider team;

- b) the design and continuous improvement of eHDSI/MyHealth@EU core services requirements and specifications as well as the operation and continuous improvement of eHDSI/MyHealth@EU core configuration and terminology services;
- c) the continuous improvement and support to the NCPeH Reference implementation; the action includes support for core services related to the continuous maintenance and development of the test and compliance check frameworks, provided by the Commission⁶⁹. The NCPeH Reference implementation is used by most of the NCPeHs to enable cross-border health care information services and the continuous improvement and operationalisation of the test and audit (compliance check) frameworks, the test and compliance check activities have been operational in MyHealth@EU since the launch of the first services in 2019;
- d) the organisation and coordination of eHDSI/MyHealth@EU communities of practice;
- e) the assessment and confirmation of NCPeH compliance with the eHDSI/MyHealth@EU requirements to conclude on potential risks to the confidentiality, integrity and availability of health data;
- f) the development of eGovEra benchmarking, supporting the capacity building and exchange of best practices between Member States;
- g) checking of compliance with the requirements of the envisaged EHDS for primary (MyHealth@EU) and expansion to secondary (EHDS2) use of health data. This action will support:
 - i. the assessment and validation of NCPeH compliance with the eHDSI/MyHealth@EU requirements to conclude on potential risks to the confidentiality, integrity and availability of health data;
 - ii. checking the compliance of EHDS2 nodes with the requirements of the EHDS network for secondary uses of health data;
- h) supporting data controllers in the MyHealth@EU to fulfil their responsibilities by:
 - i. preparing a draft Data Protection impact assessment of the processing operations involved in the MyHealth@EU, in accordance with Article 35 of Regulation (EU) 2016/67970;
 - ii. defining roles, responsibilities, procedures, forms and templates between controllers in MyHealth@EU.

The action will ensure the continuity of IT support to the core service for MyHealth@EU; the work will be done in full synergy and complementarity with related ongoing activities. The action constitutes work conducted every year to support the continuity of MyHealth@EU services. The action adds elements related to capacity building and to data protection related aspects, and extends the tasks partly to the domain of secondary use in EHDS.

Expected results from the actions are to enhance the work of Member States on cross-border sharing of patients' data and providing core services for eHDSI/MyHealth@EU infrastructure. Another expected result is to strengthen the administrative capacity of Member States in the area of e-health. In addition, this action will contribute to the deployment of a Union-wide large-scale infrastructure for reuse of health data and enhancing the EU added value of a cross-border infrastructure for secondary use of health data. Finally, the action will

⁶⁹ National activities of Member States participating in test events and compliance checks are partly funded by direct grants under the EU4Health Programme and partly by national funding.

⁷⁰ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

contribute to the compliance of MyHealth@EU with the applicable data protection requirements and contribute to enhance the EU added value of a cross-border infrastructure for primary use of health data.

The Commission plans to launch open procedures for framework contracts for “Support to primary and secondary use of health data”.

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

Indicative budget for this thematic area: EUR 6 500 000

Implementation by: DG SANTE / HaDEA

DI-p-22-22.04-22.05 Secondary use of health data - infrastructure governance

The actions under this thematic section have as objective to provide support for the development of a governance model and rules for the sharing of public health data for secondary use and for the development, deployment and operation of an IT system and data tool that will enable access to health data for secondary use, i.e. for research and development, policy-making and regulatory activities. The activity will be based on the revision, extension and enhancement of the European Core Health Indicators ('ECHI') data tool and its technical integration with the planned EHDS. Furthermore, and embracing the 'One Health' approach, the further development and implementation of the work plan 2021/2022 of the European Climate and Health Observatory aims at supporting adaptation plans and measures in Member States related to climate change and health.

This action will contribute to the overall EHDS work, in particular for the update of the ECHI data tool, thus anticipating the planned EHDS governance mechanism, which will allow Member States and the Commission to agree on the voluntary exchange of data, aligned with EU indicators and criteria.

The expected results of the actions under this thematic section linked to the European Climate and Health Observatory are the content development on several topics (e.g. heat impacts on health, climate-sensitive infectious diseases including the annual report), communication activities and outreach and improvement of the portal.

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

Indicative budget for this thematic area: EUR 1 400 000

Implementation by: DG SANTE / HaDEA

5. RECURRENT, HORIZONTAL, IT AND COMMUNICATION ACTIVITIES

The actions have as objectives the organisation of events in the field of health, the logistical support to meetings of expert groups and similar entities as well as of 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, impact assessments 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 to communicate on the EU4Health Programme and the Union priorities it supports, on actions supported by the programme, and to ensure the necessary technical expertise for horizontal activities such as graphic design or website management and maintenance. In line with the Commission's ambition to build a European Health Union for people, communication in 2022 will focus on citizen-oriented communication campaigns on political priorities including the Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, vaccine sharing, the envisaged European Health Data Space and AMR. Moreover, in accordance with Article 26 of the Regulation 2021/522 and in line with the Communication to the Commission on 'Corporate Communication action in 2021-2023 under the Multi-annual Financial Framework 2021-2027', the corporate communication of the Union's political priorities to the extent that they are related to the general objective of the EU4Health Programme will be supported.

In addition, this action covers the supporting services for SANTE Information Systems for Health, carrying out activities relating to IT Governance & Strategy; IT Quality and Security; IT architecture and rationalisation; Data Strategy, data management, analytics and visualisation; emerging technologies; development & infrastructure; applications support and general IT and digital consultancy.

Additionally, this also covers the development, operations and maintenance of cross pillar solutions and services used by the DG SANTE Health Pillar including solutions like Event management Tool (EMT), Knowledge Online on European Legislation (KOEL) and the DG SANTE Data Collection Platform (SDCP) as well as contributing towards costs for licencing and Digital Work Place for external service providers.

The expected results are:

- a) for communication: a broad coverage and higher awareness of Union health policies and increased support for them through sustained communication with a range of stakeholders, media and targeted sections of the general public and the dissemination of information through integrated communication actions;
- b) for IT: provision of corporate technical services;
- c) for evaluation: improved capacities to carry out evaluations of existing legislation and/or legislative proposals;
- d) for stakeholder-related activities: an enhanced Health Policy Platform and organisation of and participation in events; studies and evaluations, where relevant.

Within this thematic area, the Commission plans to launch open procedures for a framework contract for evaluation and impact assessment-related services and a framework contract for services related to the organisation of meetings and events as well as related activities.

Type of contracts: service, administrative arrangements, co-delegation with DG COMM

Indicative budget for this thematic area: EUR 10 392 960

Implementation by: DG SANTE / HaDEA

C. OTHER ACTIONS AND EXPENDITURE

In 2022, the Commission intends to launch the following other actions which contribute to one or several strands.

Membership fees to International Organisations and regulatory bodies

HS-o-22-23.02 and 23.03 Annual membership fee to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)⁷¹ and participation of experts from Member States in ICH meetings

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 and participation of experts from Member States in ICH meetings. The objective is to participate in the harmonisation of technical requirements, including scientific aspects, of medicinal product registration at international level.

⁷¹ Commission Decision of 23 October 2015 on the participation of the Commission as Founding Regulatory Member in the 'International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use', C(2015)7256 final.

HS-o-22-23.02 Annual contribution to the International Pharmaceutical Regulators Programme⁷² (IPRP)

This action covers the contribution to the International Pharmaceutical Regulators Programme of which the Commission is a member. The aim is to exchange information on issues of mutual concern and regulatory cooperation at international level.

HS-o-22-23.04 Annual contribution to the European Observatory on Health Systems and Policies Partnership⁷³

This action covers the contribution to the European Observatory on Health Systems and Policies Partnership to which the Commission is a participating organisation. The aim is to support and promote evidence-informed policy-making decisions on European health systems.

Indicative budget: EUR 1 400 000

Implementation by: DG SANTE / HaDEA

Various meetings: standing committees, ad-hoc meetings, committees and other events

This action intends to support the preparation and running of events and meetings through covering expert expenses including special indemnities, in particular in relation to participation in steering groups and expert panels⁷⁴, 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 participation of auditors in the GMP and GDP joint audit programme in the Union and third countries for the quality of medicines to support international harmonisation of requirements for pharmaceuticals and regulatory convergence; international activities with the regulators of the Union's main trading partners; as well as the VICH⁷⁵ committee and expert group and the participation in the VICH outreach forum. Support to the organisation of meetings of the Joint Industrial Cooperation Forum as well as its matchmaking events that will contribute to the resilience of European supply chains.

Indicative budget: EUR 2 368 595

Implementation by: DG SANTE / DG HERA / 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

⁷² Commission Decision of 18 May 2021 on the participation of the Commission as a Member in the 'International Pharmaceutical Regulators Programme', C(2021) 3312 final.

⁷³ Commission Decision of 21 December 2009 on its incorporation as a Participating Organisation of the 'European Observatory on Health Care Systems and Policies' project, C(2009)10213 final.

⁷⁴ 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(2) of the Annex VII to the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68 (OJ L 56, 4.3.1968, p. 1), and as further detailed in Annex 1 to Commission's Guide to missions and authorised travel, C(2017) 5323 final.

⁷⁵ VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration.

evaluation committees regarding calls for proposals by assessors with a specific technical expertise in the field of public health.

Indicative budget: EUR 250 000

Implementation by: DG SANTE / HaDEA

D. ACTIONS IMPLEMENTED IN INDIRECT MANAGEMENT

ACTIONS WITH A COST OF EUR 20 000 000 OR MORE

Not applicable for the present work programme.

ACTIONS WITH A COST BELOW EUR 20 000 000

CP-g-22-05.01 Protecting people in the Union and its neighbourhood from serious cross border health threats

POLICY CONTEXT

The COVID-19 pandemic has shown the need to improve and further strengthen pandemic preparedness and response mechanism at national and international level. At the World Health Assembly, the 194 members of WHO adopted on 31 May 2021 the decision to discuss a new international treaty on pandemics at a special session held in November 2021. The Council adopted on 20 May 2021 a decision⁷⁶ to support the launch of negotiations for an international treaty on the fight against pandemics within the framework of WHO. Such a treaty would support international efforts to reinforce global health security, on preparedness and response to health emergencies, in the light of lessons learnt from the pandemic.

Direct experience from COVID-19 and data from countries show the need to strengthen the Union's capacities required under International Health Regulations ('IHR') and against serious cross-border threats to health. The following capacities, among others, require specific attention: capacities at points of entry, risk communication, chemical events, biosafety and biosecurity and antimicrobial resistance, capacities to maintain routine functions of health systems while withstanding shocks, capacities and mechanisms to govern preparedness and coordinate the response through a system approach. In addition, insufficient human resource capacity across the majority of the technical areas is a transversal issue.

The proposed action will contribute to strengthening the future Union's health security architecture and related initiatives by the Commission to improve and strengthen reporting on preparedness. The proposed action complements ECDC's work as laid down in its revised mandate and builds on the joint WHO Europe and European Commission Roadmap on health security against health emergencies and other threats⁷⁷ as well as other Commission initiatives on preparedness and response. In this regard, WHO and ECDC will strengthen their collaboration and coordination on preparedness and response in countries through, *inter alia*, the European Union Health Task Force⁷⁸ (EUHTF) or to joint country missions

In accordance with Articles 7(1) and 13(7) of Regulation 2021/522 the award of the action to WHO is duly justified given that it is the international organisation responsible for the monitoring of the international health regulation, and core capacities for preparedness and

⁷⁶ <https://www.consilium.europa.eu/en/press/press-releases/2021/05/20/eu-supports-start-of-who-process-for-establishment-of-pandemic-treaty-council-decision>

⁷⁷ <https://www.euro.who.int/en/about-us/partners/the-european-union-and-its-institutions/european-commission-ec/senior-officials-meeting-som/meeting-of-senior-officials-and-technical-experts-from-who-and-the-european-commission/implementation-roadmaps-for-ec-who-europe-collaboration/som-2011.-roadmap-for-ec-who-europe-collaboration-on-health-security>

⁷⁸ Proposal for a Regulation establishing a European Centre for disease prevention and control https://ec.europa.eu/info/sites/default/files/proposal-mandate-european-centre-disease-prevention-control_en.pdf.

response. Therefore it is the sole body with the required expertise and capacity to implement the action.

The action supports the Union's global commitments and health initiatives and 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, point (d)) through the specific objectives defined in Article 4, points (g), (i) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

The objectives of this action are to:

- a) strengthen the Union's capability for prevention of, preparedness for, and detection and response to serious cross border threats at global level in particular by adopting a multi-hazard approach, inter-sectoral preparedness and response leveraging and improving existing network infrastructures. This would include contingency planning, inter-sectorial collaboration, points of entry and laboratory preparedness and biosecurity;
- b) coordinating capacities to support and enhance emergency preparedness, outbreak investigation and response, making full use of the EUHTF and support capacity monitoring and evaluation in line with the Joint External Evaluation (JEE) framework for IHR, and to meet the needs of the Member States to be carried out through intercountry assessments;
- c) strengthening cooperation, coordination and complementarity at global level, using the pooled expertise and resources of WHO and the Union to support crisis coordination and health emergency response, leveraging and strengthening the shared platforms and processes to remove duplications and increase interoperability;
- d) supporting the coordinated assessment of lessons learned from the COVID/19 pandemic and identifying opportunities for strengthening preparedness and joint implementation in complementarity with the IHR (2005) and the proposed Regulation on serious cross-border threats to health⁷⁹, supporting the assessment of lessons learned from the COVID-19 pandemic by Member States and the WHO European Region countries to find opportunities for joint implementation;
- e) conducting studies and assessment, including modelling, generating scientific evidence on the impact of non-pharmaceutical interventions in terms of prevention and response in different settings/sectors with the aim of formulating recommendations;
- f) further developing of the Epidemic Intelligence from Open Sources (EIOS) and integration into European alert and information systems.

Activities will be defined in strict collaboration with the Commission and other relevant Union agencies, particularly ECDC as a core technical partner. A detailed action log frame with specific milestones and indicators between WHO Regional Office for Europe and ECDC and relevant Union agencies and bodies will be elaborated ensuring complementarity and coordination of the effort, and encouraging the further joint development of guidance and tools for Member States as a cross-cutting and measurable objective of the action. A joint WHO-ECDC Steering Working Group will be established to coordinate implementation of the activities.

⁷⁹ Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU (COM(2020) 727 final).

EXPECTED RESULTS AND IMPACT

The action is expected to yield the following results and impacts:

- a) contribution to the strengthening of national capacities to monitor, review and report on IHR implementation to generate evidence as prerequisite for capacity strengthening activities. Specific activities will support coordinated reporting requirements under IHR mandate and EU/EC/ECDC requirements and contribute to the monitoring and evaluation of the EU and EEA countries preparedness and response, IHR core capacities and sharing of information with EC and ECDC;
- b) contribution to improved national emergency prevention, preparedness and response capacities for all hazards in line with the IHR (2005) and the proposed Regulation on serious cross-border threats to health in coordination with EC/ECDC, based on COVID-19 lessons learned. Specific activities will include joint WHO/EC/ECDC approaches to strengthening cross-border health, multi-sectoral coordination and emergency risk management programmes, pandemic preparedness planning guidance through the pandemic influenza preparedness framework⁸⁰, and strengthening risk communication and community engagement;
- c) contribution to an improved detection and coordinated response to health emergencies including through the deployment of the EUHTF and coordination with existing WHO mechanisms (e.g. Global Outbreak Alert and Response Network⁸¹ GOARN) with established and agreed operating procedures;
- d) contribution to a coordinated and operationalised One Health approach to address health threats originating in the animal-human-environment interface at global level. Specific activities will include the support to strengthening multi-sectoral and multi-stakeholder coordination to address foodborne and zoonotic diseases with the development of One Health Roadmaps and sub-regional cross-border One Health simulation exercises in coordination and collaboration with the relevant Union agencies, EFSA and ECDC.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
CP-g-22-05.01	Q1-Q2/2022	EUR 5 800 000
Procedure type	Implemented by	Type of applicants targeted
Indirect management - contribution agreement	SANTE	International organisation (WHO Regional Office for Europe)

⁸⁰ WHO pandemic influenza preparedness framework <https://apps.who.int/gb/pip/>

⁸¹ Global outbreak alert and response network (GOARN) <https://extranet.who.int/goarn/>

DP-g-22-07.02 Addressing mental health challenges

POLICY CONTEXT

Mental health is an integral and essential component of health. It is critical to individual well-being, as well as to social and economic participation. The total costs arising from mental health problems account for more than 4% of GDP across the Member States (Health at a Glance: Europe 2018). The heavy individual, economic and social burdens of mental illness are not inevitable.

Although many Member States have policies and programmes to address mental illness at different ages, the distribution of these actions is uneven throughout the life course. Furthermore, the COVID-19 pandemic has immediate and long-term consequences, including on mental health, which require action that focuses on vulnerable groups, including children and refugees and migrant populations. Hence, there is an acute need to increase awareness, knowledge sharing and capacity building in the area of mental health.

The Commission's work on NCDs and mental health builds on international policy frameworks, notably the UN Sustainable Development Goals and the 9 global voluntary targets set by WHO on NCDs.

To support the Member States in reaching the health targets of the United Nation's 2030 Agenda for Sustainable Development and its goals, the Commission has established SGPP. The expert group provides advice and expertise to the Commission to foster exchanges of relevant experience, policies and practices between the Member States on how to tackle the burden of NCDs in the Union. Therefore, addressing mental health challenges through the identification and transfer of best practices, which are developed and implemented successfully in one country, can have a concrete, direct, positive impact for citizens, health systems and society.

In the joint action **ImpleMENTAL** rolled out in 2021, the Member States will aim to roll out examples of best practices on mental health system reform and suicide prevention examples, which requires further knowledge and expertise input.

WHO holds a unique repository of knowledge and expertise in mental health and has extensive experience as regards capacity building and training, especially across countries. Its advice can be crucial to support Member States to transfer and implement better measures in this area, avoiding known pitfalls, and taking advantage of best examples, also by maximising sustainable impact of cross-country learning best practice.

In accordance with Articles 7(1) and 13(7) of Regulation 2021/522 the award of the action to WHO is duly justified as it has the required and unique extensive experience in capacity building and training across countries as well as a unique repository of knowledge in mental health to support the Member States and implement the action.

This action supports the policy objective of reducing the burden of NCDs and meets the following EU4Health Programme general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives in Article 4, points (a) and (i), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action complements and synergises with the mental health joint action (**ImpleMENTAL**) through collaboration, coordination and knowledge from the WHO Regional Office for Europe.

WHO, in close cooperation with the Commission, will be requested to provide capacity building support for Member States through training and cross-national learning, and by sharing expertise on mental health, thereby increasing skills and knowledge at practice as well as policy level.

EXPECTED RESULTS AND IMPACT

This action will complement the efforts of the joint action **ImpleMENTAL**. Specifically, it is expected to strengthen and cement the sustainable impact of the joint action’s results, both on the ground and at (sub) national policy level. For this purpose, it will seek to make the most of WHO’s unique body of knowledge and expertise in the area of mental health and in particular of WHO’s extensive experience as regards capacity building and training for mental health leadership, and cross-national learning. It will also foster synergies with WHO’s Mental Health Coalition and its European Framework for Action on Mental Health. As such it will further respond to and support Member States’ prioritisation of mental health as a topic for best practice implementation.

WHO’s advice will make a significant contribution to support Member States to design and implement better measures in this area, avoiding known pitfalls and taking advantage of best examples, also by maximising sustainable impact of cross-country learning on best practice.

WHO will regularly inform and discuss progress with the Commission, and will be invited to engage in the SGPP and/or in activities linked to the joint action on mental health.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
DP-g-22-07.02	Q2/2022	EUR 1 000 000
Procedure type	Implemented by	Type of applicants targeted
Indirect management - contribution agreement	SANTE	International organisation (WHO Regional Office for Europe)

CR-g-22-08.03 Addressing alcohol-related harm - capacity building, raising awareness and implementation of best practices in the Union

POLICY CONTEXT

Alcohol-related harm is a major public health concern in the Union; it has the highest alcohol consumption in the world; eight out of the 10 countries with the global highest level of drinking are located in the Union. While there has been an overall decrease in alcohol consumption in the WHO European Region, this decline was driven by non-EU countries, while consumption levels in the Union have stagnated and increased in some countries⁸².

In 2016, cancer was the leading cause of alcohol-attributable deaths with a share of 29%. In the same year, about 80 000 people died of alcohol-attributable cancers in the Union, and about 1.9 million years of life were lost due to premature mortality or due to disability⁸³. About half of alcohol-attributable breast cancer cases in the Union are caused by light to moderate alcohol consumption, which underlines the need for measures to reduce alcohol consumption at any level of intake among the population⁸⁴. Public awareness of the cancer risk posed by alcohol is generally low.

Benefitting from of a whole-of-government approach, the Europe's Beating Cancer Plan aims to raise awareness of and address key risk factors including harmful alcohol consumption. One of the policy objectives of the Europe's Beating Cancer Plan is to reduce harmful alcohol consumption including a target to achieve a relative reduction of at least 10% in the harmful use of alcohol by 2025.

The new draft Global Alcohol Action Plan 2022-2030 to strengthen implementation of the Global Strategy to Reduce the Harmful Use of Alcohol, which will be proposed to the World Health Assembly in May 2022, sets a new target of least a 20% relative reduction by 2030, compared with 2010 as the baseline. The WHO Regional Office for Europe, has an active network of Member State focal points, collaborating centres and civil society partnerships which can be used to support data-gathering and strategic action to support implementation of effective and cost-effective alcohol actions across the Union, including tailored support for individual countries where this is required. In particular, the WHO Regional Office for Europe efficiently supports government bodies at national and subnational levels preventing the harm done by alcohol, with an increased investment in the implementation of policies known to be effective.

In accordance with Articles 7(1) and 13(7) of Regulation 2021/522 the award of the action to WHO is duly justified since it has the required expertise and capacity to implement the action through its unique and extensive experience in capacity building, networking and training

⁸² Probst, C., Manthey, J., Neufeld, M., Rehm, J., Breda, J., Rakovac, I., & Ferreira-Borges, C. (2020). Meeting the Global NCD Target of at Least 10% Relative Reduction in the Harmful Use of Alcohol: Is the WHO European Region on Track? *International Journal of Environmental Research and Public Health*, 17(10), 3423.

⁸³ Rehm, J., & Shield, K. D. (2021). Alcohol use and cancer in the European Union. *European addiction research*, 27(1), 1-8.

⁸⁴ Killian, C., Rovira, P., Neufeld, M., Ferreira-Borges, C., Runggay, H., Soerjomataram, I., Rehm, J. (2021). Modelling the impact of increased alcohol taxation on alcohol-attributable cancers in the WHO European Region, *The Lancet Regional Health – Europe*, Volume 11, December 2021, 100225. <https://doi.org/10.1016/j.lanep.2021.100225>

across countries, will enable the Commission to deliver the outputs of the Europe's Beating Cancer Plan and to reduce alcohol-attributable harm and mortality across the Union.

This action supports the implementation of a Europe's Beating Cancer Plan flagship initiative. It implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives in Article 4, points (a) and (j), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE AND ACTIVITIES

This action aims to reduce alcohol-related harm across the Union through collaboration, coordination and support from the WHO Regional Office for Europe.

The WHO Regional Office for Europe in close cooperation with the Commission will support Member States to implement best practices and capacity-building activities, to disseminate knowledge, and carry out monitoring and surveillance activities to reduce harmful alcohol consumption in line with the targets of the UN Sustainable Development Goals. WHO will regularly inform and discuss progress with the Commission and may be invited to engage in the SGPP Cancer sub-group when relevant issues are discussed.

Activities will include:

- a) capacity building: strengthening the expertise and sharing of experience of Member States, civil society and academics through the development of an action-based policy network, utilising WHO's focal point network on alcohol, including convening annual meetings and developing a training programme and technical tools, based on assessment of the needs of the Member States. The training courses and technical tools will support alcohol policy implementation of brief interventions.
- b) work with Member States, NGOs, civil society and other stakeholders, including people with lived experience, and academics to increase health literacy and public knowledge of the links between alcohol consumption and cancer and to build advocacy for policy actions to reduce cancers attributable to alcohol.
- c) support Member States to implement evidence-based brief interventions on alcohol in primary healthcare, the workplace and social services building on previous achievements. Use of the synergies of two other WHO flagship initiatives, such as the Pan-European Mental Health Coalition and Empowerment through Digital Health, to facilitate implementation of evidence-based screening and brief interventions in primary healthcare, the workplace and social services.

EXPECTED RESULTS AND IMPACT

The expected results of this action are the following:

- a) in close cooperation with the Member States and the Commission improved technical capabilities across Member States in reducing alcohol-related harm. Increased awareness by public and policy makers of links between alcohol consumption and cancer risks and support for evidence-based alcohol policy measures to reduce these risks.
- b) development and implementation of training packages for Member States on implementation of brief interventions to reduce alcohol-related harm.
- c) strengthened capacity in national health authorities to apply innovative methods in health promotion activities on reducing alcohol-related harm.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Topic/sub-topic	Estimated launch date	Budget
CR-g-22-08.03	Q2-Q3/2022	EUR 10 000 000
Procedure type	Implemented by	Type of applicants targeted
Indirect management - contribution agreement	SANTE	International organisation (WHO Regional Office for Europe)

HS-g-22-17.08 electronic product information (ePI)

This activity covers contribution agreements with decentralised agencies, which have as an objective the setting-up and follow-up pilot of electronic product information, using, testing and evaluating the deliverables of the ePI setup project in a set of controlled real cases.

The ePI project will implement the ‘Key principles for the use of ePI for EU medicines’ adopted by EMA, the Heads of Medicines Agencies (HMA) of Member States and the Commission on 29 January 2020. It will support the development and testing of a regulatory approved electronic version of the medicinal product leaflet information thus improving access to up-to-date product information on medicines when and where needed.

Topic/sub-topic	Estimated launch date	Budget
HS-g-22-17.08	Q2-Q3/2022	EUR 750 000
Procedure type	Implemented by	Type of applicants targeted
Indirect management - contribution agreement	SANTE	Decentralised Agency (European Medicines Agency)